Sandra A. Edwards (State Bar No. 154578)
Joshua W. Malone (State Bar No. 301836)
Farella Braun + Martel LLP
235 Montgomery Street, 17th Floor
San Francisco, CA 94104
Telephone: (415) 954-4400; Fax: (415) 954-4480
sedwards@fbm.com
jmalone@fbm.com

Joe G. Hollingsworth (appearance *pro hac vice*)
Martin C. Calhoun (appearance *pro hac vice*)
Kirby T. Griffis (appearance *pro hac vice*)
William J. Cople (appearance *pro hac vice*)
Hollingsworth LLP
1350 I Street, N.W.
Washington, DC 20005
Telephone: (202) 898-5800; Fax: (202) 682-1639
jhollingsworth@hollingsworthllp.com
mcalhoun@hollingsworthllp.com
kgriffis@hollingsworthllp.com
wcople@hollingsworthllp.com

George C. Lombardi (appearance *pro hac vice*)
James M. Hilmert (appearance *pro hac vice*)
Winston & Strawn LLP
35 West Wacker Drive
Chicago, IL 60601
Telephone: (312) 558-5969; Fax: (312) 558-5700
glombard@winston.com
jhilmert@winston.com

Attorneys for Defendant
MONSANTO COMPANY

ELECTRONICALLY
FILED
Superior Court of California, County of San Francisco
06/18/2018
Clerk of the Court
BY:RONNIE OTERO
Deputy Clerk

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON,

Plaintiff,

vs.

MONSANTO COMPANY,

Defendant.

Case No. CGC-16-550128

EXHIBITS 4-10 TO:

DEFENDANT MONSANTO COMPANY'S REQUEST FOR JUDICIAL NOTICE OF U.S. ENVIRONMENTAL PROTECTION AGENCY DOCUMENTS AND FEDERAL REGISTER MATERIALS

Trial Date: June 18, 2018
Time: 9:30 a.m.
Department: 504

Exhibit 4

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

MEMORANDUM Dated: 10/30/1991
To: Robert J. Taylor & Lois Rossi (OPP)
From: William Dykstra, Ph.D. & George Z. Ghali, Ph.D. (OPP)
Re: SECOND Peer Review of Glyphosate (19 pages)

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.



Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 30 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: SECOND Peer Review of Glyphosate

CAS No. 1071-83-6
EPA Chem. Code 417300
40 CFR 180.364
TOX Chem. No.: 661A
Reg Group: List A (6B)

FROM: William Dykstra, Ph.D. William Dykstra
Toxicology Branch I (IRS)
Health Effects Division (H7509C)

and

George Z. Ghali, Ph.D. G. Ghali 8/22/91
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

TO: Robert Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Lois Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508W)

The Health Effects Division Carcinogenicity Peer Review Committee convened on June 26, 1991 to discuss and evaluate the weight of the evidence on Glyphosate with particular emphasis on its carcinogenic potential. The Committee concluded that Glyphosate should be classified as a Group E (evidence of non-carcinogenicity for humans), based upon lack of convincing carcinogenicity evidence in adequate studies in two animal species.

It should be emphasized, however, that designation of an agent in Group E is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.

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A. Individual in Attendance

1. Peer Review Committee (Signature indicates concurrence with the peer review unless otherwise stated.)

Penny Fenner-Crisp	Penelope G. Fenner-Crisp
William L. Burnam	Wm L Burnam
Karl Baetcke	Karl A. Baetcke
Marcia Van Gemert	Marcia van Gemert
Esther Rinde	E. Rinde
Hugh Pettigrew	Hugh M. Pettigrew
Marion Copley	Marion P. Copley
Lucas Brennecke	Lucas H. Brennecke
George Ghali	G. Ghali

2. Peer Review Members in Absentia (Committee members who were unable to attend the discussion; signature indicates concurrence with the overall conclusions of the Committee.)

Reto Engler	Reto Engler
Richard Hill	—
John Quest	John A. Quest
Kerry Dearfield	Kerry Dearfield
Yin-Tak Woo	Yin Tak Woo
Jean Parker	— NONCONCUR
William Sette	William Sette
Robert Beliles	DO NOT CONCUR
Julie Du	Julie Du

3. Scientific Reviewers (Committee or noncommittee members responsible for data presentation; signature indicates technical accuracy of panel report.)

William Dykstra	William Dykstra
Roger Gardner	Roger Gardner 9-5-91

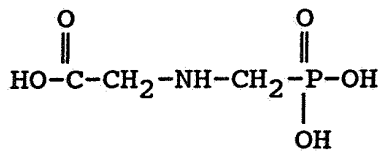
B. Background Information

Glyphosate is the isopropylamine (IPA) or sodium salt of N-(phosphonomethyl) glycine, marketed under the trade names of Roundup, Rodeo, Shackle, and Polado. Glyphosate is a wide spectrum plant growth regulator herbicide which is used to control grasses, sedges, and broadleaf weeds. It acts by the inhibition of amino acid synthesis.

Tolerances established for glyphosate and its aminomethyl phosphonic acid (AMPA) metabolite in 40 CFR 180.364 include the following:

IPA salt of glyphosate: soybeans, cotton, corn, sorghum, wheat, rice, vegetables, citrus fruits, pome fruits, stone fruits, tropical fruits, pastures, and alfalfa.

Sodium salt of glyphosate: sugarcane.



Glyphosate

On February 11, 1985, the carcinogenic potential of glyphosate was first considered by a panel (then called the Toxicology Branch Ad Hoc Committee) comprised of members of the Toxicology Branch of the Hazard Evaluation Division. The Committee, in a consensus review dated March 4, 1985, classified glyphosate as a Group C carcinogen based on an increased incidence of renal tubular adenomas in male mice. According to the consensus review, the tumor is rare, it occurred in a dose-related manner, and the incidence was outside the reported historical control range. The Committee also concluded that dose levels tested in a 26-month rat feeding study were not adequate for the assessment of glyphosate's carcinogenic potential in this species.

The kidney slides from the long-term mouse feeding study were subsequently reexamined, and one pathologist diagnosed an additional kidney tumor in control males. These findings were presented to the FIFRA Scientific Advisory Panel (SAP) which proposed that glyphosate be classified into Group D (inadequate animal evidence of carcinogenic potential). The SAP, in their meeting of February 11-12, 1986 (report dated February 24, 1986), concluded that, after adjusting for the greater survival in the high-dose mice compared to concurrent controls, no statistically significant pairwise differences existed, although the trend was significant. The SAP further noted that, although comparison of

these findings to historical control incidences yielded a statistically significant result, this finding did not override the lack of pairwise significance of comparisons to concurrent controls.

The SAP determined that the carcinogenic potential of glyphosate could not be determined from existing data and proposed that rat and/or mouse studies be repeated in order to clarify these equivocal findings.

HED deferred a decision on the repeat of an additional mouse oncogenicity study until the 1990 rat feeding study had been evaluated by the Peer Review Committee.

C. Material Evaluated

The material available for review consisted of a document prepared by Dr. William Dykstra summarizing major scientific and regulatory issues and relevant toxicology information, data evaluation records of a combined chronic toxicity/carcinogenicity study in rats and a carcinogenicity study in mice, the FIFRA Scientific Advisory Panel report dated Feb 24, 1986, a review of historical control data on mouse kidney tumors, a toxicology one-liner for the glyphosate data base and an OPP peer review report entitled "Consensus Review of Glyphosate" dated March 4, 1985.

D. Evaluation of Carcinogenicity Data

1. **Lankas, G. P. December 23, 1981. A Lifetime Study of Glyphosate in Rats. Unpublished report No. 77-2062 prepared by BioDynamics, Inc. EPA Acc. Nos. 247617 - 247621. MRID 00093879.**

a. Experimental Design

The lifetime feeding study in Sprague-Dawley rats at 50/sex/dose was conducted at dietary concentrations of glyphosate of 0, 30, 100, and 300 ppm. These concentrations were adjusted during the course of the study so that actual doses of 0, 3, 10, and 31 mg/kg/day in males and 0, 3, 11, and 34 mg/kg/day in female rats were maintained.

b. Discussion of Tumor Data

An increase in the incidence of interstitial cell tumors of the testes was observed in male rats. Because of the absence of a dose-response relationship, the lack of preneoplastic changes, the wide variability in the spontaneous incidence of this tumor, the similarity in incidences between the high-dose

group and the historical controls, and lack of any evidence of genotoxicity, it was concluded by the previous Peer Review Committee that the observed incidence did not reflect a carcinogenic response.

Additionally, there was the question of possible thyroid carcinomas in high-dose females. After a review of the slides by a consulting pathologist, and a reassessment of all relevant data, including the fact that no effect of treatment on tumor latency or the combined incidences of adenoma and carcinoma was apparent, the earlier Peer Review Committee concluded that the data did not demonstrate a carcinogenic response in the thyroid.

c. Nonneoplastic Lesions and Adequacy of Dosing Considerations

No effect of treatment on the incidence of nonneoplastic lesions was noted. No effects of treatment on survival, body weight gain, clinical pathology, or findings at necropsy were noted. Therefore, there is no evidence that the highest dose tested was adequate to evaluate the carcinogenic potential of glyphosate.

2. **Stout, L. D. and Ruecker, F. A. (1990). Chronic Study of glyphosate Administered in Feed to Albino Rats. Laboratory Project No. MSL-10495; Sept. 26, 1990. MRID No. 416438-01; Historical Controls; MRID No. 417287-00.**

a. Experimental Design

This chronic toxicity/carcinogenicity study in the rat was submitted to the Agency as a replacement study for the 26-month 1981 chronic toxicity/carcinogenicity study in the rat. In this study, randomized groups of 60 male and 60 female young (8 weeks old) Sprague-Dawley rats were fed dietary levels of 0, 2000, 8000, or 20,000 ppm or the equivalent of 0, 100, 400, and 1000 mg/kg/day of technical glyphosate for 2 years. At 12 months, 10 animals/sex/group were sacrificed.

b. Discussion of Tumor Data

Age-adjusted, statistical analyses of the tumor data are presented. The most frequently observed tumors in this study were pancreatic islet cell adenomas in males, thyroid C-cell adenomas and/or carcinomas in males and females, and hepatocellular adenomas and carcinomas in males. The following is a discussion of each type of tumor.

i. Pancreas (Tables 1 - 3)

Low-dose and high-dose males had a statistically significant increased incidence of pancreatic islet cell adenomas.

Table 1: Glyphosate - Sprague-Dawley Male Rats, Pancreatic Islet Cell Tumor Rates[+] and Cochran-Armitage Trend Test and Fisher's Exact Test Results (p values).

	Dose (ppm)			
Tumors	0	2000	8000	20,000
Carcinomas	1/43[a]	0/45	0/49	0/48
(%)	(2)	(0)	(0)	(0)
p =	0.159	0.409(n)	0.467(n)	0.472(n)
Adenomas	1/43	8/45	5/49	7/48[b]
(%)	(2)	(18)*	(10)	(15)*
p =	0.170	0.018*	0.135	0.042*
Adenomas/carcinomas	2/43	8/45	5/49	7/48
(%)	(5)	(18)	(10)	(15)
p =	0.241	0.052	0.275	0.108
Hyperplasia only	2/43	0/45	3/49	2/48[c]
(%)	(5)	(0)	(6)	(4)
p =	0.323	0.236	0.526	0.649

[+] Number of tumor-bearing animals/Number of animals examined, excluding those that died or were sacrificed before week 55.

[a] First carcinoma observed at week 105, dose 0 ppm.

[b] First adenoma observed at week 81, dose 20000 ppm.

[c] First hyperplasia observed at week 91, dose 20000 ppm.

[d] $p \leq 0.05$; Fisher's Exact test with Bonferoni correction.

Note:
Significance of trend denoted at Control. Significance of pair-wise comparison with control denoted at Dose level. If * then $p < 0.05$.

Historical control data on the incidence of pancreatic islet cell adenomas from Monsanto's EHL are shown in Table 2 below.

Table 2: EHL 87122 - Historical Control Information for Histopathological Findings (All Deaths)

Terminal Necropsy Study	Months of Date	Study Length (Months)	No. Observed	No. Affected	% Affected
1	07/83	24	68	2	2.9
2	02/85	23	59	5	8.5
3	10/85	24	69	4	5.8
4	06/85	24	57	1	1.8
5	09/88	24	60	5	8.3
6	01/89	24	60	3	5.0
7	03/89	24	59	3	5.1

Committee's interpretation: Although the incidences of the pancreatic islet cell adenomas at the low-, mid- and high-dose groups exceeded the historical control range of 1.8 to 8.5 percent in male rats, there was no statistically significant positive dose-related trend in the occurrence of these tumors in males, no progression to carcinoma, and the incidence of hyperplasia was not dose-related. Therefore, the pancreatic islet cell tumors were not considered to be compound-related. It was also noted that the incidence of this lesion in the concurrent control for males was at the low end of the historical control range. The Committee concluded that the apparent statistical significance of the pairwise comparisons of the treated male groups with the concurrent control might have been attributable to this factor and not to actual carcinogenic response.

The incidences of islet cell pancreatic tumors in the earlier rat study (Bio/dynamics Project No. 77-2062) are shown in Table 3. The incidence of pancreatic islet cell tumors for the two studies does not show a dose-related increase in adenomas or adenoma/carcinoma combined and is within the range of open literature control data for male Sprague-Dawley rats (0 to 17%) for unadjusted data.

Table 3: Incidence of Pancreatic Islet Cell Tumors in Male Sprague-Dawley Rats Given Diets Containing Glyphosate for 26 Months (first rat feeding study).

Tumors	Dose (mg/kg/day) 0	3	10	30
Hyperplasia	3/50	2/49	1/50	0/50
(%)	(6)	(4)	(2)	(0)
Adenomas	0/50	5/49	2/50	2/50
(%)	(0)	(10)	(4)	(4)
Carcinomas	0/50	0/49	0/50	1/50
(%)	(0)	(0)	(0)	(2)
Adenoma/carcinoma	0/50	5/49	2/50	3/50
(%)	(0)	(10)	(4)	(6)

ii. Thyroid (Tables 4 - 6)

C-cell adenomas were slightly increased in male and female mid- and high-dose groups as shown in Tables 4 and 5. Historical control ranges for the thyroid tumors in Sprague-Dawley rats were reported as shown in Table 6.

Committee's interpretation: Although C-cell adenomas slightly exceeded the historical control range for both sexes, there was no statistically significant trend or pairwise comparison with controls in males. In females, the incidence of C-cell adenomas was not statistically significant in the pairwise comparison with controls but had a statistically significant positive dose-related trend. However, there was no progression to carcinoma in a dose-related manner, and no significant dose-related increase in severity of grade or incidence of hyperplasia in either sex. Therefore, the C-cell adenomas in males and females are not considered compound-related.

Table 4: Glyphosate - Sprague-Dawley Male Rats, Thyroid C-Cell Tumor Rates[+] and Cochran-Armitage Trend and Fisher's Exact Test Results (p values).

	Dose (ppm)			
Tumors	0	2000	8000	20,000
Carcinomas	0/54	2/55[a]	0/58	1/58
(%)	(0)	(4)	(0)	(2)
p =	0.452	0.252	1.000	0.518
Adenomas	2/54[b]	4/55	8/58	7/58
(%)	(4)	(7)	(14)	(12)
p =	0.069	0.348	0.060	0.099
Adenoma/carcinoma	2/54	6/55	8/58	8/58
(%)	(4)	(11)	(14)	(14)
p =	0.077	0.141	0.060	0.060
Hyperplasia only	4/54	1/55	5/58[c]	4/58
(%)	(7)	(2)	(9)	(7)
p =	0.312	0.176	0.546	0.601

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[a] First carcinoma observed at week 93 at 8000 ppm.

[b] First adenoma observed at week 54 at 0 ppm.

[c] First hyperplasia observed at week 54 at 8000 ppm.

[+] Number of tumor-bearing animals/Number of animals examined, excluding those that died or were sacrificed before week 55.

Note: Significance of trend denoted at Control. Significance of pair-wise comparison with control denoted at Dose level. If * then $p < 0.05$.

Table 5: Glyphosate - Sprague-Dawley Female Rats, Thyroid C-Cell Tumor Rates[+] and Cochran-Armitage Trend Test and Fisher's Exact Tests Results (p values).

	Dose (ppm)			
Tumors	0	2000	8000	20,000
Carcinomas	0/57	0/60	1/59[a]	0/55
(%)	(0)	(0)	(2)	(0)
p =	0.445	1.000	0.509	1.000
Adenomas	2/57	2/60	6/59[b]	6/55
(%)	(4)	(3)	(10)	(11)
p =	0.031*	0.671(n)	0.147	0.124
Adenoma/carcinoma	2/57	2/60	7/59	6/55
(%)	(4)	(3)	(12)	(11)
p =	0.033*	0.671(n)	0.090	0.124
Hyperplasia only	10/57[c]	5/60	7/59	4/55
(%)	(18)	(8)	(12)	(7)
p =	0.113	0.112	0.274	0.086(n)

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[a] First carcinoma observed at week 93 at 8000 ppm.

[b] First adenoma observed at week 72 at 0 ppm.

[c] First hyperplasia observed at week 54 at 8000 ppm.

[+] Number of tumor-bearing animals/Number of animals examined, excluding those that died or were sacrificed before week 55.

(n) Negative change from control.

Note: Significance of trend denoted at Control. Significance of pair-wise comparison with control denoted at Dose level. If * then $p < 0.05$.

Table 6: Historical Control Data for the Incidence of Thyroid C-Cell Tumors in Sprague-Dawley Strain Rats.

Tumor	Range (%) Males	Females
Carcinomas	0.0 - 5.2	0.0 - 2.9
Adenomas	1.8 - 10.6	3.3 - 10.0
Hyperplasia	4.3 - 20.0	4.3 - 16.9

iii. Liver (Table 7)

There was a slight dose-related increase in hepatocellular adenomas in males but the incidence was within the range of historical controls from Monsanto's EHL. The reported historical control incidence of hepatocellular carcinomas ranged from 0 to 6.7%, and that for hepatocellular adenomas ranged from 1.4 to 18.3%. There were no dose-related increases in the incidences of other hepatocellular lesions.

Table 7: Glyphosate - Sprague-Dawley Male Rats, Hepatocellular Tumor Rates[+] and Cochran-Armitage Trend and Fisher's Exact Test Results (p values).

Tumors	Dose (ppm) 0	2000	8000	20,000
Carcinomas	3/44	2/45	1/49	2/48[a]
(%)	(7)	(4)	(2)	(4)
p =	0.324	0.489(n)	0.269(n)	0.458(n)
Adenomas	2/44	2/45	3/49	7/48[b]
(%)	(5)	(4)	(6)	(15)
p =	0.016*	0.683(n)	0.551	0.101
Adenoma/carcinoma	5/44	4/45	4/49	9/48
(%)	(11)	(9)	(8)	(19)
p =	0.073	0.486(n)	0.431(n)	0.245
Hyperplasia only	0/44	0/45	1/49[c]	0/48
(%)	(0)	(0)	(2)	(0)
p =	0.462	1.000	0.527	1.000

[a] First carcinoma observed at week 85 at 20,000 ppm.

[b] First adenoma observed at week 88 at 20,000 ppm.

[c] First hyperplasia observed at week 89 at 8000 ppm.

[+] Number of tumor-bearing animals/Number of animals examined, excluding those that died or were sacrificed before week 55.

Note: Significance of trend denoted at Control. Significance of pair-wise comparison with control denoted at Dose level. If * then $p < 0.05$.

Committee's interpretation: Despite the slight dose-related increase in hepatocellular adenomas in males, this increase was not significant in the pair-wise comparison with controls and was within the historical control range. Furthermore, there was no progression from adenoma to carcinoma and incidences of hyperplasia were not compound-related. Therefore, the slightly increased occurrence of hepatocellular adenomas in males is not considered compound-related.

c. Nonneoplastic lesions

There were no compound-related nonneoplastic lesions.

d. Adequacy of Dosing for Assessment of Carcinogenic Potential

The HDT was 20,000 ppm which is the limit dose for carcinogenicity testing in rats. However, it appears that animals could have tolerated higher doses.

3. **Hogan, G. K. (1983). A chronic feeding study of glyphosate in mice. Unpublished report prepared by Bio/Dynamics Inc., dated July 21, 1983. Report No. 77-2061. EPA Acc. Nos. 251007 - 251009, and 251014.**

a. Experimental Design

Groups of 50 male and 50 female CD-1 mice were administered glyphosate in the diet at concentrations of 1000, 5000, or 30,000 ppm for 18 months.

b. Discussion of Tumor Data

Glyphosate produced an equivocal carcinogenic response in males characterized by an incidence of renal tubular neoplasms of 1/49, 0/49, 1/50, and 3/50 in the control, low-, mid-, and high-dose groups, respectively. No kidney tumors were found in females. Historical control data from 16 studies terminated between 1978 and 1982 provided by the testing laboratory indicated that the incidence of this type of tumor was found in 2/19 control groups (1/54 and 2/60, or a total of 3/1286).

The Toxicology Branch Ad Hoc Oncogenicity Peer Review Committee, in their meeting of February 11, 1985, tentatively classified glyphosate as a "Class C" carcinogen (report dated March 4, 1985). The kidney slides were reexamined by a consulting pathologist, and data were submitted indicating that an additional kidney tumor had been found in control males (the incidence in the control group was originally reported as 0/49 before the reexamination of the slides).

The Agency then requested that additional kidney sections from the mouse study be prepared and examined. The resultant microslides were examined by a number of pathologists. These examinations revealed no additional tumors, but confirmed the presence of the tumors identified in the original study report. The tumor in the control kidney was not present in any of the additional sections.

Because of the equivocal nature of the findings, the Toxicology Branch Ad Hoc Oncogenicity Peer Review Committee asked the expert assistance of the FIFRA Scientific Advisory Panel (SAP) in determining the proper Weight-of-the-Evidence classification of the study. After reviewing all the available evidence, the SAP, in their meeting of February 11-12, 1986, proposed that glyphosate be classified as "Class D," or having "inadequate animal evidence of oncogenicity." The principal reason for this assessment by SAP was their determination that, after adjusting for the greater survival in the high-dose mice compared to concurrent controls, no statistically significant pairwise differences existed, although the trend was significant. The SAP further noted that, although comparison of these findings to historical control incidences yielded a statistically significant result, this finding did not override the lack of pairwise significance of comparisons to concurrent controls.

The SAP determined that the carcinogenic potential of glyphosate could not be determined from existing data and proposed that rat and/or mouse studies be repeated in order to clarify these equivocal findings.

Committee's interpretation: In their meeting of June 26, 1991, the Health Effects Carcinogenicity Peer Review Committee concluded that despite the fact that the incidence of renal tubular neoplasm in the high dose males exceeded that of historical controls, the biological significance of the findings was questionable because of: a) lack of significance in pairwise comparison with concurrent controls, b) there was no concurrent increase in non-neoplastic renal tubular lesions in male mice (e.g. tubular necrosis/regeneration, hyperplasia, hypertrophy ..etc), c) the examination of multiple sections of kidneys from all groups resulted in no additional neoplasms; this fact is particularly important since not only were the original sections closely scrutinized by more than one pathologist, but additional sections as well, and d) increased incidence in high dose group was very small compared to control considering the very high concentration which produced highly significant reduction in body weight gain in males. Furthermore, the increased incidence of chronic interstitial nephritis in males is not relevant to the tubular neoplasms. There was actually a decrease in renal tubular epithelial changes (basophilia and hyperplasia) in males, and although there was a dose-related increase in these changes in female mice, no tubular neoplasms were observed in females.

c. Nonneoplastic lesions:

Other nonneoplastic changes noted in high-dose male mice included centrilobular hypertrophy and necrosis of hepatocytes, chronic interstitial nephritis, and proximal tubule epithelial cell basophilia and hypertrophy in the kidneys of females. The no-observable-effect level (NOEL) for nonneoplastic chronic effects was the mid-dose level, 5000 ppm.

d. Adequacy of Dosing for Assessment of Carcinogenic Potential

Glyphosate was tested in this study at levels higher than the limit dose. Body weight gain in males of the high dose was 13, 17 and 27% less than the controls at 3, 12 and 24 months respectively. The decrease in body weight gains was statistically significant ($p < 0.01$). This effect was less obvious in females. The doses tested were considered adequate for the carcinogenic potential assessment of glyphosate.

E. Additional Toxicology Data on Glyphosate

1. Metabolism

When Sprague-Dawley rats were given a single oral dose of C-14 glyphosate, 30 to 36 percent of orally administered glyphosate was absorbed.

Data showed that less than 0.27 percent of the dose was expired as CO_2 within 24 hours. Glyphosate, per se, was the highest radiolabeled material found in the urine and feces. The minimum level of glyphosate extracted from urine and feces was 97.5 percent. Amino methyl phosphonic acid (AMPA) was found in the excreta of animals at levels of 0.2 to 0.3 percent and 0.2 to 0.4 percent in urine and feces, respectively. No detectable AMPA metabolite was found in intravenously dosed rats and high dose, orally dosed rats. There were no other metabolites of glyphosate found.

Based on analysis of radioactivity in urine and feces and using the "sigma-minus" plotting method, males and females had alpha half-lives of 2.11 and 7.52 hours and 5.00 to 6.44 hours, respectively. The beta half-lives of males and females in these groups ranged from 69.0 to 181 hours for males and 79.9 to 337 hours for females.

Less than 1 percent of the absorbed dose remains in tissues and organs, primarily bone. Repeated dosing with glyphosate

does not significantly change the metabolism, distribution, or excretion of glyphosate.

N-Nitrosoglyphosate (NNG)

The Agency has determined that carcinogenicity testing of nitroso contaminants will normally be required only in those cases in which the level of nitroso compounds exceeds 1.0 ppm [see "Pesticide Contaminated with N-nitroso Compounds, proposed policy 45 FR 42854 (June 25, 1980)"]. The levels of NNG in technical glyphosate have been examined by HED. The overall NNG content in individual samples of technical glyphosate analyzed at production plants is shown below:

Samples Analyzed		NNG Observed
No. Samples	Per cent	(ppb)
2035		
124		
24		
13		
2		

The overall data show that 92.6 percent of the individual glyphosate samples analyzed contain less than 1.0 ppm (1000 ppb) of NNG. TB concluded that the NNG content of glyphosate technical is not toxicologically significant.

2. Mutagenicity

Glyphosate has been tested in several mutagenicity assays and found to be negative in each of the three categories recommended for evaluating genotoxic potential. The acceptable studies include the following: Salmonella assay, both with and without S-9, up to toxicity or 5000 ug/plate, in vivo cytogenetic assay in rat bone marrow up to 1000 mg/kg, mammalian gene HGPRT mutation assay in CHO cells in vitro both with and without S-9 up to toxic levels (10 mg/mL) and rec assay with B. subtilis up to 2000 ug/disk.

Unacceptable studies which were also negative included DNA repair in rat hepatocytes between 0.0000135 and 0.125 mg/ml, and a dominant lethal assay in mice up to 2000 mg/kg.

3. Developmental and Reproductive Toxicity

In rats, doses up to 3500 mg/kg/day showed no evidence of malformations. Evidence of developmental toxicity in the form of unossified sternebrae and decreased fetal body weight was noted in fetuses from the high dose (3500 mg/kg/day). This dose was also toxic to dams as evidenced by weight gain

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

deficits, altered physical appearance, and mortality during treatment. The developmental and maternal toxic NOEL for this study was 1000 mg/kg/day.

In rabbits, doses up to 350 mg/kg/day showed no evidence of malformations. The highest dose tested was toxic to does as evidenced by altered physical appearance and mortality. No treatment-related developmental effects were noted. The NOEL for maternal toxicity is 175 mg/kg/day and the NOEL for developmental toxicity is 350 mg/kg/day.

In a three-generation reproduction study in the rat, the only toxicologically significant finding was focal renal tubular dilation in the kidneys of male pups from the F_{3b} generation of high-dose dams (30 mg/kg/day). The NOEL for this effect was 10 mg/kg/day. No effects on fertility, reproductive, or other study parameters were noted.

4. Structure - Activity Relationships

Currently there are no structurally related pesticides registered by the Agency which resemble glyphosate. A nonregistered pesticide, sulfosate, has been reviewed for carcinogenic potential in mice and rats and reported to be negative.

5. Acute, Subchronic and Chronic Feeding/ Oncogenicity Data

Glyphosate is not considered to be toxic to mammals (rat oral LD_{50} of 4320 mg/kg (both sexes), and a dermal LD_{50} greater than 7940 mg/kg in rabbits).

A 1-year chronic feeding study in dogs at 6/sex/dose was conducted using doses of 0, 20, 100, and 500 mg/kg/day, administered by capsule. The NOEL for the study was 500 mg/kg/day (HDT).

F. Weight of the Evidence Considerations

The Committee considered the following findings to be of significance regarding the weight-of-the-evidence determination of the carcinogenic potential of glyphosate.

1. Glyphosate was associated with increased incidences of pancreatic islet cell adenomas in male Sprague-Dawley rats at all treatment levels in comparison to the concurrent control group (Table 1). Although the low- (18%), mid- (10%) and high-dose group (15%) incidences exceeded the 1.8 to 8.5% range of historical controls from Monsanto's EHL data base, the pancreatic islet cell adenomas were not considered

compound-related for the following reasons: a) there was no statistically significant positive dose-related trend in the occurrence of these tumors or in the incidence of hyperplasia in males over the wide range of dosing (2000 to 20000 ppm), and b) there was no progression to carcinoma. Tertiary evidence from the open literature cited by the registrant showed a range of 0 to 17% for pancreatic islet cell adenomas in Sprague-Dawley male rats for unadjusted data. The incidence of pancreatic islet cell tumors for the two rat studies does not show a dose-related increase in adenomas or adenoma/carcinoma combined and is within the range of open literature control data for male Sprague-Dawley rats (0 to 17%) for unadjusted data.

No increased incidence of these tumors was observed in female rats in comparision to concurrent controls.

2. C-cell adenomas were slightly increased in male and female mid- and high-dose groups in the rat (Tables 4 and 5). Although C-cell adenomas slightly exceeded the historical control range for both sexes, there was no statistically significant trend or pairwise comparison with controls in males. In females, the incidence of C-cell adenomas was not statistically significant in the pairwise comparison with controls but had a statistically significant positive dose-related trend. However, there was no progression to carcinoma in a dose-related manner, and no significant dose-related increase in severity of grade or incidence of hyperplasia in either sex. Therefore, the C-cell adenomas in males and females are not considered compound-related.

3. There was a slight dose-related increase in hepatocellular adenomas in male rats (Table 7), but the incidence was within the range of historical controls from Monsanto's EHL. This increase was not significant in the pair-wise comparison with controls and there was no progression from adenoma to carcinoma. The incidence of hyperplasia was not compound-related. There were no dose-related increases in the incidences of other hepatocellular lesions. Therefore, the increased incidence of hepatocellular adenomas in males was not considered compound-related.

4. Glyphosate produced an equivocal carcinogenic response in male mice characterized by an incidence of renal tubular neoplasms of 1/49, 0/49, 1/50, and 3/50 in the control, low-, mid-, and high-dose groups, respectively. No kidney tumors were found in females. Historical control data from 16 studies terminated between 1978 and 1982 provided by the testing laboratory indicated that the incidence of this type of tumor was found in 2/19 control groups (1/54 and 2/60, or a total of 3/1286).

Despite the fact that the incidence of renal tubular neoplasm in the high dose males exceeded that of historical controls, the biological significance of the findings was questionable because of: a) lack of significance in pairwise comparison with concurrent controls, b) there was no concurrent increase in non-neoplastic renal tubular lesions in male mice (e.g. tubular necrosis/regeneration, hyperplasia, hypertrophy ..etc), c) the examination of multiple sections of kidneys from all groups resulted in no additional neoplasms; this fact is particularly important since not only were the original sections closely scrutinized by more than one pathologist, but additional sections as well, and d) increased incidence in high dose group was very small compared to control considering the very high concentration which produced highly significant reduction in body weight gain in males. Furthermore, the increased incidence of chronic interstitial nephritis in males is not relevant to the tubular neoplasms. There was actually a decrease in renal tubular epithelial changes (basophilia and hyperplasia) in males, and although there was a dose-related increase in these changes in female mice, no tubular neoplasms were observed in females. Overall, the Peer Review Committee did not feel that this lesion was compound-related.

5. Glyphosate was tested up to the limit dose in the rat, and up to levels higher than the limit dose in mice.

6. There was no evidence of genotoxicity for glyphosate.

7. Currently there are no structurally related pesticides registered by the Agency which resemble glyphosate. A nonregistered pesticide, sulfosate, has been reviewed for carcinogenic potential in mice and rats and was reported to be negative.

G. Classification:

Considering criteria contained in EPA Guidelines (FR 51:33992-34003, 1986] for classifying a carcinogen, the Committee concluded that Glyphosate should be classified as a Group E (evidence of non-carcinogenicity for humans), based on lack of convincing carcinogenicity evidence in adequate studies in two animal species.

It should be emphasized, however, that designation of an agent in Group E is based on the available evidence at the time of evaluation and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.

Exhibit 5

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

MEMORANDUM Dated: 4/20/1998
To: Melba Morrow (OPP)
From: William Dykstra, Ph.D. & Jess Rowland (OPP)
Re: GLYPHOSATE - Report of the Hazard Identification Assessment Review Committee (10 Pages)

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.



Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

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12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DATE: April 20, 1998

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: ***GLYPHOSATE*** - Report of the Hazard Identification Assessment Review Committee.

FROM: William Dykstra, Toxicologist. William Dykstra 4/20/98
Registration Action Branch 1
Health Effects Division (7509C)
and
Jess Rowland, Executive Secretary 4/20/98
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)

THROUGH: K. Clark Swentzel, Chairman, K. Clark Swentzel 4/21/98
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)
and
Mike Metzger, Co-Chairman
Hazard Identification Assessment Review Committee 4/21/98
Health Effects Division (7509C)

TO: Melba Morrow, Branch Senior Scientist
Registration Action Branch 1
Health Effects Division (7509C)

PC Code: 417300

On March 26, 1998, the Health Effects Division's Hazard Identification Assessment Review Committee evaluated the toxicology data base of **GLYPHOSATE,** re-assessed the Reference Dose (RfD) established in 1992 as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to glyphosate as required by the Food Quality Protection Act (FQPA) of 1996. The Committee's conclusions are presented in this report.

Printed on Recycled Paper

Committee Members in Attendance

Members present were: Mike Metzger (Co-Chairman), Clark Swentzel (Chairman), Bill Burnam, Sue Makris, Melba Morrow, Karen Hammernik, Karl Baetcke, Robert Fricke, John Redden, and Jess Rowland (Executive Secretary) . Member(s) in absentia: None. Data was presented by William Dykstra of the Registration Action Branch 1.

In attendance was also Julianna Cruz of Registration Action Branch 1.

Data Presentation:
and
Report Presentation

William Dykstra.
Toxicologist

Report Concurrence:

Jess Rowland
Executive Secretary

I. INTRODUCTION

On March 26, 1998, the Health Effects Division's Hazard Identification Assessment Review Committee evaluated the toxicology data base of Glyphosate, re-assessed the Reference Dose (RfD) established in 1992 as well as the toxicological endpoints selected for acute dietary and occupational/residential exposure risk assessments. The HIARC also addressed the potential enhanced sensitivity of infants and children from exposure to glyphosate as required by the Food Quality Protection Act (FQPA) of 1996.

II. HAZARD IDENTIFICATION

A. Acute Reference Dose (RfD)

Study Selected: None §

MRID No.: None

Executive Summary:

Dose and Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint: A review of the rat and rabbit developmental studies did not provide a dose or endpoint that could be used for acute dietary risk purposes. Additionally, there were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses and glyphosate lacks a leaving group. Therefore, it would not seem likely to inhibit esterases, which is the presumptive neurotoxic mechanism of concern for all organophosphates.

Uncertainty Factor (UF): None

This Risk Assessment is **NOT** required.

B. Chronic RfD

Study Selected: Rabbit Developmental study § 83-3(b)

MRID No.: 00046363

Executive Summary: Groups of 16/dose Dutch Belted rabbits were dosed with technical glyphosate at doses of 0, 75, 175, or 350 mg/kg/day between gestation days 6 to 27. Maternal effects were seen at only the high dose and consisted of diarrhea, nasal discharge and death [10/16]. Developmental effects were not seen at any dose tested. Therefore, the NOEL and LOEL for maternal toxicity were 175 mg/kg/day and 350 mg/kg/day, respectively.

Dose and Endpoint for Establishing RfD: NOEL = 175 mg/kg/day based on death, diarrhea, and nasal discharge at 350 mg/kg/day (LOEL).

Uncertainty Factor(s): 100 (10 x for interspecies extrapolation and 10 x for intraspecies variation).

$$\textbf{Chronic RfD} = \frac{\text{175 mg/kg/day (NOEL)}}{\text{100 (UF)}} = \textbf{2.0 mg/kg/day}$$

Comments about Study/Endpoint/Uncertainty Factor: The NOEL for maternal toxicity in the rabbit developmental study was the lowest NOEL of all the major studies which include the 24-month mouse carcinogenicity study [NOEL = 750 mg/kg/day], the 1-year dog study [NOEL = 500 mg/kg/day], 2-year chronic/onco rat study [NOEL = 400 mg/kg/day], 2-generation rat reproduction study [NOEL = 500 mg/kg/day] and rat developmental study [NOEL = 1000 mg/kg/day]

This risk assessment is required.

C. Occupational/Residential Exposure

1. Dermal Absorption

Dermal Absorption Factor: A dermal absorption factor is not applicable since dermal risk assessments are not required.

2. Short-Term Dermal - (1-7 days)

Study Selected: None §

MRID No.: None

Executive Summary: None

Dose and Endpoint for Risk Assessment: Not Applicable.

Comments about Study/Endpoint:. No systemic or dermal toxicity was seen following repeated dermal applications of technical glyphosate at 0, 100, 1000 or 5000 mg/kg/day, 6 hours/day, 5 days/week for three consecutive weeks to male and female New Zealand rabbits. The NOEL was 1000 mg/kg/day and the LOEL was 5000 mg/kg/day based on decreased food consumption in females [MRID No. 00098460]. In addition, the use of a 3% dermal absorption rate (estimated) in conjunction with the oral NOEL of 175 mg/kg/day established in the rabbit developmental study yields a dermal equivalent dose of > 5000 mg/kg/day.

This risk assessment is **NOT** required.

3. Intermediate-Term Dermal (7 Days to Several Months)

Study Selected: None

MRID No.: None

Executive Summary: None

Dose/Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint: See short term

This risk assessment is **NOT** required.

4. Long-Term Dermal (Several Months to Life-Time)

Study Selected: None

MRID No.: None

Executive Summary: None

Dose and Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint:. See short term

This risk assessment is **NOT** required.

5. Inhalation Exposure (Any Time period).

Study Selected: None

MRID No.: None

Executive Summary: None

Dose/Endpoint for Risk Assessment: Not Applicable

Comments about Study/Endpoint: Based on the low toxicity of the formulation products (Toxicity Category III or IV) and the physical characteristics of the technical product (wetcake) there is minimal concern for potential inhalation exposure or risk. The acute inhalation study was waived for technical glyphosate.

This risk assessment is **NOT** required.

D. Recommendation for Aggregate Exposure Risk Assessments

There are no registered residential uses at the present time. Therefore, aggregate exposure risk assessments will be limited to food + water.

III. CLASSIFICATION OF CARCINOGENIC POTENTIAL

1. Combined Chronic Toxicity/Carcinogenicity Study in Rats

Executive Summary : Randomized groups of 60/sex/dose Sprague-Dawley rats were fed glyphosate at dietary levels of 0, 2000, 8000, or 20,000 ppm [male: 0, 89, 362, or 940 mg/kg/day; female: 0, 113, 457, or 1183 mg/kg/day]. The NOEL was 8000 ppm [362 mg/kg/day for males and 457 mg/kg/day for females] and the LOEL was 20,000 ppm [940 mg/kg/day for males and 1183 mg/kg/day for females] based on decreased weight gain in females, decreased urinary pH in males, increased incidence of cataracts and lens abnormalities in males, and increased absolute and relative liver weight in males. The carcinogenic potential was negative.

MRID No. 41643801

Discussion of Tumor Data: The study showed a slightly increased incidence of pancreatic islet cell adenomas in the low and high dose males; hepatocellular adenomas in the low and high dose males; and thyroid C-cell adenomas in the mid and high dose males and females. The Agency concluded that these adenomas were not treatment-related and glyphosate was not considered to be carcinogenic in this study. The pancreatic islet cell adenomas did not display a positive dose-trend in their occurrence; there was no progression to carcinoma and the incidence of pancreatic hyperplasia was not dose-related. The hepatocellular adenomas were not statistically significant by pair-wise comparison; the incidence was within the range of historical controls; there was no progression to carcinoma and the hyperplasia was not compound-related. The C-cell adenomas were statistically significant by pair-wise comparison and were not dose-related; there was no progression to carcinoma and there was no significant dose-related increase in severity or incidence of hyperplasia in either sex.

Adequacy of the Dose Levels Tested: The highest dose tested was the limit dose of 20,000 ppm in both sexes.

2. Carcinogenicity Study in Mice

Executive Summary: Randomized groups of 50/sex/dose CD-1 mice were fed glyphosate in the diet for 2 years at doses of 0, 1000, 5000, or 30,000 ppm [0, 150, 750, or 4500 mg/kg/day]. The systemic NOEL was 5000 ppm and the LOEL was 30,000 ppm based on decreased weight gain in both sexes, hepatocyte necrosis and interstitial nephritis in males and increased incidence of proximal tubule epithelial basophilia and hypertrophy in females. The carcinogenic potential was negative.

MRID No. 00130406, 00150564

Discussion of Tumor Data The incidence in males of renal tubular adenomas, a rare tumor, was 1, 0, 1, and 3 in the control, low, mid, and high dose groups, respectively. Although the trend was significant, there was no statistical significance by pairwise comparison of the control and high dose group. The incidence at the high dose exceeded the occurrence of historical controls from the testing laboratory. The non-neoplastic findings in the male kidney did not occur in a increased dose-related manner and the tumorigenic findings in the kidney were considered to occur by chance rather than as a result of treatment.

Adequacy of the Dose Levels Tested: The highest dose tested [30,000 ppm] exceeded the limit dose of 7000 ppm for both sexes of mice.

3. Classification of Carcinogenic Potential The OPP Cancer Peer Review Committee classified glyphosate as a "Group E " pesticide [no evidence for carcinogenicity in two acceptable species].

IV. FQPA CONSIDERATIONS

1. Neurotoxicity:

There were no data requirements for acute or subchronic rat neurotoxicity studies since there was no evidence of neurotoxicity in any of the toxicology studies at very high doses and glyphosate lacks a leaving group. Therefore, it would not seem likely to inhibit esterases, which is the presumptive neurotoxic mechanism of concern for all organophosphates.

2 Developmental Toxicity

In a prenatal developmental toxicity study , pregnant Sprague-Dawley rats received oral administration of glyphosate (98.7%) in 0.5% aqueous methocel at 0, 300, 1000 or 3500 mg/kg/day during gestation days 6 through 19. For maternal toxicity, the NOEL was 1000 mg/kg/day and the LOEL was 3500 mg/kg/day based on diarrhea, decreased mean body weight gain, breathing rattles, inactivity, red matter around the nose and mouth, and on forelimbs and dorsal head, decreases in total implantations/dam and inviable fetuses/dam, and death (24% of the group). For developmental toxicity, the NOEL was 1000 mg/kg/day and the LOEL was 3500 mg/kg/day based on increased number of litters and fetuses with unossified sternebrae, and decreased mean fetal body weights (MRID # 00046362).

In a prenatal developmental toxicity study, pregnant New Zealand white rabbits received oral administration of glyphosate (98.7%) in 0.5% aqueous methocel at 0, 75, 175 or 350 mg/kg/day during gestation days 6 through 27. For maternal toxicity, the NOEL was 175 mg/kg/day and the LOEL was 350 mg/kg/day based on diarrhea, nasal discharge, and death (62.5% of does died by gestation day 21). Developmental toxicity was not observed at any dose tested. For developmental toxicity, the NOEL was ≥ 175 mg/kg/day (insufficient litters were available at 350 mg/kg/day to assess developmental toxicity) (MRID # 00046363).

3. Reproduction Toxicity

In a three-generation reproduction study, Sprague-Dawley rats received diets containing glyphosate at 0, 3, 10 or 30 mg/kg/day for three generations. For parental systemic toxicity, the NOEL was 30 mg/kg/day (highest dose tested). The only effect observed was an increased incidence of focal tubular dilation of the kidney (both unilateral and bilateral combined) in the high-dose male F_{3b} pups. However, this effect (focal tubular dilation of the kidneys) was not observed at the 1500 mg/kg/day level in a 2-generation rat reproduction study discussed below. Therefore, the OPP Developmental Peer Review Committee concluded that the effect seen in the three generation study was a spurious rather than glyphosate-related effect. No reproductive or offspring toxicity was observed; NOELs was ≥30 mg/kg/day (MRID # 00105995).

In a two-generation reproduction study, Sprague-Dawley rats received diets containing glyphosate at 0, 2000, 10,000 or 30,000 ppm for two generations. Treatment-related effects observed at 30,000 ppm included soft stools, very frequent, in the F_0 and F_1 males and females, decreased food consumption and body weight gain of the F_0 and F_1 males and females during the growth (premating) period, and decreased body weight gain of the F_{1a}, F_{2a} and F_{2b} male and female pups during the second and third weeks of lactation. Focal tubular dilation of the kidneys, observed in the 3-generation study, was not observed at any dose level in this study. Based on the above findings, the parental and developmental (pup) NOEL's are 500 mg/kg/day and the parental and developmental (pup) LOEL's are 1500 mg/kg/day. The reproductive toxicity NOEL is ≥1500 mg/kg/day (MRID # 41621501).

4. Additional information from the literature No studies were available

5. Determination of Susceptibility

The data provided no indication of increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to glyphosate. In the prenatal developmental toxicity study in rats, developmental toxicity was seen in the presence of maternal toxicity at the highest dose tested. No developmental toxicity was seen in the rabbits. In reproductions toxicity studies, effects in the offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

6. Recommendation for a Developmental Neurotoxicity Study

i. Evidence that suggest requiring a developmental neurotoxicity study:

There was no evidence to suggest that a developmental neurotoxicity study was needed.

ii. Evidence that do not support a need for a developmental neurotoxicity study: Rat and rabbit developmental studies and 2-generation rat reproduction study.

7. Determination of the FQPA Safety Factor:

The application of an FQPA factor for the protection of infants and children from exposure to glyphosate required by FQPA, will be determined during risk characterization by the FQPA Safety Committee. However, the HIARC, based on hazard assessment, recommends to the FQPA Safety Factor Committee that the additional 10 x factor should be removed because:

(i) The data provided no indication of increased susceptibility of rats or rabbits to in utero and/or postnatal exposure to glyphosate.

(ii) No evidence of developmental anomalies, including abnormalities in the development of fetal nervous system was observed in the pre-and/or postnatal studies.

(iii) The toxicology data base is complete and there are no data gaps.

V. DATA GAPS none

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VI SUMMARY OF TOXICOLOGY ENDPOINT SELECTION

The doses and toxicological endpoints selected for various exposure scenarios are summarized below.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	None	No toxicological endpoint attributable to a single dose was identified in oral studies including the rat and rabbit developmental toxicity studies.	
	Acute RfD = None		
Chronic Dietary	NOEL = 175 UF = 100	Mortality, diarrhea, and nasal discharge	Developmental - Rabbit
		Chronic RfD = 2.0 mg/kg/day	
Short-, Intermediate and Long-Term (Dermal)	None	No systemic toxic effects seen at doses up to 1000 mg/kg/day in the 21 day dermal toxicity study. Risk assessment is not required.	
Inhalation (Any Time Period)	None	Based on low toxicity of formulations and technical material [wet cake] inhalation study was waived. Risk assessment is not required.	

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Chemical:	**Glyphosate**
PC Code:	**417300**
HED File Code	**21100 HIARC**
Memo Date:	**04/20/98**
File ID:	**TX012586**
Accession Number:	**412-02-0011**

HED Records Reference Center
03/01/2002

Exhibit 6

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

MEMORANDUM Dated: 4/3/2009
To: Kerry Leifer (OPP)
From: Donna S. Davis, Alexandra LaMay, Matthew Lloyd,
Christine L. Olinger, Sheila Piper, Deborah Smegal, Linda Taylor, (OPP)

Re: Alkyl Amine Polyalkoxylates (JITF CST 4 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations (94 pages).

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Date: April 3, 2009

MEMORANDUM

SUBJECT: **Alkyl Amine Polyalkoxylates (JITF CST 4 Inert Ingredients).** Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations.

PC Code: 790402
Decision No.: 389251
Petition No.: 8E7382
Risk Assessment Type: Single Chemical Aggregate
TXR No.: NA
MRID No.: 46902001,46902005, 46902007, 46914604, 46918001, 46918002, 46918003, 46918004, 46930503, 47041301, 47041302, 47066302, 47097401, 47193901, 47405101

DP Barcode: D360944
Registration No.: NA
Regulatory Action: Inert Tolerance Exemption
Case No.: NA
CAS No.: 61791-26-2, 61791-31-9, 70955-14-5, 68213-26-3
40 CFR: 180.920, 180.930

FROM: Donna S. Davis, Risk Assessor, RAB VII
Alexandra LaMay, Biologist, RAB VII
Matthew Lloyd, Industrial Hygienist, RAB VII
Christine L. Olinger, Chemist, RAB VII
Sheila Piper, Dietary Exposure Assessor, RAB VI
Deborah Smegal, Toxicologist, RAB VII
Linda Taylor, Toxicologist, RAB VII
Health Effects Division (7509P)

THROUGH: Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

TO: Kerry Leifer, Team Leader
PV Shah, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

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1.0 Executive Summary

The Joint Inert Task Force (JITF) Cluster Support Team Number 4 (CST4) has submitted a petition proposing to establish exemptions from the requirement of a tolerance for the following clusters of compounds when used as inert ingredients in pesticide formulations.

> N,N-Bis-[alpha]-ethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2 – 60 moles.
>
> N,N-Bis-[alpha]-ethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2 – 60 moles.

The compounds, referred to as alkyl amine polyalkoxylates (AAPs), are not discrete compounds, but are a mixture of compounds formed from the reaction of fatty acid derived amines with either ethylene oxide or propylene oxide. The AAPs are used primarily as surfactants in pesticide formulations. The petitioner is proposing to limit the maximum amount of the inert in any end-use product to no more than 10% in fungicide and insecticide products and no more than 25% in herbicide formulations.

The toxicology database is adequate to support the use of the alkyl amine polyalkoxylates when used as inert ingredients. The AAPs are not acutely toxic by the oral and dermal routes of exposure, or via inhalation under normal use conditions. Concentrated materials are generally corrosive, eye and skin irritants and may be dermal sensitizers. There is no evidence that the AAPs are neurotoxic, mutagenic, or clastogenic.

There is no clear target organ identified across the AAPs. Following subchronic exposure to rats, some gastrointestinal irritation was observed, but no specific target organ toxicity or neurotoxicity was seen. In subchronic studies in rats and/or dogs, the most sensitive effects noted were increased mortality, clinical signs (salivation, wheezing, emesis, and/or soft feces), cataracts, cellular changes in the stomach, and liver effects characterized by enzyme induction, and pigment accumulation in Kupffer cells and bile canaliculi. There was no increased susceptibility to the offspring of rats following *in utero* exposure in two prenatal developmental toxicity studies. However, there is evidence of increased susceptibility in a reproductive screening study in rats. The points of departure (PoDs) selected for the dietary assessments are lower than the doses at which offspring toxicity occurred in the rat reproduction study and are protective of offspring toxicity occurring at higher doses. There were no residual concerns and the Food Quality Protection Act (FQPA) safety factor was reduced to 1X.

Sufficient data were provided on the chemical identify of the AAPs, however, limited data are available on the metabolism and environmental degradation of the AAPs; further, no residue data were provided. The Agency relied collectively on information provided on the representative chemical structures, the generic cluster structures, the submitted physicochemical EPI Suite™ data, structure-activity relationship information,

as well as information on other surfactants and chemicals of similar size and functionality to determine the residues of concern for this group of inert ingredients. In the absence of data, the Agency has developed an approach that uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. Acute and chronic dietary risk assessments, which assumed no more than 10% AAP in the final formulation for fungicides and insecticides and 25% for herbicides, resulted in dietary risks that were not of concern.

The Agency evaluated residential handler and post application risks for high-end residential exposure scenarios. The combined margins of exposure (MOEs) for all the residential handler scenarios were above 100, and therefore, did not demonstrate a risk of concern to the Agency.

Short-term and intermediate-term aggregate risks, which combined high end residential exposure with average food and drinking water exposures, were not of concern. Acute and long-term (chronic) aggregate risks that included food and water only, were not of concern.

HED has completed an occupational exposure and risk assessment for the AAPs. Since they can be used in a wide range of applications, HED has selected scenarios that are likely to result in high-end exposure. HED traditionally considers a level of concern (LOC) for these risk assessments to be for an MOE of 100 based on the standard 10x inter and 10x intra species extrapolation safety factors. However, HED notes that for the AAPs, the primary toxic effect seen is related to the surfactants inherent function to disrupt cell membranes resulting in irritating properties to tissues. Given that HED does not expect to see a significant difference between species for this type of effect, an LOC lower than 100 may be appropriate for the non-dietary risk assessments.

Occupational handler risks are not of concern for all scenarios except for workers using a low pressure handwand applying pesticides containing the AAPs to ornamentals in greenhouse settings. HED notes that the occupational handler assessment assumes that mixer/loader/applicators who are handling pesticides containing the AAPs for aerial and ground application on high acreage crops or turf will wear chemical-resistant gloves. HED believes this is a reasonable assumption given the volume of pesticide handled for these applications. Since MOEs for workers applying pesticides to ornamentals in greenhouses containing the AAPs in herbicides at 25%, the requested maximum allowable amount, and in herbicides and insecticides at 10%, do not exceed 100, HED has provided additional exposure and risk estimates reflecting lower percentages in final formulations. HED has provided risk estimates in this document for workers applying pesticides containing AAPs using a low pressure handwand to ornamentals in a green house setting assuming variable amounts of the AAP in herbicide formulations including 25%, 20%, 15%, 10% and 5%. For the insecticide and fungicide assessments, HED has provided estimates assuming variable amounts of the AAP in the formulations including 8%, 6% and 5%.

Occupational post application handler risks exceed an MOE of 100 on the day of

application for all scenarios except for postapplication activities involving herbicides and insecticides on corn, specifically the hand-harvesting / detassling scenario. Those scenarios resulted in MOE of 26 and 69, respectively on the day of application (Day 0). The Agency notes that it is not expected to be typical agricultural practice to apply herbicides or insecticides on the same day workers would be conducting hand harvesting and detassling activities.

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

This assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide. These studies have received the appropriate ethical review for use in risk assessment.

Regulatory Recommendation

There are no human health exposure or risk issues that would preclude the approval of an exemption from the requirement of a tolerance for the inert ingredients generically referred to as alkyl amine polyalkoxylates (AAPs), provided the following limitations are addressed specifically in the exemption statement:

- The maximum percent by weight of the AAPs in fungicide and insecticide products should be limited to no more than 10% with the one exception noted below.
- The maximum percent by weight of the AAPs in herbicide formulations should be limited to no more than 25%, with the one exception noted below.
- The maximum percent by weight of the AAPs in herbicide, fungicide and insecticide formulations intended for application by low pressure handwands to ornamentals in a green house setting may need to be reduced from the petitioner requested caps based on a risk benefit assessment for this scenario.
- HED assumed no indoor uses exist. This should be validated by RD, and restrictions on use of these inerts for indoor-use products should be mandated.

HED has no objection to the expansion of this exemption to include not only AAPs derived from animal and plant sources, but also from AAPs derived from petrochemical sources. The specific limitations noted above should be applied to the two cluster classifications that the petitioner has proposed:

> N,N-Bis-[alpha]-ethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2 – 60 moles

N,N-Bis-[alpha]-ethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2 – 60 moles

2.0 Background

Inert ingredients are those ingredients that are added to end use products that are not active ingredients. The terms "active ingredient" and "inert ingredient" are defined under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). An active ingredient is one that prevents, destroys, repels or mitigates a pest, or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. The statute defines the term "inert ingredient" as an ingredient that is not active.

As mandated by the Food Quality Protection Act (FQPA) of 1996, EPA conducted a reassessment of inert ingredients used in pesticide products to determine if they met the Agency's current standard of safety. As a result of that reassessment, the Agency published a final rule in the Federal Register (FR Notice Volume 71, No. 153, p. 45422) proposing revocation of specific exemptions from the requirement of a tolerance due to insufficient data. These tolerance exemptions are currently slated to be revoked on August 9, 2009 and included the following exemptions:

180.920 m. N,N-Bis-[alpha]-ethyl-[omega]-hydroxypoly(oxyethylene) alkylamine; the poly(oxyethylene) content averages 3 moles; the alkyl groups (C14-C18) are derived from tallow, or from soybean or cottonseed oil acids.

180.920 n. N,N-Bis (2-hydroxyethyl)alkylamine, where the alkyl groups (C8 – C18) are derived from coconut, cottonseed, soya, or tallow acids.

180.920 o. N,N-Bis 2-([omega]-hydroxypolyoxyethylene) ethyl) alkylamine; the reaction product of 1 mole N,N-bis(2-hydroxyethyl)alkylamine and 3-60 moles of ethylene oxide, where the alkyl group (C8-C18) is derived from coconut, cottonseed, soya or tallow acids.

180.920 p. N,N-Bis 2-([omega]-hydroxypolyoxyethylene/polyoxypropylene) ethyl) alkylamine; the reaction product of 1 mole N,N-bis(2-hydroxyethyl)alkylamine and 3-60 moles of ethylene oxide and propylene oxide, where the alkyl group (C8-C18) is derived from coconut, cottonseed, soya or tallow acids.

The Joint Inert Task Force (JITF) Cluster Support Team Number 4 (CST4) has submitted Petition #8E7382, proposing to consolidate and replace the four exemptions listed above with exemptions for the JITF CST4 inert ingredients known collectively as alkyl amine polyalkoxylates or "AAPs". The JITF CST4 is proposing to establish the following tolerance exemptions:

N,N-Bis-[alpha]-ethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2 – 60 moles.

N,N-Bis-[alpha]-ethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2 – 60 moles.

HED notes that while the proposed exemptions do represent a consolidation of the four exemptions slated for revocation, they also expand the previously approved exemptions to include alky amine polyalkoxylates manufactured from the reaction of ethylene oxide and propylene oxide with fatty acids derived from not only animal and plant sources, but also from petrochemical sources.

3.0 Ingredient Profile

3.1 Summary of Proposed Uses

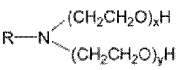
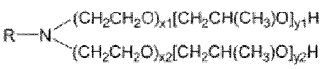
Alkyl amine polyalkoxylates are used primarily as surfactants in pesticide formulations. Additionally, the petitioner notes that these mixtures may also be used to a lesser extent as emulsifiers and wetting agents. While the AAPs are inert ingredients in all classes of pesticides, the majority of use reported by the petitioner is in herbicide and fungicide products. The petitioner indicates that currently the concentration of AAPs in formulated products generally does not exceed 25% by weight.

The petitioner is proposing to limit the use of AAPs in herbicide formulations to no more than 25% by weight and 10% by weight in all other pesticide formulations.

In addition to uses as inerts in pesticide formulations, AAPs have a variety of industrial applications. They appear to have very limited use in consumer or personal care products and the petitioner states that concentrations in potential consumer care products would be at lower concentrations than proposed in pesticide formulations.

3.2 Structural Information

The "alkyl amine polyalkoxylates" refers not to a discrete compound, but to mixtures of compounds. Information on the generic structures of these compounds and the manufacturing process to derive these surfactants is summarized in Table 3.2, below.

TABLE 3.2. Alky Amine Polyalkoxylate (AAP) Chemical Information	
Chemical Structure	These surfactants are typically complex mixtures formed from the reaction of fatty acid derived amines with either ethylene oxide or propylene oxide. The AAP carbon chain is defined in the exemption request as ranging from C8 – C18. The degree of polyalkoxylation is defined in the range of 2 to 60 moles. The generic structures for the alkylamine polyethoxylated compounds (AAP, POE) and alkylamine polypropoxylated (AAP POP) compounds are shown below.[1] **Figure 1a. Generic AAP POE Structure:** § 180.920: N,N-Bis-[[alpha]-ethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl)] C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2-60 moles.  R = Alkyl C8-18, linear or branched, saturated or unsaturated; Average x + y = 2-60 moles; x, y ≠ 0 **Figure 1b. Generic AAP POE/POP Structure:** § 180.920: N,N-Bis-[[alpha]-ethyl/methylethyl-[omega]-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl))] C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl)) content is 2-60 moles.  R = Alkyl C8-18, linear or branched, saturated or unsaturated; Average x1 + x2 + y1 + y2 = 2-60 moles; x1, x2, y1, y2 ≠ 0
Common name	Alkyl Amine Polyethoxylates (AAPs)
Use Class	Non ionic surfactants used as inert ingredients in pesticide formulations. May also be used as emulsifiers and wetting agents.
Discussion of Synthesis	AAPs are synthesized by reacting fatty acids or petrochemical derived long carbon chain acids with ammonia at high temperatures to generate long chain fatty acid type carbon amides which are dehydrated to the nitrile and then reduced to a primary fatty acid derived amine. The amine is then reacted with ethyl oxide or ethylene oxide and propylene oxide to form tertiary amine polyalkoxylates (POE or POE/POP). The alkyl amine precursors can be from plants, animals or petrochemicals.[2] The registrant has indicated (personal communication to K. Leifer) that branching consists of methyl groups and not longer branched chains.

[1] **Figure 1a and 1b excerpted directly from petition, page 8 dated June 19, 2008.**

[2] **Manufacturing process description taken from petition, page 11 dated June 19, 2008.**

3.3 Physical and Chemical Properties

As noted previously, the AAPs are not discrete chemicals, but are complex mixtures of chemicals. To address the requirement to provide information on physical and chemical properties, the registrant selected four representative compounds and modeled physicochemical data using EPI Suite™ modeling (http://www.epa.gov/opptintr/expsoure/pubs/episuite.htm). Results of the EPI Suite™ modeling as reported by the registrant are summarized in Table 3.3, below.

Table 3.3. Physicochemical Properties of Representative Alky Amine Polyalkoxylates[1]						
CAS No. (Company Name)	**Molecular Formula (MW)**	**Log K_{OW}**	**Water Solubility (mg/L)**	**Henry's Law Constant**	**Melting Point (°C)**	**Vapor Pressure (mm Hg @ 25 °C)**
61791-26-2	$C_{48}H_{97}NO_{15}$ (928.31)	3.15	381.83	4.2×10^{-33}	349.84	5.8×10^{-27}
61791-31-9 (MON 8109)	$C_{16}H_{35}NO_2$ (273.46)	3.90	299.47	1.94×10^{-9}	131.43	1.76×10^{-8}
70955-14-5	$C_{18}H_{39}NO_2$ (301.52)	4.96	19.48	4.99×10^{-10}	127.14	3.86×10^{-8}
68213-26-3 (Armoblend 557)	$C_{64}H_{129}NO_{17}$ (1184.74)	7.53	6.685×10^{-8}	2.37×10^{-34}	349.84	3.77×10^{-33}

[1] Table values taken directly from submission entitled *Petition Proposing an Exemption from the Requirement of a Tolerance for Residues of Joint Inerts Task Force Cluster 4 "Alkyl Amines Polyalkoxylates" in or on Raw Agricultural Products and Food Products.* Submitted by JITF Cluster Support Team Number 4, 6/19/2008, Table 7, pp 19 – 20.

4.0 Hazard Characterization/Assessment

4.1 Hazard and Dose-Response Characterization

4.1.1 Database Summary

The available mammalian toxicology database includes acute, subchronic repeat dose oral, developmental, reproductive, and mutagenicity data for four representative compounds of the alkyl amine polyalkoxylate (AAP) group. The toxic effects seen in the submitted studies include gastrointestinal problems due to local irritation and corrosive effects. The chemicals for which toxicity data were submitted are listed below:

►**MON 0818 [CAS 61791-26-2 (tallow); Ave POE n=15]** acute oral and dermal, eye and skin irritation, dermal sensitization, Ames, *in vivo* mouse micronucleus assay, 4-week rat (diet), 3-month rat (diet), **OECD 421** 2-generation reproduction rat screening (diet), **OECD 422** 28-day rat reproductive/developmental (diet);

►**MON 8109 [CAS 61791-31-9 (coco); Ave POE n=2]** acute oral and inhalation, eye and skin irritation studies, **OECD 422** 28-day rat repeated oral dose (dietary) reproductive/developmental;

►**ATMER® 163 [CAS 70955-14-5; C13-C15; ave POE n=2]** acute oral, skin irritation, Ames, *in* vitro human peripheral lymphocyte cytogenic assay, *in* vitro mouse lymphoma mutation assay, 90 day rat oral (gavage), 90-day dog (capsule).

►**Armoblen 557 [CAS 68213-26-3; Ave POE n=5/Ave POP n=12]** acute oral and inhalation, eye and skin irritation, Ames, 28-day rat oral (gavage)

The available toxicology data are adequate to support the requested exemption from the requirement of tolerance when used in pesticide formulations for these AAP inert compounds. In a joint meeting of the HED ToxSAC (Toxicology Science Advisory Committee) and the ROCKS (Residues of Concern Knowledge-based Subcommittee), the Agency concluded that the four surrogate chemicals (MON 0818, MON 8109, Atmer 163, and Armoblen 557) are representative of all the chemicals in the AAP cluster. Further, the ToxSAC members agreed that the currently available toxicity dataset is adequate to apply to the cluster and to characterize the potential toxic effects of these surfactants. The ROCKS members noted that there was sufficient bracketing of the range of molecular weights to represent the entire class of AAPs.

The available mammalian toxicity database includes acute, subchronic, developmental, reproductive toxicity studies *via* the oral route as well as mutagenicity data for the four compounds. While there is no chronic toxicity study, the ToxSAC noted that the effects do not increase in severity over time (4 weeks to 13 weeks). Based on the lack of progression of severity of effects with time along with the considerable similarities of effects across the species tested and the observation that the vast majority of the effects observed were related to local irritation and corrosive effects, the ToxSAC concluded that chronic studies would not be required. Moreover, an additional uncertainty factor (UF) for extrapolation from subchronic toxicity study to a chronic exposure scenario would not be needed since the severity of effects did not increase with time and similar effects (related to local irritation) occurred at comparable dose levels across species. As a result, the committee concluded that the typical 100-fold uncertainty factor (10X interspecies and 10X intraspecies) would be adequately protective. The ToxSAC noted that use of the full 10X interspecies factor will actually provide an additional margin of safety because it is not expected that humans' response to local irritation/corrosiveness effects would be markedly different from animals.

4.1.2 Toxicological Effects and Metabolism

Toxicological Effects
As previously noted, the AAPs in this inert class cover the range of C8-C18 carbon lengths and polyalkoxylation of n = 2-60. The majority of toxicology information is available for four AAPs, which is meant to represent the entire class of compounds. Details can be found in the JIFT Cluster Support Team Number 4 (2008) submission.

Generally, lower molecular weight AAPs (lower carbon chain units and less alkoxylation) may potentially be more bioavailable because they may be more easily absorbed and distributed than higher molecular weight compounds. Thus overall, the longer chain carbon amine higher polyalkoxylates should be less bioavailable.
The AAPs are not acutely toxic by the oral and dermal routes of exposure, or via inhalation under normal use conditions (i.e., maximum 25% in pesticide end-use products and non-respirable droplet sizes). Concentrated materials are generally corrosive, eye and skin irritants and may be dermal sensitizers. There is no evidence that the AAPs are mutagenic, or clastogenic.

There is no clear target organ identified across the AAPs. Following subchronic exposure to rats, some gastrointestinal irritation was observed, but no specific target organ toxicity or neurotoxicity was seen. No effects were detected in a functional observational battery (FOB) or motor activity assessment. In a subchronic rat study, the most sensitive effects noted were increased mortality, salivation, wheezing, cataracts, and micro- and macroscopic changes in the non-glandular stomach at doses as low as 30 mg/kg/day. In a subchronic dog study, the most sensitive effects included clinical signs (increased incidence of salivation, emesis, and soft feces) and liver effects characterized by enzyme induction, and pigment accumulation in Kupffer cells and bile canaliculi.

In rat developmental studies, no adverse fetal effects were seen, even at maternally toxic doses. No effects were observed on estrous cyclicity, spermatogenic endpoints, or testosterone and thyroid levels in a two-generation rat reproduction study. However, reproductive and offspring toxicity were noted for AAPs (specifically MON 0818 and MON 8109) based on litter loss, increase mean number of unaccounted-for implantation sites and decreased mean number of pups born, live litter size and postnatal survival from birth to LD 4.

Surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Thus, surfactants are often corrosive and irritating in concentrated solutions, as indicated by the acute toxicity studies for these inert materials. It is possible that some of the observed toxicity seen in the repeated studies, such as diarrhea or decreased body weight gain, can be attributed to the corrosive and irritating nature of these surfactants.

Metabolism
Very little metabolism information is available for the alkyl amine polyalkoxylates. However, it is possible to predict mammalian metabolism based on studies for the alkyl alcohol alkoxylates, which are another class of surfactants. It has been proposed that the primary metabolic pathway involves the excretion of the polyalkoxylate moiety and conversion of the alkyl amine group to a fatty acid that is then converted via oxidative degradation to carbon dioxide and water.

In general, the gastrointestinal absorption of AAPs with relatively short alkoxylate chain lengths is expected to be rapid and extensive, while less absorption is likely for the more extensively polyalkoxylated AAPs with larger molecular weights.

4.2 Dose Response Assessment

The Agency believes the dose-response assessment described herein and used for risk assessment purposes for the AAPs is conservative because the most health protective surrogate chemical was selected to represent the entire AAP class of inert ingredients.

4.2.1 Acute Reference Dose (aRfD) – All Populations

Study Selected: developmental toxicity – rat (OPPTS 870.3700)
MRID No.: 46902005
Executive Summary: See Appendix A, Guideline §870.3700

Dose and Endpoint for Risk Assessment: NOAEL = 72 mg/kg/day, based on 2 deaths on gestation day (GD) 8 (after 2 doses) at the LOAEL of 216 mg/kg/day.
Uncertainty Factor(s): 100X (10 interspecies; 10X intraspecies)

Comments about Study/Endpoint/Uncertainty Factors: The rats in this study were administered a test material that contained 71.9% of the inert ingredient to be tested, therefore the doses in this study were adjusted accordingly. The executive summary for the rat developmental toxicity study may be found in Appendix A, Section A.3 of this document.

4.2.2 Chronic Reference Dose (cRfD)

Study Selected: 90-day oral toxicity – rat (OPPTS 870.3100)
MRID No.: 47041301
Executive Summary: See Appendix A, Guideline §870.3100

Dose and Endpoint for Risk Assessment: NOAEL = 15 mg/kg/day, based on increased mortality, salivation, and posterior subcapsular cataracts in males as well as wheezing, and micro- and macro-scopic changes in the non-glandular stomach of both sexes at the systemic LOAEL of 30 mg/kg/day.
Uncertainty Factor(s): 100X (10 interspecies; 10X intraspecies)

Comments about Study/Endpoint/Uncertainty Factors: The purity of the test material was not reported in the study, but the Agency confirmed via personal communication that this inert ingredient (ATMER 163) is a nominally 100% pure product. The study provides the lowest NOAEL. Two deaths occurred at 30 mg/kg/day (on days 36 and 78). Although the duration of exposure was 90 days, there is no need for an additional uncertainty factor because the effects do not seem to increase in severity over time (4 weeks to 13 weeks). Based on the lack of progression of severity of effects with time along with the considerable similarities of effects across the species tested and the observation that the vast majority of the effects observed were related to local irritation and corrosive effects, the ToxSAC concluded that an additional UF for extrapolation from subchronic toxicity study to a chronic exposure scenario would not be needed. As a result, the ToxSAC concluded that the typical 100-fold uncertainty factor would be sufficiently protective since it is not expected that humans' response to local irritation/corrosiveness effects would be markedly different from animals. The executive summary of the subchronic oral toxicity study in rats may be found in Appendix A, Section A.3 of this document.

4.2.3 Incidental Oral (Short-Term and Intermediate-Term), Dermal (All Durations) and Inhalation (All Durations)

Study Selected: 90-day oral toxicity – rat (OPPTS 870.3100)
MRID No.: 47041301
Executive Summary: See Appendix A, Guideline §870.3100

Dose and Endpoint for Risk Assessment: NOAEL = 15 mg/kg/day, based on increased mortality, salivation, and posterior subcapsular cataracts in males as well as wheezing, and micro- and macroscopic changes in the non-glandular stomach of both sexes at the systemic LOAEL of 30 mg/kg/day.
Uncertainty Factor(s): 100X (10 interspecies; 10X intraspecies)

Comments about Study/Endpoint/Uncertainty Factors: The study provides the lowest NOAEL. Two deaths occurred at 30 mg/kg/day (days 36 and 78). Although the duration of exposure was 90 days, there is no need for an additional uncertainty factor for risk assessments reflecting longer exposure durations because the effects do not seem to increase in severity over time (4 weeks to 13 weeks). The executive summary of the subchronic oral toxicity study in rats may be found in Appendix A, Section A.3 of this document. A dermal absorption factor of 5% is recommended (see section 4.2.5). Since no inhalation absorption data are available for the surrogate chemicals, toxicity by the inhalation route was considered to be equivalent to toxicity by the oral route of exposure.

4.2.4 Dermal Absorption

There are no dermal absorption data on the AAPs. However, data on functionally and structurally similar surfactants suggest that dermal absorption of the AAPs is likely to be low. As referenced in Section B of the petition (JITF CST 4 2008), dermal absorption models commonly used in the cosmetic and detergent industries also suggest low systemic exposure for AAPs. Predicted dermal absorptions for the representative AAP chemicals using such models were said to range from negligible to 1.1% absorption. Based on the lack of data for the AAPs and the irritant properties of these surfactants, in order to be health protective, a conservative dermal absorption factor of 5% was selected.

4.3 FQPA Considerations

The toxicity database, with respect to FQPA, consists of a rat developmental study (MON 0818) and one rat reproduction study (MON 0818) to cover the C8-C18 (coco and tallow) range of carbon chain length and polyalkoxylation from the lower, more bioavailable end n=2 to the higher end n=15. A summary of these studies is in Appendix A. There are no neurotoxicity studies available for the AAPs; however, there is no indication of neurotoxicity in the available toxicity studies.

HED performed a Degree of Concern Analysis because the rat reproduction study provided evidence of increased susceptibility in the offspring relative to the parents. The purpose of the Degree of Concern analysis was (1) to determine the level of concern for

the effects observed when considered in the context of all available toxicity data; and (2) identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment.

In the case of the AAPs, there was no increased susceptibility to the offspring of rats following *in utero* exposure in the prenatal development toxicity study. However, there was evidence of increased susceptibility in the reproduction toxicity studies in rats. Offspring effects include litter loss, increased mean number of unaccounted-for implantation sites and decreased mean number of pups born, live litter size and postnatal survival from birth to LD 4 (F1) at 1000 ppm MON 0818 (41-48.6 mg/kg/day) and at 2000 ppm MON 8109 (134-148 mg/kg/day). However, the rat reproduction study identified a NOAEL of 300 ppm for both MON 0818 and MON 8109 (12-14 mg/kg/day and 23-26 mg/kg/day, respectively) for offspring effects, and the selected point of departure for the dietary, dermal and inhalation risk assessments is protective of these offspring effects, thus there are no residual concerns.

There are no residual uncertainties identified in the exposure databases. The food exposure assessments are considered to be conservative. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children.

The FQPA factor can be reduced to 1X. A 1X FQPA Safety Factor is appropriate for the following reasons:

- The toxicology database is adequate for assessing the sensitivity of infants and children to AAP exposure.
- No quantitative or qualitative increased susceptibility was demonstrated in the fetuses in the prenatal developmental toxicity study in rats following *in utero* exposure.
- Although there is some increased susceptibility in the rat reproductive toxicity study (where the offspring NOAEL of 300 ppm (12-14 mg/kg/day) was lower than the paternal NOAEL of 1000 ppm (41-48.6 mg/kg/day), the dose-response for this effect has been adequately characterized, and the point of departure for the chronic dietary, dermal and inhalation risk assessment which is based on a NOAEL of 15 mg/kg/day with a 100X uncertainty factor, is protective of the adverse offspring effects.
- Residue values used in the dietary risk assessment are unlikely to underestimate risk.

4.4 Classification of Carcinogenic Potential

There is no evidence that the AAPs are carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts for a representative large molecule, as well as a smaller molecule that had been extensively dealkylated, with the amine group intact. No structural alerts were identified. In addition, there was little concern by the Residues of Concern Knowledge-based Subcommittee (ROCKS) about any of the postulated metabolites having greater

toxicity than the parent compounds. See Appendix B for a complete description of the SAR analysis conducted for the alkyl amine polyalkoxylates.

4.5 Hazard Identification and Toxicity Endpoint Selection

A summary of the points of departure selected may be found in Table 4.5. Points of Departure for risk assessment were selected at a Joint ToxSAC/ROCKS meeting and are documented in the meeting minutes entitled "CST4 Inerts – Joint ToxSAC/ROCKS Meeting on December 9, 2008" (J. Kidwell, 1/16/2009).

The level of concern (LOC) is for MOEs which are less than 100 and is based on 10X for interspecies extrapolation from animals to humans and 10X for variation in sensitivity between humans. These LOCs are applicable to all populations, including individuals exposed in a residential setting and occupationally exposed workers.

An aggregate risk assessment can be performed for the AAPs since common endpoints were selected for the oral, dermal and inhalation routes of exposure.

Table 4.5. Summary of Toxicological Doses and Endpoints for AAPs for Use in Dietary, Non-Occupational, and Occupational Human Health Risk Assessments

Exposure/ Scenario	Point of Departure	Uncertainty Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all populations)	NOAEL = 72 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF = 1x	aRfD = aPAD= 0.72 mg/kg/day	**90-day oral toxicity study – rat** MON 0818 [CAS 61791-26-2 (tallow); Ave POE n=15] LOAEL = 216 mg/kg/day, based on mortality (2 deaths after 2 exposures; GD 2), with a total of 6/25 deaths during GD 6-15.
Chronic Dietary (All Populations)	NOAEL = 15 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF = 1x	cRfD =cPAD= 0.15 mg/kg/day	**90-day oral (gavage) toxicity study – rat ATMER®163 (CAS 70955-14-5 (C13-C15, POE n=2)** LOAEL = 30 mg/kg/day, based on increased mortality [2 deaths (days 36, 78)], salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and microscopic changes in the nonglandular stomach of both sexes.
Incidental Oral Short-Term (1–30 days) and Intermediate-Term (1-6 months)	NOAEL = 15 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF = 1x	Residential LOC for MOE = 100	**90-day oral (gavage) toxicity study – rat ATMER®163 (CAS 70955-14-5 (C13-C15, POE n=2)** LOAEL = 30 mg/kg/day, based on increased mortality [2 deaths (days 36, 78)], salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and microscopic changes in the nonglandular stomach of both sexes.

Table 4.5. Summary of Toxicological Doses and Endpoints for AAPs for Use in Dietary, Non-Occupational, and Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dermal and Inhalation (All Durations)	oral NOAEL = 15 mg/kg/day (5% dermal absorption) (inhalation absorption rate = 100%)	UF_A= 10x UF_H=10x FQPA SF = 1x	Residential/ Occupational LOC for MOE = 100	**90-day oral (gavage) toxicity study – rat ATMER®163 (CAS 70955-14-5 (C13-C15, POE n=2)** LOAEL = 30 mg/kg/day, based on increased mortality [2 deaths (days 36, 78)], salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and microscopic changes in the nonglandular stomach of both sexes.
Cancer (oral, dermal, inhalation)	Classification: No animal toxicity data available for an assessment; Based on SAR analysis, AAPs are not expected to be carcinogenic.			

Point of Departure (PoD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

4.6 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, AAPs may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

5.0 Dietary Exposure/Risk Characterization

5.1 Residues of Concern

Very limited information is available for the alkyl amine polyalkoxylates with respect to plant and animal metabolism or environmental degradation. The ROCKS Subcommittee

met in a joint meeting with the ToxSAC on December 9, 2008 to determine if the selected representative chemicals from the AAPs were representative of the entire cluster and to discuss residues of concern. The subcommittee considered the representative chemical structures, the generic cluster structures, the submitted physicochemical EPI Suite™ information as well as the structure-activity relationship analysis detailed in Appendix B of this review. Additionally, the ROCKS members considered information on other surfactants and chemicals of similar size and functionality. The committee concluded that the cluster grouping was appropriate and that there were not likely to be degradates of the alky amine polyalkoxylates that were likely to be of greater toxicological concern than the AAPs themselves.

5.2 Drinking Water Residue Profile

No monitoring data or data reflecting the concentration of these inert ingredients in drinking water is available. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for the AAPs, a value of 100 ppb based on screening level modeling was used for both the acute and chronic dietary risk assessments.

EFED conducted modeling runs on four surrogate inert chemicals using a range of physical chemical properties which bracket those expected in for the AAPs (email from D. Young to M. Metzger dated 1/15/09). EFED selected a North Carolina cotton scenario with an application date of July 1st as the scenario that would likely provide high end drinking water values for use in risk assessment. Percent crop area (PCA) factors were not applied. Simulations were run assuming a rate of 1 lb inert ingredient/A. Since degradation information was not available, three degradation scenarios were investigated: 1) chemically stable in water and soil; 2) a 100-day half-life in water and soil; and 3) a 10-day half life in water and soil. Further, two possible scenarios were investigated, one where all of the inert was applied as a single application, and the second assuming that the inert was applied evenly over a growing season. Modeled acute drinking water values ranged from 0.001 ppb to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of the EFED analysis are contained in Appendix C of this document.

HED considers the value of 100 ppb to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

5.3 Food Residue Profile

No residue data were submitted for the alkyl amine polyalkoxylate inert ingredients. In the absence of data, the Agency has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of 57 high use insecticides (22), herbicides (20), and fungicides (17). The 57 pesticides were selected based on an overall ranking scheme that included consideration of the 1999 data for active ingredients use. All herbicides at greater than 5

million lbs/yr and all fungicides and insecticides at greater than 1 million lbs/yr were included as candidate surrogate chemicals. The 57 pesticide surrogate candidates are listed in Appendix D of this risk assessment.

OPP assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

To summarize, the Agency believes the assumptions used to estimate dietary exposures lead to a very conservative assessment of dietary risk for the following reasons:

- the highest tolerance level from the surrogate pesticides for every food is used;
- 100% crop treated is assumed for all crops (every food eaten by a person each day has tolerance-level residues);
- many of these high tolerances are based on very short pre-harvest intervals where there is little time for degradation, whereas actual pesticide applications occur throughout the growing season;
- no consideration was given to potential degradation between harvest and consumption (use of tolerance level residues which are typically one to two orders of magnitude higher than actual residues found in monitoring data);
- residue values were assigned to every commodity in DEEM™ with no consideration given to potential reduction in residues from washing or cooking.

Although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. OPP does not believe that this approach underestimates exposure in the absence of residue data.

5.4 Analytical Methodology

Since this request is for an exemption from the requirement of a tolerance, an analytical method for enforcement purposes is not required to support this action.

5.5 Dietary (Food and Water) Exposure and Risk

The model and inputs used for the AAP dietary risk assessment are described briefly below. A complete description of the dietary exposure and risk assessment is provided in the memorandum entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09).

Acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which uses food consumption data from the U.S. Department of

Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

5.5.1. Acute Dietary Exposure and Risk

A screening level assessment for acute dietary (food and drinking water) exposure assessment was conducted for the alkyl amine polyalkoxylates. In the absence of actual exposure information HED assumed that the residues of the inert ingredients would be no higher than the highest exposure from 57 of the most significant active ingredients. Inherent in this assumption is the supposition that the inert ingredient will be in the final formulation at no higher percentage than the active ingredient (i.e. 50% active, 50% inert). RD has conducted a review of current formulations used in agricultural settings and has found that individual inert ingredients are not present at levels in excess of the active ingredient (personal communication K. Leifer). The highest tolerance level residue for all food forms, including meat, milk, poultry and eggs, default processing factors for dried commodities and 100% percent crop treated (%CT) were used. No monitoring data or data reflecting the concentration of these inert ingredients in drinking water is available. For the purpose of this screening level dietary risk assessment, a value of 100 ppb was used for drinking water residues for both the acute and chronic dietary risk assessments.

The initial screening level acute dietary exposure estimates for food and drinking water, assuming that the inert ingredient would be in the formulation at a level equivalent to the active ingredient (50% active ingredient; 50% AAP), identified potential risks of concern. HED conducted a more refined assessment to reflect the actual use pattern of these inert ingredients in pesticide formulations. The petitioner has indicated that these inerts will not be used at more than 10% by weight in fungicide and insecticide formulations and at no more than 25% in herbicide formulations.

In refining the dietary risk assessment, HED notes that it is the fungicide tolerances which are typically the highest and serve as the basis for the residue value used in the dietary risk assessment. This is consistent with expectation given that fungicides are often applied late in the season and herbicides and insecticides are typically used much earlier in the season, resulting in much lower residues. HED has not yet developed a dietary exposure model for inerts which would allow for inclusion of inert ingredients at different percentages in the final formulation based on class of pesticide. The current model uses predominantly fungicide residues to estimate a high end exposure. HED does not expect that allowing a maximum of 25% in the final formulation for herbicides only will have a significant impact on the dietary exposure. Across the board it appears that selecting the highest fungicide tolerance and correcting for its limitation to 10% by weight as a maximum in the final formulation, results in a higher residue input into the dietary risk assessment than selecting the highest herbicide tolerance and correcting for 25% by weight as a maximum in the final formulation.

This assertion that herbicides at 25% of the final formulation will not significantly impact risk above that resulting from use of fungicides at 10% of the final formulation is

supported by examining the major drivers in the AAP dietary risk assessment. The major drivers for the AAP dietary risk assessment are apples and grapes. For both of these commodities, the highest tolerances were from the fungicide, captan and were 25 ppm in both crops. The highest herbicide tolerance for apples and grapes was from diuron and was 1 ppm for both crops. To calculate the effective residue level to input into the refined assessment, HED has started with the assumption in the screening level that residues of the active ingredient and the inert are equivalent or that at a maximum, the inert is present in the formulation at 50%. Since the petitioner proposes to cap the use of the AAPs in fungicides to 10%, a 5-fold reduction factor is applied to the residue (25 ppm x 0.2 = 5 ppm). The proposed cap for herbicide use is 25%, so the initial residue value can be refined to account for a 2-fold reduction in the residue from the original herbicide tolerance (1 ppm x 0.5 = 0.5 ppm). Even allowing for a higher percent in the final herbicide formulation, the residue value resulting from the fungicide use is significantly higher than that of the herbicide.

Based on the refined dietary risk assessment which allows for a reduction of residues based on a lower percentage in the final formulation, the AAP dietary exposure at the 95th percentile for food and drinking water is 16% of the aPAD for the U.S. population and 44% of the aPAD for children 1-2 yrs old, the most highly exposed population subgroup. The results for all regulated subgroups are shown in Table 5.5.4, below.

5.5.2 Chronic Dietary Exposure and Risk

A conservative screening level assessment was conducted for chronic dietary (food and drinking water) exposure using the highest tolerance level residue for all food forms, including meat, milk, poultry and eggs, default processing factors for dried commodities and 100% CT. In addition, a default concentration of 100 ppb was assumed for inert ingredient residues in drinking water.

The chronic dietary exposure estimates for food and drinking water, assuming that the inert ingredient would be in the formulation at a level equivalent to the active ingredient, resulted in a screening level assessment which identified potential risks of concern. Based on the results of the screening level assessment, HED conducted a more refined assessment to reflect the actual use pattern of these inert ingredients in pesticide formulations as described above for the acute dietary assessment. The chronic dietary (food and water) exposure estimates are 27% of the cPAD for the U.S. population and 85% of the cPAD for children 1-2 yrs old, the most highly exposed population subgroup when the assessment was refined based on the proposed maximum amounts these inerts are likely to be in final formulations. See Table 5.4.4, below for a summary of results.

5.5.3 Cancer Dietary Exposure and Risk

HED has not identified any concerns for carcinogenicity relating to the AAPs; therefore, a cancer dietary exposure assessment was not performed.

5.5.4. Summary of Dietary Exposure and Risk Assessment Results

The results of the acute and chronic dietary risk assessment are shown in the summary table, below.

Table 5.5.4. Summary of Dietary (Food and Water) Exposure and Risk for AAPs

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.113767	16	0.039989	27
All Infants (< 1 year old)	0.252003	35	0.084945	57
Children 1-2 years old	**0.315197**	**44**	**0.127307**	**85**
Children 3-5 years old	0.230332	32	0.094739	63
Children 6-12 years old	0.133067	18	0.052682	35
Youth 13-19 years old	0.081379	11	0.030045	20
Adults 20-49 years old	0.079350	11	0.030455	20
Adults 50+ years old	0.079669	11	0.032072	21
Females 13-49 years old	0.081334	11	0.030647	20

The most highly exposed subgroup is bolded.

6.0 Residential (Non-Occupational) Exposure/Risk Characterization

A screening level residential exposure and risk assessment was completed for products containing alkyl amine polyalkoxylates as inert ingredients. Details of the residential exposure and risk assessment can be found in Appendix E. A summary of the residential exposure and risk assessment is presented below.

6.1 Residential Handler Exposure

Exposure Scenarios

In this assessment, the Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The residential products are typically formulated as liquids in concentrates or as wettable powders. The AAPs themselves have no pesticidal properties, and are added to pesticide formulations for their adjuvant properties. According the petition submitted by the JITF CST4, the AAPs are not added to any pesticides intended for indoor use (i.e., where the Agency would

typically assess crack and crevice/pet uses)[1]. Therefore, HED assumed no indoor uses exist; but this should be validated by RD, and restrictions on use of these inerts for indoor-use products should be mandated.

For each of the use scenarios, the Agency assessed residential handler (applicator) inhalation and dermal exposure for outdoor scenarios with high exposure potential (i.e., exposure scenarios with high end unit exposure values) to serve as a screening assessment for all potential residential pesticides containing the AAP inert ingredients.

Mixer/Loader/Applicator High Exposure Outdoor Scenarios:

- Liquid products: Low Pressure Handwand;
- Liquid products: Hose End Sprayer
- Ready to Use (RTU): Trigger Pump Sprayer Applications;

Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessments for the AAPs. Each assumption and factor is detailed below. In addition to these factors, unit exposures were used to calculate risk estimates. These unit exposures were primarily taken from the Pesticide Handlers Exposure Database (PHED). Several of the assumptions and factors used for the assessment are similar to those used in the occupational assessment presented below. Some of the factors used in the residential scenarios are highlighted below.

The Agency also used assumptions based on the Residential Exposure Assessment Standard Operating Procedures (SOPs). The duration of exposure was assumed to be short- and intermediate-term for all residential scenarios assessed. The following assumptions were used in this assessment:

- The maximum application rate per pesticide group (herbicide/pesticide/fungicide) has been assessed for the short-term exposure duration.
- The average application rate per pesticide group (herbicide/pesticide/fungicide) has been assessed for the intermediate-term exposure duration.
- Residential risk assessments are based on estimates of what homeowners would typically treat. Per HED's Residential SOPs (1997 & 2001 revision), residential pesticide handlers are assumed to mix and use a volume of 5 gallons of product per day.
- For herbicide applications, residential handlers are assumed to use 1.125 lbs AAP per day.

This estimate is based on the following assumptions:

Five (5) gallons of formulated pesticide solution are assumed to be used per day by a residential handler (Revised Residential SOPs Area Treated, February, 2001). Consistent with the residential SOPs, the density of the formulated pesticide solution is assumed to be 9 lbs/gallon. For herbicides, 25% of the five

[1] The Joint Inert Task Force (JITF) Cluster Support Team Number 4 (CST4) presented this information verbally at the January 14th, 2009 JITF/OPP Update meeting.

gallons of formulated pesticide solution can be AAPs and the product concentrate is assumed to be diluted at a 1 to 10 ratio with water.

5 gallons formulated pesticide solution*(9 lbs/gallon)*(25% AAP)*(1 part product concentrate/10 parts water) = 1.125 lbs AAP in herbicide formulated pesticide solutions per day

- For insecticide/fungicide applications, residential handlers are assumed to use 0.45 lbs AAP per day.

This estimate is based on the following assumptions:

Five (5) gallons of formulated pesticide solution are assumed to be used per day by a residential handler (Revised Residential SOPs Area Treated, February, 2001). Consistent with the residential SOPs, the density of the formulated pesticide solution is assumed to be 9 lbs/gallon. For insecticides/fungicides, 10% of the five gallons of formulated pesticide solution can be AAPs and the product concentrate is assumed to be diluted at a 1 to 10 ratio with water.

5 gallons formulated pesticide solution*(9 lbs/gallon)*(10% AAP)*(1 part product concentrate/10 parts water) = 0.45 lbs AAP in insecticide or fungicide formulated pesticide solutions per day

- Residential exposure is assessed assuming clothing consisting of a short-sleeved shirt, short pants and no gloves or respiratory protection.

Risk Characterization

For all residential handler scenarios, risk estimates are not of concern (i.e., MOEs are all greater than 100) for both the route-specific (dermal or inhalation) assessment and for the total MOE (dermal and inhalation combined). A summary of the results are provided below in Table 6.1.

The Agency believes that the scenarios assessed in this document represent worse-case exposures and risks resulting from use of pesticide products containing the AAPs in residential environments.

Table 6.1. Short- and Intermediate-Term Exposure and Risks for Residential Handlers of the AAPs

Exposure Scenario (Formulation/ Application)	Application Rate[1] (lb inert/ day)	Area Treated Daily[2] (units)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (mg/ lb inert)[3]	Dermal Dose (mg/kg /day)[4]	Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Herbicide Mixer/Loader/Applicator Scenarios									
Liquids/ Low Pressure Handwand	1.125	1	38	0.003	0.03054	4.82×10^{-5}	490	310,000	490
Liquids/ Hose End Sprayer[9]	1.125		11	0.017	0.00884	0.000273	1,700	55,000	1,600
Liquids/ Trigger Sprayer/ Home Garden	1.125		54	0.0019	0.0434	3.05×10^{-5}	350	490,000	350
Insecticide and Fungicide Mixer/Loader/Applicator Scenarios									
Liquids/ Low Pressure Handwand	0.45	1	38	0.003	0.0122	1.93×10^{-5}	1,200	780,000	1,200
Liquids/ Hose End Sprayer[9]	0.45		11	0.017	0.0035	1.09×10^{-4}	4,200	140,000	4,100
Liquids/ Trigger Sprayer/ Home Garden	0.45		54	0.0019	0.017	1.22×10^{-5}	860	1,200,000	860

[1]Application rates are based on high end application rates of products containing inerts in the AAPs multiplied by 25% to convert to application rate of just inert in an herbicides product (Herbicide products contain maximum of 25% inert from the AAPs according to Inerts Task Force). For insecticide and fungicide application rates, the AAPs multiplied by 10% to convert to application rate of just inert in an insecticide/fungicide products. Application rates for Short-Term exposure risk estimates are based on maximum product application rates. Application rates for Intermediate-Term exposure risk estimates arer based on average product application rates.

[2]Area treated daily values are back-calculated from 5 gallons of product used per day (Revised Residential SOPs 2001).

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 except for liquids hose end sprayer scenario (See footnote 9). All exposure scenarios assess exposure reflecting applicators wearing short-sleeved shirts and shorts and no respiratory protection.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7] ST Inhalation MOE = PoD (NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8] Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)
[9] Uses unit exposures from ORETF Homeowner Study (MRID 449722-01)

6.2. Residential Postapplication Exposure

Exposure Scenarios
Residential postapplication exposures result when bystanders, such as children come in contact with the AAPs in areas where end-use products have recently been applied (e.g., treated lawns or gardens). As noted above, the AAPs are not added to any pesticides intended for indoor use.

Postapplication High End Outdoor Exposure Scenarios

- Dermal exposure to treated lawns (adults/children)
- Hand-to-Mouth activity for toddlers on treated lawns (children)
- Object-to-Mouth activity for toddlers on treated lawns (children)
- Soil ingestion from treated soil (children)

The exposures from these routes and scenarios were considered individually and were also added together, where appropriate, to determine a total dose for children exposure to treated lawns. Residential postapplication exposure is assessed on the day of application, typically referred to as Day 0.

Inhalation exposures are not typically calculated for residential post-application scenarios for the formulation types applicable to the AAPs because inhalation exposures generally account for a negligible percentage of the overall body burden for most pesticide chemicals. This is particularly true for chemicals with a low vapor pressure such as the AAPs.

Exposure Data and Assumptions
A series of assumptions and exposure factors served as the basis for completing the residential postapplication risk assessments. The assumptions and factors used in the risk calculations are consistent with current HED policy for completing residential exposure assessments (i.e., *SOPs for Residential Exposure Assessment [1997 and 2001 revision]*).

Exposures to adults/children after contact with treated lawns have been addressed using the latest approaches for this scenario including:

- The adverse effects for the short- and intermediate-term dermal and inhalation endpoints are based on studies where the effects were observed in both sexes. For adult exposure, the mean for US males and females was used to estimate exposure (70 kg). For child exposure, the mean of median values for male and female 3 year olds was used to estimate exposure (15 kg).
- HED has developed standard transfer coefficient (TC) values for residential postapplication scenarios to ensure consistency in exposure assessments. For the

short-term assessment, TC values of 14,500 cm^2/hr (adults) and 5,200 cm^2/hr (children) were used. For intermediate-term risk assessment, TC values of 7,300 cm^2/hr and 2,600 cm^2/hr were used. These default transfer coefficients, found in the 2001 Residential SOPs were used to calculate postapplication exposures.

- Herbicides have a maximum of 25% by weight of AAPs in the end use product and insecticides and fungicides have a maximum of 10% by weight of the AAPs in the end use product.
- AAP application rates are derived above in Section 6.1
- Dermal absorption is assumed to be 5%.

Risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of the body burden to the toxicological PoD. Exposures were calculated by considering the potential sources of exposure (i.e., transferable residues on treated lawns), then calculating dermal and nondietary ingestion exposures.

Risk Characterization

A summary of the residential post application exposure and risk estimates are presented in Table 6.2, below. The risk estimates are expressed in terms of the MOE. In addition to estimating route specific MOEs, a total MOE was calculated for the AAPs because common toxicity endpoints were identified for the oral, dermal and inhalation routes of exposure.

Additionally, the Agency has combined risk estimates resulting from separate postapplication exposure scenarios when it is likely that they can occur simultaneously based on the use-pattern and the behavior associated with the exposed population. The combined non-dietary risks from dermal exposure and hand-to-mouth exposure on treated lawns do not demonstrate risks of concern for toddlers.

All assessed scenario risk estimates are not of concern (i.e., the MOEs for the assessed scenarios are greater than 100) for both the individual exposure scenario assessed and for the aggregate risk estimates.

Table 6.2. Residential Postapplication Short- and Intermediate-term Exposures and Risks for the AAPs				
Exposure Scenario	Application Rate (lb inert/day)[1]	Exposed Population & Exposure Duration[2]	Daily Dose (mg/kg/day)[3]	MOE[4]
Herbicide Product Scenarios				
Dermal Exposure to Treated Lawns	1.125	Adult ST	0.013	1,100
		Adult IT	0.007	2,300
		Child ST	0.022	690
		Child IT	0.011	1,400
Hand-to-Mouth from Treated Lawn		Child ST	0.0168	900
		Child IT	0.00799	1,900
Object-to-Mouth from Treated Lawn		Child	0.00421	3,600
Soil Ingestion		Child	5.635×10^{-5}	270,000
Total Aggregated Exposures*		Child ST	0.0388	390
		Child IT	0.0190	790
Insecticide and Fungicide Product Scenarios				
Dermal Exposure to Treated Lawns	0.45	Adult ST	0.0052	2,900
		Adult IT	0.003	5,000
		Child ST	0.00875	1,700
		Child IT	0.004	3,800
Hand-to-Mouth from Treated Lawn		Child ST	0.0067	2,200
		Child IT	0.0032	4,700
Object-to-Mouth from Treated Lawn		Child	0.00168	8,900
Soil Ingestion		Child	2.254×10^{-5}	670,000
Total Aggregated Exposures[5]		Child ST	0.0155	970
		Child IT	0.007	2,100

[1] Application rates derived in Section 6.1
[2] ST and IT indicate short- or intermediate-term exposure durations
[3] Daily Dose = Daily Dose algorithms for various residential postapplication scenarios outlined in Appendix E.
[4] MOE = PoD (NOAEL of 15 mg/kg/day for short- & intermediate-term exposure durations)/ Daily dose (mg/kg/day)
[5] Aggregated exposures reflect the aggregation of dermal exposure to treated lawns and HTM exposure from treated lawns (for children). Total Aggregate Exposures = (NOAEL of 15 mg/kg/day for short-term exposure durations)/ [Daily dose dermal + Daily dose HTM (mg/kg/day)]

7.0 Aggregate Risk Assessments and Risk Characterization

As previously noted, the AAPs appear to have very limited use in consumer or personal care products. Given the high end dietary exposure and residential exposure screening level assessments used to address exposure and risk from the uses of the AAPs as inerts in pesticide products, and given their limited uses and low concentrations in consumer products, HED believes that the consumer care uses are unlikely to significantly impact aggregate risk.

7.1 Acute Aggregate Risk

For the alkyl amine polyalkoxylates, the acute aggregate risk includes dietary exposures to food and drinking water. Dietary (food and water) exposures and risk are discussed in Section 5.5.1 of this memorandum. Acute aggregate risks for the AAPs are not of concern.

7.2 Short-Term/Intermediate-Term Aggregate Risk

Short-term and intermediate-term aggregate risk assessments for the AAPs combine high end residential short- or intermediate-term exposures with average food and drinking water exposures, and compare this total to a short- or intermediate term PoD. Short- and intermediate-term aggregate risks are summarized in Table 7.2. Short- and intermediate-term aggregate risks are not of concern. While the MOE for short-term aggregate exposure for children is slightly below 100, HED does not consider this MOE to represent a risk of concern for the following reasons.

- The hazard assessment for the AAPs is conservative.
    - The PoDs used to calculate aggregate risks for AAPs were based on the most toxic surrogate chemical. The AAPs are actually a mixture of compounds, so it is likely that the PoD is a conservative assessment of toxicity.
    - HED traditionally considers a level of concern (LOC) for these risk assessments to be for an MOE of 100 based on the standard 10x inter and 10x intra species extrapolation safety factors. However, HED notes that for the AAPs, the primary toxic effect seen is related to the surfactants inherent function to disrupt cell membranes resulting in irritating properties to tissues. Given that HED does not expect to see a significant difference between species for this type of effect, an LOC lower than 100 may be appropriate for the non-dietary risk assessments.

- The dietary (food and water) portion of the aggregate risk assessment is a driver in the aggregate assessment and is considered to be highly conservative.
    - The highest tolerance level from the surrogate pesticides for every food is used.
    - 100% crop treated is assumed for all crops (every food eaten by a person each day has tolerance-level residues).

- Many of these high tolerances are based on very short pre-harvest intervals where there is little time for degradation.
- No consideration was given to potential degradation between harvest and consumption (use of tolerance level residues which are typically one to two orders of magnitude higher than actual residues found in monitoring data).
- Residue values were assigned to every commodity in DEEM™ with no consideration given to potential reduction in residues from washing or cooking.

- The residential portion of the assessment is based on high-end application rates and assumes a dermal absorption of 5% which is a conservative, health protective value.

- Finally, the aggregate assessment assumes that a child would receive a high-end dietary exposure with high-end dermal and hand-to-mouth exposures concurrently.

Table 7.2. Short- and Intermediate-Term Aggregate Risk Calculations for the AAPs

	Short- and Intermediate-Term					
Population	**NOAEL mg/kg/day**	**LOC[1]**	**Max Allowable Exposure[2] mg/kg/day**	**Average Food & Water Exposure mg/kg/day**	**Residential Exposure[3] mg/kg/day**	**Aggregate MOE (food and residential)[4]**
Adult Male ST/IT	15	100	0.15	0.039989	0.056430	156
Adult Female ST/IT	15	100	0.15	0.030647	0.056430	172
Child - ST	15	100	0.15	0.127307	0.0388	90
Child - IT	15	100	0.15	0.127307	0.0190	102

[1] The LOC (Level of Concern) is based on the standard inter- and intra-species uncertainty factors totaling 100.
[2] Maximum Allowable Exposure (mg/kg/day) = PoD/LOC
[3] Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure]. Adult residential exposure combines high end dermal and inhalation handler exposure (Table 6.1) with high end post application dermal exposure (Table 6.2). Children's residential exposure combines turf dermal exposure with HTM exposures (Table 6.2).
[4] Aggregate MOE = [PoD/ (Avg Food & Water Exposure + Residential Exposure)]

7.3 Long-Term Aggregate Risk

For the alkyl amine polyalkoxylates, the long-term aggregate risk includes dietary exposures to food and drinking water. Dietary (food and water) exposures and risk are discussed in Section 5.5.2 of this memorandum. Long-Term (chronic) aggregate risks for the AAPs are not of concern.

7.4 Cancer Risk

HED has not identified any concerns for carcinogenicity; therefore, an aggregate cancer dietary exposure assessment was not performed.

8.0 Occupational Exposure/Risk Pathway

Based on examination of product labels which might potentially contain the AAPs as inert ingredients, HED has determined that exposure to handlers can occur in a variety of occupational environments. Details of the occupational exposure assessment for the alkyl amine polyalkoxylates can be found in Appendix F.

The representative occupational scenarios selected by the Agency for assessment were evaluated based on likely maximum application rates for products which may contain the AAPs as inert ingredients for the short-term exposure assessment, and average application rates for products likely to contain the AAPs as inerts for the intermediate- and long-term exposure durations. Active ingredient application rates were corrected for the maximum amount of AAPs likely to be in the final formulations to determine exposure and risk from exposure to the AAPs grouped by fungicide/insecticide or herbicide. A summary of the occupational assessment is presented below.

HED traditionally considers a level of concern (LOC) for these risk assessments to be an MOE of 100 based on the standard 10X inter and 10X intra species extrapolation safety factors. However, HED notes that for the AAPs, the primary toxic effect seen is related to the surfactants' inherent function to disrupt cell membranes resulting in irritating properties to tissues. Given that HED does not expect to see a significant difference between species for this type of effect, an LOC lower than 100 may be appropriate for the non-dietary risk assessments.

8.1 Handler Risk

Exposure Scenarios

Exposure to pesticide handlers is likely during the occupational use of pesticides containing the AAPs as inert ingredients. Dermal and inhalation exposure was estimated using the Pesticide Handlers Exposure Database (PHED) and Outdoor Residential Exposure Task Force (ORETF) data. Appendix F contains additional description about the data sources and methodology used to assess occupational exposure. The quantitative exposure/risk assessment developed for occupational handlers to support the requested exemption for the AAPs is based on the following scenarios. HED notes that these scenarios were selected to represent the scenarios with the highest potential exposure.

Mixer/Loader/Applicators:

1) Mixer/Loader for aerial application- high acreage field crops (liquids)
2) Mixer/Loader for airblast application- tree nuts crops (both liquid and wettable powder)

3) Mixer/Loader for groundboom application- high acreage field crops and turf (liquids and wettable powder)
4) Applicators for aerial application- high acreage field crops (liquid)
5) Applicators for airblast- tree nut crops
6) Applicators for groundboom- high acreage field crops and turf
7) Mixer/Loader/Applicator- low pressure handwand (liquids and wettable powders)*
8) High pressure handwand- greenhouse (wettable powders)
9) Flagging- high acreage field crops (liquids)

* Uses ORETF unit exposure data. All others use PHED data.

Risk estimates were calculated using the Margin of Exposure (MOE) which is a ratio of the toxicological PoD to the daily dose. Daily dose values are calculated by first calculating exposures by considering application parameters (i.e., rate and area treated) along with unit exposures. Exposures are then normalized by body weight to calculate dose levels. Dermal and inhalation short-term exposure is compared to the dermal and inhalation PoD of 30 mg/kg/day. Dermal and inhalation intermediate-term exposure is compared to the intermediate term dermal and inhalation PoD of 15 mg/kg/day. For the scenarios where applicable, dermal and inhalation intermediate-term exposure is compared to the long-term dermal and inhalation PoD of 15 mg/kg/day. For both short- and intermediate-term dermal assessments, exposures were adjusted for 5% dermal absorption for comparison to the POD from an oral toxicity study, and inhalation toxicity was assumed to be equivalent to oral toxicity. A combined dermal and inhalation MOE was also calculated for each exposure duration for the AAPs since common toxicity endpoints were identified for both the dermal and inhalation routes of exposure. To assess handler risks, the Agency used surrogate unit exposure data from the Pesticide Handlers Exposure Database (PHED), and ORETF data.

Occupational handler exposure assessments are completed by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with a tiered approach. The lowest tier is represented by the baseline exposure scenario followed by increasing the levels of personal protection represented by personal protective equipment or PPE (e.g., gloves, extra clothing, and respirators) and engineering controls (e.g., closed cabs and closed loading systems). This approach is always used by the Agency in order to be able to define label language using a risk-based approach and not based on generic requirements for label language. In addition, the minimal level of adequate protection for a chemical is generally considered by the Agency to be the most practical option for risk reduction. The levels of protection that form the basis for the calculations in this assessment include:

- **Baseline Exposure Scenario:** Represents typical work clothing; a long-sleeved shirt, long pants, socks, and shoes. Chemical-resistant gloves or respiratory protection are not included in this scenario.

- **Baseline Plus Gloves:** Represents the baseline exposure scenario with the use of chemical-resistant gloves. No respiratory protection is included in this scenario.

- **Engineering Controls:** Represents the use of an appropriate engineering control such as a closed cockpit. Engineering controls are not applicable to handheld application methods which have no known devices that can be used to routinely lower the exposures for these methods.

The following assumptions and factors were used in order to complete the exposure and risk assessment for occupational handlers/applicators:

- All worker scenarios were assumed to be short- and intermediate-term in exposure durations (i.e., 1-30 days and 1-6 months) with the exception of greenhouse/hothouse applications.
- For scenarios where greenhouse/hothouse applications are possible, a long-term exposure duration (6+ months) has also been calculated.
- The exposure assessment assumes an 8 hour work day.
- The maximum application rate per pesticide group (herbicide/pesticide/fungicide) has been assessed for the short-term exposure duration.
- The average application rate per pesticide group (herbicide/pesticide/fungicide) has been assessed for the intermediate-term exposure duration.
- A body weight of 70 kg was assumed because the relevant toxicological PoDs were not gender specific.
- All exposures were assessed at the baseline exposure scenario.
- For high acreage crops (e.g. corn, soybeans) where applicators can mix/load large quantities of pesticide, exposure assessments have also been completed for the baseline exposure scenario plus chemical-resistant gloves (described in the previous paragraph), and no respiratory protection.

Risk Characterization:

HED initially assessed handler exposure and risks for AAPs in fungicides, herbicides and insecticides at baseline PPE (long pants, a long-sleeved shirt, shoes, socks, no chemical-resistant gloves, and no respiratory protection) which HED considers to be the typical minimal worker clothing. When these assessments indicated that there were potential risks of concern for scenarios where workers would be handling large quantities of pesticide for high volume operations typically involving aerial applications to high acreage crops, HED repeated the assessments and included additional PPE (i.e., chemical-resistant gloves for pesticide handlers). The Agency believes workers handling large volumes of pesticides will be wearing chemical-resistant gloves.

When handlers are wearing typical worker clothing (i.e., baseline PPE) the majority of occupational handler scenarios do not indicate risks of concern. For the occupational handler scenarios which involve the handling of large volumes of pesticides, those which EPA believes that handlers will be wearing chemical-resistant gloves, occupational handler scenarios do not indicate risks of concern with the addition of chemical-resistant gloves to baseline PPE (i.e., baseline plus gloves). For the occupational scenarios that involve mixer loader applicators applying pesticides containing an AAP formulated as a wettable powder with a low pressure handwand to ornamentals in a greenhouse

environment, calculated risks resulted in MOEs below 100 when only traditional work clothes were assumed. Since the Agency does not believe that it is routine for these workers to wear gloves for these scenarios, an assessment was provided showing MOEs when the percent of AAP in the final formulation was reduced. For herbicides the assessments were provided reducing the cap from the proposed maximum of 25% to 20%, 15%, 10% and 5%. For insecticides and fungicides containing the AAPs, assessments were provided showing the impact on MOEs of reducing the maximum allowed amount in the final formulation from the proposed maximum of 10% to 8%, 6% and 5%.

Table 8.1.1. Exposure and Risks for Occupational Handlers of the AAPs in Herbicide Products (All Exposure Durations) at Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	2.6	1200	2.9	1.2	6.46	0.0535	**2**	280	**2**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.5				1.24	0.0103	**12**	1,500	**12**
Liquids/ Airblast/ Nut Tree (ST)	1.8	40			0.15	0.00123	100	12,000	100
Liquids/ Airblast/ Nut Tree (IT)	0.8				0.0663	0.00055	230	27,000	220
Liquids/ Groundboom/ High Acreage Crops (ST)	2.6	200			1.077	0.0089	**14**	1,700	**14**
Liquids/ Groundboom/ High Acreage Crops (IT)	0.5				0.207	0.001714	**72**	8,800	**72**
Liquids/ Groundboom/ Turf (ST)	2.6	40			0.215	0.00178	**70**	8,500	**69**
Liquids/ Groundboom/ Turf (IT)	0.5				0.0414	0.00034	360	44,000	360
Liquids/ Low Pressure Handwand/ Turf (ST)	1.8	5			0.0186	0.000154	800	95,000	800
Liquids/ Low Pressure Handwand/ Turf (IT)	1.8				0.0186	0.000154	800	97,000	800
Wettable Powder/ Airblast/ Nut Tree (ST)	0.4	40	3.7	43	0.0423	0.0098	350	1,500	290
Wettable Powder/ Airblast/ Nut Tree (IT)	0.4				0.0423	0.0098	350	1,500	290
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.4	200			0.2114	0.05	**70**	300	**60**
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.25				0.1321	0.031	110	490	**92**
Wettable Powder/ Groundboom/ Turf (ST)	0.4	40			0.0423	0.0098	350	1,500	290
Wettable Powder/ Groundboom/ Turf (IT)	0.25				0.026	0.00614	570	2,400	460
Wettable powder/ Low Pressure Handwand/ Turf (ST)	1.8	5			0.0238	0.0055	630	2,700	510
Wettable powder/ Low Pressure Handwand/ Turf (IT)	1.8				0.0238	0.0055	630	2,700	510
Applicator Scenarios									

Table 8.1.1. Exposure and Risks for Occupational Handlers of the AAPs in Herbicide Products (All Exposure Durations) at Baseline Exposure Scenario									
Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	2.6	1200	Eng control only: 0.0055	Eng control only: 0.068	0.0123	0.003	1,200	5,000	1,000
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.5				0.0024	0.0006	6,400	26,000	5,100
Airblast/ Nut Tree (ST)	0.4	40	0.36	4.5	0.00411	0.00103	3,600	15,000	2,900
Airblast/ Nut Tree (IT)	0.4				0.00411	0.00103	3,600	15,000	2,900
Groundboom/ High Acreage Crops (ST)	2.6	200	0.014	0.74	0.0052	0.0055	2,900	2,700	1,400
Groundboom/ High Acreage Crops (IT)	0.5				0.001	0.0011	15,000	14,000	7,300
Groundboom/ Turf (ST)	2.6	40			0.00104	0.0011	14,000	14,000	7,000
Groundboom/ Turf (IT)	0.5				0.0002	0.0002	75,000	71,000	36,000
Mixer/Loader/Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	1.8	5	no data	6.6	NA	0.00085	NA	18,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	1.8				NA	0.00085	NA	18,000	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	1.8	5	no data	1100	NA	0.1414	NA	110	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	1.8				NA	0.1414	NA	110	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	1.8				NA	0.1414	NA	110	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	1.8	5	100	30	0.6429	0.0039	**23**	3,900	**23**
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	1.8				0.6429	0.0039	**23**	3,900	**23**
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	1.8				0.6429	0.0039	**23**	3,900	**23**
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	2.6	1200	0.011	0.35	0.0245	0.0156	600	960	380
Liquid/ Flagger/ High Acreage Crops (IT)	0.5				0.0047	0.003	3,200	5,000	1,900

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by 25% to convert to application rate of just inert in an herbicides product (Herbicide products contain a maximum of 25% inert AAPs according to Inerts Task Force). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Baseline Exposure Scenario represents typical work clothing, no gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline exposure scenario and baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)

[7]ST Inhalation MOE = PoD (NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)

[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess the baseline exposure scenario and baseline inhalation exposure.
[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed in Table 8.1.1. results in a higher exposure (and therefore is health protective) than either of the two "NA" scenarios shown at baseline plus gloves dermal exposure.

Table 8.1.2. Exposure and Risks for Occupational Handlers of AAPs in Herbicide Products (All Exposure Durations) with Baseline Plus Gloves for High Acreage Mixer/ Loader Scenarios and Turf

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline + Gloves Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline + Gloves Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	2.6	1200	0.023	1.2	0.0513	0.0535	290	280	150
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.5				0.0099	0.0103	1,500	1,500	750
Liquids/ Groundboom/ High Acreage Crops (ST)	2.6	200			0.00854	0.0089	1,800	1,700	850
Liquids/ Groundboom/ High Acreage Crops (IT)	0.5				0.00164	0.001714	9,100	8,800	4,500
Liquids/ Groundboom/ Turf (ST)	2.6	40			0.0017	0.0018	8,800	8,400	4,300
Liquids/ Groundboom/ Turf (IT)	0.5				0.00033	0.00034	47,000	44,000	22,000
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.4	200	0.17	43	0.00971	0.05	1,500	300	250
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.25				0.00610	0.031	2,500	490	410

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by 25% to convert to application rate of just inert in an herbicides product (Herbicide products contain maximum of 25% inert from the AAPs according to Inerts Task Force). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline plus gloves plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7]ST Inhalation MOE = PoD (NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)
*Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline plus gloves and baseline inhalation exposure.

Table 8.1.3: Exposure and Risks for Occupational Handlers of AAPs in Herbicide Products Used in Low Pressure Handwand Applications to Ornamentals in Greenhouses (All Exposure Durations) at Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader/Applicator for Herbicide Products with 20% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	1.44	5	100	30	0.514	0.0031	**29**	4,900	**29**
Mixer/Loader/Applicator for Herbicide Products with 15% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	1.08	5	100	30	0.386	0.0023	**39**	6,500	**39**
Mixer/Loader/Applicator for Herbicide Products with 10% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.72	5	100	30	0.257	0.0015	**58**	9,700	**58**
Mixer/Loader/Applicator for Herbicide Products with 5% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.36	5	100	30	0.129	0.00077	120	19,000	120

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by variable % AAP in formulation to convert to application rate of just inert in an herbicide product. Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline exposure scenario plus baseline inhalation exposure
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7] Inhalation MOE = PoD (NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)

Table 8.1.4. Exposure and Risks for Occupational Handlers of AAPs in Insecticide Products (All Exposure Durations) at Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	0.2	1200	2.9	1.2	0.497	0.00411	**30**	3,600	**30**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.07				0.174	0.00144	**86**	10,400	**86**

Table 8.1.4. Exposure and Risks for Occupational Handlers of AAPs in Insecticide Products (All Exposure Durations) at Baseline Exposure Scenario									
Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Liquids/ Airblast/ Nut Tree (ST)	0.9	40			0.075	0.00062	200	24,000	200
Liquids/ Airblast/ Nut Tree (IT)	0.25				0.0207	0.00017	720	88,000	720
Liquids/ Groundboom/ High Acreage Crops (ST)	0.2	200			0.0829	0.00069	180	22,000	180
Liquids/ Groundboom/ High Acreage Crops (IT)	0.07				0.029	0.00024	520	63,000	520
Liquids/ Groundboom/ Turf (ST)	0.2	40			0.0166	0.000137	900	110,000	900
Liquids/ Groundboom/ Turf (IT)	0.07				0.0058	0.000048	2,600	310,000	2,600
Liquids/ Low Pressure Handwand/ Turf (ST)	0.72	5			0.0075	0.00006	2,000	240,000	2,000
Liquids/ Low Pressure Handwand/ Turf (IT)	0.72				0.0075	0.00006	2,000	240,000	2,000
Wettable Powder/ Airblast/ Nut Tree (ST)	0.6	40	3.7	43	0.0634	0.01474	240	1,000	190
Wettable Powder/ Airblast/ Nut Tree (IT)	0.3				0.0317	0.00737	470	2,000	380
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.2	200			0.1057	0.025	140	600	120
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.07				0.037	0.0086	410	1,700	330
Wettable Powder/ Groundboom/ Turf (ST)	0.2	40			0.02	0.0049	700	3,100	600
Wettable Powder/ Groundboom/ Turf (IT)	0.07				0.0074	0.00172	2,000	8,700	1,600
Wettable powder/ Low Pressure Handwand/ Turf (ST)	0.72	5			0.0095	0.0022	1,600	7,000	1,300
Wettable powder/ Low Pressure Handwand/ Turf (IT)	0.72				0.0095	0.0022	1,600	6,800	1,300
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	0.2	1200	Eng control only: 0.0055	Eng control only: 0.068	0.0009	0.0002	16,000	65,000	13,000
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.07				0.0003	0.0001	45,000	180,000	36,000
Airblast/ Nut Tree (ST)	0.9	40	0.36	4.5	0.0093	0.002314	1,600	6,500	1,300

Table 8.1.4. Exposure and Risks for Occupational Handlers of AAPs in Insecticide Products (All Exposure Durations) at Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Airblast/ Nut Tree (IT)	0.25				0.0026	0.000643	5,800	23,000	4,700
Groundboom/ High Acreage Crops (ST)	0.2	200	0.014	0.74	0.0004	0.000423	38,000	35,000	18,000
Groundboom/ High Acreage Crops (IT)	0.07				0.00014	0.000148	110,000	100,000	52,000
Groundboom/ Turf (ST)	0.2	40			0.00008	0.000085	190,000	180,000	90,000
Groundboom/ Turf (IT)	0.07				0.00003	0.00003	540,000	510,000	260,000
Mixer/Loader/ Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	0.72	5	no data	6.6	NA	0.00034	NA	44,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	0.72				NA	0.00034	NA	44,000	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	0.72		no data	1100	NA	0.05657	NA	270	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	0.72				NA	0.05657	NA	270	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	0.72				NA	0.05657	NA	270	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	0.72	5	100	30	0.257	0.00154	**58**	19,000	**58**
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	0.72				0.257	0.00154	**58**	9,700	**58**
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	0.72				0.257	0.00154	**58**	9,700	**58**
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	0.2	1200	0.011	0.35	0.0019	0.0012	7,900	13,000	4,800
Liquid/ Flagger/ High Acreage Crops (IT)	0.07				0.00066	0.00042	23,000	36,000	14,000

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by 10% to convert to application rate of just inert in an insecticide product (Insecticide products contain maximum of 10% inert from the AAPs according to Inerts Task Force). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate- (IT) and long-term (LT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline exposure scenario and baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7]ST Inhalation MOE = PoD (NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)
[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess the baseline exposure scenario and baseline inhalation exposure.
[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed in Table 8.1.4. results in a higher exposure (and therefore is health protective) than either of the two "NA" scenarios shown at baseline plus gloves dermal exposure.

Table 8.1.5. Exposure and Risks for Occupational Handlers of AAPs in Insecticide Products (All Exposure Durations) with Baseline Plus Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline + Gloves Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline + Gloves Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	0.2	1200	0.023	1.2	0.00394	0.00411	3,800	3,600	1,900
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.07				0.00138	0.00144	11,000	10,400	5,300

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by 10% to convert to application rate of just inert in an insecticide product (Insecticide products contain maximum of 10% inert from the AAPs according to Inerts Task Force). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline plus gloves and baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7]ST Inhalation MOE = PoD (NOAEL of 30 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)
*Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline plus gloves and baseline inhalation exposure.

Table 8.1.6: Exposure and Risks for Occupational Handlers of AAPs in Insecticides Products Used in Low Pressure Handwand Applications to Ornamentals in Greenhouses (All Exposure Durations) at Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader/Applicator for Insecticides Products with 8% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.576	5	100	30	0.2057	0.0012	**73**	12,000	**72**
Mixer/Loader/Applicator for Insecticides Products with 6% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.432	5	100	30	0.1543	0.0009	**97**	16,000	**97**
Mixer/Loader/Applicator for Insecticides Products with 5% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.36	5	100	30	0.129	0.00077	120	19,000	120

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by variable % AAP in formulation to convert to application rate of just inert in an insecticide product. Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline exposure scenario and baseline inhalation exposure
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7]ST Inhalation MOE = PoD (NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)

Table 8.1.7. Exposure and Risks for Occupational Handlers of AAPs in Fungicide Products (All Exposure Durations) with Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	0.5	1200	2.9	1.2	1.243	0.010286	**12**	1,500	**12**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.07				0.174	0.00144	**86**	10,000	**86**
Liquids/ Airblast/ Nut Tree (ST)	1.1	40			0.09114	0.000754	160	20,000	160

Table 8.1.7. Exposure and Risks for Occupational Handlers of AAPs in Fungicide Products (All Exposure Durations) with Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Liquids/ Airblast/ Nut Tree (IT)	0.3				0.0249	0.000206	600	73,000	600
Liquids/ Groundboom/ High Acreage Crops (ST)	0.5	200			0.207	0.001714	**70**	9,000	**70**
Liquids/ Groundboom/ High Acreage Crops (IT)	0.07				0.029	0.00024	520	63,000	510
Liquids/ Groundboom/ Turf (ST)	0.5	40			0.0414	0.000343	360	44,000	360
Liquids/ Groundboom/ Turf (IT)	0.07				0.0058	0.000048	2,600	310,000	2,600
Liquids/ Low Pressure Handwand/ Turf (ST)	0.72	5			0.0075	0.000062	2,000	240,000	2,000
Liquids/ Low Pressure Handwand/ Turf (IT)	0.72				0.0075	0.000062	2,000	240,000	2,000
Wettable Powder/ Airblast/ Nut Tree (ST)	0.7	40	3.7	43	0.074	0.0172	200	870	170
Wettable Powder/ Airblast/ Nut Tree (IT)	0.2				0.02114	0.004914	710	3,100	580
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.1	200			0.0529	0.012286	280	1,200	230
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.06				0.03171	0.00737	470	2,000	380
Wettable Powder/ Groundboom/ Turf (ST)	0.1	40			0.0106	0.002457	1,400	6,000	1,200
Wettable Powder/ Groundboom/ Turf (IT)	0.06				0.0063	0.00147	2,400	10,000	1,900
Wettable powder/ Low Pressure Handwand/ Turf (ST)	0.72	5			0.00951	0.002211	1,600	6,800	1,300
Wettable powder/ Low Pressure Handwand/ Turf (IT)	0.72				0.00951	0.002211	1,600	6,800	1,300
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	0.5	1200	Eng control only: 0.0055	Eng control only: 0.068	0.0024	0.0006	6,500	25,000	5,000
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.07				0.0003	0.0001	45,000	180,000	36,000
Airblast/ Nut Tree (ST)	0.7	40	0.36	4.5	0.0072	0.0018	2,100	8,500	1,700
Airblast/ Nut Tree (IT)	0.3				0.0031	0.000771	4,900	19,000	3,900

Table 8.1.7. Exposure and Risks for Occupational Handlers of AAPs in Fungicide Products (All Exposure Durations) with Baseline Exposure Scenario

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Groundboom/ High Acreage Crops (ST)	0.5	200	0.014	0.74	0.001	0.001057	15,000	14,000	7,500
Groundboom/ High Acreage Crops (IT)	0.07				0.00014	0.000148	110,000	100,000	52,000
Groundboom/ Turf (ST)	0.5	40			0.0002	0.000211	75,000	70,000	37,000
Groundboom/ Turf (IT)	0.07				0.00003	0.000029	540,000	510,000	260,000
Mixer/Loader/ Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	0.72	5	NA	6.6	NA	0.000339	NA	44,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	0.72				NA	0.000339	NA	44,000	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	0.72		NA	1100	NA	0.05657	NA	270	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	0.72				NA	0.05657	NA	270	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	0.72				NA	0.05657	NA	270	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	0.72	5	100	30	0.257	0.001543	**58**	9,700	**58**
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	0.72				0.257	0.001543	**58**	9,700	**58**
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	0.72				0.257	0.001543	**58**	9,700	**58**
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	0.5	1200	0.011	0.35	0.0047	0.003	3,200	5,000	1,900
Liquid/ Flagger/ High Acreage Crops (IT)	0.07				0.00066	0.00042	23,000	36,000	14,000

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by 10% to convert to application rate of just inert in an fungicide product (Fungicide products contain maximum of 10% inert from the AAPs according to the Inerts Task Force). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) exposures are based on average application rates.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline exposure scenario and baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7] ST Inhalation MOE = PoD (a NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8] Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)
[9] Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess the baseline exposure scenario and baseline inhalation exposure.
[10] These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed in Table 8.1.7. results in a higher exposure (and therefore is health protective) than either of the two "NA" scenarios shown at baseline plus gloves dermal exposure.

Table 8.1.8. Exposure and Risks for Occupational Handlers of AAPs in Fungicide Products (All Exposure Durations) with Baseline Plus Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline + Gloves Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline + Gloves Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	0.5	1200	0.023	1.2	0.00986	0.010286	1,500	1,500	750
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.07				0.00138	0.00144	11,000	10,000	5,300
Liquids/ Groundboom/ High Acreage Crops (ST)	0.5	200			0.00164	0.0017	9,100	8,800	4,500
Liquids/ Groundboom/ High Acreage Crops (IT)	0.07				0.00023	0.00024	65,000	63,000	32,000

[1] Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by 10% to convert to application rate of just inert in an fungicide product (Fungicide products contain maximum of 10% inert from the AAPs according to the Inerts Task Force). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) exposures are based on average application rates.
[2] Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3] Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline plus gloves and baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.
[4] Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7] ST Inhalation MOE = PoD (a NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8] Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)

Table 8.1.9: Exposure and Risks for Occupational Handlers of AAPs in Fungicides Products Used in Low Pressure Handwand Applications to Ornamentals in Greenhouses (All Exposure Durations) at Baseline Exposure Scenario (14% AAP in Formulation)

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader/Applicator for Fungicide Products with 8% AAP in Formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.576	5	100	30	0.2057	0.0012	**73**	12,000	**72**
Mixer/Loader/Applicator for Fungicide Products with 6% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.432	5	100	30	0.1543	0.0009	**97**	16,000	**97**
Mixer/Loader/Applicator for Fungicide Products with 5% AAP in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals	0.36	5	100	30	0.129	0.00077	120	19,000	120

[1]Application rates are based on maximum application rates of products containing inerts in the AAPs multiplied by variable % AAP in formulation to convert to application rate of just inert in a fungicides product. Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline exposure scenario and baseline inhalation exposure
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 15 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7]ST Inhalation MOE = PoD (NOAEL of 15 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total MOE = 1/ (1/Dermal MOE + 1/Inhalation MOE)

8.2 Occupational Postapplication Risk

HED uses the term postapplication to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Postapplication exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for postapplication exposure.

Inhalation exposures are not typically calculated for occupational post-application scenarios because inhalation exposures generally account for a negligible percentage of the overall body burden for most pesticide chemicals. This is particularly true for chemicals with a low vapor pressure such as the AAPs.

Exposure Scenarios

This assessment is considered to be a screening level estimate, demonstrating that there are minimal potential risks to workers re-entering fields treated with pesticides containing the AAPs as inert ingredients. While the AAPs are present in formulations designated for crops besides those assessed in this document, risk estimates for those occupational postapplication scenarios are expected to be less than those scenarios assessed in this document (i.e., calculated MOEs will be higher). The three occupational postapplication scenarios assessed are for postapplication activities associated with:

- Tall field/row crops (including scouting, weeding, hand harvesting sweet corn)
- Turf (golf course/sod farm) (including mowing, transplanting, hand weeding)
- Vine/Trellis crops (including scouting, training, tying, thinning, and grape girding and cane turning)

Exposure Data and Assumptions

The assumptions used in the postapplication risk assessment calculations are detailed as follows:

- The average occupational workday is assumed to be 8 hours.
- The adverse effects for the short- and intermediate-term dermal PoD's are based on studies where the effects were observed in both sexes; therefore, the body weight of 70 kg was used to estimate exposure.
- HED has developed standard transfer coefficient values for occupational postapplication scenarios to ensure consistency in exposure assessments. These standard values were used to calculate postapplication exposures.
- Anticipated post-application activities and their respective dermal transfer coefficients (TCs) are summarized in Table 8.2.1. The TC information is based on the Science Advisory Council for Exposure Policy Number 3.1.
- The transfer coefficient for sod transplanting, and hand weeding used to represent dermal exposure is from Agriculture Reentry Task Force (ARTF) data; study ARF-035 (MRID 45432303).
- Calculations of postapplication exposures are completed using maximum application rates of the products of that type of pesticide (herbicide, insecticide, or fungicide) for short-term exposures and average application rates of products for intermediate-term exposures.
- Herbicides assessed can contain a maximum of 25% AAP in any product formulation; insecticides and fungicides contain a maximum of 10% in any product formulation.
- No postapplication data were submitted for the AAPs; a default 20% of the application rate (for agricultural crops) and 5% (for turf) is considered available as a transferrable residue with a 10% default daily dissipation rate.
- Dermal absorption is assumed to be 5%.

Risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of the exposure to the toxicological PoD.

Risk Characterization

A variety of pesticide formulations contain AAPs. PPE is usually not required for worker re-entry, and therefore these postapplication risk estimates are based on the baseline exposure scenario (i.e., typical work clothing but no gloves). Typically, HED characterizes the risk estimate in relation to the restricted entry interval (REI) for a particular active ingredient. While REIs for specific products are not discussed in this risk assessment, occupational post-application scenarios assessed generally result in MOEs that do not indicate risks of concern on Day 0 (the day of application) except for two postapplication scenarios.

Occupational postapplication risk estimates are presented in Table 8.2.1. The risk estimates for the three exposure scenarios assessed resulted in MOEs do not demonstrate risks of concern (i.e., MOEs > 100) on Day 0, except for two scenarios:

1) the short-term worker postapplication activities involving herbicides on corn, specifically the hand-harvesting harvesting/ detassling scenario. That scenario resulted in an MOE of **53** on the day of application (Day 0). Assuming an herbicide application at the maximum application rate, the MOE would exceed 100 for this scenario at day 13 after application. The Agency notes that it is not expected to be typical agricultural practice to apply herbicides on the same day workers would be conducting hand harvesting and detassling activities. As noted earlier in this assessment, herbicides and insecticides are typically applied relatively early in a growing season. All other postapplication scenarios result in MOEs that do not demonstrate risks of concern on the day of application (Day 0).
2) the short-term worker postapplication activities involving insecticides on corn, specifically the hand-harvesting harvesting/ detassling scenario. That scenario resulted in an MOE of **69** on the day of application (Day 0). Assuming an insecticide application at the maximum application rate, the MOE would exceed 100 for this scenario at day 4 after application. The Agency notes that it is not expected to be typical agricultural practice to apply insecticides on the same day workers would be conducting hand harvesting and detassling activities. As noted earlier in this assessment, herbicides and insecticides are typically applied relatively early in a growing season. All other postapplication scenarios result in MOEs that do not demonstrate risks of concern on the day of application (Day 0).

Table 8.2.1. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for the AAPs

Crop & Exposure Duration	Application Rate (lb inert /A)	Work Activity	Transfer Coefficient[1] (cm^2/hr)	Day after Treatment[2]	DFR_t (µg/cm^2)[3]	Daily Dose (mg/kg/day)[4]	MOE[5]
Herbicide Product Scenarios							
Corn (ST)	2.6	Scout, weed low foliage	100	0	5.834	0.0033	4,500
		Scout, weed high foliage	400	0		0.0133	1,100
		Scout, irrigate, weed high foliage	1,000	0		0.0333	450

Table 8.2.1. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for the AAPs							
Crop & Exposure Duration	**Application Rate (lb inert /A)**	**Work Activity**	**Transfer Coefficient[1] (cm^2/hr)**	**Day after Treatment[2]**	**DFR_t (µg/cm^2)[3]**	**Daily Dose (mg/kg/day)[4]**	**MOE[5]**
		Harvesting/ detassling	17,000	0		0.5667	**26**
Days till MOE > 100							**13**
Corn (IT)	0.3	Scout, weed low foliage	100	0	0.673	0.0004	39,000
		Scout, weed high foliage	400	0		0.0015	9,700
		Scout, irrigate, weed high foliage	1,000	0		0.0038	3,900
		Harvesting/ detassling	17,000	0		0.0654	230
Grapes (Table) (ST)	1.2	Hedge, irrigate, weed, scout, train, tie	500	0	2.693	0.0077	1,900
		Scout, train, tie	1,000	0		0.0154	970
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0769	200
		Cane turning, girdle	10,000	0		0.1539	100
Grapes (Table) (IT)	0.7	Hedge, irrigate, weed, scout, train, tie	500	0	1.571	0.0045	3,300
		Scout, train, tie	1,000	0		0.0090	1,700
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0449	330
		Cane turning, girdle	10,000	0		0.0898	170
Turf/ sod (ST)	2.6	Mowing	500	0	1.458	0.004	3,800
		Transplant, weed, harvest	6,800	0		0.057	260
Turf/ Sod (IT)	0.3	Mowing	500	0	0.168	0	31,000
		Transplant, weed, harvest*	6,800	0		0.007	2,300
Insecticide Product Scenarios							
Corn (ST)	1.0	Scout, weed low foliage	100	0	2.244	0.0013	12,000
		Scout, weed high foliage	400	0		0.0051	2,900
		Scout, irrigate, weed high foliage	1,000	0		0.0128	1,200
		Harvesting/ detassling	17,000	0		0.2180	**69**
Days till MOE > 100							**4**

Table 8.2.1. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for the AAPs							
Crop & Exposure Duration	**Application Rate (lb inert /A)**	**Work Activity**	**Transfer Coefficient[1] (cm^2/hr)**	**Day after Treatment[2]**	**DFR_t (µg/cm^2)[3]**	**Daily Dose (mg/kg/day)[4]**	**MOE[5]**
Corn (IT)	0.1	Scout, weed low foliage	100	0	0.224	0.0001	120,000
		Scout, weed high foliage	400	0		0.0005	29,000
		Scout, irrigate, weed high foliage	1,000	0		0.0013	12,000
		Harvesting/ detassling	17,000	0		0.0218	690
Grapes (Table) (ST)	0.7	Hedge, irrigate, weed, scout, train, tie	500	0	1.571	0.0045	3,300
		Scout, train, tie	1,000	0		0.009	1,700
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0449	330
		Cane turning, girdle	10,000	0		0.0898	170
Grapes (Table) (IT)	0.3	Hedge, irrigate, weed, scout, train, tie	500	0	0.673	0.0019	7,800
		Scout, train, tie	1,000	0		0.0038	3,900
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0192	780
		Cane turning, girdle	10,000	0		0.0385	390
Turf/ sod (ST)	1.0	Mowing	500	0	0.561	0.002	10,000
		Transplant, weed, harvest	6,800	0		0.022	700
Turf/ Sod (IT)	0.1	Mowing	500	0	0.056	0	94,000
		Transplant, weed, harvest*	6,800	0		0.002	6,900
Fungicide Product Scenarios							
Corn (ST)	0.5	Scout, weed low foliage	100	0	1.122	0.0006	24,000
		Scout, weed high foliage	400	0		0.0026	6,000
		Scout, irrigate, weed high foliage	1,000	0		0.0064	2,400
		Harvesting/ detassling	17,000	0		0.1090	140
Corn (IT)	0.1	Scout, weed low foliage	100	0	0.224	0.0001	120,000
		Scout, weed high foliage	400	0		0.0005	29,000

Table 8.2.1. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for the AAPs							
Crop & Exposure Duration	**Application Rate (lb inert /A)**	**Work Activity**	**Transfer Coefficient[1] (cm^2/hr)**	**Day after Treatment[2]**	**DFR_t (µg/cm^2)[3]**	**Daily Dose (mg/kg/day)[4]**	**MOE[5]**
		Scout, irrigate, weed high foliage	1,000	0		0.0013	12,000
		Harvesting/ detassling	17,000	0		0.0218	690
Grapes (Table) (ST)	0.5	Hedge, irrigate, weed, scout, train, tie	500	0	1.122	0.0032	4,700
		Scout, train, tie	1,000	0		0.0064	2,400
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0321	470
		Cane turning, girdle	10,000	0		0.0641	240
Grapes (Table) (IT)	0.2	Hedge, irrigate, weed, scout, train, tie	500	0	0.449	0.0013	12,000
		Scout, train, tie	1,000	0		0.0064	2,300
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0128	1,200
		Cane turning, girdle	10,000	0		0.0256	580
Turf/ sod (ST)	0.5	Mowing	500	0	0.28	0.001	19,000
		Transplant, weed, harvest*	6,800	0		0.011	1,400
Turf/ Sod (IT)	0.1	Mowing	500	0	0.056	0	94,000
		Transplant, weed, harvest*	6,800	0		0.002	6,900

* The TC from this exposure scenario uses ARTF data - study ARF-035 (MRID 45432303).

9.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the USDA under the Continuing Survey of Food Intake by Individuals (CSFII) and are used in pesticide risk assessments for all registered

food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas postapplication are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

10.0 Human Studies

This assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide. These studies, listed below, have received the appropriate ethical review for use in risk assessment.

> The PHED Task Force, 1998. The Pesticide Handler Exposure Database (PHED), Version 1.1. Task Force members: Health Canada, U.S. Environmental Protection Agency, the California Department of Pesticide regulation, and the American Crop Protection Association; released August 1998.
>
> ORETF Handler Studies (MRID 44972201): Outdoor Residential Exposure Task

APPENDIX A

A.1 Acute Toxicity Profile for Alkyl Amine Polyalkoxylates

Table A.1. Acute Toxicity Profile of Alkyl Amine Polyalkoxylates

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-1	Acute Oral – rat	46902001	**MON 0818 (CAS 61791-26-2) Tallow, POE n=15** LD50 = ♂ 1436.7 mg/kg LD50 = ♀ 1315.1 mg/kg (reported as 1200 mg/kg)	III
81-1	Acute Oral – rat	ICI CTL	**ATMER® 163 (CAS 70955-14-5) C13-C15, POE n=2** LD50 = 1500 mg/kg	III
81-1	Acute Oral – rat	CIT	**Armoblen 557 (CAS 68213-26-3) Tallow, POE n=5/12** LD50 =1663 mg/kg	III
81-1	Acute Oral – rat	CPT	**Ethomeen C/12 (CAS 61791-31-9)** **Coco, POE 2** LD50 = 6600 mg/kg	IV
81-1	Acute Oral – rat	Safepharm	**Ethomeen C/15 (CAS 61791-14-8) Coco, POE n=5** LD50 >200 mg/kg	II
81-1	Acute Oral – rat	Safepharm	**Ethomeen T/12 (CAS 61791-44-4)** **Tallow, POE 2** LD50 = >2000 mg/kg	III
81-1	Acute Oral – rat	Safepharm	**Ethomeen S/12 (CAS 73246-96-5)** **Soya, POE 2** LD50 = 1260 mg/kg	III
81-2	Acute Dermal - rabbit	46902001	**MON 0818 (CAS 61791-26-2)** LD50 > 1260 mg/kg	II

Table A.1. Acute Toxicity Profile of Alkyl Amine Polyalkoxylates				
Guideline No.	**Study Type**	**MRIDs #**	**Results**	**Toxicity Category**
81-3	Acute Inhalation - rat	CIVO/TNO	**Armoblen 557 (CAS 68213-26-3)** LC50 (**4 hr**) 0.66 mg/L (0.42-0.85)	III
		Temple U	**Ethomeen C/12 (CAS 61791-31-9)** LC 50 (**1 hr**) 0.98 mg/L)	III
		Temple U	**Ethomeen T/12 (CAS 61791-44-4)** LC50 (**1 hr**) 3.19 mg/L	IV
81-4	Primary Eye Irritation Rabbit	46902001	**MON 0818 (CAS 61791-26-2)** Corrosive	I
		CIVO/TNO	**Armoblen 557 (CAS 68213-26-3)** Non-irritating/non-corrosive	
		Leberco Lab	**Ethomeen C/12 (CAS 61791-31-9)** Severely irritating (irreversible corneal opacity, iritis, redness, sewlling, discharge of conjunctiva (2 studies)	
		CPT	**Ethomeen T/12 (CAS 61791-44-4)** Corrosive	
		FDRL	**Ethomeen T/25 (CAS 61791-26-2)** Persistent extreme corneal opacity, iritis, necrosis of conjunctiva tissue (3 studies)	
		PSL	**Ethomeen T/30 (CAS 61791-26-2)** Corrosive	
		CPT	**Ethomeen T/25 (CAS 61791-26-2)** Persistent extreme corneal opacity, iritis, necrosis; corrosive	
			Ethomeen T/30 (CAS 61791-26-2) Corrosive	

Table A.1. Acute Toxicity Profile of Alkyl Amine Polyalkoxylates				
Guideline No.	**Study Type**	**MRIDs #**	**Results**	**Toxicity Category**
81-5	Primary Skin Irritation - rabbit	46902001 EB0467 CIT Safepharm Safepharm IBR-US, Inc Safepharm	**MON 0818 (CAS 61791-26-2)** Severely irritating to skin **ATMER® 163 CAS 70955-14-5** Corrosive (undiluted) **Armoblen 557 (CAS 68213-26-3)** Non-irritant **Ethomeen C/12 (CAS 61791-31-9)** Moderate to severe irritant (4 hr) **Ethomeen C/12 (CAS 61791-31-9)** Moderate to severe irritant (4 hr) **Ethomeen C/25 (CAS 61791-14-8)** Minimally irritating (4 hr) **Ethomeen T/15 (CAS 61791-26-2)** Severely irritating but not corrosive (4 hr)	II
81-6	Dermal Sensitization Guinea pig	46918001 Hill Top MB Lab	**MON 0818 (CAS 61791-26-2)** Dermal sensitizer **Ethomeen T/12 (CAS 61791-44-4)** Not a sensitizer **Ethomeen T/12 (CAS 61791-44-4)** May be a sensitizer to sensitive individuals (mice)	

A.2. Toxicity Profile for the Alkyl Amine Polyalkoxylates

Table A.2. Toxicology Profile of the Alkyl Amine Polyalkoxylates

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100 90-day/4-week oral toxicity SD rats **MON 0818** **CAS 61791-26-2 (tallow, POE 15))**	MRID 46918003C (90-day) 1990 MRID 46918002C (28-day) 1989 0, 500, 1500, 4500 ppm 0, 33/39.9, 99.3/123.1, 291.6/356.6 ♂/♀mg/kg/day Acceptable/guideline	NOAEL = 500 ppm (33/39.9 mg/kg/day) LOAEL = 1500 ppm (99.3/123.1 mg/kg/day, based on irritation in the intestines and colon (hypertrophy and vacoulation of histiocytes in lamina propria of jejunum and ileum and histiocytosis and accumulation of macrophage aggregates in mesenteric lymph nodes.
870.3100 4-week oral toxicity SD rats **MON 0818** **CAS 61791-26-2 (tallow, POE n=15)**	MRID 46918002C/46918002/ 47066302/47066302C (2006/2007) 0. 800, 2000, 5000 ppm (males 51.7, 122.8, 268.7 mg/kg/day; females 63.2, 159.9, 324.8 mg/kg/day) Acceptable/nonguideline (RF)	NOAEL = males 51.7 mg/kg/day LOAEL = males 122.8 mg/kg/day, based on reduced body weight gain and food consumption NOAEL = females 159.9 mg/kg/day LOAEL = females 324.8 mg/kg/day, based on reduced body weight, body-weight gain, food consumption, and irritation in the colon (soft stools).
870.3100 90-Day oral toxicity Sprague-Dawley (Crl:CD®BR) rats **AMTER® 163** **CAS 70955-14-5 (C13-C15, POE n=2)**	MRID 47041301 (1991) 0, 15, 30, or 150 mg/kg/day *via* gavage Acceptable/guideline	NOAEL = 15 mg/kg/day LOAEL = 30 mg/kg/day, based on increased mortality, salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and microscopic changes in the nonglandular stomach of both sexes. 2 death @30 mg/kg/day (days 36, 78); 5 deaths @150 mg/kg/day (males days 56, 59, 78 and 82; female day 79) @150 mg/kg/day, males ↓BWG 30%/females 15%; wheezing & salivation from wk 2 on
870.3150 90-Day oral toxicity in nonrodents (beagles) **ATMER® 163** **CAS 70955-14-5 (C13-C15, POE n=2)**	MRID 47041302 (1991) 0, 15, 30, 100 mg/kg/day (capsules) Acceptable/nonguideline	NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day, based on clinical signs (increased incidence of salivation, emesis, and soft feces (with mucus alone or mucus and bile-like material)) in males and females, increased alanine aminotransferase (ALT/SGPT) levels in females, and an increased incidence of pigment accumulation in the Kupffer cells and bile canaliculi in the livers of females.

Table A.2. Toxicology Profile of the Alkyl Amine Polyalkoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3100 28-day oral toxicity CD rats **Armoblen 557** **CAS 68213-26-3 (Tallow, POE n=5/12)**	MRID 47193901 (1994) 0, 15, 75, or 200 mg/kg/day (gavage) Unacceptable (upgradeable)/guideline (% a.i.)	NOAEL = 75 mg/kg/day (males) LOAEL = 200 mg/kg/day, based on decreased body weight, body weight gain and food conversion efficiency in males; NOAEL = 200 mg/kg/day (females) HDT
870.3700a Prenatal developmental (Charles River Crl:CDBr female rats) **MON 0818** **CAS 61791-26-2 (tallow, POE n=15)**	MRID 46902005 (1990) 0 (corn oil), 15, 100, 300 mg/kg/day GD 6-15 (gavage) 71.9% a.i. Acceptable/guideline	Maternal NOAEL = 100 mg/kg/day Maternal LOAEL = 300 mg/kg/day, based on mortality, clinical signs (rales, soft stools, mucoid feces, diarrhea; females rales, yellow anogenital staining), and decreased body weight, body-weight gain, food consumption. Developmental toxicity NOAEL = 300 mg/kg/day, HDT
870.3800 (screening) Reproduction and fertility effects Crl:CD(SD) IGS BR Sprague-Dawley rats (10 weeks old at start) Screening study **(extended to two generations (↓ live litter size)** assessed gonadal function, mating behavior, conception, parturition, lactation of F0 and F12 generations; developmental of F1 (PND 70) and F2 (PND 4) generations **MON 0818** **CAS 61791-26-2 (tallow, POE n=15)**	MRID 47097401 (2007) 0, 100, 300, 1000 ppm (diet) males F0 (5.5, 16.6, 56.1)/ F1 (5.0, 14.9, 52.8) mg/kg/day females F0 (6.7, 19.5, 66.6)/ F1 (6.9, 18.9, 64.9) mg/kg/day 10 weeks prior to mating 69-73% a.i. Acceptable/nonguideline reproductive performance, fertility, mating performance, blood samples for testosterone &/or thyroid hormone conc. F1 (1/sex/litter @ necropsy); sperm evaluation (motility/morphology) F1 males; estrous cyclicity; litter size, viability, clinical signs, BW/BWG; developmental parameters (sexual & physical); macroscopic abnormalities @ necropsy (F1 & F2 pups)	Reproductive/offspring NOAEL = 300 ppm (F0/F1males 16.6/14.9; F0/F1 females 19.5/18.9 mg/kg/day Reproductive/offspring LOAEL =1000 ppm (F0/F1males 56.1/52.8; F0/F1 females 66.6/64.9 mg/kg/day, based on litter loss, increase mean number of unaccounted-for implantation sites and decreased mean number of pups born, live litter size and postnatal survival from birth to LD 4 (F1). At 1000 ppm, 3 F0 dams w/ small litters (2-4 pups/litter), and some of these pups died before PND 4; effect not repeated in F2 litters Systemic toxicity NOAEL = 1000 ppm (F0/F1males 56.1/52.8; P/F1 females 66.6/64.9 mg/kg/day, HDT

Table A.2. Toxicology Profile of the Alkyl Amine Polyalkoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
OECD 422 Crl:CD(SD) IGS BR rats **MON 0818** **CAS 61791-26-2 (tallow, POE n=15)** **MON 8109** **CAS 61791-31-9 (Coco, POE n=2)**	MRID 47405101 (2008) MON 8109: 0, 30, 100, 300, 2000 ppm (diet; administered for 14 days prior to mating until study termination) males: 0, 2, 8, 23, 134 mg/kg/day females: 0, 3, 9, 26, 148 mg/kg/day MON 0818: 1000 ppm (diet; administered for 14 days prior to mating until study termination) males: 0, 76 mg/kg/day females: 0, 86 mg/kg/day	MON 0818: parental toxicity/reproductive/ developmental NOAEL = 1000 ppm males 76 mg/kg/day; females 86 mg/kg/day. MON 8109: reproductive NOAEL = 2000 ppm (males 134 mg/kg/day; females (148 mg/kg/day) reproductive LOAEL was not demonstrated. MON 8109 parental toxicity NOAEL = 300 ppm (males 23 mg/kg/day; females 26 mg/kg/day) LOAEL = 2000 ppm (males 134 mg/kg/day; females: 148 mg/kg/day), based on clinical signs, decreased body weight and food consumption (both sexes) MON 8109 developmental toxicity NOAEL = 300 ppm (males 23 mg/kg/day; females 26 mg/kg/day) Developmental toxicity LOAEL = 2000 ppm (males 134 mg/kg/day; females 148 mg/kg/day, based on decreased postnatal survival, reduced live litter size on postnatal day 0, reduced number of pups born, and reduced number of implantation sites.. *FOB and locomotor activity (recorded for 6 males/group nearend of study; 6 females/group on LD 4)* no treatment-related effects reported on FOB or motor activity
Bacterial reverse mutation test 870.5100 **MON 59112** **No CAS#**	MRID 46914604 strains TA1535, TA1537, TA98 and TA100 of *Salmonella typhimurium* and strain WP2 *uvr*A of *Eschericha coli* 0, 1, 3.33, 10, 33.3, 100 or 333 µg/plate with and without S9 activation for the *Salmonella* strains and 0, 10, 33.3, 100, 333, 1000 or 3330 µg/plate +/-S9 for WP2 *uvr*A. Acceptable/guideline	No evidence of induced mutant colonies over background

Table A.2. Toxicology Profile of the Alkyl Amine Polyalkoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
Bacterial reverse mutation test 870.5100 **MON 0818** **CAS 61791-26-2 (tallow)**	MRID 46918004 strains TA1535, TA1537, TA98 and TA100 of *Salmonella typhimurium* (0.001, 0.003, 0.01, 0.03 or 0.1 mg/plate with S9 & 0.0003, 0.001, 0.003, 0.01 or 0.03 mg/plate without S9. repeat assay on TA1535 and TA1537 (± S9). cytotoxicity not observed; second cytotoxicity assay. Concentrations of MON 0818 ranging from 0.01 to 1.0 mg/plate +S9 and 0.003 to 0.3 mg/plate –S9 were tested in strain TA98; 0.001 to 0.10 mg/plate ±S9 in TA100; 0.001 to 0.1 mg/plate –S9 in TA1535; 0.003 to 0.3 mg/plate +S9 and 0.001 to 0.1 mg/plate –S9 in TA1537. Acceptable/guideline	MON 0818 was tested up to cytotoxic concentrations in all strains, but failed to induce a mutagenic response in this test system. The positive controls induced the expected mutagenic responses in the appropriate strain. **There was no evidence of induced mutant colonies over background.**
Mammalian erythrocyte micronucleus test 870. 5395 **MON 0818** **CAS 61791-26-2 (tallow)**	MRID 46902007 (1998) 100 mg/kg Acceptable/guideline	No significant increase in frequency of micronecleated polychromatic erythrocytes in bone marrow after any harvest time up to maximum tolerated dose.
Mammalian erythrocyte micronucleus test 870. 5395 **MON 59112** **No CAS#**	MRID 46930503 (2000) 0, 375, 750 or 1500 mg/kg male mice;0, 500, 1000 or 2000 mg/kg female mice Acceptable/guideline	No significant increase in the frequency of MPCEs in any treatment group at either harvest time

A.3. Toxicity Study Executive Summaries

Subchronic repeat dose toxicity studies

EXECUTIVE SUMMARY: In a 90-day oral toxicity study (MRID 46918003), MON 0818 (71.9% a.i., Lot No. PIT-8907-757-1) was administered in the diet *ad libitum* to three groups of 10 male and 10 female Sprague-Dawley rats for 90 days. Target test diet concentrations were 500, 1500, or 4500 ppm (equivalent to 33.0, 99.3, 291.6 mg/kg

bw/day in males and 39.9, 123.1, and 356.6 mg/kg bw/day in females). A similar concurrent control group of rats received basal diet only. Doses were selected based on a previous 28-day range-finding study (MRID 46918002C).

Exposure to MON 0818 in the diet at the mid- and high-dose levels of 1500 and 4500 ppm resulted in statistically- and toxicologically-significant effects. Toxicity observed at 4500 ppm consists of clinical signs (soft stools, 3 incidences in 2 males and 86 incidences in all females) observed from day 16 through day 92 of the study, decreased mean body weights throughout the study (ranging from 12-20% and 8-18% in males and females, respectively), and decreased mean total body weight gains in males (31%) and females (35%). Food consumption was also significantly reduced throughout most of the study (13 weeks for males and 10 weeks for females), particularly during the first week of the study (32% decrease in males and 27% decrease in females). Since a food efficiency assessment was not conducted, it is not possible to determine if the decreases in body weights, body weight gains, and food consumption were due, in part, to the unpalatability of the diet. Statistically-significant changes in hematological parameters observed in females may be a result of the inflammation observed in the intestines. Statistically-significant changes in clinical chemistry parameters and organ weights observed in high-dose males and females are likely a result of decreased food consumption/nutrient absorption and body weight.

At both the 1500 and 4500 ppm dose levels, microscopic examination conducted at necropsy revealed lesions, including: (1) hypertrophy and/or vacuolation of histiocytes in the lamina propria of the ileum in all high-dose males and females, and 4 of 10 mid-dose males and 4 of 10 mid-dose females; (2) hypertrophy and/or vacuolation of histiocytes in the lamina propria of the jejunum in 4 of 10 high-dose males, 7 of 10 high-dose females, and 1 mid-dose female; and (3) sinus histiocytosis in 9 of 10 high-dose males, 6 of 10 high-dose females, and 2 of 10 mid-dose males and females; and (4) accumulation of macrophage aggregates in the cortex and medullary cords of the mesenteric lymph node in 8 of 10 high-dose males, 7 of 10 high-dose females, and 2 of 10 mid-dose females. These inflammatory changes are likely the cause of the soft stools observed during the study and are considered treatment-related.

No statistically-significant treatment related effects on body weight, body weight gain, food consumption, hematological/clinical chemistry parameters, and organ weights were observed at the low-dose level of 500 ppm. In addition, no gross abnormalities or histopathological findings related to treatment were observed at this dose level.

Based on review of the study, the no-observable-adverse-effect-level (NOAEL) for MON 0818 is 500 ppm (33.0 mg/kg bw/day in males and 39.9 mg/kg bw/day in females). The lowest-observable-adverse-effect-level (LOAEL) is 1500 ppm (99.3 mg/kg/day in males and 123.1 mg/kg bw/day in females), based on irritation in the intestines and colon (hypertrophy and vacuolation of histiocytes in the lamina propria of the jejunum and ileum, and histiocytosis and accumulation of macrophage aggregates in the mesenteric lymph nodes).

This study is classified as **Acceptable/Guideline** and satisfies the guideline requirement for a 90-day oral toxicity study in rodents (OPPTS 870.3100).

EXECUTIVE SUMMARY: In a 90-day oral gavage toxicity study (MRID 47041301), ATMER® 163 (100% a.i.; batch/lot # not reported) was administered to 20 Sprague-Dawley (Crl:CD®BR) rats/sex/dose at concentrations of 0, 15, 30 or 150 mg/kg bw/day. Deionized water was administered to controls.

There were no toxicologically significant compound-related effects based on the assessment of clinical chemistry and the limited assessment of organ weights. Urinalysis was not done.

Numerous clinical signs were observed in animals dosed at 150 mg/kg bw/day. The most notable signs were wheezing and salivation, which were seen from all animals and in some animals treated with 30 mg/kg bw/day. Other clinical signs observed in both sexes dosed at 150 mg/kg bw/day included blood crust and/or red discharge (nose), dyspnea, rhinorrhea, opaque eyes, redness, hunched posture, thin, urine stains, rough haircoat, desquamation and an increased incidence of alopecia. Two males treated with 30 mg/kg bw/day, as well as four males and one female treated with 150 mg/kg bw/day, died during the study. Statistically significant body weight and body weight gain deficits were observed in both sexes dosed at 150 mg/kg bw/day; overall body weight gains were 30.5% and 15.3% lower than control values in males and females, respectively. Statistically significant decreased food consumption was seen at 150 mg/kg bw/day in males only. The ophthalmoscopic assessment revealed posterior subcapsular cataracts in males at 30 and 150 mg/kg bw/day and in females at 150 mg/kg bw/day while complete cataracts were found only at 150 mg/kg bw/day in both sexes. Increased mean values for platelet count, white blood cell count, segmented neutrophil count and lymphocyte count were seen at the 150 mg/kg bw/day dose in both males and females; all of the increases were statistically significant except the increased lymphocyte count in males. These findings are often associated with tissue inflammation. Inflammation and other relevant findings were observed in the lungs and stomach of both sexes at this dosage. The only noteworthy compound-related gross pathology findings were in the nonglandular stomach and eyes. The findings in the nonglandular stomach, desquamation and alteration of mucosa, were found primarily in males and females dosed at 150 mg/kg bw/day, however, some alterations of mucosa were also seen in animals dosed at 30 mg/kg bw/day. Opaque eyes, which were seen in both sexes at 150 mg/kg bw/day were consistent with the ophthalmoscopic findings of complete cataracts. Compound-related histopathologic findings included inflammation in the lungs of males and females dosed at 150 mg/kg bw/day and the nonglandular stomach of males and females dosed at 30 and 150 mg/kg bw/day. The inflammation in lungs might have been associated with inadvertent aspiration since previous studies have established that ATMER® 163 is a primary irritant. Dose-related incidences of acanthosis in the nonglandular stomach were seen in males and females dosed at 30 and 150 mg/kg bw/day. The only noteworthy finding in the glandular stomach was suppurative inflammation at terminal sacrifice in two females dosed at 150 mg/kg bw/day. Additionally, the microscopic assessment

showed cataracts in the eyes of both sexes dosed at 150 mg/kg bw/day; most were bilateral.

The LOAEL for ATMER® 163 in Sprague Dawley rats in this study is 30 mg/kg bw/day based on increased mortality, salivation, and posterior subcapsular cataracts in males as well as wheezing, and macro- and microscopic changes in the nonglandular stomach of both sexes. The NOAEL is 15 mg/kg bw/day.

Although there were several deficiencies (See Study/Report Deficiencies), this 90-day oral toxicity study in rats is **Acceptable/Guideline** and satisfies the guideline requirement for a 90-day oral toxicity study (OPPTS 870.3100; OECD 408) in a rodent species. Although several guideline-recommended organs were not weighed, there were no compound-related gross or histopathologic changes observed in the omitted organs.

EXECUTIVE SUMMARY: In a subchronic (90-day) oral toxicity study (MRID 47041302), ATMER® 163 (100% a.i.; batch/lot# not provided) was administered *via* capsule to three groups of 4 male and 4 female beagle dogs for 13 weeks at dose levels of 15, 30, or 100 mg/kg bw/day. A similar concurrent control group of dogs received empty capsules only. There were no unscheduled deaths during the study. All dogs survived until termination.

Exposure to ATMER® 163 *via* capsules at the high-dose level of 100 mg/kg bw/day resulted in statistically- and toxicologically-significant effects. Toxicity observed at 100 mg/kg bw/day included the clinical signs of increased incidence of salivation, emesis, and soft feces (noted with mucus alone or mucus and bile-like material). Salivation was observed in all of the males and females beginning during week 3 of the study (6 of the 8 animals) and continuing over a period of 5 to 11 weeks. Emesis was also observed in all of the males and females and was first observed during the first two weeks of the study in 7 of the 8 animals and continued over a period of 1 to 11 weeks. Soft feces (mucoid) were observed in 3 of the 4 males and in all of the females over a period of 2-7 weeks; soft feces (mucoid/bilious) were observed in the high-dose animals (3 males and 2 females) over a period of 1-3 weeks. All of these clinical signs are considered treatment-related based on the high frequency of occurrence and clear dose-response relationship. In addition, mean alanine aminotransferase (ALT/SGPT) levels were significantly increased (154%), relative to controls, in females. Microscopic examination conducted at necropsy revealed an increased in pigment accumulation in the Kupffer cells and bile canaliculi in the livers of all females. The increased pigment accumulation was not observed in any of the treated males or in the low- and mid-dose females. Other microscopic findings were observed, but are not dose-related or are found in control animals as well as treated animals.

The statistically-significant increase (22%) in mean red blood cell (RBC) counts, relative to controls, observed in high-dose females was within the historical control range. The significant increases (6%) in mean calcium levels observed in the mid- and high-dose females were small in magnitude, and the observed significant decrease (23%) in mean

blood urea nitrogen (BUN) levels in the mid-dose males did not follow a dose response pattern. All of the changes are considered to be incidental to treatment.

No statistically-significant effects on body weight, body weight gain, food consumption, or organ weights were observed at any dose level. In addition no gross abnormalities or ophthalmological changes related to treatment were observed.

Based on review of the study, the no-observable-adverse-effect level (NOAEL) for ATMER® 163 is 30 mg/kg bw/day. The lowest-observable-adverse-effects-level (LOAEL) is 100 mg/kg bw/day, based on clinical signs (increased incidence of salivation, emesis, and soft feces (with mucus alone or mucus and bile-like material)) in males and females, increased alanine aminotransferase (ALT/SGPT) levels in females, and an increased incidence of pigment accumulation in the Kupffer cells and bile canaliculi in the livers of females.

This study is classified as **Acceptable/Nonguideline** and does satisfy the guideline requirement for a 90-day oral toxicity study in nonrodents (OPPTS 870.3150).

EXECUTIVE SUMMARY: In a four-week oral toxicity study (MRID 47193901), Armoblen 557 (a.i. not provided, Batch No. B.31401-1) was administered daily by gavage to groups of five male and five female CD rats at concentrations of 0, 15, 75, or 200 mg/kg bw/day.

All rats survived until scheduled termination. Salivation in males and females at 75 and 200 mg/kg bw/day was probably due to the taste of the test material and was not considered toxicologically significant. Noisy respiration reported in 1-3 females receiving 200 mg/kg bw/day was not associated with postmortem effects and therefore, was not considered toxicologically significant. Brown staining around the muzzle observed occasionally in females at 75 mg/kg bw/day and males and females at 200 mg/kg bw/day was not considered toxicologically significant. Mean body weight was decreased in males (11-17% lower than controls) and females (4-7% lower than controls) at 200 mg/kg bw/day. The overall bodyweight gain was decreased in males receiving 75 mg/kg bw/day (13% lower than controls) and in males and females receiving 200 mg/kg bw/day (27% and 14% lower than controls, respectively). Overall food consumption for females receiving 200 mg/kg bw/day was decreased (10% lower than control). Food consumption was decreased in males at 200 mg/kg bw/day during Week 1 only. The overall food conversion efficiency was decreased in males at 75 and 200 mg/kg bw/day (13 and 23% lower than controls, respectively).

Alterations in hematology and clinical chemistry parameters were either not treatment-related or not toxicologically significant. Increases in the absolute and relative adrenal weights in males and females at 200 mg/kg bw/day were not accompanied by microscopic findings and were not considered toxicologically significant.

Based on decreased body weight, body weight gain and food conversion efficiency, a LOAEL of 200 mg/kg bw/day for Armoblen 557 in male CD rats was established; the NOAEL in male CD rats was 75 mg/kg bw/day. A LOAEL for Armoblen 557 in female CD rats was not established. The NOAEL in female CD rats was 200 mg/kg bw/day.

This 28-day oral toxicity study in the rat is **Unacceptable/Guideline/Upgradeable** and does not satisfy the guideline requirement for a repeat dose 28-day oral toxicity study (OPPTS 870.3050; OECD 407) in rats. The study may be upgraded to acceptable with submission of the percent active ingredient used for the study.

EXECUTIVE SUMMARY: In a 28-day oral toxicity study (MRID 46918002C), MON 0818 (70.6% a.i.; Lot XLI-320 [MRID 46918002]) was administered to groups of ten Sprague-Dawley rats/sex/dose in the diet at dose levels of 0, 800, 2000, and 5000 ppm (0, 51.7, 122.8, and 268.7 mg/kg bw/day for males, respectively, and 0, 63.2, 159.9, and 324.8 mg/kg bw/day for females, respectively). Males and females were sacrificed on Days 28 and 29, respectively, and subjected to gross necropsy.

All rats survived until scheduled termination. No significant treatment-related effects were found at 800 ppm of MON 08189 in the diet. When fed a diet containing 2000 ppm of MON 0818, toxicity was evident in male rats over the first eight days of the study as a reduction in body weight gain (-62%), food consumption (-18% g/kg bw/day), and food efficiency (-80%). The male rats were not able to recover by the end of the study, with overall body weight gain reduced 34% relative to controls. No effects on body weight were observed in females fed 2000 ppm.

Dietary exposure to 5000 ppm resulted in toxicity as indicated by reduced body weight, body weight gain, food consumption, and food efficiency in males and females, and irritation of the colon, particularly in females. Mean average body weight in males and females was reduced by 15-19% and 10-13% of controls, respectively, with terminal body weight reduced by 23% and 15%, respectively. Body weight gain was most severely affected during the first week of dosing, with body weight gain in males and females reduced by 183% and 455% of controls, respectively; overall body weight gain (Days 1-28/29) was significantly reduced by 89% and 102%, respectively. Food consumption (g/day) was statistically reduced at all dosing intervals in males and females. When corrected for body weight, food consumption (g/kg bw/day) was reduced in males over days 1-8 and 8-16 by 51% and 11%, respectively, and in females on Days 1-8 by 48% and over the entire dosing period of Days 1-29 by 11%. Food efficiency was statistically decreased over Days 1-8 in high-dose males and females by 315% and 1091%, respectively, and increased in high-dose females on Days 16-22 by 131%. Irritation of the colon was evidenced as an increased incidence of soft stool in both sexes (3/10 males affected a total of 4 times; 8/10 females affected 24 times), and pathological findings of prominent/enlarged lymphoid aggregates in the colon of 5 of 10 treated females.

Based on reduced body weight gain and food consumption in mid-dose male rats, a LOAEL of 2000 ppm for MON 0818 (122.8 mg/kg bw/day) was established. The NOAEL was 800 ppm (51.7 mg/kg bw/day) for males. A LOAEL of 5000 ppm for MON 0818 (324.8 mg/kg bw/day) was established for female Sprague Dawley rats based on reduced body weight, body weight gain, food consumption, and irritation in the colon. The corresponding NOAEL for female rats was 2000 ppm (159.9 mg/kg bw/day).

This 28-day oral toxicity study in the rat is **Acceptable/Non-guideline** and does not satisfy the guideline requirement for a repeat dose 28-day oral toxicity study (OPPTS 870.3050; OECD 407). The study had a number of deficiencies, including lack of analyses of the concentration, stability, and homogeneity of the test material in the diet; no hematology or clinical chemistry analyses were performed; no rationale for dose selection was provided; and a full microscopic examination was not conducted on control and high-dose animals. These deficiencies did not compromise the integrity of the study, however, in that the study was designed to set dose levels for a subsequent 90-day oral rat study (MRID 46918003C).

Developmental/Reproduction Toxicity Studies

EXECUTIVE SUMMARY: In a developmental toxicity study (MRID 46902005), MON 0818 (71.9 % a.i., Lot No. PIT-8907-7571) was administered in Mazola® Corn Oil to 25 Charles River Crl:CDBr female rats/dose by gavage at dose levels of 0 (corn oil only), 15, 100 or 300 mg/kg bw/day from days 6 through 15 of gestation. On day 20 of gestation, all surviving females were sacrificed for a scheduled Cesarean section. Developmental parameters observed and noted included: number of viable fetuses, early and late resorptions, total implantations, total corpora lutea, sex and weight of fetuses and external, visceral and skeletal examinations of all fetuses.

Six of the twenty-five high-dose females died during gestation days (GD) 8-13 (2 on GD 8; 1 on GD 10 and GD 11, and 2 on GD13). Clinical signs were also observed in the high-dose females and included: rales (12/25), labored respiration (3/25), yellow uro- (15/25) or anogenital (14/25) matting and mucoid feces (22/25) compared to none of the control animals. Few to no clinical signs were observed in the mid-dose and low-dose females. High-dose females weighed significantly ($p<0.01$) less than the controls from study day 9 until sacrifice at study day 20. High dose females also gained 59% less weight compared to controls during treatment (days 6-16). Body weight was similar to controls in the low- and mid-dose groups. Gravid uterine weight was not affected by treatment in any of the groups. High-dose females ate statistically ($p < 0.01$) less food compared to the control rats with the most significant decrease (55% less than controls) on days 6-9 before gradually improving to become comparable to controls by day 16. Overall for days 6-16, the high-dose group ate 29% less than the controls. Food consumption for the low-dose and mid-dose females was comparable to that of controls throughout the study, except for days 6-9 when the mid-dose group had a statistically

significant ($p<0.05$) decrease. There were no treatment-related effects observed on liver weight or gross pathology at necropsy in any of the treated dams.

The maternal lowest-observed-adverse-effect level (LOAEL) for MON 0818 in rats is 300 mg/kg bw/day, based on increased mortality, clinical signs, and decreased body weight, body weight gain, and food consumption. The maternal no-observed-adverse-effect level (NOAEL) for MON 0818 is 100 mg/kg bw/day.

No treatment-related differences were observed in the mean number of corpora lutea, implantations, live fetuses or resorptions. Mean fetal weight was not affected by maternal treatment with the test article. The mean number of malformations on external examination of the fetuses from the high-dose dams appeared to be high but most were observed in a single one fetus and a dose response was not observed. On visceral examination, in the high-dose group, one fetus was missing a urinary bladder, one fetus had stenosis of the right carotid artery and two fetuses had situs inversus. One control fetus also had situs inversus. These were not considered treatment-related as there was not a dose response for the situs inversus and the others were within the historical control data range. Vertebral anomalies with or with/out rib anomalies were observed in one fetus in the high-dose group but this was within the range of historical control data. No malformations were observed in the low- or mid-dose groups. Several skeletal variations in the sternebrae and ribs were identified but they were observed in both the control and treated groups at similar incidences and are not considered treatment-related.

The developmental lowest-observed-adverse-effect level (LOAEL) for MON 0818 in rats could not be determined as no effects were associated with treatment. The developmental no-observed-adverse-effect level (NOAEL) for MON 0818 is 300 mg/kg bw/day.

The developmental toxicity study in the rat is classified **acceptable/Guideline** and **satisfies** the guideline requirement for a developmental toxicity study (OPPTS 870.3700; OECD 414) in the rat.

EXECUTIVE SUMMARY: In a screening study (MRID 47097401), the potential reproductive toxicity and developmental (prenatal and postnatal) toxicity of the test article, MON 0818 (69-73% a.i.; Lot# GLP-0309-14324-I), was evaluated in CD (Sprague-Dawley) rats through two successive generations. The study was designed to evaluate the effects of MON 0818 on male and female reproduction within the scope of a screening study. The study was extended to a two-generation study when a decrease in live litter size was observed at the high-dose level. In the study, MON 0818 was administered orally via the diet to three groups of 20 male and 20 female CD rats. Target test diet concentrations were 100, 300 or 1000 ppm. A similar concurrent control group of rats received basal diet only. At approximately 10 weeks of age, the P animals were dosed via diet for at least 70 days prior to mating and continuing to sacrifice (males) or LD 21 (females). All P adults were sacrificed following selection of the F_1 generation on PND 21.

Selection of parents for the F_1 generation was made from the weaned F_1 litters. Between PND 21 or 22 and 70, the weanling F_1 animals (3/sex/litter, if possible) were administered the test diet on a mg/kg basis (so not to overexpose the rapidly growing F_1 animals) at target concentrations of 0, 6, 18, or 61 mg/kg/day for the F_1 males and 0, 7, 22, or 74 mg/kg/day for the F_1 females. Beginning on PND 70, the F_1 animals selected for breeding from the control and high-dose groups only (2/sex/litter) were administered the test diet at a constant concentration (0 or 1000 ppm) for a minimum of 80 to 88 days prior to mating. The selected F_1 males continued to receive the test diet throughout mating and continuing until sacrifice (after the F_2 pups reached LD 4). The selected F_1 females continued to receive the test diet throughout mating, gestation and lactation and until the day of sacrifice (after the F_2 pups reached LD 4).

Mortality and clinical signs, body weights, body weight gains, food consumption, reproductive function, fertility and mating performance, absolute and relative organ weights, macroscopic abnormalities at necropsy, and histopathological findings were recorded for all parental/adult animals. In addition, blood samples for testosterone and/or thyroid hormone concentration determinations were collected from one F_1 male and one F_1 female per litter at the scheduled necropsy. Sperm evaluation (motility and morphology) was also performed on all F_1 male animals at termination. Litter size, viability, clinical signs, body weights, body weight gains, developmental (sexual and physical) parameters, and macroscopic abnormalities at necropsy were recorded for the F_1 and F_2 pups.

Survival and clinical conditions, mean body weights and food consumption (pre-mating, gestation, and lactation), reproductive performance, mean organ weights, and macroscopic and microscopic morphology of the P and F_1 parental generations were unaffected by administration of MON 0818 at all dose levels. Treatment-related effects were also not seen in estrous cyclicity, spermatogenic endpoints and testosterone and thyroid hormone levels of the F_1 generation or in the clinical signs, mean body weights, and developmental landmarks of the F_1 and F_2 pups, as well as the litter viability and postnatal survival of the F_2 litters.

Potential treatment-related effects were observed in litter loss, increased mean number of unaccounted-for implantation sites, and decreased mean number of pups born, live litter size and postnatal survival from birth to LD 4 in the high-dose P females and F_1 litters. These effects were limited to a small number of litters, not always statistically-significant, and were not reproduced in the F_2 litters. However, the increased (statistically-significant) mean number of unaccounted-for implantation sites exceeded the maximum mean value in the laboratory historical control data. While not statistically-significant, the corresponding reduced number of pups born and live litter size, as well as the reduced postnatal survival, were at or below the limits observed in the laboratory historical control data.

Therefore, the lowest-observed-adverse-effect level (LOAEL) for parental reproductive toxicity (P) and offspring developmental/neonatal toxicity (F_1) is 1000

ppm (56.1 and 52.8 mg product/kg/day (equivalent to 41 and 38.5 mg/kg/day) for the P and F_1 males, respectively, and 66.6 and 64.9 mg product/kg/day (equivalent to 48.6 and 47 mg/kg/day) for P and F_1 females, respectively), based on litter loss, increase mean number of unaccounted-for implantation sites and decreased mean number of pups born, live litter size and postnatal survival from birth to LD 4. The no-observed-adverse-effect level (NOAEL) is 300 ppm (16.6 and 14.9 mg product /kg/day (equivalent to 12 and 11 mg/kg/day) for the P and F_1 males, respectively, and 19.5 and 18.9 mg product/kg/day (equivalent to 14 and 13.7 mg/kg/day) for the P and F_1 females, respectively). The NOAEL for parental (P and F_1) systemic toxicity is 1000 ppm. A LOAEL for parental systemic toxicity was not determined.

This study is classified as **Acceptable-Nonguideline.** The study was conducted as an extended screening study. It does not fully satisfy the requirements for a two-generation reproductive study (OPPTS 870.3800) in rats because: (1) the test substance was not administered to the F_1 offspring until the F_2 generation was weaned; (2) only the F_1 males and females from the control and high-dose group were selected for breeding; (3) the P generation did not contain a sufficient number of mating pairs to yield at least 20 pregnant females; and, (4) spermatogenic endpoints were only assessed for F_1 males.

EXECUTIVE SUMMARY: In a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (MRID 47405101) MON 8109 (100% a.i., Lot # GLP-0611-17816-I) or MON 0818 (100% a.i., Lot # GLP-0609-17646-I) was administered to 12 Crl:CD(SD) rats/sex/dose in the diet at dose levels of 0, 30, 100, 300, or 2000 ppm MON 8109 (males 0, 2, 8, 23, 134 mg/kg/day; females 0, 3, 9, 26, 148 mg/kg/day) or 1000 ppm MON 0818 (males 76 mg/kg/day; females 86 mg/kg/day) for 14 consecutive days prior to mating (both sexes) and throughout gestation and lactation day 4 (females). Males received the test or basal diets for a total of 71-72 days, and the females received the test or basal diets for a total of 69-72 days. Functional observational battery (FOB) and locomotor activity data were recorded for 6 males/group near the end of diet administration and for 6 females/group on lactation day 4. Parental animals were sacrificed approximately 2.5 weeks after lactation day 4, and offspring were sacrificed on lactation day 4.

No mortality related to MON 8109 exposure occurred. Increased incidences of red material around the nose, reddened nose, and reddened mouth were test substance-related findings in males and females treated with 2000 ppm MON 8109. Mean body weight losses were noted at 2000 ppm MON 8109 in male and females during the first week of test diet administration. Lower mean body weight (8-12%) and/or body weight gain (males 37%; females 17%) with corresponding reduction in food consumption were observed in the animals from this group throughout the study. Male at the 2000 ppm MON 8109 dose level displayed decreased liver, kidney, thyroid, and heart weights, which can be attributed to the reduction in body weight. The females from this group had a lower number of implantation sites and lower live litter size. Offspring of these females had lower postnatal survival on PND0, PND0-1, PND1-4, and birth to PND4 compared to the control group. No effect of treatment was observed in male and female mating and fertility, male copulation and female conception indices, gestation length, functional

observational battery, locomotor activity, hematology, or serum chemistry. No test substance-related findings were noted in the 30, 100, or 300 ppm MON 8109 group males, females, or offspring.

No mortality related to MON 0818 exposure occurred. One female in the 1000 ppm MON 0818 group was found dead with dystocia on lactation day 1 and another was euthanized *in extremis* on gestation day 30 and found to have a ruptured uterus. No treatment-related effects were observed in male and female mating and fertility, male copulation and female conception indices, gestation length, functional observational battery, locomotor activity, hematology, or serum chemistry following exposure to 1000 ppm MON 0818.

The parental systemic LOAEL is 2000 ppm MON 8109 (134 mg/kg bw/day in males, 148 mg/kg bw/day in females), based on clinical findings, decreased mean body weight and body weight gain, and food consumption. The parental systemic NOAEL is 300 ppm MON 8109 (23 mg/kg bw/day in males, 26 mg/kg bw/day in females).

The developmental LOAEL is 2000 ppm MON 8109 (134 mg/kg bw/day in males, 148 mg/kg bw/day in females), based on decreased postnatal survival, decreased live litter size on postnatal day 0, reduced number of pups born, and reduced number of implantation sites. The developmental NOAEL is 300 ppm MON 8109 (23 mg/kg bw/day in males, 26 mg/kg bw/day in females).

A reproductive LOAEL for MON 8109 was not demonstrated. The reproductive NOAEL is 2000 ppm MON 8109 (134 mg/kg bw/day in males, 148 mg/kg bw/day in females).

A parental LOAEL for MON 0818 was not demonstrated. The parental NOAEL is 1000 ppm MON 0818 (76 mg/kg bw/day in males, and 86 mg/kg bw/day in females).

The reproductive/developmental toxicity LOAEL for MON 0818 was not demonstrated in this study. The reproductive/developmental toxicity NOAEL is 1000 ppm MON 0818 (76 mg/kg bw/day in males, and 86 mg/kg bw/day in females).

This study is **acceptable (guideline)** and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) in the rat for MON 8109 and MON 0818 (limit test).

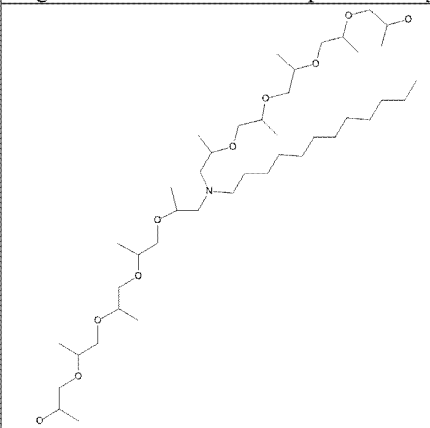
APPENDIX B

B.1. Structure-Activity Relationship (SAR) Discussion

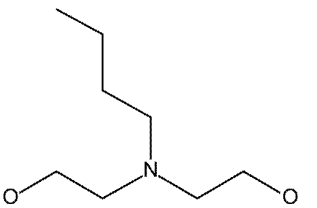
HED used DEREK for Windows (V. 11) to assess the potential toxicity of compounds in the inerts mixture. The products in this cluster are complex mixtures with compounds similar in structure, but of various carbon chain lengths. Therefore two compounds were

subjected to the DEREK analysis: one compound that represented a larger molecule expected in the mixture, and a small molecule that represents a potential environmental degradate, based on the postulated environmental degradation pathway. These compounds were selected on the basis that potential toxicity of intermediate-sized chemicals will be represented by the large and small chemicals selected. The structures are shown in Figure 1 below.

Figure 1. Structures of Compounds Subjected to Structure-Activity Analysis



Example large molecule



Example Postulated Environmental Degradate

Derek for Windows (LHASA Ltd.) is an expert system for the prediction of toxicity. It relies on a knowledge base of structural alerts and rules developed by scientists. When a test compound is inputted into the program, Derek for Windows scans the test compound for structural alerts contained within its database that are associated with specific toxicological endpoints and applies a series of reasoning rules to determine the likelihood of toxicity for the test compound. Information is provided on the rules used to make the prediction, along with descriptions of structural alerts identified, comments, available example compounds linked to the alerts and literature references.

DEREK did not identify any structural alerts of concern for the larger molecule tested, and a single respiratory irritation alert was identified for the smaller molecule. The respiratory irritation alert is expected for small amine molecules, which are known to be irritating. DEREK has developed more alerts for genotoxicity and carcinogenicity than other endpoints in the system. Considering what is already known about these specific compounds and other long-chain fatty acid compounds, along with the lack of structural alerts for carcinogenicity, chronic toxicity, or genotoxicity, HED has no specific concerns regarding chronic exposures other than those identified in the subchronic toxicity studies for this cluster.

APPENDIX C

C.1. Drinking Water Surrogate Analysis

Summary of Drinking Water Estimates of Four Surrogate Inert Chemicals

Notes:

1. Used a North Carolina cotton scenario with application date on July 1. This scenario should be a good representative of the numbers that you can expect from EFED. Also tried manipulation of application dates and weather files to ensure that there are no aberrations; these values look good in that regard.

2. PCA factors were not applied, but the impact of applying such factors (i.e., 0.5 to 0.9) would be insignificant in comparison to the vast uncertainties surrounding generation of concentrations from surrogate chemicals as well as uncertainties regarding the actual timing of applications.

3. All simulations were made at approximately 1 lb/A. Concentrations resulting from other application rates will be directly proportional to the application rate.

4. Table 1 gives the normalized concentration estimates for the case where all mass is applied on a single day. This should be the most conservative case.

5. Table 2 gives the normalized concentration estimates for the case where mass is distributed evenly over a 100-day period (April to June).

6. A range of degradation rates were used because degradation information was not available. 3 simulations were made 1) chemically stable in water and soil, 2) a 100 day half life in water and soil, and 3) a 10-day half life in water and soil. This should cover degradation.

7. Table 3 gives the chemical inputs used in the simulations.

Table 1. DW concentration for application lumped on a single day. (This maximizes the acute concentrations.) All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Estimates based on Stable Assumption				
Acute (ppb)	1.1	41	33	0.005
Chronic	0.69	15	19	0.003
Cancer	0.47	12	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
Acute (ppb)	0.74	36	22	0.003
Chronic	0.33	8.8	7.7	0.002
Cancer	0.25	6.4	6.4	0.001
Estimates based on assumption of a 10-day half life in soil and water				
Acute (ppb)	0.48	25	15	0.002
Chronic	0.04	1.1	0.96	0.0002
Cancer	0.03	0.65	0.60	0.0002

Table 2. DW concentration for applications spread out over a 100-day period. This simulates a more even distribution of pesticide over the growing season. All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Spread Out Values				
Estimates based on Stable Assumption				
Acute (ppb)	0.98	29	28	0.004
Chronic	0.70	13	18	0.003
Cancer	0.48	10	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
	0.57	21	17	0.003
	0.36	6.9	7.2	0.002
	0.27	5.3	6.4	0.001

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Estimates based on assumption of a 10-day half life in soil and water				
	0.16	7.8	4.3	0.001
	0.04	0.79	0.77	0.0002
	0.03	0.61	0.63	0.0002

Table 3 Chemical Inputs used in Simulations.

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Chemical Inputs:				
MW	*928*	*274*	*302*	*1185*
Solubility (mg/L)	*382*	*299*	*19.5*	*6.69e-8*
V.P. (mmHg)	*5.8e-27*	*1.76e-8*	*3.86e-8*	*3.77e-33*
Koc (ml/g)	*9.44e6*	*152*	*1345*	*2.57e9*

APPENDIX D

D.1. Listing of the Surrogate Active Ingredients

Table D.1. Listing of the 57 "Significant" Surrogate Active Ingredients

Insecticides (22)	Herbicides (20)	Fungicides (15)
Acephate	Acetochlor	Azoxystrobin
Aldicarb	Alachlor	Benomyl
Azinphos-methyl	Atrazine	Captan
Bifenthrin	Bentazon	Chlorothalonil
Carbaryl	Cyanazine (no food uses registered)	Fenarimol
Chlorpyrifos	Dicamba	Fosetyl-Al
Cryolite	Dimethenamid	Iprodione
Diazinon	Diuron	Mancozeb
Dimethoate	EPTC	Maneb
Endosulfan	Ethafluralin	Mefenoxam
Ethion	Fluometuron (registered on cotton only)	Metiram
Imidacloprid	Glyphosate	Tetraconazole
Lambda-Cyhalothrin	MCPA	Thiram
Methamid	Metolachlor	Thiophanate-methyl
Methomyl	Molinate (no food uses registered)	Ziram
Methyl Parathion	Pendimethalin	
Oxydemeton-methyl	Propanil	
Permethrin	Simazine	
Phorate	Trifluralin	
Phosmet	2,4-D	
Propargite		
Terbufos		

APPENDIX E

E.1. Residential Exposure Assessment Introduction

This document is a summary of the methods used to calculate residential exposures to the JITF inert cluster inert ingredients. These methods and a basic description of how they are used were taken from References A and B [available at the end of Appendix E]. These references also contain more detailed information on the rationale behind these methods. Only those methods pertinent to the JITF inert cluster inert ingredients exposures are discussed in this document.

Tasks associated with residential pesticide handlers are categorized using one of the following terms:

- Mixers and/or Loaders: these individuals perform tasks in preparation for an application. For example, mixers/loaders would mix and prepare the product prior to application.
- Mixer/Loader/Applicators and or Loader/Applicators: these individuals are involved in the entire pesticide application process (they do all job functions related to a pesticide application event). These individuals would perform the mix/load function, transfer the product (containing the inert) into the application equipment, and then complete the product application.

A chemical can produce different effects based on how long a person is exposed, how frequently exposures occur, and the level of exposure. HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. HED completes both short- and intermediate-term assessments for residential scenarios in all cases because these kinds of exposures are likely and acceptable use/usage data are not available to justify deleting intermediate-term scenarios. Based on use data, HED believes that residential exposures to the JITF inert cluster inert ingredients through applied pesticide formulations may occur over a single day or up to weeks at a time for many use-patterns and that intermittent exposure over several weeks may also occur. Long-term handler exposures are not generally expected to occur for long-term exposure scenarios,

While occupational assessments are typically completed by HED using different levels of risk mitigation, residential handler scenarios are assessed assuming short-sleeve shirts and shorts for the handler.

The exposure assessment team used a rate of 4.5 lbs product/A. This estimate is based on the following assumptions: Five (5) gallons of formulated pesticide solution are assumed to be used per day by a residential handler (Revised Residential SOPs Area Treated, February, 2001). Consistent with the residential SOPs, the density of the formulated pesticide solution is assumed to be 9 lbs/gallon. The product concentrate is assumed to be diluted at a 1 to 10 ratio with water.

5 gallons formulated pesticide solution*(9 lbs/gallon)*(1 part product concentrate/10 parts water) = 4.5 lbs product per day

This application rate of product can be multiplied by the percentage of inert in each product type (herbicide, insecticide or fungicide) to be used as application rates in the risk assessment to account for inert in the product.

E2. Residential Handler/Applicator Exposures

The Agency believes that there are distinct job functions or tasks related to applications and that exposures can vary depending on the specifics of each task. Job requirements (e.g., amount of chemical to be used in an application), the kinds of equipment used, the crop or target being treated, and the circumstances of the user (e.g., the level of protection used by an applicator) can cause exposure levels to differ in a manner specific to each application event.

Exposure Data Sources

The Agency uses exposure scenarios to describe the various types of handler exposures that may occur for a specific active ingredient. The use of scenarios as a basis for exposure assessment is very common as described in the U.S. EPA Guidelines for Exposure Assessment (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992). Information from the current labels, use and usage information, toxicology data, and exposure data were all key components in the development of the exposure scenarios. The Agency has developed a series of general descriptions for tasks that are associated with pesticide applications. A residential handler is a term used to describe those individuals who are involved in the pesticide application process. As residential products typically are already mixed, residential handler exposure scenarios are based on application exposure only.

A chemical can produce different effects based on how long a person is exposed, how frequently exposures occur, and the level of exposure. The Agency classifies exposures up to 30 days as short-term and exposures greater than 30 days up to several months as intermediate-term. Based on use data and label instructions, the Agency believes that residential exposures to the JITF inert cluster inert ingredients may occur over a single day or up to 30 days at a time for the use patterns. Long-term handler exposures are not expected to occur for chemicals in the JITF inert cluster inert ingredients cluster.

Other parameters are also defined from use and usage data such as application rates and application frequency. The Agency typically completes exposure assessments using maximum application rates for each scenario to ensure there are no concerns for each specific use.

No chemical-specific handler exposure data were submitted in support of this action to inform daily dose calculations. It is the policy of HED to use data from PHED Version 1.1 as presented in the PHED Surrogate Exposure Guide (8/98) to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available (HED Science Advisory Council for Exposure [ExpoSAC] Draft Policy # 7, dated 1/28/99). Additionally, typical HED standard values were used for the amount treated per day (ExpoSAC Policy # 9, dated 7/5/00).

The residential handler/applicator exposures are calculated using unit exposure data from the Pesticide Handlers Exposure Database (PHED). PHED was designed by a task force of representatives from the US EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based upon the number of observations and the available quality control data. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposures for many residential scenarios that can be used to ensure consistency in exposure assessments. Unit exposures are used which represent different levels of personal protection as described above. Protection factors were used to calculate unit exposures for varying levels of personal protection if data were not available.

ORETF Handler Studies (MRID 449722-01): A report was submitted by the ORETF (Outdoor Residential Exposure Task Force) that presented data in which the application of various products used on turf by homeowners and lawn care operators (LCOs) was monitored. All of the data submitted in this report were completed in a series of studies. These studies are summarized in the HED Memorandum "Summary of HED's Reviews of ORETF Chemical Handler Exposure Studies: MRID 449722-01", DP Barcode D261948 of April 30, 2001. The studies performed used dacthal as a surrogate compound with a target application rate of 2.0 lbs/ai. All studies were conducted in accordance with current Agency guidelines, have been reviewed by HED and Health Canada, and the data generated were of high quality.

Assumptions for Handler Exposure Scenarios

General assumptions regarding the residential handler scenarios assessed are as follows:

- Residential handler exposure estimates were based on surrogate data from the Pesticide Handlers Exposure Database (PHED, V.1.1, 1998) and Outdoor Residential Exposure Task Force (ORETF) data. Appendix E contains additional information about the data sources used to assess residential exposure.
- HED has developed standard unit exposures for many scenarios to ensure consistency in exposure assessments. These standard values were used to calculate handler exposures for the associated scenarios.
- The adverse effects for the short- and intermediate-term dermal and inhalation endpoints are based on studies where the effects were not gender specific, therefore, the body weight of an average human (70 kg) was used to estimate exposure.
- The daily areas treated were defined for each handler scenario (in appropriate units) by determining the amount that can be reasonably treated by a residential handler in a single day. When possible, the assumptions for daily areas treated are taken from the Health Effects Division Science Advisory Committee on Exposure Policy 9: "Standard Values for Daily Acres Treated in Agriculture".

Residential Handler Exposure and Risk Calculations

Residential Handler Exposure and Risk Calculations

Potential dermal and inhalation daily exposures for occupational handlers were calculated using the following formulas:

Daily Inhalation Exposure (mg inert /day) = UE (µg inert/ lb inert) * CF * AR * AT

Daily Dermal Exposure (mg inert / day) = UE (mg inert / lb inert) * AR * AT

Where:
UE = Unit Exposure (from PHED) (µg or mg inert / lb inert)
CF = conversion factor to convert µg to mg (1 mg /1000 µg)- for inhalation exposure only
AR = application rate (lb inert/ A)
AT = daily acres treated (Acres/day)

The inhalation and dermal daily doses were calculated using the following formulas:

Daily Inhalation Dose (mg /kg/day) = Daily Inhalation Exposure (mg /day) * 1/Body Weight (kg) * 1 (100% Inhalation absorption)

Daily Dermal Dose (mg /kg/day) = Daily Dermal Exposure (mg /day) * 1/Body Weight (kg) * 0.05 (5% Dermal absorption)

Margin of Exposure: Dermal and inhalation risks for each application handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the PoD to the daily dose of concern. All MOE values were calculated for dermal and inhalation exposure levels.

Where:

MOE = PoD (mg/kg/day) / ADD (mg/kg/day)

MOE = Margin of Exposure: value used by HED to represent risk or risk estimates (unitless)
PoD = Point of Departure
NOAEL = No Observed Adverse Effect Level: Dose level in a toxicity study
ADD = Average Daily Dose: the absorbed dose received from exposure to a pesticide in a given scenario

Risk estimates are presented for the route of exposure in each scenario, because risk mitigation measures are specific to the route of exposure.

Total Margins of Exposure: Where appropriate, the endpoint selected for both dermal and inhalation exposure is combined to include both dermal and inhalation routes of exposure using the following equation.

Total MOE = 1/ (1/ Dermal MOE + 1/ Inhalation MOE)

The level of concern for all assessments is established by the uncertainty factor. The level of concern is an MOE of 100 for the JITF inert cluster inert ingredients dermal and inhalation residential exposure scenarios (short- and intermediate-term exposure duration.

E3. Residential Postapplication Exposures

No crop-specific dislodgeable foliar residue (DFR) or transferable turf residue (TTR) data is available for the JITF inert cluster inert ingredients. A default residential postapplication assessment was conducted, including a default 5% of the JITF inert cluster inert ingredients application rate as the initial concentration and a 10% daily dissipation rate. This is adapted from the ExpoSAC SOP No. 003 (May 7th, 1998 - Revised August 7th, 2000).

Assumptions for Handler Exposure Scenarios

General assumptions regarding the residential handler scenarios assessed are as follows:

- The average residential workday is assumed to be 8 hours.
- The adverse effects for the short- and intermediate-term dermal PoDs are based on studies where the effects were observed in both sexes, therefore, the body weight of an average human (70 kg) was used to estimate exposure.
- HED has developed standard transfer coefficient values for residential postapplication scenarios to ensure consistency in exposure assessments. These standard values were used to calculate postapplication exposures.
- No postapplication data were submitted for the inert cluster; a default 5% of the application rate is used in conjunction with 10% default daily dissipation rate.

Residential Postapplication Outdoor Exposure and Risk Calculations

General assumptions regarding the occupational handler scenarios assessed are as follows:

- The adverse effects for the short- and intermediate-term dermal and inhalation endpoints are based on studies where the effects were observed in both sexes, therefore, the body weight of an average human (70 kg) was used to estimate exposure. The body weight of an average child is 15 kg.
- HED has developed standard transfer coefficient values for occupational postapplication scenarios to ensure consistency in exposure assessments.

Potential dermal postapplication exposure was calculated using the following formulas:

Adult and Child Dermal Exposure to Treated Lawns:

$$ADD = \frac{TTR * TC * ET * CF1 * DA}{BW}$$

Where:
ADD= Average Daily Dose (mg/kg/day)
TTR= Turf Transferable Residue ($\mu g/cm^2$)
TC = Transfer Coefficient (cm^2/hr) (14,500 cm^2/hr for adults, 5,200 cm^2/hr for children for short-term exposure durations; and 7,300 cm^2/hr for adults, 2,600 cm^2/hr for children for intermediate-term exposure durations)

ET = Exposure Time (2 hr)
CF1 = Conversion Factor (1 mg / 1000 µg)
DA = Dermal Absorption Factor (5%)
BW = Body Weight (70 kg for adult, 15 kg for child)

$$TTR = AR * (1\text{-}D)^{t} * F * CF1 * CF2$$

Where:
AR = Application Rate (lb inert/acre)
F = fraction of inert retained on foliage or 5% (unitless)
D = fraction of residue that dissipates daily or 10% (unitless)
t = number of days after application day (Day 0; day of application)
CF1 = 4.54×10^{8} µg/lb
CF2 = 24.7×10^{-9} acre/cm^2

Hand to Mouth Exposure to Child on Treated Turf (from SOP 2.3.2):

The following equation is used to calculate the nondietary ingestion exposures that are attributable to hand-to-mouth behavior on treated turf:

$$ADD = \frac{TTR * SA * SE * Freq * CF1 * ET}{BW}$$

Where:
ADD = Average daily dose (mg/kg/day)
TTR= turf transferable residue (µg/cm^2)
SA= Surface area of child hand- 3 fingers (20 cm^2/event)
SE = Saliva Extraction Factor (0.5)
Freq = Frequency of hand-to-mouth events (20 events/hr for short-term exposures, 9.5 events/hr for long-term exposures)
CF1 = 1 mg/ 1000 µg
ET = Exposure Time (2 hours)
BW = Body weight (15 kg for child)

$$TTR = AR * (1\text{-}D)^{t} * F * CF1 * CF2$$

Where:
AR = Application Rate (lb inert/acre)
F = fraction of inert retained on foliage/surface or 5% (unitless)
D = fraction of residue that dissipates daily or 10% (unitless)
t = number of days after application day (0 days); day of application
CF1 = 4.54×10^{8} µg/lb
CF2 = 24.7×10^{-9} acre/cm^2

Object to Mouth Exposure to Child:

The following equation is used to calculate the nondietary ingestion exposures that are attributable to object-to-mouth behavior on treated turf:

$$ADD = \frac{TTR * IgR * CF1}{BW}$$

Where:
TTR = object transferable residue ($\mu g/cm^2$)
IgR = Ingestion Rate for mouthing per day (25 cm^2/day)
CF1 = 1 mg / 1000 µg
BW = Body weight (15 kg for child)

$$TTR = AR * (1\text{-}D)^t * F * CF1 * CF2$$

Where:
AR = Application Rate (lb inert/acre)
F = fraction of inert retained on object or 20% (unitless)
D = fraction of residue that dissipates daily or 10% (unitless)
t = number of days after application day (0 days); day of application
CF1 = 4.54×10^8 µg/lb
CF2 = 24.7×10^{-9} acre/cm^2

Soil Ingestion Exposure to Child:

The following equation is used to calculate the nondietary ingestion exposures that are attributable to soil ingestion on treated turf:

$$ADD = \frac{SR * IgR * CF1}{BW}$$

Where:
ADD = Average daily dose (mg/kg/day)
SR = Soil Residue, 1 cm depth of surface soil, (µg/g)
IgR = Ingestion Rate for daily soil ingestion (100 mg/day)
CF1 = Conversion Factor (1 g / 1,000,000 µg)
BW = Body weight (15 kg for child)

$$\text{Soil Residue (SR)} = AR * CF1 * CF2 * CF3 * F * (1\text{-}D)^t$$

Where:
AR= application rate (lb inert/ A)
CF1 = 4.54 x 10^{8} µg/lb
CF2 = 24.7 x 10^{-9} acre/cm^2
CF3 = Conversion factor (0.67 cm^3 / g soil)
F = fraction of inert retained on soil or 100% (unitless)
D = fraction of residue that dissipates daily (unitless)
t = postapplication day on which exposure is being assessed (t = 0, day of application)

The Aggregate Risk for inert cluster is calculated for residential postapplication by adding the daily doses for child dermal exposure to lawns and child hand-to-mouth exposure to treated lawns. This method is used because the PoD is the same for both of the above scenarios. Then, the risk estimate is calculated by dividing the PoD by the combined daily dose.

Assumptions for Dermal Dose from Pesticide Residues on Turf:

- On the day of application, it may be assumed that 5% of the application rate are available from the turfgrass as dislodgeable residue.
- Postapplication is assessed on the same day the pesticide is applied because it is assumed that the homeowner could be exposed to turfgrass immediately after application. Therefore, postapplication exposures are based on day 0 (i.e., the day of application).
- The upper percentile dermal transfer coefficient is assumed to be 14,500 cm^2/hr for adults and 5,200 cm^2/hr for children for short-term durations; and 7,300 cm^2/hr for adults and 2,600 cm^2/hr for children for intermediate-term durations. The transfer coefficient cm^2/hr is a calculated mean, based on the Jazzercise method, which is believed to result in an upper percentile estimate of the transfer coefficient for this scenario.
- The duration of exposure for children and adults is assumed to be 2 hours per day. The 95th percentile value for playing on grass is 121 minutes per day for both age groups 1-4 years and 18-64 years (U.S. EPA 1996).

Assumptions for Potential Dose among children from Incidental Nondietary Ingestion of Pesticide Residues on Residential Lawns from Hand-to-Mouth Transfer:

- On the day of application, it may be assumed that 5% of the application rate is available on the turfgrass as dislodgeable residue.
- Postapplication activities are assessed on the same day that the pesticide is applied because it is assumed that children could play on the lawn immediately after application.
- The surface portion of three fingers of a toddler's hand put in mouth is 20 cm^2.
- The Hand-to-Mouth (HTM) exposure frequency is 20 times per hour for short term exposures.
- The HTM exposure frequency is 9.5 times per hour for intermediate term exposures.

- The duration of exposure for toddlers is assumed to be 2 hours per day. The 95th percentile value for playing on grass is 121 minutes per day for both age groups 1-4 years and 18-64 years (U.S. EPA 1996).
- Toddlers (age 3 years), used to represent the 1 to 6 year old age group, are assumed to weigh 15 kg. (U.S. EPA 1996).
- The saliva extraction factor is 50%.

Assumptions for Potential Dose among Toddlers from the Ingestion of Pesticide-Treated Turfgrass:

- On the day of application, it may be assumed that 20% of the application rate is available on the turfgrass as dislodgeable residue.
- Postapplication activities are assessed on the same day that the pesticide is applied because it is assumed that children could play on the lawn immediately after application.
- The assumed ingestion rate for grass for toddlers (age 3 years) is 25 cm^2/day. This value is intended to represent the approximate area from which a child may grasp a handful of grass.

Assumptions for Potential Dose among Toddlers from Incidental Ingestion of Soil from Pesticide-Treated Residential Areas:

- On the day of application, it is assumed 100% of the application rate is located within the soil's uppermost 1 cm.
- Postapplication must be assessed on the same day the pesticide is applied because it is assumed that toddlers could play on the lawn or other outdoor treated areas immediately after application.
- The assumed soil ingestion rate for children (age 1-6 years) is 100 mg/day (U.S. EPA 1996).

References

(A) PHED Surrogate Exposure Guide, V1.1. Health Effects Division, Office of Pesticide Program. August, 1998.

(B) Series 875 - Occupational and Residential Exposure Test Guidelines, Group B - Post Application Exposure Monitoring Test Guidelines. U.S. EPA. February 10, 1998.

APPENDIX F

F.1. Occupational Exposure Assessment Introduction

This document is a summary of the methods used to calculate occupational exposures to the inert cluster inert ingredients. These methods and a basic description of how they are used were taken from References A and B. These references also contain more detailed information on the rationale behind these methods. Only those methods pertinent to the JITF inert cluster inert ingredients exposures are discussed in this document.

Tasks associated with occupational pesticide handlers are categorized using one of the following terms:

- Mixers and/or Loaders: these individuals perform tasks in preparation for an application. For example, mixers/loaders would mix and prepare the product prior to application.
- Mixer/Loader/Applicators and or Loader/Applicators: these individuals are involved in the entire pesticide application process (they do all job functions related to a pesticide application event). These individuals would perform the mix/load function, transfer the product (containing the inert) into the application equipment, and then complete the product application.

A chemical can produce different effects based on how long a person is exposed, how frequently exposures occur, and the level of exposure. HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. HED completes both short- and intermediate-term assessments for occupational scenarios in all cases because these kinds of exposures are likely and acceptable use/usage data are not available to justify deleting intermediate-term scenarios. Based on use data, HED believes that occupational exposures to the JITF inert cluster inert ingredients may occur over a single day or up to weeks at a time for many use-patterns and that intermittent exposure over several weeks may also occur. Some applicators may apply the products containing inerts over a period of weeks, because they are commercial applicators who are completing multiple applications for multiple clients. Long-term handler exposures can occur in ornamental treatment scenarios, where handlers can apply pesticides all year long in greenhouses and hothouses.

Usually occupational handler exposure assessments are completed by HED using different levels of risk mitigation. Typically, HED uses a tiered approach. The lowest tier is designed as the baseline exposure scenario (i.e. long-sleeve shirt, long pants, shoes, socks, no respirator). If risks are of concern at the baseline exposure scenario, then increasing levels of PPE (i.e. gloves, respirators) are evaluated. If risk remains a concern with maximum PPE, then engineering controls (i.e. enclosed cabs or cockpits, water-soluble packaging, and closed mixing/loading systems) are evaluated. This approach is used to ensure that the lowest level of risk mitigation that provides adequate protection is selected, since the addition of PPE and engineering controls involves an additional expense to the user and (in the case of PPE) also involves an additional

burden to the user due to decreased comfort and dexterity and increased heat stress and respiratory stress.

F2. Occupational Handler/Applicator Exposures

The Agency believes that there are distinct job functions or tasks related to applications and that exposures can vary depending on the specifics of each task. Job requirements (e.g., amount of chemical to be used in an application), the kinds of equipment used, the crop or target being treated, and the circumstances of the user (e.g., the level of protection used by an applicator) can cause exposure levels to differ in a manner specific to each application event.

Exposure Data Sources

The Agency uses exposure scenarios to describe the various types of handler exposures that may occur for a specific active ingredient. The use of scenarios as a basis for exposure assessment is very common as described in the U.S. EPA Guidelines for Exposure Assessment (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992). Information from the current labels, use and usage information, toxicology data, and exposure data were all key components in the development of the exposure scenarios. The Agency has developed a series of general descriptions for tasks that are associated with pesticide applications. Tasks associated with occupational pesticide handlers are categorized using one of the following terms:

- Mixers and/or Loaders: These individuals perform tasks in preparation for an application. For example, prior to application, mixer/loaders would mix the JITF inert cluster inert ingredients and load them into the holding tank of the groundboom.

- Applicators: These individuals operate application equipment during the release of a pesticide product into the environment. These individuals can make applications using equipment such as groundboom.

- Mixer/Loader/Applicators and or Loader/Applicators: These individuals are involved in the entire pesticide application process (i.e., they do all job functions related to a pesticide application event). These individuals would transfer the JITF inert cluster inert ingredients into the application equipment and then also apply it.

A chemical can produce different effects based on how long a person is exposed, how frequently exposures occur, and the level of exposure. The Agency classifies exposures up to 30 days as short-term and exposures greater than 30 days up to several months as intermediate-term. Based on use data and label instructions, the Agency believes that occupational the JITF inert cluster inert ingredients exposures may occur over a single day or up to 30 days at a time for the use patterns. Long-term handler exposures are not expected to occur for the JITF inert cluster inert ingredients.

Other parameters are also defined from use and usage data such as application rates and application frequency. The Agency typically completes exposure assessments using maximum application rates for each scenario to ensure there are no concerns for each specific use.

Occupational handler exposure assessments are completed by the Agency using different levels of risk mitigation. Typically, the Agency uses a tiered approach. The lowest tier is designated as the baseline exposure scenario (i.e., no respirator). If risks are of concern at baseline attire, then increasing levels of personal protective equipment or PPE (e.g., respirators) are evaluated. If risks remain of concern with maximum PPE, then engineering controls (e.g., enclosed cabs, water-soluble packaging, and closed mixing/loading systems) are evaluated. This approach is used to ensure that the lowest level of risk mitigation that provides adequate protection is selected, since the addition of PPE and engineering controls involves an additional expense to the user. PPE also involves an additional burden to the user due to decreased comfort and dexterity and increased heat stress and respiratory stress.

No chemical-specific handler exposure data were submitted in support of this action to inform daily dose calculations. It is the policy of HED to use data from PHED Version 1.1 as presented in the PHED Surrogate Exposure Guide (8/98) to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available (HED Science Advisory Council for Exposure [ExpoSAC] Draft Policy # 7, dated 1/28/99). Additionally, typical HED standard values were used for the amount treated per day (ExpoSAC Policy # 9, dated 7/5/00).

The occupational handler/applicator exposures are calculated using unit exposure data from the Pesticide Handlers Exposure Database (PHED). PHED was designed by a task force of representatives from the US EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts – a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based upon the number of observations and the available quality control data. While data from PHED provide the best available information on handler

exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposures for many occupational scenarios that can be used to ensure consistency in exposure assessments. Unit exposures are used which represent different levels of personal protection as described above. Protection factors were used to calculate unit exposures for varying levels of personal protection if data were not available.

ORETF Handler Studies (MRID 449722-01): A report was submitted by the ORETF (Outdoor Residential Exposure Task Force) that presented data in which the application of various products used on turf by homeowners and lawn care operators (LCOs) was monitored. All of the data submitted in this report were completed in a series of studies. These studies are summarized in the HED Memorandum "Summary of HED's Reviews of ORETF Chemical Handler Exposure Studies: MRID 449722-01", DP Barcode D261948 of April 30, 2001. The studies performed used dacthal as a surrogate compound with a target application rate of 2.0 lbs/ai. All studies were conducted in accordance with current Agency guidelines, have been reviewed by HED and Health Canada, and the data generated were of high quality.

Assumptions for Handler Exposure Scenarios

General assumptions regarding the occupational handler scenarios assessed are as follows:

- Occupational handler exposure estimates were based on surrogate data from the Pesticide Handlers Exposure Database (PHED, V.1.1, 1998)
- HED has developed standard unit exposures for many occupational scenarios to ensure consistency in exposure assessments. These standard values were used to calculate handler exposures for the associated scenarios.
- The adverse effects for the short- and intermediate-term dermal and inhalation endpoints are based on studies where the effects were not gender specific, therefore, the average adult body weight representing the general U.S. population (70 kg) was used.
- The daily areas treated were defined for each handler scenario by determining the amount that can be reasonably treated in a single day. The assumptions for daily areas treated are taken from the Health Effects Division Science Advisory Committee on Exposure Policy 9: "Standard Values for Daily Acres Treated in Agriculture".

Table F2: Occupational Handler Dermal and Inhalation Unit Exposures used for Occupational Handler Assessments

Exposure Scenario*	Dermal Unit Exposure (mg/ lb ai)				Inhalation Unit Exposure (µg/ lb ai)			
	Baseline	Baseline + Gloves	Max PPE	Eng. Control	Baseline	Baseline + Gloves	Max PPE	Eng. Control
Mixer/Loader Scenarios								
Liquids/ Aerial Application/ High Acreage Crops	2.9	0.023	0.017	0.0086	1.2	0.24	0.12	0.083
Liquids/ Airblast/ Nut Tree								
Liquids/ Groundboom/ High Acreage Crops								
Liquids/ Groundboom/ Turf								
Liquids/ Low Pressure Handwand/ Turf								
Wettable Powder/ Airblast/ Nut Tree	3.7	0.17	0.13	0.0098	43	8.6	4.3	0.24
Wettable Powder/ Groundboom/ High Acreage Crops								
Wettable Powder/ Groundboom/ Turf								
Wettable powder/ Low Pressure Handwand/ Turf								
Applicator Scenarios								
Liquid/ Aerial Application/ High Acreage Crops	NA	NA	NA	0.0055	NA	NA	NA	0.068
Airblast/ Nut Tree	0.36	0.24	0.13	0.019	4.5	0.9	0.45	0.09
Groundboom/ High Acreage Crops	0.014	0.014	0.011	0.0051	0.74	0.148	0.074	0.043
Groundboom/ Turf								
Mixer/Loader/Applicator Scenarios								
Low Pressure Handwand/ Turf (ORETF data)	NA	0.65	0.36	NA	6.6	1.32	0.66	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals	NA	8.6	6.2	NA	1100	220	110	NA
Liquid/ Low Pressure Handwand/ Ornamentals	100	0.43	0.37	NA	30	6	3	NA
Flagger Scenarios								
Liquid/ Flagger/ High Acreage Crops	0.011	0.012	0.011	0.0022	0.35	0.07	0.035	0.007

Values are reported in the PHED Surrogate Exposure Guide dated August 1998.

APPLICATION RATES USED FOR THE JITF INERT INGREDIENTS RISK ASSESSMENT

Table F3: Application Rates* used for Occupational Handler Exposure Assessment			
Exposure Scenario (Formulation/ Application/ Crop)	Product Type	Short-Term (Maximum Rate)	Intermediate-term (Average Rate)
Mixer/Loader Scenarios			
Liquids/ Aerial Application/ High Acreage Crops	Herbicide	10.4	2
	Insecticide	2	0.7
	Fungicide	5	0.7
Liquids/ Airblast/ Nut Tree	Herbicide	7.2	3.2
	Insecticide	9	2.5
	Fungicide	11	3
Liquids/ Groundboom/ High Acreage Crops	Herbicide	10.4	2
	Insecticide	2	0.7
	Fungicide	5	0.7
Liquids/ Groundboom/ Turf	Herbicide	10.4	2
	Insecticide	2	0.7
	Fungicide	5	0.7
Liquids/ Low Pressure Handwand/ Turf	Herbicide	7.2	7.2
	Insecticide		
	Fungicide		
Wettable Powder/ Airblast/ Nut Tree	Herbicide	1.6	1.6
	Insecticide	6	3
	Fungicide	7	2
Wettable Powder/ Groundboom/ High Acreage Crops	Herbicide	1.6	1
	Insecticide	1.6	0.7
	Fungicide	1	0.6
Wettable Powder/ Groundboom/ Turf	Herbicide	1.6	1
	Insecticide	1.6	0.7
	Fungicide	1	0.6
Wettable powder/ Low Pressure Handwand/ Turf	Herbicide	7.2	7.2
	Insecticide		
	Fungicide		
Applicator Scenarios			
Liquid/ Aerial Application/ High Acreage Crops	Herbicide	10.4	2
	Insecticide	2	0.7
	Fungicide	5	0.7
Airblast/ Nut Tree	Herbicide	1.6	1.6
	Insecticide	9	2.5
	Fungicide	7	3
Groundboom/ High Acreage Crops	Herbicide	10.4	2
	Insecticide	2	0.7
	Fungicide	5	0.7

Table F3: Application Rates* used for Occupational Handler Exposure Assessment			
Exposure Scenario (Formulation/ Application/ Crop)	Product Type	Short-Term (Maximum Rate)	Intermediate-term (Average Rate)
Groundboom/ Turf	Herbicide	10.4	2
	Insecticide	2	0.7
	Fungicide	5	0.7
Mixer/Loader/ Applicator Scenarios			
Low Pressure Handwand/ Turf (ORETF data)	Herbicide	7.2	7.2
	Insecticide		
	Fungicide		
Wettable Powder/ Low Pressure Handwand/ Ornamentals	Herbicide		
	Insecticide		
	Fungicide		
Liquid/ Low Pressure Handwand/ Ornamentals	Herbicide		
	Insecticide		
	Fungicide		
Flagger Scenarios			
Liquid/ Flagger/ High Acreage Crops	Herbicide	10.4	2
	Insecticide	2	0.7
	Fungicide	5	0.7

* Application rates are multiplied by the percentage of inert in each product type when used as application rates in the risk assessment.

Occupational Handler Exposure and Risk Calculations

Daily Exposure: Daily inhalation handler exposure is estimated for each applicable handler task with the application rate, the amount handled in a day, and the applicable inhalation unit exposure using the following formula:

*Daily Exposure (mg ai/day) = Unit Exposure (mg ai/lb ai handled) * Application Rate (lbs ai/gal) * Daily Area Treated (gal/day)*

Where:

Daily Exposure	=	Amount (mg or µg ai/day) inhaled that is available for inhalation absorption;
Unit Exposure	=	Unit exposure value (mg or µg ai/day) derived from August 1998 PHED data;
Application Rate	=	Normalized application rate based on a logical unit treatment, such as gallons. Maximum values are generally used (lb ai/gal); and
Daily Area Treated	=	Normalized application area based on a logical unit treatment such as gallons per day (gal/day).

Daily Dose: The daily inhalation dose is calculated by normalizing the daily exposure by body weight and adjusting, if necessary, with an appropriate inhalation absorption factor. For all inhalation exposure scenarios for the JITF inert cluster inert ingredients, an average adult body weight of 70 kilograms was used. For inhalation exposures, an absorption factor of 100% was assumed.

Daily dose was calculated using the following formula:

*Average Daily Dose (mg/kg/day = (Daily Exposure (mg ai/day) * (Absorption Factor (100%) / Body Weight (kg)*

Where:

Average Daily Dose	=	Absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day);
Daily Exposure	=	Amount (mg ai/day) inhaled that is available for inhalation absorption;
Absorption Factor	=	A measure of the amount of chemical that crosses a biological boundary such as the lungs (% of the total available absorbed); and
Body Weight	=	Body weight determined to represent the population of interest in a risk assessment (kg).

Margins of Exposure: Noncancer inhalation risks for each applicable handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the daily dose to the toxicological endpoint of concern. All MOE values were calculated inhalation exposure levels using the formula below:

MOE = (NOAEL (mg/kg/day) / Average Daily Dose (mg/kg/day)

Where:

MOE	=	Margin of Exposure, value used by HED to represent risk or how close a chemical exposure is to being a concern (unitless);
ADD	=	Average Daily Dose or the absorbed dose received from exposure to a pesticide in a given scenario (mg pesticide active ingredient/kg body weight/day); and
NOAEL	=	Dose level in a toxicity study, where no observed adverse effects (NOAEL) occurred in the study

The level of concern for all assessments is established by the uncertainty factor. The uncertainty factor is 100 for the JITF inert cluster inert ingredients inhalation occupational exposure scenarios for all exposure durations.

Total Margins of Exposure: Where appropriate, the endpoint selected for both dermal and inhalation exposure is combined to include both dermal and inhalation routes of exposure using the following equation.

Total MOE = 1/ (1/ Dermal MOE + 1/ Inhalation MOE)

F3. Occupational Postapplication Exposures

No crop-specific dislodgeable foliar residue (DFR) or transferable turf residue (TTR) data is available for the JITF inert cluster inert ingredients. A default occupational postapplication assessment was conducted, including a default 20% of the JITF inert cluster inert ingredients application rate as the initial concentration and a 10% daily dissipation rate. This is adapted from the ExpoSAC SOP No. 003 (May 7th, 1998 - Revised August 7th, 2000).

Assumptions for Handler Exposure Scenarios

General assumptions regarding the occupational handler scenarios assessed are as follows:

- The average occupational workday is assumed to be 8 hours.
- The adverse effects for the short- and intermediate-term dermal PoDs are based on studies where the effects were observed in both sexes, therefore, the body weight of an average human (70 kg) was used to estimate exposure.
- HED has developed standard transfer coefficient values for occupational postapplication scenarios to ensure consistency in exposure assessments. These standard values were used to calculate postapplication exposures.
- No postapplication data were submitted for the JITF inert cluster inert ingredients; a default 20% of the application rate for foliar crop or 5% of the application rate for turf is used in conjunction with 10% default daily dissipation rate.

Because the postappplication assessment was conducted for a few specific crop groups with high exposure worker reentry activity patterns, HED customized the JITF inert cluster inert ingredient application rate for the three postapplication crop groupings (corn/grapes/turf & sod). See Table 3 below.

Table 3: Application Rates used for Occupational Postapplication Scenarios

Crop	Product Type	Short-Term (Maximum Rate)	Intermediate-term (Average Rate)
Corn	Herbicide	10.4	1.2
	Insecticide	10	1
	Fungicide	5	1
Grapes	Herbicide	4.8	2.28
	Insecticide	7	3
	Fungicide	5	2
Turf/Sod	Herbicide	10.4	1.2
	Insecticide	10	1
	Fungicide	5	1

* Application rates are multiplied by the percentage of inert in each product type when used as application rates in the risk assessment to account for inert in the product.

Occupational Postapplication Exposure and Risk Calculations

Potential dermal postapplication exposure was calculated using the following formulas (Appropriate dermal absorption used):

$$\text{Dislodgable Foliar Residue } (\mu g/cm^2) = AR * F * (1\text{-}D)^t * CF1 * CF2$$

Where:
AR = Application Rate (lb inert/acre)
F = fraction of ai retained on foliage or 20% for foliar crop or 5% for turf (unitless)
D = fraction of residue that dissipates daily or 10% (unitless)
t = number of days after application day (days)
CF1 = 4.54×10^8 µg/lb
CF2 = 24.7×10^{-9} acre/cm^2

$$\text{Daily Dermal Dose (mg/kg/day)} = \frac{DFR_t * CF3 * Tc * DA * ET}{BW \text{ (kg)}}$$

Where:
DFRt = dislodgable foliar residue on day "t" (µg/cm^2)
CF3 = 1×10^{-3} mg/µg
Tc = transfer coefficient (cm^2/hr)
DA = dermal absorption factor (unitless)
ET = exposure time (hr/day)
BW = body weight (kg)

Margin of Exposure: Dermal risks for the postapplication scenarios are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological point of departure to the daily dose of concern.

$$MOE = PoD \text{ (typically a NOAEL in mg/kg/day)} / ADD \text{ (mg/kg/day)}$$

Where:
MOE = Margin of Exposure: value used by HED to represent risk or risk estimates (unitless)
Po D = Point of Departure
NOAEL = No Observed Adverse Effect Level: Dose level in a toxicity study
ADD = Average Daily Dose: the absorbed dose received from exposure to a pesticide in a given scenario

References

(B) PHED Surrogate Exposure Guide, V1.1. Health Effects Division, Office of Pesticide Program. August, 1998.

(C) Series 875 - Occupational and Residential Exposure Test Guidelines, Group B - Post Application Exposure Monitoring Test Guidelines. U.S. EPA. February 10, 1998.

Exhibit 7

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

MEMORANDUM Dated: 6/8/2009
To: Kerry Leifer (OPP)
From: Donna S. Davis, Byong-Han Chin, Alexandra LaMay, Matthew Lloyd, Christine L. Olinger, Sheila Piper (OPP)

Re: Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives (AAAPDs and AAASDs - JITF CST 2 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations (84 pages).

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

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1.0 Executive Summary

The Joint Inert Task Force (JITF) Cluster Support Team Number 2 (CST 2) has submitted a petition proposing to establish an exemption from the requirement of a tolerance under 40 CFR §180.920 for the "alkyl alcohol alkoxylate phosphate derivatives" (AAAPDS) and under 40 CFR §180.910 and 40 CFR §180.930 for the "alkyl alcohol alkoxylate sulfate derivatives" (AAASDs) when used as inert ingredients in pesticide formulations without limitation.

The toxicology database is adequate to assess risk for this group of compounds when used as inert ingredients in pesticide formulations. The AAASD and AAAPD surfactants are not acutely toxic by the oral and dermal routes of exposure under normal use conditions; however, concentrated materials are generally moderate to severe eye and skin irritants and may be skin sensitizers. Following subchronic exposure to rats, gastrointestinal irritation (increased incidences of hyperplasia, submucosal edema, and ulceration) was observed, but no specific target organ toxicity or neurotoxicity was seen. No effects were detected in a functional observational battery (FOB) or motor activity assessment. No reproductive effects were noted in the database. Developmental toxicity was observed; however, effects were seen only in one study and were in the presence of maternal toxicity. Further, a clear NOAEL was established for the developmental effects and this NOAEL is significantly higher than the points of departure (PoD) selected for regulation. There are no carcinogenicity concerns based on structure activity modeling. Points of departure (PoDs) for chronic dietary, incidental oral, inhalation and dermal exposure were selected from the OECD Test Guideline 416 reproduction and fertility effects study in rats. The endpoint was decrease in absolute and relative liver weights and increased incidence in the number of animals with minimal hepatocyte necrosis in males.

Sufficient data were provided on the chemical identity of the AAAPDs and AAASDs; however, limited data are available on the metabolism and environmental degradation of these compounds. The Agency relied collectively on information provided on the representative chemical structures, the submitted physicochemical EPI Suite™ data, structure-activity relationship information, as well as information on other surfactants and chemicals of similar size and functionality to determine the residues of concern for these inert ingredients. The Agency has concluded that since metabolites and environmental degradates are not likely to be more toxic than the parent compounds, a risk assessment based on the parent compounds is not likely to underestimate risk.

No residue data were provided for the AAAPDs and AAASDs. In the absence of data, the Agency has developed an approach that uses surrogate information to derive upper bound exposure estimates for the subject inert ingredients. No adverse effect attributable to a single exposure was identified for these inert ingredients; therefore an acute dietary risk assessment is not appropriate. Chronic dietary (food and water) risk assessments for the AAAPD and AAASD inert ingredients did not identify any risks of concern provided these inert ingredients are no more than 30% by weight of the final formulation.

A screening level residential exposure and risk assessment was completed for products containing AAASDs and AAAPDs. For all residential handler and post application scenarios, risk estimates are not of concern.

Provided the AAASDs and AAAPDs are limited to no more than 30% by weight in the final formulation, aggregate risks are not of concern for the U.S. population and all subpopulations, including children 1 – 2 years of age, the most highly exposed subgroup.

HED has completed an occupational exposure and risk assessment for the AAASD and AAAPD inerts assuming that these inerts are limited to no more than 30% by weight in the final formulation. Occupational handler risks are not of concern for all scenarios. HED notes that the occupational handler assessment assumes that mixer/loader/applicators who are handling pesticides containing the AAASD and AAAPD inerts for aerial and ground application on high acreage crops will wear chemical-resistant gloves. HED believes this is a reasonable assumption given the volume of pesticide handled for these applications.

Occupational post application handler risks are not of concern on the day of application for all scenarios.

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

This assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide. These studies have received the appropriate ethical review for use in risk assessment.

Regulatory Recommendation

Provided the concentrations of the AAAPDs and AAASDs are limited to no more than 30% by weight in pesticide end-use products, there are no human health risk considerations that would preclude the establishment of the requested exemptions from the requirement of a tolerance as follows.

Under 40 CFR §180.920 for:

> α-Alkyl (minimum C_6 linear or branched, saturated and or unsaturated)-[ω]-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; minimum oxyethylene content averages 2 moles; minimum oxypropylene content is 0 moles, limited to no more than 30% by weight in end-use products.

Under 40 CFR §180.910 and 40CFR §180.930 for:

> α-Alkyl (C_6 – C_{15})-ω-hydroxypoly(oxyethylene) sulfate, and ammonium, calcium, magnesium, potassium, sodium and zinc salts, poly(oxyethylene) content averages 2-4 moles, limited to no more than 30% by weight in end-use products.

HED notes that this human health risk assessment would also support the use of the AAAPD inert ingredients in pesticide formulations intended for use post-harvest as well as for use on livestock should the petitioner desire to expand the requested use.

2.0 Background

Inert ingredients are those ingredients that are added to end use products that are not active ingredients. The terms "active ingredient" and "inert ingredient" are defined under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). An active ingredient is one that prevents, destroys, repels or mitigates a pest, or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. The statute defines the term "inert ingredient" as an ingredient that is not active.

As mandated by the Food Quality Protection Act (FQPA) of 1996, EPA conducted a reassessment of tolerances and exemptions from the requirement of tolerances for inert ingredients used in pesticide products to determine if they met FFDCA's revised standard of safety. As a result of that reassessment, the Agency published a final rule in the Federal Register (FR Notice Volume 71, No. 153, p. 45422, Aug 9, 2006) proposing revocation of specific exemptions from the requirement of a tolerance due to insufficient data.

In response to the proposed revocation, the JITF CST 2 has submitted a petition dated February 11, 2009 proposing to establish exemptions from the requirement of a tolerance as follows:

Under 40 CFR §180.920 for:

> α-Alkyl (minimum C_6 linear or branched, saturated and or unsaturated)-[ω]-hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium and zinc salts of the phosphate esters; minimum oxyethylene content averages 2 moles; minimum oxypropylene content is 0 moles.

Under 40 CFR §180.910 and 40CFR §180.930 for:

> α-Alkyl ($C_6 - C_{15}$)-ω-hydroxypoly(oxyethylene) sulfate, and ammonium, calcium, magnesium, potassium, sodium and zinc salts, poly(oxyethylene) content averages 2-4 moles.

Establishment of the requested exemptions from the requirement of a tolerance would allow use of the AAAPDs in pesticide formulations intended for pre-harvest application only and would allow use of the AAASD inert ingredients in pesticide formulations used pre- and post-harvest as well as on livestock. Additionally, the JITF notes that these descriptors formally expand upon the previous descriptors for the AAAPDs and AAASDs to include C_6 congers, which have historically been considered covered by previous descriptors by the Agency, despite not being officially codified.

3.0 Ingredient Profile

3.1 Summary of Proposed Uses

The AAAPD and AAASD surfactants are currently used in pesticide formulations, as well as in household cleaning products, laundry detergents and personal care products, such as hand cleaners. The petitioner has noted that the AAAPDs were previously cleared for use in pesticide formulations intended for pre-harvest applications and the AAASDs were cleared for use in pesticide formulations used pre- and post-harvest use as well as for formulations applied to livestock.

The Agency notes that the risk assessment screening methodologies developed to assess exposure and risk from inert ingredients, assumes that the inert ingredient is used in a pesticide formulations that may be applied both pre- and post-harvest, as well as to animals. At this time, the methodology can not be refined to address inert ingredients used in pesticide formulations intended only for pre-harvest use. Therefore, should the petitioner seek to expand the use of the AAAPDs, this risk assessment will support use of the AAAPDs for pre- and post-harvest uses as well as for use in pesticide formulations applied to livestock.

3.2 Structural Information

The Alkyl Alcohol Alkoxylate Phosphate (AAAPD) and Alkyl Alcohol Alkoxylate Sulfate Derivatives (AAASD) are comprised of a hydrophobic aliphatic alcohol moiety, a hydrophilic polyalkoxylate backbone with either a phosphate or sulfate derivative (ester or salt) terminating group. The hydrophilic polyalkoxylate backbone may consist of a repeating units derived from ethylene oxide (polyoxyethylene, POE) or derived from a mixture of ethylene oxide and propylene oxide (polyoxyethylene /polyoxypropylene, POE/POP).

Information on the generic structures of these compounds is summarized in Table 3.2.1, below. A detailed listing of the chemicals included in this group may be found in Table 3.2.2.

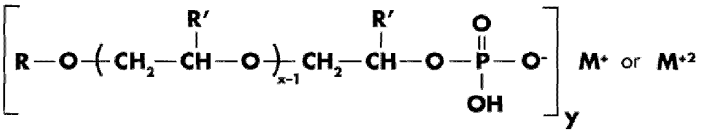
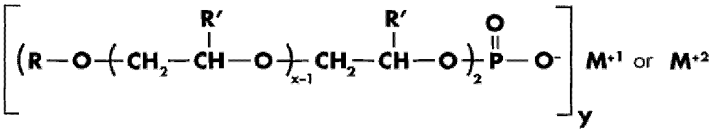
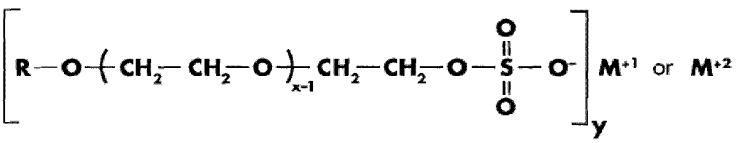
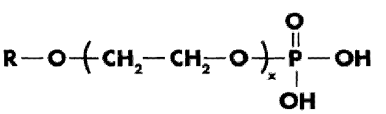
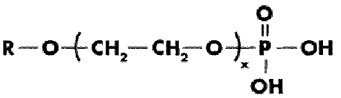
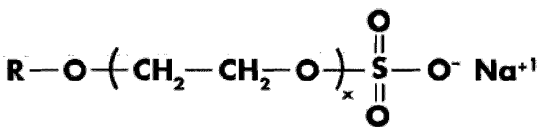
Table 3.2.1. Alkyl Alcohol Alkoxylate Phosphate (AAAPD) and Alkyl Alcohol Alkoxylate Sulfate Derivatives (AAASD) Chemical Information	
Generic Chemical Structure of AAPDs [1]	 Mono ester/salt  Di ester/salt R = Minimum C_6 linear, branched, saturated and/or unsaturated R' = H or H and CH_3 x = Average minimum 2 moles POE and 0 moles POP For M^{+} = H^{+}, NH_4^{+}, $OH–CH_2–CH_2–NH_3^{+}$, Na^{+}, K^{+}, y = 1 For M^{+2} = Ca^{+2}, Mg^{+2}, Zn^{+2}, y = 2
Generic Chemical Structure of AASDs	 R = C_6 – C_{15} linear saturated x = 2–4 average moles POE For M^{+1} = H^{+}, NH_4^{+}, Na^{+}, K^{+}, y = 1 For M^{+2} = Ca^{+2}, Mg^{+2}, Zn^{+2}, y = 2
Test Compounds for Toxicity Testing	
Structure	 R = C_8 – C_{10} linear x = Average 3–20 POE
CAS No.	68130-47-2
CAS Registry Nomenclature	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{8-10}-alkyl ethers, phosphates

Table 3.2.1. Alkyl Alcohol Alkoxylate Phosphate (AAAPD) and Alkyl Alcohol Alkoxylate Sulfate Derivatives (AAASD) Chemical Information	
Structure	 R = C_{11} – C_{14} branched x = Average 3–20 moles POE
CAS No.	78330-24-2
CAS Registry Nomenclature	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{11-14}-isoalkyl ethers, C_{13}-rich, phosphates
Structure	 R = C_{12} saturated x = Average 2–4 moles POE
CAS No.	68891-38-3
CAS Registry Nomenclature	Poly(oxy-1,2-ethanediyl), α-sulfo-ω-hydroxy-, C_{12-14}-alkyl ethers, sodium salts

[1] Figure excerpted from petition, "*Petition Proposing An Exemption From The Requirement Of Tolerance For Residues Of Joint Inerts Task Force Cluster 2 Alkyl Alcohol Alkoxylate Phosphate And Sulfate Derivatives In Or On Raw Agricultural Products And Food Products*", page 11, dated February 11, 2009.

Table 3.2.2 Listing of Chemicals included in the Cluster	
CAS Number	**Descriptor**
AAAPD	
9046-01-9	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, phosphate
39464-66-9	Poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate
50643-20-4	Poly(oxy-1,2-ethanediyl), α-hexadecyl-ω-hydroxy-, phosphate
52019-36-0	Poly(oxy-1,2-ethanediyl), α-decyl-ω-hydroxy-, phosphate
68071-35-2	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-alkyl ethers, Phosphates
68458-48-0	Polyphosphoric acids, esters with polyethylene glycol decyl ether
68585-36-4	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{10-14}-alkyl ethers, phosphates
68815-11-2	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-branched alkyl ethers, phosphates
68908-64-5	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{10-12}-alkyl ethers, phosphates
68511-37-5	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-14}-alkyl ethers, phosphates
68130-47-2	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{8-10}-alkyl ethers, phosphates
42612-52-2	Poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate, sodium salt
58318-92-6	Poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate, potassium salt
60267-55-2	Poly(oxy-1,2-ethanediyl), α-hexadecyl-ω-hydroxy, phosphate, potassium salt
68070-99-5	Poly(oxy-1,2-ethanediyl), α-decyl-ω-hydroxy-, phosphate, potassium salt
68186-36-7	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, phosphate, potassium salt
68186-37-8	Poly(oxy-1,2-ethanediyl), α-decyl-ω-hydroxy-, phosphate, sodium salt
68610-65-1	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-alkyl ethers, phosphates, sodium salts

Table 3.2.2 Listing of Chemicals included in the Cluster	
CAS Number	**Descriptor**
68071-17-0	Poly(oxy-1,2-ethanediyl), α-isodecyl-ω-hydroxy-, phosphate, potassium salt
936100-29-7	(branched C10) Poly(oxy-1,2-ethanediyl), α-phosphono-ω-[(2-propylheptyl)oxy]-, potassium salt (1:2).
936100-30-0	(branched C10) Poly(oxy-1,2-ethanediyl), α-phosphono-ω-[(2-propylheptyl)oxy]-, sodium salt (1:2)
73038-25-2	Poly(oxy-1,2-ethanediyl), α-isotridecyl-ω-hydroxy-, phosphate
78330-24-2	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{11-14}-isoalkyl ethers, C_{13}-rich, phosphates
154518-39-5	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono(C_{10}-rich C_{9-11}-isoalkyl) ethers, phosphates
317833-96-8	Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-14}-sec-alkyl ethers, phosphates
108818-88-8	Poly(oxy-1,2-ethanediyl), α-isodecyl-ω-hydroxy-, phosphate
873662-29-4	Poly(oxy-1,2-ethanediyl), α-phosphono-ω-[(2-propylheptyl) oxy]
61837-79-4	Poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy-, phosphate monoethanolamine salt
68311-02-4	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, phosphate monoethanolamine salt
68425-73-0	Poly(oxy-1,2-ethanediyl), α-decyl-ω-hydroxy-, phosphate monoethanolamine salt
37280-82-3	Oxirane, methyl-, polymer with oxirane, phosphate
68649-29-6	Oxirane, methyl-, polymer with oxirane, mono-C_{10-16}-alkyl ethers, phosphates
67711-84-6	Oxirane, methyl-, polymer with oxirane, phosphate, potassium salt
68891-13-4	Oxirane, methyl-, polymer with oxirane, mono-C_{10-16}-alkyl ethers, phosphates, potassium salts
AASDs POE Sulfates	
9004-82-4	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-(dodecyloxy)-, sodium salt
68585-34-2	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-hydroxy-, C_{10-16}-alkyl ethers, sodium salts
68891-38-3	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-hydroxy-, C_{12}-C_{14}-alkyl ethers, sodium salts
9004-84-6	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-(tridecyloxy)-
13150-00-0	Ethanol, 2-[2-[2-(dodecyloxy)ethoxy]ethoxy]-, hydrogen sulfate, sodium salt
26183-44-8	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-(dodecyloxy)-
68611-55-2	Sulfuric acid, mono-C_{10-16}-alkyl esters
68511-39-7	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-hydroxy-, C_{12-15}-alkyl ethers
AASDs POE Sulfate Salts	
3088-31-1	Ethanol, 2-[2-(dodecyloxy)ethoxy]-, hydrogen sulfate, sodium salt
9004-82-4	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-(dodecyloxy)-, sodium salt
25446-78-0	Ethanol, 2-[2-[2-(tridecyloxy)ethoxy]ethoxy]-, hydrogen sulfate, sodium salt
32612-48-9	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-(dodecyloxy)-, ammonium salt
50602-06-7	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-(dodecyloxy)-, potassium salt
62755-21-9	Poly(oxy-1,2-ethanediyl), α -sulfo-ω-(dodecyloxy)-, magnesium salt
68424-50-0	Fatty acids, tall-oil, C_{12-15}-alkyl esters, sulfated, sodium salt
73665-22-2	Poly(oxy-1,2-ethanediyl), α sulfo-ω-hydroxy-, C_6-C_{10}-alkyl ethers, sodium salts

3.3 Physical and Chemical Properties

Physicochemical data were estimated for the AAAPD/AAASD cluster using publicly available Estimation Program Interface suite (EPI Suite™) modeling (http://www.epa.gov/opptintr/exposure/pubs/episuite.htm and are provided in Table 3.3. The basis for the estimated Estimation Program Interface suite (EPI Suite™) modeling physicochemical calculations and model capabilities are described in the EPA document titled The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program (EPA 1999). The EPA EPI Suite™ 3.2 model calculations for water solubility are based on Kow (WSKOWWIN model) and molecular fragments (WATERNT

model). EPA has cautioned in the publication OPPTS Pollution Prevention P2 Network (EPA, 2005), that EPI suiteTM 3.2 water solubility calculations are not reliable for dispersible compounds such as surfactants.

The registrant provided EPI Suite™ estimates for all CAS numbers in the cluster. The properties are provided for representative products from all sub-classes, including the products used in the toxicity testing and those with the highest molecular weights and Log K_{ow}s in the table below.

Table 3.3. Physicochemical Properties of Representative AAAPD/AAASD compounds [1]

CAS No.	Descriptor[2]	Molecular Weight	Log K_{ow}	Vapor Pressure (mm Hg @ 25°C)	Water Solubility (mg/L)[3]
AAAPD Surfactants					
50643-20-4	C16	542.7	5.28	6.06×10^{-11}	0.012 1.7186
52019-36-0	C10	458.3	2.33	6.06×10^{-11}	13.36 2421.6
68130-64-5	C11	472.56	2.83	6.06×10^{-11}	4.145 724.71
68130-47-2	C9	444.51	1.84	1.56×10^{-11}	43.05 8083.9
AAAPD Salts					
68070-99-5	C10, K salt	496.62	-0.86	1.78×10^{-10}	4060 4672.9
60267-55-2	C16, K salt	580.79	2.09	1.78×10^{-10}	3.527 3.2769
Branched AAAPD					
73038-25-2	Iso C13	538.71	0.54	1.78×10^{-10}	138.7 208.02
78330-24-2	Iso C13	500.62	3.73	6.06×10^{-11}	0.4595 108.5
317833-96-8	Sec-alkyl C13	514.64	4.22	6.06×10^{-11}	0.1422 32.389
AAAPD Monoethanolamine Salts					
61837-79-4	Linear C12	559.68	1.39	6.06×10^{-11}	19.02 59341
Oxirane Phosphate Acid					
68649-29-6	C16	548.85	6.34	1.94×10^{-14}	0.00432 0.3
Oxirane Phosphate Salt					
68891-13-4	C16	622.87	3.34	1.78×10^{-10}	0.159 0.4056
AAASD Alkyl Ether Sulfate Acids					
68585-34-2	C10, Na, POE n=2	348.43	0.16	1.44×10^{-14}	4615 0.4956
68891-38-3	C14 Na, POE n=2	404.54	2.13	4.53×10^{-16}	43.95 0.0041
AAASD Salts					
50602-06-7	C12, K, POE n = 3	436.65	0.87	1.83×10^{-16}	327.7 0.0831
68424-50-0	C12 – C15, Na	462.62	2.34	1.32×10^{-17}	12.4 0.0022
73665-02-2	C6, Na	292.33	-1.8	4.4×10^{-13}	4.7×10^{5}

Table 3.3. Physicochemical Properties of Representative AAAPD/AAASD compounds [1]					
CAS No.	Descriptor[2]	Molecular Weight	Log K_{ow}	Vapor Pressure (mm Hg @ 25°C)	Water Solubility (mg/L)[3]
	POE n=2				58.47

[1] Table values taken from petition.
[2] Descriptor describes number of carbons assumed in the EPI Suite Model and the counter ions for the salts. POE denotes moles of ethoxylation.
[3]First value is generated using the WSKOWWIN model that calculates the solubility based on the Octanol/Water partition coefficient, and the second value was generated using the WATERNT model that calculates the value using molecular fragments.

4.0 Hazard Characterization/Assessment

4.1 Hazard and Dose-Response Characterization

4.1.1 Database Summary

The existing toxicology database for the AAAPD and AAASD inert ingredients includes acute, subchronic, developmental, reproductive and mutagenicity studies as well as an OECD Test Guideline 422 combined repeated dose toxicity study with the reproduction/developmental toxicity screening tests, an OECD 416 reproduction and fertility effects study, and developmental toxicity study.

The OECD Test Guideline 422 study is a combined repeated dose toxicity study with reproduction/developmental toxicity test parameters. This study provides information on the possible health hazards likely to arise from repeated exposure over a relatively limited period of time. The method comprises the basic repeated dose toxicity study as well as a reproduction/developmental toxicity screening test and also places emphasis on neurological effects as a specific endpoint. Therefore, the study can provide information on general toxicity as well as possible developmental, reproductive, and neurological effects. It can also provide basic indications of immunological effects.

The chemicals for which toxicity data were submitted are listed in Table 4.1, below.

Table 4.1. Representative AAAPDs and AAASDs and Available Toxicological Data		
Inert Tested	CAS No.	Studies Available
AAAPD C12	CAS 39464-66-9	Acute dermal [cited in JITF Cluster Support Team 2 submission (2009)]
AAAPD Saturated C8-C10 linear with average POE n=3-20	CAS 68130-47-2	OECD 422 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (MRID 47673901)
AAAPD C11-C14 branched with average POE n=3-20	CAS 78330-24-2	OECD 422 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (MRID 47673902)
AAASD C12-15 sodium salt	CAS 68424-50-0	Two-year drinking water rat study [cited in JITF Cluster Support Team 2 submission (2009)]

Table 4.1. Representative AAAPDs and AAASDs and Available Toxicological Data		
Inert Tested	**CAS No.**	**Studies Available**
(POE n=3)		
AAASD C12 sodium salt	CAS 9004-82-4	Mutagenicity, acute oral [cited in JITF Cluster Support Team 2 submission (2009)]
AAASD C12-14 sodium salt	CAS 68891-38-3	Eye and skin irritation, dermal sensitization [cited in JITF Cluster Support Team 2 submission (2009)] 90-day oral toxicity in rat (MRID 47060901) Rat Developmental study (MRID 47060902) OECD 416 rat reproduction and fertility effects study (MRID 47060903)

The available toxicology data are adequate to support the requested exemption from the requirement of tolerance when used in pesticide formulations for these AAASD and AAAPD inert ingredients.

4.1.2 Toxicological Effects and metabolism

Toxicological Effects
The AAASD and AAAPD surfactants are not acutely toxic by the oral and dermal routes of exposure under normal use conditions. Concentrated materials are generally moderate to severe eye and skin irritants and may be skin sensitizers. There is no evidence of mutagenicity in the mouse lymphoma L5178 TK +/- gene mutation study.

Following subchronic exposure to rats, gastrointestinal irritation (increased incidences of hyperplasia, submucosal edema, and ulceration) was observed, but no specific target organ toxicity or neurotoxicity was seen. No effects were detected in a functional observational battery (FOB) or motor activity assessment.

In a rat developmental toxicity study conducted with the AAASD surfactant, no maternal or developmental toxicity was observed at 700 mg/kg/day. In an OECD 416 reproduction and fertility effects study conducted with the AAASD surfactant, the only significant effects observed were liver effects characterized by dose-related decrease in absolute and relative liver weight and an increased incidence in the number of animals with "minimal" hepatocyte necrosis in males. There were no treatment-related effects on reproductive parameters or the offspring.

In an OECD 422 study conducted with the AAAPD surfactant CAS RN 78330-24-2, parental toxicity was observed based on lesions in the forestomach and thymus atrophy in females. Developmental toxicity observed was based on increased number of stillborn pups and pups dying and clinical observations (coldness to the touch, discolored heads, and a lack of nesting behavior); however, reproductive toxicity was not observed.

In the second OECD 422 study conducted with the AAAPD surfactant CAS RN 68130-47-2, parental toxicity was observed based on clinical signs (rales and excessive salivation), reduced body weight, and lesions in the forestomach. Reproductive, developmental, and offspring toxicity were not observed at any dose level.

In general, surfactants are surface-active materials that can damage the structural integrity of cellular membranes at high dose levels. Thus, surfactants are often corrosive and irritating in concentrated solutions. It is possible that some of the observed toxicity seen in the repeated studies, such as irritation of forestomach or decreased body weight gain, can be attributed to the corrosive and irritating nature of these surfactants.

Metabolism
As stated in the petition (JITF Cluster Support Team Number 2), it is generally accepted that increased ethoxylation decreases lipophilicity resulting in decreased absorption and decreased toxicity. The lower molecular weight alkoxylates should be absorbed and distributed more readily than higher molecular weight alkoxylates and be more toxic. The representative ethoxylated compound tested has the lowest weight percent ethoxylation and lowest molecular weight of the series and is potentially the most bioavailable of the series.

Metabolic pathways for AAAPD and AAASD surfactants are proposed by JITF CST 2 (2009). By analogy to other polyethoxylated alcohols, such as the alkyl alcohol alkoxylate surfactants, the petition states that it can be anticipated that all compounds for this series would undergo comparable metabolism. The AAAPD surfactants should initially be metabolized to generate the corresponding alkyl alcohol and the POE (or POE/POP) phosphate glycol which is then acted upon by phosphotases to generate phosphate and a dephosphorylated polyalkoxylate glycol. The dephosphorylated polyalkoxylate glycols should be conjugated and excreted or hydrolyzed and oxidized to various degraded metabolites before being conjugated and excreted. The alky alcohols would be oxidized and degraded by fatty acid oxidation metabolic pathways.

The C16 AAASD surfactants with POE n=3 are readily absorbed and excreted primarily in the urine, whereas, the C16 AAASD surfactants with POE n=9 are poorly absorbed and excreted primarily in the feces. The alkyl groups of the C11 or C12 AAASD surfactants with POE n=3 are hydrolyzed and the alkyl alcohols would be oxidized and degraded by fatty acid oxidation metabolic pathways, while the sulfate groups are excreted without hydrolysis.

4.2 Dermal Absorption

There are no dermal absorption data on the AAAPD and AAASD surfactants. Given the physicochemical properties of these inert ingredients, including their relatively high molecular weights and water solubility, and further based on the fact that they are large cross-linked molecules, the Agency would expect the dermal absorption to be very low for these compounds. This risk assessment uses 5% dermal absorption as a likely upper bound, conservative value.

4.3 Carcinogenic potential

There is no evidence that the AAAPD and AAASD surfactants are carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts. No structural alerts were identified. In addition, there was little concern about any of the postulated metabolites having greater toxicity than the parent compounds.

4.4 FQPA Considerations

The toxicity database consists of two OECD Test Guideline 422 studies on the AAAPD inerts, an OECD 416 reproduction and fertility effects study, and developmental toxicity study on the AAASD inerts. The executive summaries for these studies are presented in Appendix A.

For both the AAAPDs and the AAASDs, there was no increased susceptibility to the offspring of rats following prenatal and post-natal exposure in the reproductive/developmental toxicity studies. In a rat developmental study with the AAASD surfactant, no maternal or developmental toxicity was observed at the limit dose. In the OECD 416 study with the AAASD inert, the only significant effects observed were liver effects characterized by dose-related decrease in absolute and relative liver weight and an increased incidence in the number of animals with "minimal" hepatocyte necrosis in males. No treatment-related effects were observed on reproduction or the offspring.

In the OECD Test Guideline 422 study conducted with the AAAPD surfactant CAS RN 68130-47-2, offspring toxicity was not observed. In the second OECD 422 study conducted with the AAAPD surfactant CAS RN 78330-24-2, increased susceptibility was demonstrated as evidenced by the increased number of stillborn pups and pups dying within lactation day (LD) 4/5 and clinical observations (coldness to the touch, discolored heads, and a lack of nesting behavior) at 800 mg/kg/day where lesions in the forestomach and thymus atrophy was observed in the parental animals. A clear NOAEL (200 mg/kg/day) was established for developmental effects. However, since the point of departure selected from the OECD 416 study for chronic exposure is 87 mg/kg/day, this value is protective of the developmental effects observed at the higher doses levels.

There are no residual uncertainties identified in the exposure databases. The food exposure assessments are considered to be conservative. The food and drinking water assessment is not likely to underestimate exposure to any subpopulation, including those comprised of infants and children.

The FQPA factor can be reduced to 1X. A 1X FQPA Safety Factor is appropriate for the following reasons:

- The toxicology database is adequate for assessing the sensitivity of infants and children to AAAPD and AAASD exposures.
- Increased susceptibility was demonstrated in the offspring in the OECD 422 study with CAS 78330-24-2 following prenatal and post-natal exposure at 800 mg/kg/day. However, there is a clear NOAEL for these effects (200 mg/kg/day) and the point of departure selected from the OECD Test Guideline 416 study for chronic exposure, 87 mg/kg/day, is protective of the developmental effects observed at the higher dose level.
- No susceptibility was demonstrated in the offspring in the OECD Test Guideline 422 study with CAS 68130-47-2 following prenatal and post-natal exposure at 800 mg/kg/day.
- No susceptibility was demonstrated in the offspring in the OECD Test Guideline 416 and developmental toxicity studies with CAS 68891-38-3.

- No evidence of neurotoxicity was demonstrated.
- Residue values used in the dietary risk assessment and exposure values used in the residential assessment are unlikely to underestimate risk.

4.5 Toxicity Endpoint Selection and Levels of Concern

A summary of the points of departure (PoDs) selected may be found in Table 4.5. The residential, occupational and aggregate level of concern (LOC) is for MOEs that are less than 100 and is based on 10X for interspecies extrapolation from animals to humans and 10X for variation in sensitivity between humans. These LOCs are applicable to all populations, including individuals exposed in a residential setting and occupationally exposed workers.

An aggregate risk assessment across routes can be performed for the AAAPD and AAASD surfactants since common endpoints were selected for the oral, dermal and inhalation routes of exposure.

Table 4.5. Summary of Toxicological Doses and Endpoints for Alkyl Alcohol Alkoxylate phosphate and sulfate derivatives for Use in Dietary, Non-Occupational, and Occupational Human Health Risk Assessments Human Health Risk Assessments

Exposure/ Scenario	Point of Departure	Uncertainty Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all populations)	No appropriate endpoint was identified for acute dietary assessment			
Chronic Dietary (All Populations)	NOAEL = 87 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF = 1x	cRfD = 0.87 mg/kg/day cPAD= 0.87 mg/kg/day	Reproduction/fertility effects in male rats (MRID 47060903) LOAEL = 223 mg/kg/day based on a dose-related decrease in absolute (-13%) and relative liver (-10%) weight and an increased incidence in the number of animals with "minimal" hepatocyte necrosis in males (6/30 in the high-dose group compared to 1/30 in the control group).
Incidental Oral , Dermal and Inhalation (all durations)	NOAEL = 87 mg/kg/day (5% dermal absorption) inhalation hazard assumed to be equivalent to oral hazard	UF_A= 10x UF_H=10x FQPA SF = 1x	LOC = 100 for residential LOC = 100 for occupational	Reproduction/fertility effects in male rats (MRID 47060903) LOAEL = 223 mg/kg/day based on a dose-related decrease in absolute (-13%) and relative liver (-10%) weight and an increased incidence in the number of animals with "minimal" hepatocyte necrosis in males (6/30 in the high-dose group compared to 1/30 in the control group).
Cancer (oral, dermal, inhalation)	Classification: Based on SAR analysis, the AAAPD and AAASD surfactants are not expected to be carcinogenic.			

Point of Departure (PoD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level.

LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

4.6 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, the AAAPD and AAASD surfactants may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

5.0 Dietary Exposure/Risk Characterization

5.1 Residues of Concern

Very limited information is available for the AAAPD and AAASD inerts with respect to plant and animal metabolism or environmental degradation. The Agency considered the representative chemical structures, the generic cluster structures, the submitted physicochemical EPI Suite™ information as well as the structure-activity relationship analysis detailed in Appendix B of this review and information on other surfactants and chemicals of similar size and functionality. The Agency concluded that the cluster grouping was appropriate.

Considering the large size and polarity of the AAAPD and AAASD molecules, it is unlikely they would readily absorbed by livestock or taken up by plants for further metabolism. Based on SAR analysis the AAAPD and AAASD are unlikely to degrade in the environment to compounds that are more toxic than the parent compounds. Estimates of residues in food are conservative as described in Section 5.3, and adequately represent all residues of parent and any potential metabolites which might be formed. Therefore, the Agency's dietary risk assessment is not likely underestimate dietary risk.

Structure activity analysis conducted using DEREK Version 11 did not identify any structural alerts of concern for the chemicals screened (see Appendix B for specific structures screened). Considering what is already known about these specific compounds and other long-chain fatty acid compounds, along with the lack of structural alerts for carcinogenicity, chronic toxicity, or genotoxicity, HED has no specific concerns regarding chronic toxicity other than that identified in the toxicity studies available for this cluster.

5.2 Drinking Water Residue Profile

No monitoring data or data reflecting the concentration of these inert ingredients in drinking water is available.

EFED conducted modeling runs on four surrogate inert chemicals using a range of physical chemical properties. The physical chemical properties of the surrogate chemicals bracket those expected for the AAAPDs and AAASDs. EFED selected a North Carolina cotton scenario with an application date of July 1st as the scenario that would likely provide high end drinking water values for use in risk assessment. Percent crop area (PCA) factors were not applied. Simulations were run assuming a rate of 1 lb inert ingredient/A. Since degradation information was not available, three degradation scenarios were investigated: 1) chemically stable in water and soil; 2) a 100-day half-life in water and soil; and 3) a 10-day half life in water and soil. Further, two possible scenarios were investigated, one where all of the inert was applied as a single application, and the second assuming that the inert was applied evenly over a growing season. Modeled acute drinking water values ranged from 0.001 ppb to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of the EFED analysis are contained in Appendix C of this document.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for the AAAPD and AAASD inerts, a value of 100 ppb based on screening level modeling was used for both the acute and chronic dietary risk assessments for the parent compounds and for any potential metabolites of concern. HED considers the value of 100 ppb to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

5.3 Food Residue Profile

No residue data were submitted for AAAPD and AAASD inert ingredients. In the absence of data, the Agency has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of 57 high use insecticides (22), herbicides (20), and fungicides (17). The 57 pesticides were selected based on an overall ranking scheme that included consideration of the 1999 data for active ingredients use. All herbicides at greater than 5 million lbs/yr and all fungicides and insecticides at greater than 1 million lbs/yr were included as candidate surrogate chemicals.

OPP assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

To summarize, the Agency believes the assumptions used to estimate dietary exposures lead to a very conservative assessment of dietary risk for the following reasons:

- the highest tolerance level from the surrogate pesticides for every food is used;
- 100% crop treated (%CT) is assumed for all crops (every food eaten by a person each day has tolerance-level residues);
- many of these high tolerances are based on very short pre-harvest intervals where there is little time for degradation, whereas actual pesticide applications occur throughout the growing season;
- no consideration was given to potential degradation between harvest and consumption (use of tolerance level residues which are typically one to two orders of magnitude higher than actual residues found in monitoring data);
- residue values were assigned to every commodity in DEEM™ with no consideration given to potential reduction in residues from washing or cooking.

Although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. OPP does not believe that this approach underestimates exposure in the absence of residue data.

5.4 Analytical Methodology

Since this request is for an exemption from the requirement of a tolerance, an analytical method for enforcement purposes is not required to support this action.

5.5 Dietary (Food and Water) Exposure and Risk

The model and inputs used for the dietary risk assessments are described briefly in Section 5.3, above and below. A complete description of the dietary exposure and risk assessment is provided in the memorandum for a different inert ingredient cluster entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09).

A chronic aggregate dietary (food and drinking water) exposure and risk assessment was conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

5.5.1. Acute Dietary Exposure and Risk

No adverse effects attributable to a single exposure to the AAAPDs and AAASDs were seen in the toxicity databases; therefore, an acute dietary risk assessment is not appropriate.

5.5.2. Chronic Dietary Exposure and Risk

A conservative screening level dietary (food and water) assessment was conducted using the highest tolerance level residue for all food forms, including meat, milk, poultry and eggs, default processing factors for dried commodities and 100% CT. In addition, a default concentration of 100 ppb was assumed for inert ingredient residues in drinking water.

HED notes that dietary (food and water) risks alone assuming equal concentrations of inert ingredient and active ingredient in the formulation were not of concern. However, when those risks were aggregated with residential uses for children, the resulting aggregate expsoure resulted in margins of exposure (MOEs) of less than 100. Therefore, HED has incorporated a 30% cap on the use of these inert ingredients in pesticide formulations into the risk calculations to show that aggregate risks are not of concern.

The chronic dietary exposure estimates for food and drinking water are below HED's level of concern (<100% cPAD) for the U.S. population and all subpopulations. AAAPD and AAASD inert dietary exposure for food and drinking water is 13% of the cPAD for the U.S. population and 43% of the cPAD for children 1-2 yrs old, the most highly exposed population subgroup when the amount of the inert ingredient in the pesticide formulation is limited to no more than 30% by weight. See Table 5.4.4, below for a summary of results.

5.5.3. Cancer Dietary Exposure and Risk

HED has not identified any concerns for carcinogenicity relating to the AAAPD and AAASD inert ingredients; therefore, a cancer dietary exposure assessment was not performed.

5.5.4. Summary of Dietary Exposure and Risk Assessment Results

The results of the chronic dietary risk assessment are shown in the summary table, below. The input and output files from the dietary assessment are included in Appendix D.

Table 5.5.4. Summary of Dietary (Food and Drinking Water) Exposure and Risk for Alkyl Alcohol Alkoxylate Phosphate (AAAPD) and Alkyl Alcohol Alkoxylate Sulfate Derivatives (AAASD) with 30% Cap Incorporated

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	No acute endpoint selected		0.115748	13
All Infants (< 1 year old)			0.241013	28
Children 1-2 years old			**0.375655**	**43**
Children 3-5 years old			0.278347	32
Children 6-12 years old			0.153995	18
Youth 13-19 years old			0.087082	10
Adults 20-49 years old			0.087428	10
Adults 50+ years old			0.092074	11
Females 13-49 years old			0.088018	10

The most highly exposed subgroup is bolded.

6.0 Residential (Non-Occupational) Exposure/Risk Characterization

A screening level residential exposure and risk assessment was completed for products containing AAASD and AAAPD inert ingredients. Details of the assumptions informing the residential exposure and risk assessment can be found in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09. A summary of the residential exposure and risk assessment is presented below.

The level of concern (LOC) for these risk assessments is an MOE of 100 based on the standard 10X inter-species and 10X intra-species extrapolation safety factors.

6.1 Residential Handler Exposure

Exposure Scenarios
The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The AAASD and AAAPD inerts are used in pesticide formulation that may be used around the home. These residential pesticide products are typically formulated as liquids in concentrates or as wettable powders. In addition, these inerts may be used in pesticide products applied to pets as aerosol sprays intended for flea control on carpeted surfaces and bedding, or as shampoo products applied to pets. Lastly, these inerts may be present in home cleaning products. HED conducted an assessment to represent worst-case residential exposure by assessing:

- AAASD and AAAPDs in pesticide formulations (fungicides/insecticides/herbicides); (Outdoor Scenarios)
- AAASD and AAAPDs in disinfectant-type uses; (Indoor Scenarios)
- AAASD and AAAPDs in aerosol spray and shampoo pet products; (Pet Product Scenarios)

Based on information contained in the petition, the AAASD and AAAPD inerts can be present in consumer cleaning products. Therefore, HED assessed the disinfectant-type products containing the AAASD and AAAPD inerts using exposure scenarios used by OPP's Antimicrobials Division to represent worst-case residential handler exposure.

Mixer/Loader/Applicator High Exposure Outdoor Scenarios:
The mixer/loader/applicator high exposure outdoor scenarios use data from the Outdoor Residential Exposure Task Force:

- Liquid products: Low Pressure Handwand (ORETF data)
- Liquid products: Hose End Sprayer (ORETF data)
- Ready to Use (RTU): Trigger Pump Sprayer Applications (ORETF data)

Exposure Data and Assumptions:
A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessments for the AAASD and AAAPD inerts. Each assumption and factor is detailed below. In addition to these factors, unit exposures were used to calculate risk estimates.

The Agency used assumptions based on the Residential Exposure Assessment Standard Operating Procedures (Residential SOPs). Key assumptions used in this assessment are summarized below.

- The maximum application rate for the inert based on its use in a class of pesticide (herbicide/insecticide/fungicide) has been assessed for the short-term exposure duration.
- Residential risk assessments are based on high-end estimates of what homeowners would typically treat. Per HED's Residential SOPs (1997 & 2001 revision), residential pesticide handlers are assumed to mix and use a volume of 5 gallons of product per day.

- For outdoor pesticide applications, residential handlers are assumed to use a total of 1.35 lbs AAASD and AAAPDs per day. This estimate is based on the following assumptions:
    - Five (5) gallons of formulated pesticide solution are assumed to be used per day by a residential handler (Revised Residential SOPs Area Treated, February, 2001). Consistent with the residential SOPs, the density of the formulated pesticide solution is assumed to be 9 lbs/gallon. The proposed limit to the amount of AAASD and AAAPD inert in the pesticide products is 30%. Therefore 30% of any pesticidal product is assumed to be AAASD and AAAPD. Product concentrates are assumed to be diluted at a 1 to 10 ratio with water.

5 gallons formulated pesticide solution*(9 lbs/gallon)*(30% AAASD and AAAPDs)*(1 part product concentrate/10 parts water) = 1.35 lbs AAASD and AAAPDs in formulated pesticide solutions per day

- Residential exposure is assessed assuming clothing consisting of a short-sleeved shirt, short pants and no gloves or respiratory protection, the typical clothing for a home applicator.
- A dermal absorption factor of 5% was assumed based on the molecular weights and physical-chemical properties of the compounds. While there is no data provided for the AAASD and AAAPD inerts to quantify the dermal absorption, given the molecular weights and solubility properties of this compound, dermal absorption is not likely to exceed 5%.

HED believes the duration of exposure for most homeowner applications of home garden and lawn care products is best represented by the short-term duration (1 to 30 days). These exposure scenarios include the application of herbicides to lawns and insecticides/fungicides to gardens, ornamental plants, or lawns. While these types of applications may be applied on consecutive days, they are not likely to exceed 30 consecutive application days.

Mixer/Loader/Applicator High Exposure Indoor Scenarios:
The mixer/loader/applicator high exposure outdoor scenarios use data from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study, and the Pesticide Handlers Exposure Database:

- Liquid Products: Mopping Use (CMA data)
- Liquids Products: Wiping Use (CMA data)
- Aerosol Spray/Trigger pump/Air Deodorization Use (PHED data)

The Agency used assumptions based on methodology developed by the Anti-Microbial Division (AD) of the Office of Pesticide Programs and the Residential SOPs to assess exposure and risk from indoor use of household cleaning products containing the AAASD and AAAPD inerts. Based on information from RD, the Agency assumed that the maximum percentage by weight in indoor products would be 10% AAASD and AAAPDs.

Unit Exposure Values: Unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the PHED data presented in HED's Residential SOPs (USEPA, 1997).

"**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and

Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09 contains additional information about the disinfectant-type exposure scenarios assessed in this document.

The following key assumptions were used in this assessment:

- For the mopping scenario, the CMA dermal and inhalation unit exposure values for ungloved mopping were used (71.6 mg/lb inert. and 2.38 mg/lb inert, respectively). These values are based on data collected from six replicates mopping floors and receiving exposure via contact with the mop or with the bucket.
- For the wiping scenario, the CMA dermal and inhalation unit exposure values for ungloved wiping were used (2,870 mg/lb inert and 67.3 mg/lb inert, respectively). These values are based on data collected from six replicates (dental technicians) who used a finger pump sprayer to apply the product and then wiped the surfaces with a paper towel.
- For aerosol spray, trigger pump and air deodorization scenarios, the PHED dermal and inhalation unit exposure values are 220 mg/lb inert and 2.4 mg/lb inert, respectively. The values are based on homeowners applying an aerosol insecticide to baseboards in kitchens and are representative of a handler wearing short pants and a short sleeve shirt, with no gloves.

The quantities handled/treated were estimated based on information from various sources and assumptions.

- For the mopping scenarios, it was assumed that 1 gallon of diluted solution is used. HED assumes that cleaning products are assumed to have the same density as water (8.34 lbs/gallon). While typical product concentrate directions indicate that 1 oz concentrated product per 1 gallon of water should be used, HED followed the AD SOP and assumed a dilution factor of 2 oz concentrated product/128 oz (1 gallon) of water for the residential handler risk assessment to represent heavy-duty cleaning formulations. Based on information from RD, the Agency assumed that the maximum percentage by weight in indoor products would be 10% AAASD and AAAPDs.

1 gallon formulated pesticide solution*(8.34 lbs/gallon)*(10% AAASD and AAAPDs)*(2 oz/ 128 oz dilution factor) = 0.013 lbs AAASD and AAAPDs in formulated pesticide solutions per day

- For the wiping and trigger pump spray scenarios, it was assumed that 0.5 liter (0.13 gal) of ready-to-use (RTU) solution is used. For anti-microbial products, 10% AAASD and AAAPDs in product is assumed.

0.13 gallon formulated pesticide solution*(8.34 lbs/gallon)*(10% AAASD and AAAPDs) = 0.108 lbs AAASD and AAAPDs in formulated pesticide solutions per day

- For the aerosol foam spray and air deodorization scenarios, it is assumed that one can of product is used. For the aerosol spray/trigger pump/air deodorization scenario, it is

assumed that a 12 oz net weight product is used (0.094 gallons). 10% AAASD and AAAPDs inert in antimicrobial product assumed.

0.094 gallon formulated pesticide solution*(8.34 lbs/gallon)*(10% AAASD and AAAPDs) = 0.078 lbs AAASD and AAAPDs in formulated pesticide solutions per day

- A dermal absorption factor of 5% was assumed based on the physical-chemical properties of the compounds, including their molecular weights and water solubility properties. Given that these are large cross linked molecules, HED believes that dermal absorption for these inert ingredients will be low. HED considers 5% to be an upper bound estimate of dermal absorption.

HED believes the duration of exposure for most homeowner applications of indoor cleaning products is believed to be best represented by the short-term duration (1 to 30 days) because the different scenarios (i.e. methods of application) are assumed to be episodic, not daily. In addition, homeowners are assumed to use different cleaning products with varying active and inert ingredients.

Mixer/Loader/Applicator High Exposure Pet Product Scenarios:

- Aerosol Spray scenario (Spray applications to pets and/or pet bedding)
- Pet Shampoo scenario (Shampoo application to pets)

Products intended for use on pets contain less than 8% AAASD and AAAPDs in the formulation. Therefore, the residential handler exposure assessment assumed that products associated with the pet use scenarios contained up to 8% AAASD and AAAPD in pet products. Typically, HED would also assess a pet shampoo scenario to reflect a high-end dermal exposure scenario associated with pets.

The following key assumptions were used in this assessment:

- For aerosol spray scenario, the PHED dermal and inhalation unit exposure values are 220 mg/lb inert and 2.4 mg/lb inert, respectively. The values are based on homeowners applying an aerosol insecticide to baseboards in kitchens and are representative of a handler wearing short pants and a short sleeve shirt, with no gloves.
- For shampoo scenario, the carbaryl and MGK shampoo study (MRID 44658401 and MRID 46601001, respectively) dermal and inhalation unit exposure values are 1661 mg/lb inert and 0.06 mg/lb inert, respectively. These values are based on the geometric mean of the combined unit exposure values.

The quantities handled/treated were estimated based on information from various sources and assumptions.

- For the aerosol spray and air deodorization scenarios, it is assumed that one-half can of spray product is used. It is assumed that a 12 oz net weight product is used, so half of this can is 6 oz (0.047 gallons). The density of the product is assumed to be that of water, 8.34 lbs/gallon.
- For the shampoo scenario, it is assumed that one-quarter of a bottle of shampoo is used. It is assumed that a 12 oz net weight product is used, so one quarter of a bottle is 3 oz

(0.1875 lbs). Shampoo pet products were used to assess postapplication exposure to pet product as these types of products are used in large quantities on the pet. One-quarter of a 12 oz shampoo product was assumed to be applied to the pet for short- and intermediate-term exposure durations. The pet shampoo application rate is a conservative estimate based on the amount of shampoo product applied in the Carbaryl and MGK shampoo studies (MRID 44658401 and MRID 46601001, respectively). According to the Carbaryl and MGK studies, the average amount of shampoo product applied to each animal was 27,240 mg and 33,900 mg, respectively. Our assessment assumes 85,000 mg of product applied in each application (one quarter of a 12 oz bottle), so this assumption is conservative.

- 8% AAASD and AAAPD inert in pet product is assumed.
- A dermal absorption factor of 5% is assumed. HED considers this to be an upper bound estimate of dermal absorption.

The duration of exposure for most homeowner applications of pet products is believed to be best represented by the short-term duration (1 to 30 days) because the pest pressure for these scenarios is assumed to be episodic, not daily.

Risk Summary

For all residential handler scenarios, risk estimates are not of concern (i.e., MOEs are all greater than 100) for both the route-specific (dermal or inhalation) assessment and for the total MOE (dermal and inhalation combined). A summary of the results are provided below in Tables 6.1, below.

The Agency believes that the handler scenarios assessed represent worse-case exposures and risks resulting from use of indoor and outdoor pesticide products and cleaning products containing the AAASD and AAAPD inerts in residential environments.

Table 6.1. Short-term Exposure and Risks for AAASD and AAAPDs Residential Handlers									
Exposure Scenario (Formulation/ Application)	Application Rate[1] (lb inert/ gallon)	Quantity Handled/ Treated per day[2]	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (mg/ lb inert)[3]	Dermal Dose (mg/kg /day)[4]	Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Outdoor Products									
Liquids/ Low Pressure Handwand (ST) (ORETF data)	0.27 lb/gal	5 gallons	38	0.003	0.037	5.8E-5	2,400	1,500,000	2,400
Liquids/ Hose End Sprayer, Lawn (ST) (ORETF data)	0.27 lb/gal	5 gallons	11	0.017	0.0106	0.00033	8,200	270,000	8,000
Liquids/ Trigger Sprayer/ Home Garden (ST) (ORETF data)	0.27 lb/gal	5 gallons	54	0.0019	0.052	3.7E-5	1,700	2,400,000	1,700
Indoor Products									
Indoor hard surface, Mopping (ST) (CMA data)	0.013 lb/gal	1 gallon	71.6	2.38	0.00067	0.00044	130,000	200,000	78,000
Indoor hard surface, Wiping (ST) (CMA data)	0.834 lb/gal	0.13 gallons	2870	67.3	0.222	0.104	390	830	270
Indoor hard surface, Aerosol spray (ST) (PHED data)	0.834 lb/gal	0.094 gallons (12 oz)	220	2.4	0.0123	0.0027	7,100	32,000	5,800
Pet Products									
Pet Spray Product (ST) (PHED data)	0.667 lb/gal	0.047 gallons (6 oz)	220	2.4	0.0049	0.00107	18,000	81,000	15,000
Pet Shampoo Product (ST) (MRID 44658401 and 46601001)	0.015 lbs	NA	1661	0.06	0.018	0.000013	4,900	6,800,000	4,900

[1]Application rates are based on maximum application rates of products containing AAASD and AAAPD inerts multiplied by 30% for outdoor products and 10% for indoor products and 8% for pet products to convert from product application rate to inert application rate.

[2]Quantity treated daily values are back-calculated from 5 gallons of product used per day (Revised Residential SOPs 2001) for outdoor products. Indoor products are assumed to be used at 1 gallon of solution for the mopping scenario, 0.5 L of solution for the wiping scenario, and a 12 oz can of spray for the aerosol spray/air deodorization scenario. Pet spray products are assumed to be used at a rate of half of a 12 oz can of product, pet shampoo products are assumed to be used at a rate of one quarter of a 12 oz bottle of product.

[3]Unit Exposure data sources are identified in the exposure scenario column. All exposure scenarios assess exposure reflecting applicators wearing short-sleeved shirts and shorts and no respiratory protection.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb /gal) * Quantity handled (gallons/day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (mg inert / lb inert) * Application Rate (lb /gal) * Quantity handled (gallons/day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dermal dose (mg/kg/day)

[7] Inhalation MOE = PoD (NOAEL of 87 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8] Total MOE = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily dose inhalation (mg/kg/day)]

6.2 Residential Postapplication Exposure

Exposure Scenarios
Residential postapplication exposures result when bystanders, such as children come in contact with the AAASD and AAAPD inerts in areas where end-use products have recently been applied (e.g., treated lawns, gardens or recently cleaned surfaces). The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. HED conducted an assessment to represent worst-case residential exposure by assessing post application exposures and risks from:

- AAASD and AAAPDs in pesticide formulations (fungicides/ insecticides/ herbicides); (Outdoor Scenarios)
- AAASD and AAAPDs in disinfectant-type uses; (Indoor Scenarios)
- AAASD and AAAPDs in shampoo pet treatments; (Pet Product Scenarios)

The Agency considers dermal (adults and children) or incidental oral (children only) the primary exposure routes for the AAASD and AAAPD inerts. Inhalation exposures are not typically calculated for postapplication scenarios because inhalation exposures generally account for a negligible percentage of the overall body burden for most pesticide chemicals. Any inhalation exposure through the postapplication route will be less than the inhalation exposures assessed by residential handlers above in section 6.1.

For all postapplication exposure scenarios, exposures are assessed at short- and intermediate-term exposure durations because residues may be present on treated lawns, indoor treated surfaces, or on treated pets for lengths of time consistent with short- and intermediate-term exposure. Additionally, residential postapplication exposure can occur in commercially treated environments (e.g., schools, child care facilities, hospitals). If the products are used on a routine basis (i.e., daily), exposures may occur over an intermediate-term time duration (30 days – 6 months).

Postapplication High End Outdoor Exposure Scenarios
- Dermal exposure to treated lawns (adults/children)
- Hand-to-Mouth activity for toddlers on treated lawns (children)
- Object-to-Mouth activity for toddlers on treated lawns (children)
- Soil ingestion from treated soil (children)

The exposures from these routes and scenarios were considered individually and were also added together, where appropriate, to determine a total dose for children exposure to treated lawns. Residential postapplication exposure is assessed on the day of application, typically referred to as Day 0.

Exposure Data and Assumptions
A series of assumptions and exposure factors served as the basis for completing the residential postapplication risk assessments. The assumptions and factors used in the risk calculations are consistent with current HED policy for completing residential exposure assessments (i.e., *SOPs for Residential Exposure Assessment [1997 and 2001 revision]*).

Exposures to adults/children after contact with treated lawns have been addressed using the latest approaches for this scenario including:

- For adult exposure, the mean for US males and females was used to estimate exposure (70 kg). For child exposure, the mean of median values for male and female 3 year olds was used to estimate exposure (15 kg).
- HED has developed standard transfer coefficient (TC) values for residential postapplication scenarios to ensure consistency in exposure assessments. For the short-term assessment, TC values of 14,500 cm^2/hr (adults) and 5,200 cm^2/hr (children) were used. For intermediate-term risk assessment, TC values of 7,300 cm^2/hr (adults) and 2,600 cm^2/hr (children) were used. These default transfer coefficients, found in the 2001 Residential SOPs, were used to calculate postapplication exposures.
- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2 (based on the surface area of three fingers of a toddler's hand). For short-term exposures, it is assumed that there were 20 events per hour (90th percentile, according to the SOP) and for intermediate-term exposures, it was assumed that there were 9.5 event/hour (mean value).
- The exposure time used is 4 hours a day (USEPA, 2000 and 2001).
- The saliva extraction efficiency used is 50% (USEPA, 2000 and 2001).
- Pesticidal products are assumed to contain a maximum of 30% AAASD and AAAPDs by weight in the end use products.
- The relevant application rates for AAASD and AAAPDs containing products are derived above in Section 6.1
- A dermal absorption factor of 5% was assumed based on the molecular weights and physical-chemical properties of the compounds. HED considers this to be an upper bound estimate of dermal absorption.

Postapplication High End Indoor Exposure Scenarios

Standard methodologies based on HED's Residential SOPs were used to assess residential postapplication exposure to hard surface cleaners.

The Agency assumed that the maximum percentage by weight in indoor products would be 10% AAASD and AAAPDs. Based on an overall query of products that contain AAASD and AAAPDs, this reflects a high-end concentration.

Typically, the Agency assesses disinfectant-type products for the short-term exposure duration (1 to 30 days). This assumption is supported by the fact that the different scenarios (i.e. methods of application) are episodic, not daily. In addition, homeowners are assumed to use different cleaning products with varying active and inert ingredients. However, intermediate-term exposure is assessed for children because disinfectant products are used frequently in schools and day care centers where children can spend significant amounts of time. In those environments, cleaning products can be used on a daily basis.

The Agency used assumptions based on the Residential SOPs. The following key assumptions were used in this assessment:

- Toddlers (3 years old) were used to represent the 1 to 6 year old age group and are assumed to weigh 15 kg, the mean of median values for male and female toddlers (USEPA, 2000 and 2001).
- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2 (based on the surface area of three fingers of a toddler's hand). For short-term exposures, it is assumed that there were 20 events per hour (90th percentile, according to the SOP) and for intermediate-term exposures, it was assumed that there were 9.5 event/hour (mean value).
- The exposure time was 4 hours a day (USEPA, 2000 and 2001).
- The saliva extraction efficiency was 50% (USEPA, 2000 and 2001).
- No label information was available to represent the volume of disinfectant to be used for cleaning surfaces such as floors. It was assumed that the diluted treatment solution was applied at a rate of 1 gallon per 1,000 sq. ft^1.
- The maximum application rate on the product labels for application to hard surfaces is 8.34 lbs product/gal, based on the density of water. The amount of product used is assumed to be 0.5 gallons per day at a rate of 1 gallon/1000 ft^2, (i.e., 0.5 gallons for 500 ft^2). Therefore, the application rate used for the hard surface cleaner scenario in the post application scenario was $1.3x10^{-5}$ lbs inert/ft^2 [(1 gallon of product used * 8.34 lbs/gallon)/1000 ft^2 cleaned = 0.008 lb product/ft^2); (0.008 lb product/ ft^2 * 10% inert in a given disinfectant formulation * 2 oz/128 oz dilution factor= $1.3x10^{-5}$ lb/ft^2 /per day)] (See Table 6.2: Indoor Cleaning Products)
- No data is available regarding the quantity of solution residue left on the floor after treatment. As a conservative measure, it was assumed that 25% of the cleaner remains after the final mopping. This assumption has been used by the AD for other Office of Pesticide Program risk assessments.
- No transferable residue data were available that could be used to estimate the transfer factor from the floor to skin. Therefore, it is assumed that 10% of the deposition rate is available for dermal transfer (USEPA, 2000 and 2001).
- Dermal absorption of 5% is assumed. HED considers this to be an upper bound estimate of dermal absorption.

Postapplication High End Pet Product Exposure Scenarios

Standard methodologies based on HED's Residential SOPs were used to assess residential postapplication exposure to pesticidal products used on pets. Shampoo products were assessed as these products are applied in large quantities to the pet for flea control, and thus are the most readily available for postapplication residue exposure.

Based on information from RD, the Agency assumed that the maximum percentage by weight in pet products would be 8% AAASD and AAAPDs.

Shampoo pet products were used to assess postapplication exposure to pet product as these types of products are used in large quantities on the pet. One-quarter of a 12 oz shampoo product was assumed to be applied to the pet for short- and intermediate-term exposure durations. The pet shampoo application rate is a conservative estimate based on the amount of shampoo product

applied in the Carbaryl and MGK shampoo studies (MRID 44658401 and MRID 46601001, respectively). According to the Carbaryl and MGK studies, the average amount of shampoo product applied to each animal was 27,240 mg and 33,900 mg, respectively. This assessment assumes 85,000 mg of product applied in each application (one quarter of a 12 oz bottle), so this assessment is conservative. This assumption of the amount of shampoo used varies from that in the current residential SOPs, but is consistent with proposed updated methodologies.

The residue of pesticidal shampoo treatments on pets is expected to remain available for transfer and exposures are expected to occur over a short- and intermediate-term time duration (1- 30 days, 30 days – 6 months, respectively).

The Agency used assumptions based on the Residential SOPs. The following key assumptions were used in this assessment:

- Toddlers (3 years old) were used to represent the 1 to 6 year old age group and are assumed to weigh 15 kg, the median for male and female toddlers (USEPA, 2000 and 2001).
- Application rate is based on the size of shampoo treatment. Short- and intermediate-term exposures were estimated assuming one quarter the size of a 12 ounce shampoo bottle, or 3 ounces per day for the exposure duration. This means for AAASD and AAAPDs, 6800 mg of inert are used for short- and intermediate-term exposure durations [3 ounces * (28350 mg/oz) * 8% inert in product = 6800 mg inert]. This assumption of the amount of shampoo used varies from that in the current residential SOPs, but is consistent with proposed updated methodologies.
- It is assumed that one pet is contacted per day.
- On the day of application, it may be assumed that 5% (0.05) of the maximum application rate is available on the pet's body and transferred to the adult/toddler as a dislodgeable residue. This value is believed to be an upper-percentile assumption based on the properties of the AAASD and AAAPDs. The assumption of 5% transfer varies from the current SOPs, but is coinsistent with proposed updated methodologies.
- Postapplication activities are assed on the same day that the pesticide is applied because it is assumed that individuals could come in contact with the pet immediately after application.
- The surface animal of a dog is determined using a representative (average) animal, or a medium-sized (30 lb) dog. Estimated risks are based on an even loading of residues across the entire surface of a 30 lb dog, where Surface area (cm^2) = ((12.3 * (BW (lb)*454)^0.65)) = 2490 cm^2 from HED's 1993 Wildlife Exposure Factors Handbook.

Pet Product Postapplication Dermal Exposure Assumptions:

- HED default value for the surface area of an adult hug is 5625 cm^2; a toddler hug is 1875 cm^2 (US EPA, 1999 SAP).
- Dermal absorption of 5% is assumed. HED considers this to be an upper bound estimate of dermal absorption.

Pet Product Postapplication HTM Exposure Assumptions:

- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2, representing the surface area of the child's hands entering the mouth (assumed to be 3 fingers).
- Saliva extraction efficiency is assumed to be 50% (i.e. every time the hand goes in the mouth approximately half of the residues on the hand are removed).
- The approach used to address the hand-to-mouth exposure pathway has been modified since 1999 Draft Policy 13, "Postapplication Exposure Assessment for Children from Treated Pets." In the revised approach, the frequency term has been modified to an equilibrium approach analogous to the dermal exposure component (i.e., the frequency = 1 event/day). This approach was revised since the data from which the transferable residues concentrations were determined rely on a continuous contact (grooming) technique that would lead to concentrations on the hands which are anticipated to be significantly higher than would result from petting/hugging.

Risks were calculated using the Margin of Exposure (MOE) approach, which compares a toxicological PoD to an exposure estimate. Exposure algorithms and additional information on calculating the risk estimates for residential postapplication exposure can be found in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09.

Risk Summary

A summary of the residential postapplication exposure and risk estimates are presented in Table 6.2, below. Short- and intermediate-term post application risks for children are not of concern. The individual route-specific and combined non-dietary risks from dermal exposure and hand-to-mouth exposure for the outdoor scenarios and indoor scenarios do not demonstrate risks of concern for toddlers (i.e., the MOEs for the assessed scenarios are greater than 100) for both the short- and intermediate-term exposure durations.

Risk Characterization

At this time, residue dissipation data or reliable use pattern data are not available, including the frequency and duration of use of antimicrobial products in the residential setting. The Agency does not believe that the use patterns of many residential products result in intermediate-term exposure. However, the Agency notes that intermediate-term exposure to children may occur in areas where disinfecting products are used more frequently (i.e., schools and day care centers).

Table 6.2. Residential Postapplication Short- and Intermediate-term Exposures and Risks for AAASD and AAAPDs				
Exposure Scenario	Application Rate[1]	Exposed Population & Exposure Duration[2]	Daily Dose (mg/kg/day)[3]	MOE[4]
Outdoor Lawn Products				
Dermal Exposure to Treated Lawns	1.35 lb/day	Adult ST	0.0157	5,500
		Adult IT	0.0079	11,000
		Child ST	0.026	3,300
		Child IT	0.013	6,600
Hand-to-Mouth from Treated Lawn		Child ST	0.0202	4,300
		Child IT	0.0096	9,100
Object-to-Mouth from Treated Lawn		Child ST	0.005	17,000
		Child IT		
Soil Ingestion		Child ST	6.76E-5	1,300,000
		Child IT		
Total Lawn Combined Exposures*		Child ST	0.0462	1,900
		Child IT	0.0226	3,800
Indoor Cleaning Product				
Dermal Exposure to Treated Indoor Surface	1.3E-5 lb/ft^2	Child ST	0.0035	25,000
		Child IT		
Hand-to-Mouth from Treated Indoor Surface		Child ST	0.0085	10,000
		Child IT	0.004	22,000
Total Surface Combined Exposures*		Child ST	0.012	7,300
		Child IT	0.0075	12,000
Pet Product				
Dermal Exposure to Treated Pet	6800 mg/day	Adult ST	0.2285	380
		Adult IT		
	6800 mg/day	Child ST	0.356	240
		Child IT		
Hand-to-Mouth from Treated Pet	6800 mg/day	Child ST	0.038	2,300
		Child IT		
Total Pet Combined Exposures*	6800 mg/day	Child ST	0.393	220
		Child IT		

[1] Application rates for outdoor products are derived in Section 6.1 Application rates for indoor and pet products are derived in Section 6.2.

[2] ST and IT indicate short- or intermediate-term exposure durations

[3] Daily Dose = Daily Dose algorithms for various residential postapplication scenarios outlined in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09.

[4] MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dose (mg/kg/day)

[5] Combined exposures reflect the aggregation of dermal exposure to treated areas and HTM exposure from treated areas (for children). Total Combined Exposures = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily dose HTM(mg/kg/day)]

7.0 Aggregate Risk Assessments and Risk Characterization

7.1 Acute Aggregate Risk

There was no hazard attributable to a single exposure seen the in the toxicity database for the AAAPDs and AAASDs; therefore, an acute aggregate risk assessment is not required.

7.2 Short-Term/Intermediate-Term Aggregate Risk

Short-term and intermediate-term aggregate risk assessments for the AAAPD and AAASD inert ingredients combine high end residential short- or intermediate-term exposures with average food and drinking water exposures, and compare this total to a short- or intermediate term PoD.

Short- and intermediate term residential exposures inputs into the aggregate risk assessment are summarized in Table 7.2.1.

Table 7.2.1. Short- and Intermediate-Term Residential Exposures for the AAAPDs and AAASDs Aggregate Risk Assessment

Population	Handler Exposure (mg/kg/day)[1]	Postapplication Exposure (mg/kg/day)[2]	Residential Exposure (mg/kg/day)[3]
Short-Term			
Adult Male	0.326 Source: Table 6.1 Indoor hard surface, Wiping (ST)	0.2285 Source: Table 6.2 ST Dermal Exposure to Treated Pets	0.5545
Adult Female	0.326 Source: Table 6.1 Indoor hard surface, Wiping (ST)	0.2285 Source: Table 6.2 ST Dermal Exposure to Treated Lawns	0.5545
Child	N/A	0.393 Source: Table 6.2 Total Pet Combined Exposures	0.393
Intermediate-Term			
Adult Male	N/A	0.2285 Source: Table 6.2 IT Dermal Exposure to Treated Pets	0.2285
Adult Female	N/A	0.2285 Source: Table 6.2 IT Dermal Exposure to Treated Pets	0.2285
Child	N/A	0.393 Source: Table 6.2 Total Pet Combined Exposures	0.393

[1] Handler exposure, which is applicable to adult populations only, combines high end dermal and inhalation handler exposure. This exposure is included in the short-term aggregate assessment for adults only, as HED does not believe that residential handlers will have intermediate-term exposures.

[2] Postapplication exposure for adults, includes high end dermal exposure to treated pets. Postapplication exposure for children combines postapplication exposures from dermal and incidental oral exposure from exposure to treated pets. Both short- and intermediate-term durations are appropriate for post-application exposures.

[3] Residential exposure is the sum of the handler (adults only) and post application exposures.

Short- and intermediate-term aggregate risks are summarized in Table 7.2.2. Provided these inert ingredients do not exceed 30% in pesticide end-use products, short- and intermediate-term aggregate risks are not of concern for adults or children. HED notes that for the pet products assessed, the Agency assumed 8% as a maximum in the formulation.

Table 7.2.2. Short- and Intermediate-Term Aggregate Risk Calculations for AAAPDs and AAASDs

Population	PoD mg/kg/day	LOC[1]	Max Allowable Exposure[2] mg/kg/day	Average Food & Water Exposure mg/kg/day	Residential Exposure[3] mg/kg/day	Aggregate MOE (food and residential)[4]
Short-Term						
Adult Male	87	100	0.87	0.092074	0.5545	130
Adult Female	87	100	0.87	0.088018	0.5545	140
Child	87	100	0.87	0.375655	0.393	110
Intermediate-Term						
Adult Male	87	100	0.87	0.092074	0.2285	270
Adult Female	87	100	0.87	0.088018	0.2285	280
Child	87	100	0.87	0.375655	0.393	110

[1] The LOC (Level of Concern) is based on the standard inter- and intra-species uncertainty factors totaling 100.
[2] Maximum Allowable Exposure (mg/kg/day) = PoD (Point of Departure)/LOC
[3] Residential Exposure = [Oral exposure + Dermal exposure + Inhalation Exposure]. Sources identified above in Table 7.2
[4] Aggregate MOE = [PoD/ (Avg Food & Water Exposure + Residential Exposure)]

7.3 Long-Term Aggregate Risk

For the AAAPDs and AAASDs, long-term aggregate risk includes dietary exposures to food and drinking water. Dietary (food and water) exposures and risk are discussed in Section 5.5.2 of this memorandum. Long-Term (chronic) aggregate risks for these inert ingredients are not of concern.

7.4 Cancer Risk

HED has not identified any concerns for carcinogenicity; therefore, an aggregate cancer dietary exposure assessment was not performed.

8.0 Occupational Exposure/Risk Pathway

Based on examination of product labels which may contain the AAASD and AAAPDs as inert ingredients, HED has determined that exposure to handlers can occur in a variety of occupational environments. Details of the occupational exposure assessment for the AAASD and AAAPDs inerts can be found in the document "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751," 5/7/09.

The representative occupational scenarios selected by the Agency for assessment were evaluated based on likely maximum application rates for products which may contain the AAASD and AAAPDs inerts for the short-term exposure assessment, and average application rates for products likely to contain AAASD and AAAPDs as inerts for the intermediate- and long-term exposure durations. Active ingredient application rates were corrected for the maximum amount of AAASD and AAAPDs likely to be in the final formulations to determine exposure and risk from exposure to AAASD and AAAPDs grouped by fungicide/insecticide or herbicide. A summary of the occupational assessment is presented below.

The level of concern (LOC) for these risk assessments is an MOE of 100 based on the standard 10X inter and 10X intra species uncertainty safety factors.

8.1 Handler Risk

Exposure Scenarios

Exposure to pesticide handlers is likely during the occupational use of pesticides containing the AAASD and AAAPD inert ingredients. Dermal and inhalation exposure was estimated using PHED and ORETF data. The quantitative exposure/risk assessment developed for occupational handlers to support the requested exemption from the requirement of a tolerance for the AAASDs and AAAPDs is based on the following scenarios. HED notes that these scenarios were selected to represent the scenarios with the highest potential exposure.

Mixer/Loader/Applicators:

1) Mixer/Loader for aerial application- high acreage field crops (liquids)
2) Mixer/Loader for airblast application- tree nuts crops (both liquid and wettable powder)
3) Mixer/Loader for groundboom application- high acreage field crops and turf (liquids and wettable powder)
4) Applicators for aerial application- high acreage field crops (liquid)
5) Applicators for airblast- tree nut crops

6) Applicators for groundboom- high acreage field crops and turf
7) Mixer/Loader/Applicator- low pressure handwand (liquids and wettable powders)*
8) High pressure handwand- greenhouse (wettable powders)
9) Flagging- high acreage field crops (liquids)

* Uses ORETF unit exposure data. All others use PHED data.

Risk estimates were calculated using the Margin of Exposure (MOE) which is a ratio of the toxicological PoD to the daily dose. Daily dose values are calculated by first calculating exposures by considering application parameters (i.e., rate and area treated) along with unit exposures. Exposures are then normalized by body weight to calculate dose levels. Dermal and inhalation short- and intermediate-term exposure is compared to the dermal and inhalation PoD of 87 mg/kg/day (same PoD for short- and intermediate-term exposure durations). For the scenarios where applicable, dermal and inhalation long-term exposure is compared to the long-term dermal and inhalation PoD of 87 mg/kg/day. For short-, intermediate-, and long-term dermal assessments, exposures were adjusted for a 5% dermal absorption. A combined dermal and inhalation MOE was also calculated for each exposure duration for the AAASD and AAAPD inerts since common toxicity endpoints were identified for both the dermal and inhalation routes of exposure. To assess handler risks, the Agency used surrogate unit exposure data from the Pesticide Handlers Exposure Database (PHED), and ORETF data.

The following assumptions and factors were used in order to complete the exposure and risk assessment for occupational handlers/applicators:

- All worker scenarios were assumed to be short- and intermediate-term in exposure durations (i.e., 1-30 days and 1-6 months) except the greenhouse/hothouse scenario.
- For scenarios where greenhouse/hothouse applications are possible, long-term exposure (6+ months) was assessed.
- The exposure assessment assumes an 8 hour work day.
- The maximum application rate per pesticide group (herbicide/insecticide/fungicide) has been assessed for the short-term exposure duration.
- The average application rate per pesticide group (herbicide/insecticide/fungicide) has been assessed for the intermediate-term exposure duration.
- A body weight of 70 kg was assumed because the relevant toxicological PoDs were not gender specific.
- The baseline clothing level for occupational exposure scenarios is considered to be an individual wearing long pants, a long-sleeved shirt, shoes, socks, no chemical-resistant gloves, and no respiratory protection.
- For high acreage crops (e.g. corn, soybeans) where applicators can mix/load large quantities of pesticide, exposure assessments have also been completed for baseline dermal PPE (Personal Protective Equipment) plus chemical-resistant gloves, and no respiratory protection.
- 30% of any pesticidal product is assumed to be AAASD and AAAPDs.

Risk Characterization:
HED initially assessed handler exposure and risks for the AAASD and AAAPD inerts in fungicides, herbicides and insecticides at baseline PPE (long pants, a long-sleeved shirt, shoes, socks, no chemical-resistant gloves, and no respiratory protection) which HED considers to be standard agricultural worker clothing. When these assessments indicated that there was potential risks of concern for scenarios where workers would be handling large quantities of pesticide for high volume operations typically involving aerial applications to high acreage crops, HED repeated the assessments and included additional PPE (i.e., chemical-resistant gloves for pesticide handlers). See Table 8.1.2 for herbicide products, Table 8.1.4 for insecticide products, and Table 8.1.6 for fungicide products. HED has included an assessment for workers handling high volumes of chemicals, which includes gloves, as the Agency believes workers handling these volumes of pesticides will be wearing chemical-resistant gloves.

When handlers are wearing standard worker clothing (i.e., baseline PPE) the majority of occupational handler scenarios do not indicate risks of concern. For the occupational handler scenarios which involve the handling of large volumes of pesticides, those which EPA believes that handlers will be wearing chemical-resistant gloves, occupational handler scenarios do not indicate risks of concern with the addition of chemical-resistant gloves to baseline PPE (i.e., minimum dermal PPE).

For the mixer/loader/applicator scenarios described in the occupational handler tables (below), the ORETF handler studies have no data for baseline dermal exposure because the handlers in the study wore gloves and no respiratory protection. HED believes baseline exposure is relevant to assess for these exposure scenarios (i.e., baseline dermal PPE and no respiratory protection). Therefore, both ORETF and PHED scenarios are shown in the mixer/loader/applicator section of the occupational handler tables. Baseline inhalation MOEs are reported "as is" because ORETF study participants did not wear respiratory protection. Additional explanation of the ORETF studies is available in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751," 5/7/09.

Table 8.1.1. Exposure and Risks for Occupational Handlers of AAAPD and AAASD in Herbicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	3.12	1200	2.9	1.2	7.76	0.064	**11**	1,400	**11**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.6				1.49	0.0123	**58**	7,000	**58**
Liquids/ Airblast/ Nut Tree (ST)	2.16	40			0.179	0.00148	490	59,000	480
Liquids/ Airblast/ Nut Tree (IT)	0.96				0.08	0.00066	1,100	130,000	1,100
Liquids/ Groundboom/ High Acreage Crops (ST)	3.12	200			1.293	0.0107	**67**	8,100	**67**
Liquids/ Groundboom/ High Acreage Crops (IT)	0.6				0.249	0.0021	350	42,000	350
Liquids/ Groundboom/ Turf (ST)	3.12	40			0.259	0.0021	340	41,000	330
Liquids/ Groundboom/ Turf (IT)	0.6				0.05	0.0004	1,800	210,000	1,700
Liquids/ Low Pressure Handwand/ Turf (ST)	2.16	5			0.022	0.00019	3,900	470,000	3,900
Liquids/ Low Pressure Handwand/ Turf (IT)	2.16				0.022	0.00019	3,900	470,000	3,900
Wettable Powder/ Airblast/ Nut Tree (ST)	0.48	40	3.7	43	0.0507	0.0118	1,700	7,400	1,400
Wettable Powder/ Airblast/ Nut Tree (IT)	0.48				0.0507	0.0118	1,700	7,400	1,400
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.48	200			0.254	0.059	340	1,500	280
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.3				0.159	0.0369	550	2,400	450
Wettable Powder/ Groundboom/ Turf (ST)	0.48	40			0.0507	0.0118	1,700	7,400	1,400
Wettable Powder/ Groundboom/ Turf (IT)	0.3				0.0317	0.0074	2,700	12,000	2,200
Wettable powder/ Low Pressure Handwand/ Turf (ST)	2.16	5			0.0285	0.0066	3,000	13,000	2,500
Wettable powder/ Low Pressure Handwand/ Turf (IT)	2.16				0.0285	0.066	3,000	13,000	2,500
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	3.12	1200	Eng control only: 0.0055	Eng control only: 0.068	0.0147	0.0036	5,900	24,000	4,700
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.6				0.0028	0.0007	31,000	120,000	25,000
Airblast/ Nut Tree (ST)	0.48	40	0.36	4.5	0.005	0.0012	18,000	70,000	14,000
Airblast/ Nut Tree (IT)	0.48				0.005	0.0012	18,000	70,000	14,000
Groundboom/ High Acreage Crops (ST)	3.12	200	0.014	0.74	0.0062	0.0066	14,000	13,000	6,800
Groundboom/ High Acreage Crops (IT)	0.6				0.0012	0.0013	73,000	69,000	35,000
Groundboom/ Turf (ST)	3.12	40			0.0013	0.0013	70,000	66,000	34,000
Groundboom/ Turf (IT)	0.6				0.00024	0.00025	360,000	340,000	180,000
Mixer/Loader/Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	2.16	5	No Data	6.6	NA	0.00102	NA	85,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	2.16				NA	0.00102	NA	85,000	NA

Table 8.1.1. Exposure and Risks for Occupational Handlers of AAAPD and AAASD in Herbicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	2.16	5	No Data	1100	NA	0.17	NA	510	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	2.16				NA	0.17	NA	510	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	2.16				NA	0.17	NA	510	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	2.16	5	100	30	0.771	0.0046	110	19,000	110
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	2.16				0.771	0.0046	110	19,000	110
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	2.16				0.771	0.0046	110	19,000	110
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	3.12	1200	0.011	0.35	0.029	0.019	3,000	4,600	1,800
Liquid/ Flagger/ High Acreage Crops (IT)	0.6				0.0057	0.0036	15,000	24,000	9,400

[1]Application rates are based on maximum application rates of products containing inerts in AAASD and AAAPDs multiplied by 30% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 30% inert AAASD and AAAPD). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Baseline Dermal PPE is single layer clothing, no gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dermal dose (mg/kg/day)

[7]ST Inhalation MOE = PoD (NOAEL of 87 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily inhalation dose (mg/kg/day)]

[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline dermal (no gloves) plus baseline inhalation exposure.

[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed has a higher unit exposure at baseline dermal exposure than either of the two scenarios shown at baseline PPE plus gloves dermal exposure.

Table 8.1.2. Exposure and Risks for Occupational Handlers of AAASD and AAAPDs in Herbicide Products (All Exposure Durations) with Baseline Dermal PPE and Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Min PPE Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Min PPE Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)[9]	3.12	1200	0.023	1.2	0.062	0.064	1,400	1,400	690
Liquids/ Aerial Application/ High Acreage Crops (IT)[9]	0.6				0.012	0.0123	7,400	7,000	3,600
Liquids/ Groundboom/ High Acreage Crops (ST)[9]	3.12	200			0.0103	0.0107	8,500	8,100	4,200
Liquids/ Groundboom/ High Acreage Crops (IT)[9]	0.6				0.002	0.0021	44,000	42,000	22,000

[1]Application rates are based on maximum application rates of products containing inerts in AAASD and AAAPDs multiplied by 30% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 30% inert AAASD and AAAPDs). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Scenarios shown are with Baseline Dermal PPE plus gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess minimum dermal PPE (with gloves) plus baseline inhalation exposure.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dermal dose (mg/kg/day)

[7] Inhalation MOE = PoD (NOAEL of 87 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily dose inhalation (mg/kg/day)]

[9] Exposure scenarios assess minimum dermal PPE (baseline PPE plus gloves) plus baseline inhalation exposure.

Table 8.1.3. Exposure and Risks for Occupational Handlers of AASPD and AAASD in Insecticide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	0.6	1200	2.9	1.2	1.49	0.012	**58**	7,000	**58**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.21				0.522	0.0043	170	20,000	170
Liquids/ Airblast/ Nut Tree (ST)	2.7	40			0.224	0.0019	390	47,000	390
Liquids/ Airblast/ Nut Tree (IT)	0.75				0.062	0.0005	1,400	170,000	1,400
Liquids/ Groundboom/ High Acreage Crops (ST)	0.6	200			0.249	0.0021	350	42,000	350
Liquids/ Groundboom/ High Acreage Crops (IT)	0.21				0.087	0.0007	1,000	120,000	990
Liquids/ Groundboom/ Turf (ST)	0.6	40			0.05	0.0004	1,800	210,000	1,700

Table 8.1.3. Exposure and Risks for Occupational Handlers of AASPD and AAASD in Insecticide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Liquids/ Groundboom/ Turf (IT)	0.21				0.017	0.00014	5,000	600,000	5,000
Liquids/ Low Pressure Handwand/ Turf (ST)	2.16	5			0.0224	0.0002	3,900	470,000	3,900
Liquids/ Low Pressure Handwand/ Turf (IT)	2.16				0.0224	0.0002	3,900	470,000	3,900
Wettable Powder/ Airblast/ Nut Tree (ST)	1.8	40			0.19	0.044	460	2,000	370
Wettable Powder/ Airblast/ Nut Tree (IT)	0.9				0.095	0.022	910	3,900	740
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.48	200			0.254	0.059	340	1,500	280
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.21		3.7	43	0.111	0.026	780	3,400	640
Wettable Powder/ Groundboom/ Turf (ST)	0.48	40			0.051	0.012	1,700	7,400	1,400
Wettable Powder/ Groundboom/ Turf (IT)	0.21				0.022	0.0052	3,900	17,000	3,200
Wettable powder/ Low Pressure Handwand/ Turf (ST)	2.16	5			0.029	0.0066	3,000	13,000	2,500
Wettable powder/ Low Pressure Handwand/ Turf (IT)	2.16				0.029	0.0066	3,000	13,000	2,500
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	0.6	1200	Eng control only: 0.0055	Eng control only: 0.068	0.0028	0.0007	31,000	120,000	25,000
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.21				0.001	0.0002	88,000	360,000	70,000
Airblast/ Nut Tree (ST)	2.7	40	0.36	4.5	0.028	0.0069	3,100	13,000	2,500
Airblast/ Nut Tree (IT)	0.75				0.0077	0.0019	11,000	45,000	9,000
Groundboom/ High Acreage Crops (ST)	0.6	200	0.014	0.74	0.0012	0.0013	73,000	69,000	35,000
Groundboom/ High Acreage Crops (IT)	0.21				0.00042	0.00044	210,000	200,000	100,000
Groundboom/ Turf (ST)	0.6	40			0.00024	0.00025	360,000	340,000	180,000
Groundboom/ Turf (IT)	0.21				0.00008	0.00009	1,000,000	980,000	500,000
Mixer/Loader/Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	2.16	5	NA	6.6	NA	0.00102	NA	85,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	2.16				NA	0.00102	NA	85,000	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	2.16	5	NA	1100	NA	0.1697	NA	510	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	2.16				NA	0.1697	NA	510	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	2.16				NA	0.1697	NA	510	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	2.16	5	100	30	0.7714	0.0046	110	19,000	110
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	2.16				0.7714	0.0046	110	19,000	110
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	2.16				0.7714	0.0046	110	19,000	110

Table 8.1.3. Exposure and Risks for Occupational Handlers of AASPD and AAASD in Insecticide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	0.6	1200	0.011	0.35	0.0057	0.0036	15,000	24,000	9,400
Liquid/ Flagger/ High Acreage Crops (IT)	0.21				0.002	0.0013	44,000	69,000	27,000

[1]Application rates are based on maximum application rates of products containing inerts in AAASD and AAAPDs multiplied by 30% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 30% inert AAASD and AAAPDs). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Baseline Dermal PPE is single layer clothing, no gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dermal dose (mg/kg/day)

[7]ST Inhalation MOE = PoD (NOAEL of 87 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily inhalation dose (mg/kg/day)]

[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline dermal (no gloves) plus baseline inhalation exposure.

[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed has a higher unit exposure at baseline dermal exposure than either of the two scenarios shown at baseline PPE plus gloves dermal exposure.

Table 8.1.4. Exposure and Risks for Occupational Handlers of AAASD and AAAPDs in Insecticide Products (All Exposure Durations) with Baseline Dermal PPE and Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Min PPE Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Min PPE Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)[9]	0.6	1200	0.023	1.2	0.012	0.0123	7,400	7,000	3,600
Liquids/ Aerial Application/ High Acreage Crops (IT)[9]	0.21				0.0041	0.0043	21,000	20,000	10,000

[1]Application rates are based on maximum application rates of products containing inerts in the AAASD and AAAPDs multiplied by 30% to convert to application rate of just inert in an insecticide product (Insecticide products assumed to contain maximum of 30% AAASD and AAAPD inert). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess minimum dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7] Inhalation MOE = PoD (NOAEL of 87 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total Combined MOE = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily dose inhalation (mg/kg/day)]
[9] Exposure scenarios assess minimum dermal PPE (baseline PPE plus gloves) plus baseline inhalation exposure.

Table 8.1.5. Exposure and Risks for Occupational Handlers of AAAPD and AAASD in Fungicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	1.5	1200	2.9	1.2	3.73	0.0309	**23**	2,800	**23**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.21				0.52	0.0043	170	20,000	170
Liquids/ Airblast/ Nut Tree (ST)	3.3	40			0.27	0.0023	320	38,000	320
Liquids/ Airblast/ Nut Tree (IT)	0.9				0.075	0.00062	1,200	140,000	1,200
Liquids/ Groundboom/ High Acreage Crops (ST)	1.5	200			0.62	0.005	140	17,000	140
Liquids/ Groundboom/ High Acreage Crops (IT)	0.21				0.087	0.00072	1,000	120,000	990
Liquids/ Groundboom/ Turf (ST)	1.5	40			0.124	0.00103	700	85,000	690
Liquids/ Groundboom/ Turf (IT)	0.21				0.017	0.00014	5,000	600,000	5,000
Liquids/ Low Pressure Handwand/ Turf (ST)	2.16	5			0.022	0.0002	3,900	47,000	3,900
Liquids/ Low Pressure Handwand/ Turf (IT)	2.16				0.022	0.0002	3,900	47,000	3,900
Wettable Powder/ Airblast/ Nut Tree (ST)	2.1	40	3.7	43	0.222	0.052	390	1,700	320
Wettable Powder/ Airblast/ Nut Tree (IT)	0.6				0.063	0.015	1,400	5,900	1,100
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.3	200			0.159	0.037	550	2,400	450
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.18				0.095	0.022	910	3,900	740
Wettable Powder/ Groundboom/ Turf (ST)	0.3	40			0.032	0.0074	2,700	12,000	2,200
Wettable Powder/ Groundboom/ Turf (IT)	0.18				0.019	0.0044	4,600	20,000	3,700
Wettable powder/ Low Pressure Handwand/ Turf (ST)	2.16	5			0.029	0.0066	3,000	13,000	2,500
Wettable powder/ Low Pressure Handwand/ Turf (IT)	2.16				0.029	0.0066	3,000	13,000	2,500
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	1.5	1200	Eng control only: 0.0055	Eng control only: 0.068	0.007	0.0017	12,000	50,000	9,900
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.21				0.001	0.0002	88,000	360,000	70,000
Airblast/ Nut Tree (ST)	2.1	40	0.36	4.5	0.022	0.0054	4,000	16,000	3,200
Airblast/ Nut Tree (IT)	0.9				0.0093	0.0023	9,400	38,000	7,500
Groundboom/ High Acreage Crops (ST)	1.5	200	0.014	0.74	0.003	0.0032	29,000	27,000	14,000

Table 8.1.5. Exposure and Risks for Occupational Handlers of AAAPD and AAASD in Fungicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Groundboom/ High Acreage Crops (IT)	0.21				0.00042	0.00044	210,000	200,000	100,000
Groundboom/ Turf (ST)	1.5	40			0.0006	0.00063	150,000	140,000	70,000
Groundboom/ Turf (IT)	0.21				0.00008	0.00009	1,000,000	980,000	500,000
Mixer/Loader/Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	2.16	5	No Data	6.6	NA	0.001	NA	85,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	2.16				NA	0.001	NA	85,000	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	2.16	5	No Data	1100	NA	0.17	NA	510	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	2.16				NA	0.17	NA	510	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	2.16				NA	0.17	NA	510	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	2.16	5	100	30	0.77	0.0046	110	19,000	110
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	2.16				0.77	0.0046	110	19,000	110
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	2.16				0.77	0.0046	110	19,000	110
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	1.5	1200	0.011	0.35	0.014	0.009	6,200	9,700	3,800
Liquid/ Flagger/ High Acreage Crops (IT)	0.21				0.002	0.0013	44,000	69,000	27,000

[1]Application rates are based on maximum application rates of products containing inerts in AAASD and AAAPDs multiplied by 30% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 30% inert AAASD and AAAPD). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Baseline Dermal PPE is single layer clothing, no gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dermal dose (mg/kg/day)

[7]ST Inhalation MOE = PoD (NOAEL of 87 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily dose inhalation (mg/kg/day)]

[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline dermal (no gloves) plus baseline inhalation exposure.

[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed has a higher unit exposure at baseline dermal exposure than either of the two scenarios shown at baseline PPE plus gloves dermal exposure.

Table 8.1.6. Exposure and Risks for Occupational Handlers of AAASD and AAAPDs in Fungicide Products (All Exposure Durations) with Baseline Dermal PPE and Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Min PPE Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Min PPE Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)[9]	1.5	1200	0.023	1.2	0.03	0.031	2,900	2,800	1,400
Liquids/ Aerial Application/ High Acreage Crops (IT)[9]	0.21				0.0041	0.0043	21,000	20,000	10,000

[1]Application rates are based on maximum application rates of products containing inerts in the AAASD and AAAPDs multiplied by 30% to convert to application rate of just inert in a fungicide product (Fungicide products assumed to contain maximum of 30% inert from the AAASD and AAAPDs). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess minimum dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg) * Dermal Absorption Factor of 5% (0.05)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 87 mg/kg/day)/ Daily dermal dose (mg/kg/day)
[7] Inhalation MOE = PoD (NOAEL of 87 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total Combined MOE = (NOAEL of 87 mg/kg/day)/ [Daily dose dermal + Daily dose inhalation (mg/kg/day)]
[9] Exposure scenarios assess minimum dermal PPE (baseline PPE plus gloves) plus baseline inhalation exposure.

8.2 Occupational Postapplication Risk

HED uses the term postapplication to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Postapplication exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for postapplication exposure.

Inhalation exposures are not typically calculated for postapplication scenarios because inhalation exposures generally account for a negligible percentage of the overall body burden for most pesticide chemicals. This is particularly true for chemicals with a low vapor pressure such as the AAASD and AAAPDs cluster.

Exposure Scenarios

This assessment is considered to be a screening level estimate, demonstrating that there are minimal potential risks to workers re-entering fields treated with pesticides containing the AAASD and AAAPDs as inert ingredients. While the AAASD and AAAPDs are present in formulations designated for crops besides those assessed in this document, risk estimates for

those occupational postapplication scenarios are expected to be less than those scenarios assessed in this document (i.e., calculated MOEs will be higher). The three occupational postapplication scenarios assessed are for postapplication activities associated with:

- Tall field/row crops (including scouting, weeding, hand harvesting sweet corn)
- Turf (golf course/sod farm) (including mowing, transplanting, hand weeding)
- Vine/Trellis crops (including scouting, training, tying, thinning, and grape girding and cane turning)

Exposure Data and Assumptions

Key assumptions used in the postapplication risk assessment calculations are detailed as follows:

- The average occupational workday is assumed to be 8 hours.
- The adverse effects for the short- and intermediate-term dermal PoD's are based on studies where the effects were observed in both sexes; therefore, the body weight of 70 kg was used to estimate exposure.
- HED has developed standard transfer coefficient values for occupational postapplication scenarios to ensure consistency in exposure assessments. These standard values were used to calculate postapplication exposures.
- Anticipated postapplication activities and their respective dermal transfer coefficients (TCs) are summarized in Table 8.2. The TC information is based on the Science Advisory Council for Exposure Policy Number 3.1.
- TC for sod transplanting, hand weeding is from data using Agriculture Re-entry Task Force (ARF) Study ARF-035 (MRID 45432303).
- Calculations of postapplication exposures are completed using maximum application rates of the products of that type of pesticide (herbicide, insecticide, or fungicide) for short-term exposures and average application rates of products for intermediate-term exposures.
- Herbicides/insecticides/fungicides assessed can contain a maximum of 30% AAASD and AAAPDs in any product formulation.
- No postapplication data were submitted for the AAASD and AAAPDs cluster; a default 20% of the application rate (for agricultural crops) and 5% (for turf) is considered available as a transferrable residue with a 10% default daily dissipation rate.
- Dermal absorption of 5% was assumed based on the molecular weight and solubility properties of the compounds. HED considers this to be an upper bound estimate of dermal absorption.

Risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of the body burden to the toxicological PoD.

A variety of pesticide formulations may potentially contain AAASD and AAAPDs as an inert ingredient. PPE is usually not required for worker re-entry, and therefore these postapplication risk estimates are based on baseline PPE (no gloves). Typically, HED characterizes the risk estimate in relation to the restricted entry interval (REI) for a particular active ingredient. However, since this assessment is to support an exemption from the requirement of a tolerance without a requirement for an REI, MOEs have been calculated on the day of application (Day 0).

Risk Summary

Occupational postapplication risk estimates are presented in Table 8.2. The risk estimates for the the exposure scenarios assessed resulted in MOEs do not demonstrate risks of concern (i.e., MOEs > 100) on Day 0.

Table 8.2. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for AAAPD and AAASD

Crop & Exposure Duration	Application Rate (lb inert /A)	Work Activity	Transfer Coefficient[1] (cm^2/hr)	Day after Treatment[2]	DFR_t (µg/cm^2)[3]	Daily Dose (mg/kg/day)[4]	MOE[5]
Herbicide Products							
Corn (ST)	3.12	Scout, weed low foliage	100	0	7.001	0.004	22,000
		Scout, weed high foliage	400	0		0.016	5,400
		Scout, irrigate, weed high foliage	1,000	0		0.04	2,200
		Harvesting/ detassling	17,000	0		0.6801	130
Corn (IT)	0.36	Scout, weed low foliage	100	0	0.808	0.0005	190,000
		Scout, weed high foliage	400	0		0.0018	47,000
		Scout, irrigate, weed high foliage	1,000	0		0.0046	19,000
		Harvesting/ detassling	17,000	0		0.0785	1,100
Grapes (Table) (ST)	1.44	Hedge, irrigate, weed, scout, train, tie	500	0	3.231	0.0092	9,400
		Scout, train, tie	1,000	0		0.0185	4,700
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0923	940
		Cane turning, girdle	10,000	0		0.1846	470
Grapes (Table) (IT)	0.84	Hedge, irrigate, weed, scout, train, tie	500	0	1.885	0.0054	16,000
		Scout, train, tie	1,000	0		0.0108	8,100
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0539	1,600
		Cane turning, girdle	10,000	0		0.1077	810
Turf/ sod (ST)	3.12	Mowing	500	0	1.75	0.005	17,000
		Transplant, weed, harvest	6,800	0		0.068	1,300
Turf/ Sod (IT)	0.36	Mowing	500	0	0.202	0.001	150,000
		Transplant, weed, harvest	6,800	0		0.008	11,000

Table 8.2. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for AAAPD and AAASD

Crop & Exposure Duration	Application Rate (lb inert /A)	Work Activity	Transfer Coefficient[1] (cm^2/hr)	Day after Treatment[2]	DFR_t ($\mu g/cm^2$)[3]	Daily Dose (mg/kg/day)[4]	MOE[5]
Insecticide Product							
Corn (ST)	3	Scout, weed low foliage	100	0	6.731	0.0038	23,000
		Scout, weed high foliage	400	0		0.0154	5,700
		Scout, irrigate, weed high foliage	1,000	0		0.0385	2,300
		Harvesting/ detassling	17,000	0		0.6539	130
Corn (IT)	0.3	Scout, weed low foliage	100	0	0.673	0.0004	230,000
		Scout, weed high foliage	400	0		0.0015	57,000
		Scout, irrigate, weed high foliage	1,000	0		0.0038	23,000
		Harvesting/ detassling	17,000	0		0.0654	1,300
Grapes (Table) (ST)	2.1	Hedge, irrigate, weed, scout, train, tie	500	0	4.712	0.0135	6,500
		Scout, train, tie	1,000	0		0.0269	3,200
		Harvest, pull, thin, prune, train, tie	5,000	0		0.1346	650
		Cane turning, girdle	10,000	0		0.2693	320
Grapes (Table) (IT)	0.9	Hedge, irrigate, weed, scout, train, tie	500	0	2.019	0.0058	15,000
		Scout, train, tie	1,000	0		0.0113	7,500
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0577	1,500
		Cane turning, girdle	10,000	0		0.1154	750
Turf/ sod (ST)	3	Mowing	500	0	1.683	0.005	18,000
		Transplant, weed, harvest	6,800	0		0.065	1,300
Turf/ Sod (IT)	0.3	Mowing	500	0	0.168	0.0005	180,000
		Transplant, weed, harvest	6,800	0		0.007	13,000
Fungicide Products							
Corn (ST)	1.5	Scout, weed low foliage	100	0	3.366	0.0019	45,000
		Scout, weed	400	0		0.0077	11,000

Table 8.2. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for AAAPD and AAASD

Crop & Exposure Duration	Application Rate (lb inert /A)	Work Activity	Transfer Coefficient[1] (cm^2/hr)	Day after Treatment[2]	DFR_t ($\mu g/cm^2$)[3]	Daily Dose (mg/kg/day)[4]	MOE[5]
		high foliage					
		Scout, irrigate, weed high foliage	1,000	0		0.0192	4,500
		Harvesting/ detassling	17,000	0		0.327	270
Corn (IT)	0.3	Scout, weed low foliage	100	0	0.673	0.0004	230,000
		Scout, weed high foliage	400	0		0.0015	57,000
		Scout, irrigate, weed high foliage	1,000	0		0.0038	23,000
		Harvesting/ detassling	17,000	0		0.0654	1,300
Grapes (Table) (ST)	1.5	Hedge, irrigate, weed, scout, train, tie	500	0	3.366	0.0096	9,000
		Scout, train, tie	1,000	0		0.0192	4,500
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0962	900
		Cane turning, girdle	10,000	0		0.1923	450
Grapes (Table) (IT)	0.6	Hedge, irrigate, weed, scout, train, tie	500	0	1.346	0.0038	23,000
		Scout, train, tie	1,000	0		0.0077	11,000
		Harvest, pull, thin, prune, train, tie	5,000	0		0.0385	2,300
		Cane turning, girdle	10,000	0		0.0769	1,100
Turf/ sod (ST)	1.5	Mowing	500	0	0.841	0.002	36,000
		Transplant, weed, harvest	6,800	0		0.033	2,700
Turf/ Sod (IT)	0.3	Mowing	500	0	0.168	0.0005	180,000
		Transplant, weed, harvest	6,800	0		0.007	13,000

[1] Transfer coefficient from Science Advisory Council for Exposure: Policy Memo #003 "Agricultural Transfer Coefficients" 05/07/98.

2 DAT = Day After Treatment

[3] DFR = Application rate (lbs inert/acre) * fraction of active ingredient that remains on foliage (0.2 for crop, 0.05 for turf)* (1-D(10% dissipation))$^{(t=0)}$ * 4.54 µg/lb * 24.7 x10-9 acre/cm^2

[4] Daily Dose = DFR ($\mu g/cm^2$) * Tc (cm^2/hr) * (1 mg/1000 µg) * ET (8 hrs/day) * DA (5% dermal absorption) / body weight (70 kg)

[5] MOE = PoD (NOAEL of 87 mg/kg/day) / Daily Dose (mg/kg/day)

9.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the USDA under the Continuing Survey of Food Intake by Individuals (CSFII) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas postapplication are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

10.0 Human Studies

This assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide. These studies, listed below, have received the appropriate ethical review for use in risk assessment.

> The PHED Task Force, 1998. The Pesticide Handler Exposure Database (PHED), Version 1.1. Task Force members: Health Canada, U.S. Environmental Protection Agency, the California Department of Pesticide regulation, and the American Crop Protection Association; released August 1998.
>
> ORETF Handler Studies (MRID 44972201): Outdoor Residential Exposure Task
>
> MRID 466010-01: Human Exposure During and Following Use of a Pyrethrins/Piperonyl Butoxide/MGK-264 Shampoo Formulation on Dogs – Volume I & II
>
> MRID 446584-01: Dermal Exposure and Inhalation Exposure to Carbaryl by Commercial Pet Groomers during Applications of Adams™ Carbaryl Shampoo

Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642)

APPENDIX A. Toxicity Data

A.1. Toxicity Profiles for the AAAPD and AAASD Inerts

Table A.1.1 Acute Toxicity Profile of AAAPD and AAASD

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-1	Acute Oral - rat	JITF Cluster Support Team 2 submission (2009)	CAS 9004-82-4 C12 AAASD sodium salt 1600 mg/kg	III
81-2	Acute Dermal -rabbit	JITF Cluster Support Team 2 submission (2009)	CAS 39464-66-9 C12 AAAPD 5010 mg/kg	IV
81-3	Acute Inhalation – rat	Not available		
81-4	Primary Eye Irritation rabbit	JITF Cluster Support Team 2 submission (2009)	CAS 68891-38-3 C12-14 AAASD sodium salt Moderate to severe irritant	II
81-5	Primary Skin Irritation	JITF Cluster Support Team 2 submission (2009)	CAS 68891-38-3 C12-14 AAASD sodium salt Moderate to severe irritant	
81-6	Dermal Sensitization	JITF Cluster Support Team 2 submission (2009)	CAS 68891-38-3 C12-14 AAASD sodium salt Not skin sensitizer	

Table A.1.2 Toxicology Profile of AAAPD and AAASD Inerts		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3100 90-Day oral toxicity (Wistar HSD/Win:Wu rats) Oral gavage	MRID 47060901 (1994) 0%, 0.25%, 0.75%, or 2.25% (equivalent to 25, 75, and 225 mg/kg//day)mg/kg/day) (70% pure) Texapon N 70 CAS 68891-38-3 Linear C12 AAASD sodium salt with POE n=2-4 Acceptable/non-guideline	NOAEL = 75 mg/kg/day LOAEL = 225 mg/kg/day (HDT), based on increased incidences of hyperplasia, submucosal edema, and ulceration of the forestomach
870.3700a Prenatal developmental in Sprague-Dawley, CD® rats Oral gavage	MRID 47060902 (1994) 0, 100, 300, and 1000 mg/kg GD 6-15 (equivalent to doses of 0, 70, 210 and 700 mg/kg/day) (70.1% pure) TEXAPON N 70 CAS 68891-38-3 Linear C12 AAASD sodium salt with POE n=2-4 Acceptable/non-guideline	Maternal NOAEL = 700 mg/kg/day, HDT Maternal LOAEL = not identified Developmental NOAEL = 700 mg/kg/day, HDT Developmental LOAEL = Not identified

Table A.1.2 Toxicology Profile of AAAPD and AAASD Inerts

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3800 OECD 416 Reproduction and fertility effects Drinking water Wistar rats	MRID 47060903 (1999) MRID 47112401 (Addendum to MRID 47060903) 0, 0.03, 0.1, or 0.3% (equivalent to 0, 30, 100, or 300 mg/kg/day) (27% pure) Texapon NSO (sodium laurel ether sulfate) CAS 68891-38-3 Linear C12 AAASD sodium salt with POE n=2-4 acceptable/guideline Mean test substance intake: 0, 27.4, 86.6, 222.9 mg/kg/day for F0 males; 0, 39, 120.9, 316.2 mg/kg/day for P-F1a for females; 0, 38.8, 117.2, 337.9 mg/kg/day for P-F1b for females; 0, 38.6, 126, 333.5 mg/kg/day for F1 males; 0, 45, 149.5, 369.4 mg/kg/day for F1 females.	Parental NOAEL = 86.6 mg/kg/day in males Parental LOAEL = 222.9 mg/kg/day based on a dose-related decrease in absolute and relative liver weight and an increased incidence in the number of animals with "minimal" hepatocyte necrosis in males Parental NOAEL = 316.2 mg/kg/day in females Parental LOAEL = not identified in females Reproductive/Developmental/offspring NOAEL = 316.2 mg/kg/day Reproductive/Developmental/offspring LOAEL = not identified
OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test Oral gavage SD strain	MRID 47673901 (2009) 0, 25, 50, 200, or 800 mg/kg /day. (purity not available) CAS No. 68130-47-2 Saturated C8-C10 linear AAAPD with average POE n=3-20 Acceptable/Guideline	Parental systemic NOAEL = 200 mg/kg/day. parental systemic LOAEL = 800 mg/kg day based on clinical signs, reduced body weight, and lesions in the forestomach reproductive/developmental/offspring NOAEL = 800 mg/kg/day (HDT)

Table A.1.2 Toxicology Profile of AAAPD and AAASD Inerts

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test Oral gavage SD strain	MRID 47673902 (2009) 0, 25, 50, 200, or 800 mg/kg /day. (99.75% pure) CAS No. 78330-24-2 C11-C14 branched AAAPD with average POE n=3-20 Acceptable/Guideline	Parental systemic NOAEL = 200 mg/kg/day. parental systemic LOAEL = 800 mg/kg/day based on lesions in the forestomach and thymus atrophy in females reproductive/ NOAEL = 800 mg/kg /day (HDT) developmental/offspring NOAEL = 200 mg/kg/day developmental/offspring LOAEL = 800 mg/kg/day based on increased number of stillborn pups and pups dying and clinical observations
Two year drinking water rat study	JITF Cluster Support Team 2 submission (2009) CAS 68424-50-0 C12-15 AAASD sodium salt (POE n=3)	NOAEL = greater than 75 mg/kg/day (only dose tested)
Mouse lymphoma L5178 TK +/- gene mutation study	JITF Cluster Support Team 2 submission (2009) CAS 9004-82-4 C12 AAASD sodium salt	Negative

A.2. Executive Summaries

EXECUTIVE SUMMARY: In a 90-day oral toxicity study (MRID 47060901), Texapon N 70 (70.1% a.i.; Lot No. 198/3) was administered to groups of 10 HSD/Win:Wu male and female rats/sex/dose by gavage five days/week at concentrations of 0%, 0.25%, 0.75%, or 2.25% in the vehicle "aqua dest." (likely distilled water but not entirely clear as translated) at a volume of 10 ml/kg bw/day (equivalent to test doses on a nominal basis of 25, 75, and 225 mg/kg bw/day). Additional groups of five rats/sex/dose were treated similarly and evaluated following a 28-day recovery period to assess potential reversibility of toxic effects observed.

No treatment-related effects on body weight, food or water intake, hematology, clinical chemistry, ophthalmoscopic parameters, or effects on mortality or moribundity were found in male and female rats treated with up to 225 mg/kg/day for 90 days. No effects were found on the absolute or relative organ weight of treated rats, and no evidence of macro- or microscopic systemic toxicity was found. The forestomachs of most male and some female rats in the main study high-dose group showed increased incidences of hyperplasia, submucosal edema, and ulceration. The microscopic effects were consistent with those effects observed at necropsy. In general, the incidence and severity of the lesions were greater in male than female rats. Following the 28-day recovery period, no treatment-related effects were found in mid- and high-dose male and female rats. In high-dose male and female rats, the regeneration of the mucosa was incomplete. The incomplete regeneration was characterized by mild hyperplasia and a few inflammatory cells in the submucosa. No ulceration was observed in high-dose rats following the recovery period.

The LOAEL in male and female Wistar rats for Texapon N 70 is 225 mg/kg/day, based on increased incidence of forestomach lesions. A NOAEL was 75 mg/kg/day. At the end of the recovery period, hyperplasia and inflammation persisted in high-dose rats.

This 90-day oral toxicity study in the rat is **Acceptable/Non-Guideline** and does not satisfy the guideline requirement for a 90-day oral toxicity study (OPPTS 870.3100; OECD 408) in the rat. It is noted that animals were only treated for 5 days per week allowing a two day recovery period for test animals (only 68-69 treatments in this 90-day study). In addition, this results in dose levels significantly lower than those reported on the basis of "area under the curve". This is not an acceptable procedure and inconsistent with testing guidelines.

EXECUTIVE SUMMARY: In a prenatal developmental toxicity study (MRID 470609-02), Texapon N 70 (Lot/Batch # 198/3; 70.1% a.i.) was administered to 24 mated female Sprague-Dawley, CD® rats/dose by gavage at dose levels of 0, 100, 300, and 1000 mg/kg/ day (equivalent to doses of 0, 70, 210 and 700 mg a.i./kg/day). Rats were dosed from gestation day (GD) 6 to 15. Control animals were dosed with the distilled water vehicle. Dams were weighed on GD 0, 6, 16 and 20 and sacrificed on GD 20. The weights of the placenta and the uterus were also measured. Macroscopic examination of all maternal organs and microscopic examination of the uterus were conducted. Live fetuses were removed by Caesarian section, sexed, weighed and examined for gross external malformations. Fetuses were sacrificed and necropsied for visceral and skeletal abnormalities.

Oral administration of Texapon N 70 did not result in any mortality or clinical signs of toxicity in the treated dams. In addition, the body weight and body weight gains were comparable among control and treated groups. No compound-related differences were noted in mean post-implantation losses, mean numbers of resorptions, embryonic deaths, total number of fetuses and litter size. A statistically significant decrease in mean pre-implantation losses in mid-dose females (300 mg/kg bw/day), relative to controls, did not show a dose-response and was within the normal range of background variation for this rodent strain. Mean fetal, placental and uterine weights did not differ significantly among groups. A significant change in the fetal sex ratio (increased % males) in the high-dose group, as compared with controls, was reported to be within normal background variation and incidental to treatment.

No external, visceral or skeletal malformations were observed in the fetuses of treated dams in any dose groups as compared with controls. A significant increase in the number of fetuses with incomplete ossification of the hyoid bone (skeletal variant) occurred in the mid-dose group; however, there was no dose-response and this finding was considered to be a litter effect because it only occurred in a small number of litters.

The maternal and developmental NOAELs were both 700 mg/kg/day, the highest dose tested. The LOAELs could not be determined.

This prenatal developmental toxicity study in the rat is **ACCEPTABLE/NON-GUIDELINE** study and does not satisfy guideline requirements for a prenatal developmental toxicity study [OPPTS 870.3700] in rodents. An actual limit dose was not attained in this developmental toxicity study and no maternal toxicity was observed at the highest dose level tested. While the high dose level was reported to be 1000 mg/kg/day, since the inert ingredient only comprised 70% of the test material, the high dose level was only 700 mg/kg/day. As dosing was not apparently adjusted based on the most recent body weight, dosing on an mg/kg/day basis was actually lower than 700 mg/kg/day.

EXECUTIVE SUMMARY: In a reproduction and fertility effects study (MRID 47060903), Texapon NSO (Lot/Batch # 103/96; 27% a.i. in aqueous solution) were evaluated in CD (Sprague-Dawley) rats through two successive generations. The test article was administered orally via purified drinking water to three groups of 30 male and 30 female CD rats. Target drinking water concentrations were 0, 0.03, 0.1, or 0.3% (equivalent to 0, 30, 100, or 300 mg/kg/day). The control group received only vehicle. Drinking water concentrations of the test substance were reduced to 0.015, 0.05 and 0.15% for the low-, mid- and high-dose females, respectively, during lactation. The rationale given by the study author for these dose changes was to maintain a more constant test substance intake relative to body weight, based on the assumption that drinking water consumption would be significantly greater during lactation than during other periods. Mean test substance intake were as follows: 0, 27.4, 86.6 and 222.9 mg/kg/day for F_0 males; 0, 39, 120.9 and 316.2 for P-F_{1a} females; 0, 38.8, 117.2 and 337.9 for P-F_{1b} females; 0, 38.6, 126 and 333.5 for F_1 males; and 0, 45, 149.5 and 369.4 mg/kg/day for F_1 females. P females were sacrificed following weaning of the F_{1b} litters on LD 21. The P males were dosed for 11 weeks prior to mating and throughout the mating and postmating period. The P females were dosed for 2 weeks prior to mating and throughout the mating, gestation, and lactation periods. Due to a reduced number of litters (F_{1a}) in all groups (including the control)

relative to historical control data for the laboratory, P females were mated again following F_{1a} weaning on lactation day (LD 21) and a subsequent 2-week second premating interval. Each female was paired with a different male than the one used in the first mating to produce a second litter (F_{1b}). Dosing was continuous for P males until sacrifice after the second mating period and for P females during the second premating, mating, gestation, and lactation periods.

In the P generation, body weight gains varied sporadically but body weights and food consumption were generally comparable among groups during the premating and postmating periods for males and the premating, gestation and lactation periods for females. Drinking water consumption was significantly reduced in high-dose males and females during several weeks over the course of the study.

Absolute liver, brain and prostate gland weights were significantly reduced in high-dose P males. A statistically-significant dose-related reduction in relative liver weight (to body weight) was observed in males in all dose groups. A statistically-significant reduction in the relative liver weight (to brain weight) was only observed in high-dose males. No statistically-significant changes in either absolute or relative organ weights were noted in P females. High-dose males also exhibited an increased incidence in the number of animals with "minimal" hepatocyte necrosis (6/30 in the high-dose group compared to1/30 in the control group).

In the F_1 generation adults, body weight gains were statistically significantly reduced during the final week of lactation in all treated F_1 groups but mean terminal body weights did not differ among treated and control animals. Food consumption was comparable among groups, although mean drinking water consumption was significantly decreased during weeks 2-11 of the premating period in high-dose F_1 females and during GD 7-14 and 14-20 in high-dose F_1 animals. Terminal body weights did not differ significantly among F_1 groups of either sex. Significant reductions in absolute and relative (to body weight) liver weights were observed in mid- and high-dose F_1 males. Relative kidney weights were statistically increased in high-dose males.

No changes in measured fertility, mating, and reproductive indices and parameters were reported for either parental generation. Litter size, sex ratio, pup survival and viability, body weight, body weight gain, and measures of physical development were comparable among all groups in the F_1 and F_2 groups.

The LOAEL for the parental toxicity is 0.3% (222.9 mg/kg/day), based on a dose-related decrease in absolute (13%↓) and relative liver weights and an increased incidence in the number of animals with "minimal" hepatocyte necrosis in P males. The LOAEL for the parental toxicity is not identified in females. The NOAEL for the parental toxicity is 0.1% (86.6 mg/kg/day) in males and 0.3% (316.2 mg/kg/day) in females.

The LOAEL for the reproductive/developmental toxicity is not identified. The NOAEL for the reproductive toxicity/developmental is 0.3% (316.2 mg/kg/day).

This study is classified as **Acceptable/Guideline**. It satisfies the guideline requirements for a two-generation reproductive study (OPPTS 870.3800; OECD 416) in rats.

EXECUTIVE SUMMARY: In a Combined Repeated Dose Toxicity Study with a Reproduction/Developmental Toxicity Screening Test (MRID 47673901), (C8-C10) Poly(oxy-1,2-ethanediyl),α-hydro-ω-hydroxy-, mono-C8-10-alkyl ethers, phosphates (PHEP; CAS # 68130-47-2; Lot # 1160482, purity not available due to no developed analytical method) was administered to 10 Crl:CD(SD) rats/sex/dose by gavage at dose levels of 0, 25, 50, 200, or 800 mg/kg bw/day.

Excessive salivation (slight to severe) was a frequent observation throughout the experimental period in both sexes at the 800 mg/kg dose level, as were rales (lung sounds) in male rats at this dose. Rales were observed in 4/10 females at the high dose, and in 4/10 males at the next lower dose (200 mg/kg/day).

Mean body weight gain was reduced in male rats in the 800 mg/kg dose group throughout the study, but only significantly so ($p<0.01$) during the first two weeks of treatment. Body weight was not affected in females at the high dose until gestation. Maternal body weight gain in the 800 mg/kg/day dose group was significantly reduced on days 0 to 7 (-55% relative to controls) and 0 to 20 (-16%) of gestation, and in the 200 mg/kg/day dose group during GD 0-20 by -14%. Food consumption was decreased by 16% in males at the highest PHEP dose level ($p<0.05$). There were no body weight or food consumption effects at the two lowest dose levels.

No effect was observed on functional observation battery or motor activity measurements at any PHEP dose. There were no significant or biologically meaningful differences in estrous cycling, clinical chemistry, and hematology observations between the control and treated groups. Mating, fertility, and litter parameters (for example, implantation sites/litter, number born live/litter, number of litters, mean litter size) were not affected by the test material.

The absolute weight of the liver in high dose females was increased (12.6%; not significant), and the weight of the liver relative to both body and brain weights ($p<0.01$; $p<0.05$) was significantly increased. Minimal extramedullary hematopoiesis was observed in the liver of male (1/5) and female (2/4) rats from the high dose group. Microscopic changes related to PHEP were observed in the non-glandular stomach (forestomach) of all rats examined (both sexes) from the 800 mg/kg dose group. These changes consisted of mild to moderate hyperplasia and hyperkeratosis of the nonglandular epithelium (severity of 2 to 3 on a scale of 4), often accompanied by minimal to moderate inflammation of the submucosa (severity = 1 - 3).

There were no adverse clinical signs or adverse effect on pup weight observed in the F_1 generation pups. All of the pups appeared normal during necropsy examination.

The repeated oral toxicity LOAEL for PHEP in rats is 800 mg/kg based on clinical signs, reduced body weight, and lesions in the forestomach. The NOAEL in rats is 200 mg/kg/day.

A reproductive/developmental LOAEL was not demonstrated in this study. The reproductive/developmental NOAEL in rats is 800 mg/kg/day.

This study is **Acceptable/Guideline** and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test

(OECD 422) in the rat. Study deficiencies are noted, most of which can be addressed by providing additional historical control data on rats of this strain and age.

EXECUTIVE SUMMARY: In a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (MRID 47673902), iso C11-C14 branched phosphate alkyl ether (99.75% a.i.; Batch no. U87J242831) was administered to ten Crl:CD(SD) rats/sex/dose by gavage at dose levels of 0, 25, 50, 200 or 800 mg/kg/day. Parental animals were administered either the vehicle (controls) or the test substance solutions beginning 14 days prior to mating with males receiving a total of at least 46 doses. Females continued with treatment through the day of sacrifice which was gestation day (GD) 24 for rats not delivering a litter or lactation day (LD) 4 for rats delivering a litter. Five rats/sex/group were given a functional observational battery (FOB) and motor activity assessment and the other five/sex/group were used for hematology, clinical chemistry and histopathological examination.

There were no treatment-related effects in parental animals on mortality, FOB, motor activity, reproductive parameters, hematology or clinical chemistry parameters and organ weight. Adverse clinical signs observed in the 800 mg/kg/day animals included increased salivation, rales (males only) and urine-stained abdominal fur. The 800 mg/kg/day females also had increased incidence of un-groomed coats and dehydration during gestation, compared to the controls.

Body weight and food consumption were not affected with treatment in either the males or females during the pre-mating period. Males gained 14% less weight than the controls for the entire treatment period (days 1-46). The 800 mg/kg/day females during gestation and lactation had decreases, although not statistically significant, of body weight, body weight gain and food consumption. Mean weight gain during gestation was 20% less than that of controls and during lactation days 1-4, control females gained 3.3 grams and the 800 mg/kg/day females lost 5.3 grams.

One to three females out of five in the 800 mg/kg group had thickening of the squamous mucosa in the non-glandular stomach (forestomach) due to hyperplasia and hyperkeratosis as well as ulcers, inflammation and edema. These lesions were not observed in any of the 800 mg/kg males. Two of the females with the forestomach lesions also had marked thymic atrophy.

The parental LOAEL is 800 mg/kg bw/day based on clinical signs in both genders and gastric irritation and thymus atrophy in the females. The parental NOAEL is 200 mg/kg bw/day.

Effects were observed in the pups from dams treated with 800 mg/kg/day. The number of stillbirths and pups dying within LD 4/5 were increased when compared to controls and the viability index in the group was 88% versus 98% in the control pups. The 800 mg/kg/day pups also were observed to have coldness to the touch, discolored heads, and a lack of nesting behavior.

The reproductive NOAEL are 800 mg/kg bw/day, the highest dose tested. The reproductive NOAELs were not obtained.

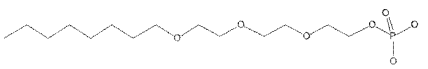
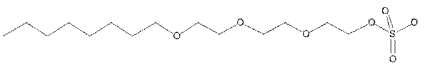
The developmental/offspring LOAEL is 800 mg/kg bw/day in male and female pups based on the increased number of stillborn pups and pups dying and clinical observations. The developmental/offspring NOAEL is 200 mg/kg bw/day.

This study is **Acceptable/Guideline** and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OPPTS 870.3650; OECD 422) in rats.

APPENDIX B. Structure-Activity Relationship (SAR) Discussion

HED used DEREK for Windows (V. 11) to assess the potential toxicity of compounds in the inerts mixture. As described in Section 3 of this document these compounds are Alkyl Alcohol Alkoxylate Phosphate (AAAPD) and Alkyl Alcohol Alkoxylate Sulfate Derivatives (AAASD) are comprised of a hydrophobic aliphatic alcohol moiety, a hydrophilic polyalkoxylate backbone with either a phosphate or sulfate derivative (ester or salt) terminating group. A representative phosphate compound and a representative sulfate compound were subjected to DEREK analysis and are shown in Figure B-1 below.

Figure B-1. Structure of Compound Subjected to Structure-Activity Analysis

	
Example Phosphate	Example Sulfate

Derek for Windows (LHASA Ltd.) is an expert system for the prediction of toxicity. It relies on a knowledge base of structural alerts and rules developed by scientists. When a test compound is inputted into the program, Derek for Windows scans the test compound for structural alerts contained within its database that are associated with specific toxicological endpoints and applies a series of reasoning rules to determine the likelihood of toxicity for the test compound. Information is provided on the rules used to make the prediction, along with descriptions of structural alerts identified, comments, available example compounds linked to the alerts and literature references.

DEREK did not identify any structural alerts of concern for the chemicals screened. DEREK has developed more alerts for genotoxicity and carcinogenicity than other endpoints in the system. Considering what is already known about these specific compounds and other long-chain fatty acid compounds, along with the lack of structural alerts for carcinogenicity, chronic toxicity, or genotoxicity, HED has no specific concerns regarding chronic exposures other than those identified in the toxicity studies for this cluster.

APPENDIX C. Drinking Water Surrogate Analysis

Summary of Drinking Water Estimates of Four Surrogate Inert Chemicals

Notes:

1. Used a North Carolina cotton scenario with application date on July 1. This scenario should be a good representative of the numbers that you can expect from EFED. Also tried manipulation of application dates and weather files to ensure that there are no aberrations; these values look good in that regard.

2. PCA factors were not applied, but the impact of applying such factors (i.e., 0.5 to 0.9) would be insignificant in comparison to the vast uncertainties surrounding generation of concentrations from surrogate chemicals as well as uncertainties regarding the actual timing of applications.

3. All simulations were made at approximately 1 lb/A. Concentrations resulting from other application rates will be directly proportional to the application rate.

4. Table 1 gives the normalized concentration estimates for the case where all mass is applied on a single day. This should be the most conservative case.

5. Table 2 gives the normalized concentration estimates for the case where mass is distributed evenly over a 100-day period (April to June).

6. A range of degradation rates were used because degradation information was not available. 3 simulations were made 1) chemically stable in water and soil, 2) a 100 day half life in water and soil, and 3) a 10-day half life in water and soil. This should cover degradation.

7. Table 3 gives the chemical inputs used in the simulations.

Table 1. DW concentration for application lumped on a single day. (This maximizes the acute concentrations.) All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Estimates based on Stable Assumption				
Acute (ppb)	1.1	41	33	0.005
Chronic	0.69	15	19	0.003
Cancer	0.47	12	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
Acute (ppb)	0.74	36	22	0.003
Chronic	0.33	8.8	7.7	0.002
Cancer	0.25	6.4	6.4	0.001
Estimates based on assumption of a 10-day half life in soil and water				
Acute (ppb)	0.48	25	15	0.002
Chronic	0.04	1.1	0.96	0.0002
Cancer	0.03	0.65	0.60	0.0002

Table 2. DW concentration for applications spread out over a 100-day period. This simulates a more even distribution of pesticide over the growing season. All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Spread Out Values				
Estimates based on Stable Assumption				
Acute (ppb)	0.98	29	28	0.004
Chronic	0.70	13	18	0.003
Cancer	0.48	10	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
	0.57	21	17	0.003
	0.36	6.9	7.2	0.002
	0.27	5.3	6.4	0.001
Estimates based on assumption of a 10-day half life in soil and water				
	0.16	7.8	4.3	0.001
	0.04	0.79	0.77	0.0002
	0.03	0.61	0.63	0.0002

Table 3 Chemical Inputs used in Simulations.

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Chemical Inputs:				
MW	*928*	*274*	*302*	*1185*
Solubility (mg/L)	*382*	*299*	*19.5*	*6.69e-8*
V.P. (mmHg)	*5.8e-27*	*1.76e-8*	*3.86e-8*	*3.77e-33*
Koc (ml/g)	*9.44e6*	*152*	*1345*	*2.57e9*

APPENDIX D. Dietary Input and Output Files

D.1. Chronic Dietary Exposure and Risk Assessment Results

U.S. Environmental Protection Agency Ver. 2.00
DEEM-FCID Chronic analysis for INERTS CST 2 (AAAPD) (1994-98 data)
Residue file name: C:\Deemfcid\inerts\Inerts_57active_CST2_30%_100ppbH2Orev2.R98
Adjustment factor #2 used.
Analysis Date 05-27-2009/15:51:15 Residue file dated: 05-27-2009/15:50:11/8
Reference dose (RfD, Chronic) = .87 mg/kg bw/day
COMMENT 1: Inert 57 active ingredients + drinking water (100ppb); 30% formulation

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.115748	13.3%
U.S. Population (spring season)	0.118143	13.6%
U.S. Population (summer season)	0.117146	13.5%
U.S. Population (autumn season)	0.113702	13.1%
U.S. Population (winter season)	0.114059	13.1%
Northeast region	0.125718	14.5%
Midwest region	0.115129	13.2%
Southern region	0.103688	11.9%
Western region	0.126614	14.6%
Hispanics	0.121976	14.0%
Non-hispanic whites	0.113456	13.0%
Non-hispanic blacks	0.111973	12.9%
Non-hisp/non-white/non-black	0.149214	17.2%
All infants (< 1 year)	0.241013	27.7%
Nursing infants	0.128652	14.8%
Non-nursing infants	0.283670	32.6%
Children 1-6 yrs	0.298678	34.3%
Children 7-12 yrs	0.144669	16.6%
Females 13-19 (not preg or nursing)	0.083957	9.7%
Females 20+ (not preg or nursing)	0.090416	10.4%
Females 13-50 yrs	0.093530	10.8%
Females 13+ (preg/not nursing)	0.099125	11.4%
Females 13+ (nursing)	0.116724	13.4%
Males 13-19 yrs	0.089537	10.3%
Males 20+ yrs	0.087241	10.0%
Seniors 55+	0.092286	10.6%
Children 1-2 yrs	0.375655	43.2%
Children 3-5 yrs	0.278347	32.0%
Children 6-12 yrs	0.153995	17.7%
Youth 13-19 yrs	0.087082	10.0%
Adults 20-49 yrs	0.087428	10.0%
Adults 50+ yrs	0.092074	10.6%
Females 13-49 yrs	0.088018	10.1%

D.2. Dietary Exposure and Risk Assessment Input Files

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U.S. Environmental Protection Agency                                Ver. 2.00
DEEM-FCID Chronic analysis for INERTS CST 2 (AAAPD)               1994-98 data
Residue file: C:\Deemfcid\inerts\Inerts_57active_CST2_30%_100ppbH2Orev2.R98
                                                                Adjust. #2 used
Analysis Date 05-27-2009            Residue file dated: 05-27-2009/15:50:11/8
Reference dose (RfD) = 0.87 mg/kg bw/day
Comment:Inert 57 active ingredients + drinking water (100ppb); 30% formulation
--------------------------------------------------------------------------------
Food Crop                                          Residue       Adj.Factors      Comment
EPA Code  Grp  Food Name                             (ppm)
                                                                 #1        #2
-------- ---- ------------------------------   ---------- ------     ------   -------
95000010 O    Acerola                              2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
18000020 18   Alfalfa, seed                       0.500000   1.000      0.600   glypho
  Full comment: glyphosate
14000030 14   Almond                               1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
14000031 14   Almond-babyfood                      1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
14000040 14   Almond, oil                          1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
14000041 14   Almond, oil-babyfood                 1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
04010050 4A   Amaranth, leafy                    100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
95000060 O    Amaranth, grain                      5.000000   1.000      0.600   glypho
  Full comment: glyphosate [wheat]
11000070 11   Apple, fruit with peel              25.000000   1.000      0.600   captan
11000080 11   Apple, peeled fruit                 25.000000   1.000      0.600   captan
11000081 11   Apple, peeled fruit-babyfood        25.000000   1.000      0.600   captan
11000090 11   Apple, dried                        25.000000   8.000      0.600   captan
11000091 11   Apple, dried-babyfood               25.000000   8.000      0.600   captan
11000100 11   Apple, juice                        25.000000   1.000      0.600   captan
11000101 11   Apple, juice-babyfood               25.000000   1.000      0.600   captan
11000110 11   Apple, sauce                        25.000000   1.000      0.600   captan
11000111 11   Apple, sauce-babyfood               25.000000   1.000      0.600   captan
12000120 12   Apricot                             15.000000   1.000      0.600   TM
12000121 12   Apricot-babyfood                    15.000000   1.000      0.600   TM
12000130 12   Apricot, dried                      15.000000   6.000      0.600   TM
12000140 12   Apricot, juice                      15.000000   1.000      0.600   TM
12000141 12   Apricot, juice-babyfood             15.000000   1.000      0.600   TM
01030150 1CD  Arrowroot, flour                     1.000000   1.000      0.600   diuron
  Full comment: diuron (potato transl]
01030151 1CD  Arrowroot, flour-babyfood            1.000000   1.000      0.600   diuron
  Full comment: diuron (potato transl]
95000160 O    Artichoke, globe                     5.000000   1.000      0.600   permet
  Full comment: permethrin
01030170 1CD  Artichoke, Jerusalem                 1.000000   1.000      0.600   diuron
  Full comment: diuron (potato transl]
04010180 4A   Arugula                            100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
95000190 O    Asparagus                           10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95000200 O    Avocado                             25.000000   1.000      0.600   fosety
  Full comment: fosetyl-al
09020210 9B   Balsam pear                         15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
95000220 O    Bamboo, shoots                       0.200000   1.000      0.600   glypho
  Full comment: glyphosate
95000230 O    Banana                              10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95000231 O    Banana-babyfood                     10.000000   1.000      0.600   carbar
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  Full comment: carbaryl
95000240 O    Banana, dried                    10.000000   3.900      0.600   carbar
  Full comment: carbaryl
95000241 O    Banana, dried-babyfood           10.000000   3.900      0.600   carbar
  Full comment: carbaryl
15000250 15   Barley, pearled barley           20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15000251 15   Barley, pearled barley-babyfood  20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15000260 15   Barley, flour                    20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15000261 15   Barley, flour-babyfood           20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15000270 15   Barley, bran                     30.000000   1.000      0.600   glypho
  Full comment: glyphosate for bran
19010280 19A  Basil, fresh leaves               50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19010281 19A  Basil, fresh leaves-babyfood      50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19010290 19A  Basil, dried leaves              260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19010291 19A  Basil, dried leaves-babyfood     260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
06030300 6C   Bean, black, seed                 7.000000   1.000      0.600   maneb
06020310 6B   Bean, broad, succulent           10.000000   1.000      0.600   maneb;
  Full comment: maneb;carbaryl (CG 6)
06030320 6C   Bean, broad, seed                 7.000000   1.000      0.600   maneb
06020330 6B   Bean, cowpea, succulent          10.000000   1.000      0.600   maneb;
  Full comment: maneb;carbaryl (CG 6)
06030340 6C   Bean, cowpea, seed                5.000000   1.000      0.600   carbar
  Full comment: carbaryl
06030350 6C   Bean,  great northern, seed       7.000000   1.000      0.600   maneb
06030360 6C   Bean, kidney, seed                7.000000   1.000      0.600   maneb
06020370 6B   Bean, lima, succulent            10.000000   1.000      0.600   maneb;
  Full comment: maneb;carbaryl (CG 6)
06030380 6C   Bean, lima, seed                  7.000000   1.000      0.600   maneb
06030390 6C   Bean, mung, seed                  2.000000   1.000      0.600   triflu
  Full comment: trifluralin
06030400 6C   Bean, navy, seed                  7.000000   1.000      0.600   maneb
06030410 6C   Bean, pink, seed                  7.000000   1.000      0.600   maneb
06030420 6C   Bean, pinto, seed                 7.000000   1.000      0.600   maneb
06010430 6A   Bean, snap, succulent             5.000000   1.000      0.600   chloro
  Full comment: chlorothalonil
06010431 6A   Bean, snap, succulent-babyfood    5.000000   1.000      0.600   chloro
  Full comment: chlorothalonil
21000440 M    Beef, meat                        2.000000   1.000      0.600   endosu
  Full comment: endosulfuran
21000441 M    Beef, meat-babyfood               2.000000   1.000      0.600   endosu
  Full comment: endosulfuran
21000450 M    Beef, meat, dried                 2.000000   1.920      0.600   endosu
  Full comment: endosulfuran
21000460 M    Beef, meat byproducts             1.000000   1.000      0.600   diuron
21000461 M    Beef, meat byproducts-babyfood    1.000000   1.000      0.600   diuron
21000470 M    Beef, fat                        13.000000   1.000      0.600   endosu
  Full comment: endosufuran
21000471 M    Beef,fat-babyfood                13.000000   1.000      0.600   endosu
  Full comment: endosufuran
21000480 M    Beef, kidney                      4.000000   1.000      0.600   glypho
  Full comment: glyphosate; 2,4-D
21000490 M    Beef, liver                       5.000000   1.000      0.600   endosu
  Full comment: endosulfuran
21000491 M    Beef, liver-babyfood              5.000000   1.000      0.600   endosu
  Full comment: endosulfuran
01010500 1AB  Beet, garden, roots               5.000000   1.000      0.600   carbar
  Full comment: carbaryl
01010501 1AB  Beet, garden, roots-babyfood      5.000000   1.000      0.600   carbar
  Full comment: carbaryl
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02000510 2    Beet, garden, tops                50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin (CG 2)
01010520 1A   Beet, sugar                       15.000000   1.000      0.600   chlorp
  Full comment: chlorpyrifos
01010521 1A   Beet, sugar-babyfood              15.000000   1.000      0.600   chlorp
  Full comment: chlorpyrifos
01010530 1A   Beet, sugar, molasses             15.000000   1.000      0.600   chlorp
  Full comment: chlorpyrifos
01010531 1A   Beet, sugar, molasses-babyfood    15.000000   1.000      0.600   chlorp
  Full comment: chlorpyrifos
95000540 O    Belgium endive                   100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
13010550 13A  Blackberry                        40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13010560 13A  Blackberry, juice                40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13010561 13A  Blackberry, juice-babyfood       40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13020570 13B  Blueberry                        40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13020571 13B  Blueberry-babyfood               40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13010580 13A  Boysenberry                      40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
14000590 14   Brazil nut                        1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
95000600 O    Breadfruit                        0.200000   1.000      0.600   glypho
  Full comment: glyphosate
05010610 5A   Broccoli                         60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
05010611 5A   Broccoli-babyfood                60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
05010620 5A   Broccoli, Chinese                60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
05020630 5B   Broccoli raab                    60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
05010640 5A   Brussels sprouts                 60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
15000650 15   Buckwheat                         0.100000   1.000      0.600   metola
  Full comment: metolachlor
15000660 15   Buckwheat, flour                  0.100000   1.000      0.600   metola
  Full comment: metolachlor
01010670 1AB  Burdock                          10.000000   1.000      0.600   carbar
  Full comment: carbaryl (carrot)
14000680 14   Butternut                         1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
05010690 5A   Cabbage                          60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
05020700 5B   Cabbage, Chinese, bok choy       60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
05010710 5A   Cabbage, Chinese, napa           60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
05010720 5A   Cabbage, Chinese, mustard        60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
95000730 O    Cactus                            0.500000   1.000      0.600   glypho
  Full comment: glyphosate
95000740 O    Canistel                          2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
09010750 9A   Cantaloupe                       15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
04020760 4B   Cardoon                         100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
95000770 O    Carob                             0.050000   1.000      0.600   chloro
  Full comment: chlorothanil
01010780 1AB  Carrot                          10.000000   1.000      0.600   carbar
  Full comment: carbaryl
01010781 1AB  Carrot-babyfood                 10.000000   1.000      0.600   carbar
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  Full comment: carbaryl
01010790 1AB  Carrot, juice                          10.000000   1.000      0.600   carbar
  Full comment: carbaryl
09010800 9A   Casaba                                 15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
14000810 14   Cashew                                  1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
01030820 1CD  Cassava                                 1.000000   1.000      0.600   diuron
  Full comment: diuron [potato transl]
01030821 1CD  Cassava-babyfood                        1.000000   1.000      0.600   diuron
  Full comment: diuron [potato transl]
05010830 5A   Cauliflower                            60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
01010840 1AB  Celeriac                               10.000000   1.000      0.600   carbar
  Full comment: carbaryl (carrot)
04020850 4B   Celery                                100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
04020851 4B   Celery-babyfood                       100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
04020860 4B   Celery, juice                         100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
04020870 4B   Celtuce                               100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
09020880 9B   Chayote, fruit                         15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
95000890 O    Cherimoya                               2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
12000900 12   Cherry                                 50.000000   1.000      0.600   captan
12000901 12   Cherry-babyfood                        50.000000   1.000      0.600   captan
12000910 12   Cherry, juice                          50.000000   1.000      0.600   captan
12000911 12   Cherry, juice-babyfood                 50.000000   1.000      0.600   captan
14000920 14   Chestnut                                1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
40000930 P    Chicken, meat                           5.000000   1.000      0.600   carbar
  Full comment: carbaryl
40000931 P    Chicken, meat-babyfood                  5.000000   1.000      0.600   carbar
  Full comment: carbaryl
40000940 P    Chicken, liver                          5.000000   1.000      0.600   iprodi
  Full comment: iprodione
40000950 P    Chicken, meat byproducts                1.000000   1.000      0.600   glypho
  Full comment: glyphosate
40000951 P    Chicken, meat byproducts-babyfoo        1.000000   1.000      0.600   glypho
  Full comment: glyphosate
40000960 P    Chicken, fat                            5.000000   1.000      0.600   carbar
  Full comment: carbaryl
40000961 P    Chicken, fat-babyfood                   5.000000   1.000      0.600   carbar
  Full comment: carbaryl
40000970 P    Chicken, skin                           5.000000   1.000      0.600   carbar
  Full comment: carbaryl
40000971 P    Chicken, skin-babyfood                  5.000000   1.000      0.600   carbar
  Full comment: carbaryl
06030980 6C   Chickpea, seed                          7.000000   1.000      0.600   maneb
06030981 6C   Chickpea, seed-babyfood                 7.000000   1.000      0.600   maneb
06030990 6C   Chickpea, flour                         7.000000   1.000      0.600   maneb
01011000 1AB  Chicory, roots                         10.000000   1.000      0.600   carbar
  Full comment: carbaryl [carrot]
02001010 2    Chicory, tops                          50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin (CG 2)
09021020 9B   Chinese waxgourd                       15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
19011030 19A  Chive
              110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                     50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
              210-Cooked; Fresh or N/S; Cook Meth N/S
                                                     50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
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               211-Cooked; Fresh or N/S; Baked 50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
               212-Cooked; Fresh or N/S; Boiled
                                               50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
               213-Cooked; Fresh or N/S; Fried 50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
               221-Cooked; Frozen; Baked       50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
               240-Cooked; Canned; Cook Meth N/S
                                               50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
               242-Cooked; Canned; Boiled      50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herbs]
04011040 4A   Chrysanthemum, garland          100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
19021050 19B  Cinnamon                         38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
19021051 19B  Cinnamon-babyfood               38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
10001060 10   Citrus citron                   10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10001070 10   Citrus hybrids                  10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10001080 10   Citrus, oil                     10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
95001090 O    Cocoa bean, chocolate            0.050000   1.000      0.600   chloro
  Full comment: chlorothalonil
95001100 O    Cocoa bean, powder               0.050000   1.000      0.600   chloro
  Full comment: chlorothalonil
95001110 O    Coconut, meat                    0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95001111 O    Coconut- meat-babyfood           0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95001120 O    Coconut, dried                   0.100000   2.100      0.600   glypho
  Full comment: glyphosate
95001130 O    Coconut, milk                    0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95001140 O    Coconut, oil                     0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95001141 O    Coconut, oil-babyfood            0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95001150 O    Coffee, roasted bean             1.000000   1.000      0.600   glypho
  Full comment: glyphosate
95001160 O    Coffee, instant                  1.000000   1.000      0.600   glypho
  Full comment: glyphosate
05021170 5B   Collards                        60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
19011180 19A  Coriander, leaves                30.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19011181 19A  Coriander, leaves-babyfood       30.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19021190 19B  Coriander, seed                  38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
19021191 19B  Coriander, seed-babyfood         38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
15001200 15   Corn, field, flour               0.150000   1.000      0.600   lambda
  Full comment: lambda-cyhalothrin
15001201 15   Corn, field, flour-babyfood      0.150000   1.000      0.600   lambda
  Full comment: lambda-cyhalothrin
15001210 15   Corn, field, meal                1.000000   1.000      0.600   glypho
  Full comment: glyphosate
15001211 15   Corn, field, meal-babyfood       1.000000   1.000      0.600   glypho
  Full comment: glyphosate
15001220 15   Corn, field, bran                1.000000   1.000      0.600   glypho
  Full comment: glyphosate
15001230 15   Corn, field, starch              1.000000   1.000      0.600   glypho
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  Full comment: glyphosate
15001231 15   Corn, field, starch-babyfood       1.000000   1.000      0.600   glypho
  Full comment: glyphosate
15001240 15   Corn, field, syrup                 1.000000   1.500      0.600   glypho
  Full comment: glyphosate
15001241 15   Corn, field, syrup-babyfood        1.000000   1.500      0.600   glypho
  Full comment: glyphosate
15001250 15   Corn, field, oil                   3.000000   1.000      0.600   chloro
  Full comment: chloropyrifos
15001251 15   Corn, field, oil-babyfood          3.000000   1.000      0.600   chloro
  Full comment: chloropyrifos
15001260 15   Corn, pop                          0.500000   1.000      0.600   mancoz
  Full comment: mancozeb
15001270 15   Corn, sweet                        5.000000   1.000      0.600   maneb;
  Full comment: maneb;carbaryl
15001271 15   Corn, sweet-babyfood               5.000000   1.000      0.600   maneb;
  Full comment: maneb;carbaryl
95001280 O    Cottonseed, oil                   35.000000   1.000      0.600   glypho
  Full comment: glyphosate
95001281 O    Cottonseed, oil-babyfood          35.000000   1.000      0.600   glypho
  Full comment: glyphosate
11001290 11   Crabapple                         20.000000   1.000      0.600   phosme
  Full comment: phosmet
95001300 O    Cranberry                         10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95001301 O    Cranberry-babyfood                10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95001310 O    Cranberry, dried                  10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95001320 O    Cranberry, juice                  10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95001321 O    Cranberry, juice-babyfood         10.000000   1.000      0.600   carbar
  Full comment: carbaryl
04011330 4A   Cress, garden                    100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
04011340 4A   Cress, upland                    100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
09021350 9B   Cucumber                          15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
13021360 13B  Currant                          40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13021370 13B  Currant, dried                   40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
04011380 4A   Dandelion, leaves                100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
01031390 1CD  Dasheen, corm                      1.000000   1.000      0.600   diuron
  Full comment: diuron [potato transl]
02001400 2    Dasheen, leaves                   50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin (CG 2)
95001410 O    Date                               0.200000   1.000      0.600   glypho
  Full comment: glyphosate
13011420 13A  Dewberry                         40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
19021430 19B  Dill, seed                        38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
19011440 19A  Dillweed                         50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herb]
70001450 P    Egg, whole                         1.500000   1.000      0.600   iprodi
  Full comment: iprodione
70001451 P    Egg, whole-babyfood                1.500000   1.000      0.600   iprodi
  Full comment: iprodione
70001460 P    Egg, white                         1.500000   1.000      0.600   iprodi
  Full comment: iprodione
70001461 P    Egg, white (solids)-babyfood       1.500000   1.000      0.600   iprodi
  Full comment: iprodione
70001470 P    Egg, yolk                          1.500000   1.000      0.600   iprodi
  Full comment: iprodione
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70001471 P    Egg, yolk-babyfood                1.500000   1.000      0.600   iprodi
  Full comment: iprodione
08001480 8    Eggplant                         10.000000   1.000      0.600   carbar
  Full comment: carbaryl
13021490 13B  Elderberry                       40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
04011500 4A   Endive                          100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
95001510 O    Feijoa                           2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
04021520 4B   Fennel, Florence                100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
95001530 O    Fig                              7.000000   1.000      0.600   maneb
95001540 O    Fig, dried                       7.000000   1.000      0.600   maneb
14001550 14   Filbert                          1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
14001560 14   Filbert, oil                     1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
80001570 F    Fish-freshwater finfish          2.000000   1.000      0.600   diuron
  Full comment: diuron [catfish]
80001580 F    Fish-freshwater finfish, farm ra 2.000000   1.000      0.600   diuron
80001590 F    Fish-saltwater finfish, tuna     2.000000   1.000      0.600   diuron
  Full comment: diuron [catfish]
80001600 F    Fish-saltwater finfish, other    2.000000   1.000      0.600   diuron
  Full comment: diuron [catfish]
80001610 F    Fish-shellfish, crustacean       3.000000   1.000      0.600   glypho
  Full comment: glyphosate [shellfish]
80001620 F    Fish-shellfish, mollusc          3.000000   1.000      0.600   glypho
  Full comment: glyphosate [shellfish]
20001630 20   Flaxseed, oil                    5.000000   1.000      0.600   carbar
  Full comment: carbaryl
03001640 3    Garlic                           0.200000   1.000      0.600   glypho
  Full comment: glyphosate (CG 3)
03001650 3    Garlic, dried                    0.200000   1.000      0.600   glypho
  Full comment: glyphosate (CG 3)
03001651 3    Garlic, dried-babyfood           0.200000   1.000      0.600   glypho
  Full comment: glyphosate (CG 3)
01031660 1CD  Ginger                           0.200000   1.000      0.600   glypho
  Full comment: glyphosate
01031661 1CD  Ginger-babyfood                  0.200000   1.000      0.600   glypho
  Full comment: glyphosate
01031670 1CD  Ginger, dried                    0.200000   1.000      0.600   glypho
  Full comment: glyphosate
01011680 1AB  Ginseng, dried                   4.000000   1.000      0.600   iprodi
  Full comment: iprodione
23001690 M    Goat, meat                       2.000000   1.000      0.600   endosu
  Full comment: endosulfan
23001700 M    Goat, meat byproducts            1.000000   1.000      0.600   diuron
  Full comment: diuron; propanil
23001710 M    Goat, fat                       13.000000   1.000      0.600   endosu
  Full comment: endosulfan
23001720 M    Goat, kidney                     4.000000   1.000      0.600   endosu
  Full comment: endosulfan; 2,4-D
23001730 M    Goat, liver                      5.000000   1.000      0.600   endosu
  Full comment: endosulfan
13021740 13B  Gooseberry                      40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
95001750 O    Grape                           25.000000   1.000      0.600   captan
95001760 O    Grape, juice                    25.000000   1.000      0.600   captan
95001761 O    Grape, juice-babyfood           25.000000   1.000      0.600   captan
95001770 O    Grape, leaves                   25.000000   1.000      0.600   captan
95001780 O    Grape, raisin                   25.000000   1.000      0.600   captan
95001790 O    Grape, wine and sherry          25.000000   1.000      0.600   captan
10001800 10   Grapefruit                      10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10001810 10   Grapefruit, juice               10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
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06031820 6C   Guar, seed                          7.000000   1.000      0.600   maneb
06031821 6C   Guar, seed-babyfood                7.000000   1.000      0.600   maneb
95001830 O    Guava                              2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95001831 O    Guava-babyfood                     2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19011840 19A  Herbs, other
              110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              150-Uncooked; Cured etc; Cook Meth N/S
                                                50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              210-Cooked; Fresh or N/S; Cook Meth N/S
                                                50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              211-Cooked; Fresh or N/S; Baked 50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              212-Cooked; Fresh or N/S; Boiled
                                                50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              213-Cooked; Fresh or N/S; Fried 50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              215-Cooked; Fresh or N/S; Boiled/baked
                                                50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              221-Cooked; Frozen; Baked         50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              230-Cooked; Dried; Cook Meth N/S
                                               260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              232-Cooked; Dried; Boiled        260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              233-Cooked; Dried; Fried         260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              240-Cooked; Canned; Cook Meth N/S
                                               260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              242-Cooked; Canned; Boiled       260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              250-Cooked; Cured etc; Cook Meth N/S
                                               260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              252-Cooked; Cured etc; Boiled    260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
              253-Cooked; Cured etc; Fried     260.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19011841 19A  Herbs, other-babyfood             50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
14001850 14   Hickory nut                        1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
95001860 O    Honey                             30.000000   1.000      0.600   glypho
  Full comment: glyphosate[sugarcane mol trans]
95001861 O    Honey-babyfood                    30.000000   1.000      0.600   glypho
  Full comment: glyphosate[sugarcane mol trans]
09011870 9A   Honeydew melon                    15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
95001880 O    Hop                                1.000000   1.000      0.600   methyl
  Full comment: methyl parathion
24001890 M    Horse, meat                        2.000000   1.000      0.600   endosu
  Full comment: endosulfuran
01011900 1AB  Horseradish                        5.000000   1.000      0.600   carbar
  Full comment: carbaryl
13021910 13B  Huckleberry                       40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
95001920 O    Jaboticaba                         2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
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95001930 O    Jackfruit                          2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
05021940 5B   Kale                              60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
95001950 O    Kiwifruit                         25.000000   1.000      0.600   phosme
  Full comment: phosmet
05011960 5A   Kohlrabi                          60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
10001970 10   Kumquat                           10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
03001980 3    Leek                               3.000000   1.000      0.600   methom
  Full comment: methomyl
10001990 10   Lemon                             10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002000 10   Lemon, juice                      10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002001 10   Lemon, juice-babyfood             10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002010 10   Lemon, peel                       10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
19012020 19A  Lemongrass                        50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herb]
06032030 6C   Lentil, seed                      10.000000   1.000      0.600   carbar
  Full comment: carbaryl
04012040 4A   Lettuce, head                    100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
04012050 4A   Lettuce, leaf                    100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
10002060 10   Lime                              10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002070 10   Lime, juice                       10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002071 10   Lime, juice-babyfood              10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
13012080 13A  Loganberry                        40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
95002090 O    Longan                             3.000000   1.000      0.600   imidac
  Full comment: imidacloprid
11002100 11   Loquat                             2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95002110 O    Lychee                             3.000000   1.000      0.600   imidac
  Full comment: imidacloprid
95002120 O    Lychee, dried                      3.000000   1.850      0.600   imidac
  Full comment: imidacloprid
14002130 14   Macadamia nut                      1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
95002140 O    Mamey apple                        0.200000   1.000      0.600   glypho
  Full comment: glyphosate
95002150 O    Mango                              2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95002151 O    Mango-babyfood                     2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95002160 O    Mango, dried                       2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95002170 O    Mango, juice                       2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95002171 O    Mango, juice-babyfood              2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95002180 O    Maple, sugar                      15.000000   1.000      0.600   chlorp
  Full comment: chlorpyrifos [sugarbeet]
95002190 O    Maple syrup                       15.000000   1.000      0.600   chlorp
  Full comment: chlorpyrifos [sugarbeet]
19012200 19A  Marjoram                          50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herb]
19012201 19A  Marjoram-babyfood                 50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [herb]
28002210 M    Meat, game                         2.000000   1.000      0.600   endosu
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  Full comment: endosulfan
27002220 D    Milk, fat                          2.000000   1.000      0.600   endosu
  Full comment: endosulfan
27002221 D    Milk, fat - baby food/infant for   2.000000   1.000      0.600   endosu
  Full comment: endosulfan
27012230 D    Milk, nonfat solids                0.500000   1.000      0.600   iprodi
  Full comment: iprodione
27012231 D    Milk, nonfat solids-baby food/in   0.500000   1.000      0.600   iprodi
  Full comment: iprodione
27022240 D    Milk, water                        0.500000   1.000      0.600   iprodi
  Full comment: iprodione
27022241 D    Milk, water-babyfood/infant form   0.500000   1.000      0.600   iprodi
  Full comment: iprodione
27032251 D    Milk, sugar (lactose)-baby food/   0.500000   1.000      0.600   iprodi
  Full comment: iprodione
15002260 15   Millet, grain                      2.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002270 O    Mulberry                          40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al [blueberry]
95002280 O    Mushroom                           5.000000   1.000      0.600   permet
  Full comment: permethrin
05022290 5B   Mustard greens                    60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
12002300 12   Nectarine                         25.000000   1.000      0.600   captan
15002310 15   Oat, bran                         20.000000   1.000      0.600   mancoz
  Full comment: mancozeb
15002320 15   Oat, flour                        20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15002321 15   Oat, flour-babyfood               20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15002330 15   Oat, groats/rolled oats           20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15002331 15   Oat, groats/rolled oats-babyfood  20.000000   1.000      0.600   glypho
  Full comment: glyphosate
08002340 8    Okra                              10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002350 O    Olive                             10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002360 O    Olive, oil                        10.000000   1.000      0.600   carbar
  Full comment: carbaryl
03002370 3    Onion, dry bulb                    7.000000   1.000      0.600   maneb;
  Full comment: maneb; ziram
03002371 3    Onion, dry bulb-babyfood           7.000000   1.000      0.600   maneb;
  Full comment: maneb; ziram
03002380 3    Onion, dry bulb, dried             7.000000   9.000      0.600   maneb;
  Full comment: maneb; ziram
03002381 3    Onion, dry bulb, dried-babyfood    7.000000   9.000      0.600   maneb;
  Full comment: maneb; ziram
03002390 3    Onion, green                      10.000000   1.000      0.600   fosety
  Full comment: fosetyl-al
10002400 10   Orange                            10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002410 10   Orange, juice                     10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002411 10   Orange, juice-babyfood            10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002420 10   Orange, peel                      10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
95002430 O    Palm heart, leaves                 0.200000   1.000      0.600   glypho
  Full comment: glyphosate
95002440 O    Palm, oil                          0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95002441 O    Palm, oil-babyfood                 0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95002450 O    Papaya                            15.000000   1.000      0.600   chloro
  Full comment: chlorothanil
95002451 O    Papaya-babyfood                   15.000000   1.000      0.600   chloro
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  Full comment: chlorothanil
95002460 O    Papaya, dried                    15.000000   1.800      0.600   chloro
  Full comment: chlorothanil
95002470 O    Papaya, juice                    15.000000   1.000      0.600   chloro
  Full comment: chlorothanil
04012480 4A   Parsley, leaves                 100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
19012490 19A  Parsley, dried leaves            12.000000   1.000      0.600   carbar
  Full comment: carbaryl
19012491 19A  Parsley, dried leaves-babyfood   12.000000   1.000      0.600   carbar
  Full comment: carbaryl
01012500 1AB  Parsley, turnip rooted            2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
01012510 1AB  Parsnip                           5.000000   1.000      0.600   carbar
  Full comment: carbaryl
01012511 1AB  Parsnip-babyfood                 5.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002520 O    Passionfruit                     3.000000   1.000      0.600   chloro
  Full comment: chlorothanil
95002521 O    Passionfruit-babyfood            3.000000   1.000      0.600   chloro
  Full comment: chlorothanil
95002530 O    Passionfruit, juice              3.000000   1.000      0.600   chloro
  Full comment: chlorothanil
95002531 O    Passionfruit, juice-babyfood     3.000000   1.000      0.600   chloro
  Full comment: chlorothanil
95002540 O    Pawpaw                           2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
06022550 6B   Pea, succulent                  10.000000   1.000      0.600   carbar
  Full comment: carbaryl
06022551 6B   Pea, succulent-babyfood         10.000000   1.000      0.600   carbar
  Full comment: carbaryl
06032560 6C   Pea, dry                         8.000000   1.000      0.600   glypho
  Full comment: glyphosate
06032561 6C   Pea, dry-babyfood                8.000000   1.000      0.600   glypho
  Full comment: glyphosate
06012570 6A   Pea, edible podded, succulent    3.000000   1.000      0.600   bentaz
  Full comment: bentazon
06032580 6C   Pea, pigeon, seed                8.000000   1.000      0.600   glypho
  Full comment: glyphosate
06022590 6B   Pea, pigeon, succulent          10.000000   1.000      0.600   carbar
  Full comment: carbaryl
12002600 12   Peach                           15.000000   1.000      0.600   captan
12002601 12   Peach-babyfood                  15.000000   1.000      0.600   captan
12002610 12   Peach, dried                    15.000000   7.000      0.600   captan
12002611 12   Peach, dried-babyfood           15.000000   7.000      0.600   captan
12002620 12   Peach, juice                    15.000000   1.000      0.600   captan
12002621 12   Peach, juice-babyfood           15.000000   1.000      0.600   captan
95002630 O    Peanut                           5.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002640 O    Peanut, butter                   5.000000   1.890      0.600   carbar
  Full comment: carbaryl
95002650 O    Peanut, oil                      0.600000   1.000      0.600   azoxys
  Full comment: azoxystrobin
11002660 11   Pear                            25.000000   1.000      0.600   captan
11002661 11   Pear-babyfood                   25.000000   1.000      0.600   captan
11002670 11   Pear, dried                     25.000000   6.250      0.600   captan
11002680 11   Pear, juice                     25.000000   1.000      0.600   captan
11002681 11   Pear, juice-babyfood            25.000000   1.000      0.600   captan
14002690 14   Pecan                            1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
08002700 8    Pepper, bell                    10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08002701 8    Pepper, bell-babyfood           10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08002710 8    Pepper, bell, dried             10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08002711 8    Pepper, bell, dried-babyfood    10.000000   1.000      0.600   carbar
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  Full comment: carbaryl
08002720 8    Pepper, nonbell                    10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08002721 8    Pepper, nonbell-babyfood           10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08002730 8    Pepper, nonbell, dried             10.000000   1.000      0.600   carbar
  Full comment: carbaryl
19022740 19B  Pepper, black and white            38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
19022741 19B  Pepper, black and white-babyfood   38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
95002750 O    Peppermint                        200.000000   1.000      0.600   glypho
  Full comment: glyphosate
95002760 O    Peppermint, oil                   200.000000   1.000      0.600   glypho
  Full comment: glyphosate
95002770 O    Persimmon                           3.000000   1.000      0.600   imidac
  Full comment: imidacloprid
95002780 O    Pine nut                            1.000000   1.000      0.600   glypho
  Full comment: glyphosate
95002790 O    Pineapple                           2.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002791 O    Pineapple-babyfood                  2.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002800 O    Pineapple, dried                    2.000000   5.000      0.600   carbar
  Full comment: carbaryl
95002810 O    Pineapple, juice                    2.000000   1.000      0.600   carbar
  Full comment: carbaryl
95002811 O    Pineapple, juice-babyfood           2.000000   1.000      0.600   carbar
  Full comment: carbaryl
14002820 14   Pistachio                           1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
95002830 O    Plantain                           10.000000   1.000      0.600   carbar
  Full comment: carbaryl [banana]
95002840 O    Plantain, dried                    10.000000   3.900      0.600   carbar
  Full comment: carbaryl [banana]
12002850 12   Plum                               10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
12002851 12   Plum-babyfood                      10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
12002860 12   Plum, prune, fresh                 10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
12002861 12   Plum, prune, fresh-babyfood        10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
12002870 12   Plum, prune, dried                 10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
12002871 12   Plum, prune, dried-babyfood        10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
12002880 12   Plum, prune, juice                 10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
12002881 12   Plum, prune, juice-babyfood        10.000000   1.000      0.600   captan
  Full comment: captan;carbaryl
95002890 O    Pomegranate                         0.900000   1.000      0.600   imidac
  Full comment: imidacloprid
25002900 M    Pork, meat                          2.000000   1.000      0.600   endosu
  Full comment: endosulfan
25002901 M    Pork, meat-babyfood                 2.000000   1.000      0.600   endosu
  Full comment: endosulfan
25002910 M    Pork, skin                         13.000000   1.000      0.600   endosu
  Full comment: endosulfan
25002920 M    Pork, meat byproducts               1.000000   1.000      0.600   diuron
25002921 M    Pork, meat byproducts-babyfood      1.000000   1.000      0.600   diuron
25002930 M    Pork, fat                          13.000000   1.000      0.600   endosu
  Full comment: endosulfan
25002931 M    Pork, fat-babyfood                 13.000000   1.000      0.600   endosu
  Full comment: endosulfan
25002940 M    Pork, kidney                        4.000000   1.000      0.600   glypho
  Full comment: glyphosate
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25002950 M    Pork, liver                          5.000000   1.000      0.600   endosu
  Full comment: endosulfan
01032960 1C   Potato, chips                        1.000000   1.000      0.600   imidac
  Full comment: imidacloprid
01032970 1C   Potato, dry (granules/ flakes)       1.000000   6.500      0.600   diuron
01032971 1C   Potato, dry (granules/ flakes)-b     1.000000   6.500      0.600   diuron
01032980 1C   Potato, flour                        1.000000   1.000      0.600   diuron
01032981 1C   Potato, flour-babyfood               1.000000   1.000      0.600   diuron
01032990 1C   Potato, tuber, w/peel                1.000000   1.000      0.600   diuron
01032991 1C   Potato, tuber, w/peel-babyfood       1.000000   1.000      0.600   diuron
01033000 1C   Potato, tuber, w/o peel              1.000000   1.000      0.600   diuron
01033001 1C   Potato, tuber, w/o peel-babyfood     1.000000   1.000      0.600   diuron
60003010 P    Poultry, other, meat                 5.000000   1.000      0.600   carbar
  Full comment: carbaryl
60003020 P    Poultry, other, liver                5.000000   1.000      0.600   iprodi
  Full comment: iprodione
60003030 P    Poultry, other, meat byproducts      1.000000   1.000      0.600   glypho
  Full comment: glyphosate
60003040 P    Poultry, other, fat                  5.000000   1.000      0.600   carbar
  Full comment: carbaryl
60003050 P    Poultry, other, skin                 5.000000   1.000      0.600   carbar
  Full comment: carbaryl
95003060 O    Psyllium, seed                      10.000000   1.000      0.600   propan
  Full comment: propanil [rice]
10003070 10   Pummelo                             10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
09023080 9B   Pumpkin                             15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
09023090 9B   Pumpkin, seed                       15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
11003100 11   Quince                              10.000000   1.000      0.600   mancoz
  Full comment: mancozeb
95003110 O    Quinoa, grain                        5.000000   1.000      0.600   glypho
  Full comment: glyphosate
29003120 M    Rabbit, meat                         2.000000   1.000      0.600   endosu
  Full comment: endosulfan
04013130 4A   Radicchio                          100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
01013140 1AB  Radish, roots                        5.000000   1.000      0.600   carbar
  Full comment: carbaryl
02003150 2    Radish, tops                        50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin (CG 2)
01013160 1AB  Radish, Oriental, roots             5.000000   1.000      0.600   carbar
  Full comment: carbaryl
02003170 2    Radish, Oriental, tops              50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin (CG 2)
05023180 5B   Rape greens                         60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
20003190 20   Rapeseed, oil                       10.000000   1.000      0.600   glypho
  Full comment: glyphosate
20003191 20   Rapeseed, oil-babyfood              10.000000   1.000      0.600   glypho
  Full comment: glyphosate
13013200 13A  Raspberry                          40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13013201 13A  Raspberry-babyfood                 40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13013210 13A  Raspberry, juice                   40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
13013211 13A  Raspberry, juice-babyfood          40.000000   1.000      0.600   fosety
  Full comment: fosetyl-al (berries)
04023220 4B   Rhubarb                            100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
15003230 15   Rice, white                         10.000000   1.000      0.600   propan
  Full comment: propanil
15003231 15   Rice, white-babyfood                10.000000   1.000      0.600   propan
  Full comment: propanil
15003240 15   Rice, brown                         10.000000   1.000      0.600   propan
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  Full comment: propanil
15003241 15   Rice, brown-babyfood          10.000000   1.000      0.600   propan
  Full comment: propanil
15003250 15   Rice, flour                   10.000000   1.000      0.600   propan
  Full comment: propanil
15003251 15   Rice, flour-babyfood          10.000000   1.000      0.600   propan
  Full comment: propanil
15003260 15   Rice, bran                    40.000000   1.000      0.600   propan
  Full comment: propanil
15003261 15   Rice, bran-babyfood           40.000000   1.000      0.600   propan
  Full comment: propanil
01013270 1AB  Rutabaga                      5.000000   1.000      0.600   carbar
  Full comment: carbaryl
15003280 15   Rye, grain                    5.000000   1.000      0.600   mancoz
  Full comment: mancozeb
15003290 15   Rye, flour                    5.000000   1.000      0.600   mancoz
  Full comment: mancozeb
20003300 20   Safflower, oil                85.000000   1.000      0.600   glypho
  Full comment: glyphosate
20003301 20   Safflower, oil-babyfood       85.000000   1.000      0.600   glypho
  Full comment: glyphosate
01013310 1AB  Salsify, roots                5.000000   1.000      0.600   carbar
  Full comment: carbaryl
02003320 2    Salsify, tops                 50.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin (CG 2)
95003330 O    Sapote, Mamey                 2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
19013340 19A  Savory                       38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
95003350 O    Seaweed                       60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
95003351 O    Seaweed-babyfood              60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
95003360 O    Sesame, seed                  0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95003361 O    Sesame, seed-babyfood         0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95003370 O    Sesame, oil                   0.100000   1.000      0.600   glypho
  Full comment: glyphosate
95003371 O    Sesame, oil-babyfood          0.100000   1.000      0.600   glypho
  Full comment: glyphosate
03003380 3    Shallot                       0.200000   1.000      0.600   pendim
  Full comment: pendimethalin
26003390 M    Sheep, meat                   2.000000   1.000      0.600   endosu
  Full comment: endosulfan
26003391 M    Sheep, meat-babyfood          2.000000   1.000      0.600   endosu
  Full comment: endosulfan
26003400 M    Sheep, meat byproducts        5.000000   1.000      0.600   endosu
  Full comment: endosulfan
26003410 M    Sheep, fat                    13.000000   1.000      0.600   endosu
  Full comment: endosulfan
26003411 M    Sheep, fat-babyfood           13.000000   1.000      0.600   endosu
  Full comment: endosulfan
26003420 M    Sheep, kidney                 4.000000   1.000      0.600   glypho
  Full comment: glyphosate
26003430 M    Sheep, liver                  5.000000   1.000      0.600   glypho
  Full comment: glyphosate
15003440 15   Sorghum, grain                15.000000   1.000      0.600   glypho
  Full comment: glyphosate
15003450 15   Sorghum, syrup                15.000000   1.000      0.600   glypho
  Full comment: glyphosate
95003460 O    Soursop                       2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
06003470 6    Soybean, seed                 20.000000   1.000      0.600   glypho
  Full comment: glyphosate
06003480 6    Soybean, flour                5.000000   1.000      0.600   carbar
  Full comment: carbaryl
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06003481 6    Soybean, flour-babyfood            5.000000   1.000      0.600   carbar
  Full comment: carbaryl
06003490 6    Soybean, soy milk                  5.000000   1.000      0.600   carbar
  Full comment: carbaryl
06003491 6    Soybean, soy milk-babyfood or in   5.000000   1.000      0.600   carbar
  Full comment: carbaryl
06003500 6    Soybean, oil                       0.300000   1.000      0.600   bifent
  Full comment: bifenthrin
06003501 6    Soybean, oil-babyfood              0.300000   1.000      0.600   bifent
  Full comment: bifenthrin
95003510 O    Spanish lime                       3.000000   1.000      0.600   imidac
  Full comment: imidacloprid
95003520 O    Spearmint                        200.000000   1.000      0.600   glypho
  Full comment: glyphosate
95003530 O    Spearmint, oil                   200.000000   1.000      0.600   glypho
  Full comment: glyphosate
19023540 19B  Spices, other                     38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
19023541 19B  Spices, other-babyfood            38.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin [spice]
04013550 4A   Spinach                          100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
04013551 4A   Spinach-babyfood                 100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
09023560 9B   Squash, summer                    15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
09023561 9B   Squash, summer-babyfood           15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
09023570 9B   Squash, winter                    15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
09023571 9B   Squash, winter-babyfood           15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
95003580 O    Starfruit                         2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95003590 O    Strawberry                       75.000000   1.000      0.600   fosety
  Full comment: fosetyl-al
95003591 O    Strawberry-babyfood              75.000000   1.000      0.600   fosety
  Full comment: fosetyl-al
95003600 O    Strawberry, juice                75.000000   1.000      0.600   fosety
  Full comment: fosetyl-al
95003601 O    Strawberry, juice-babyfood       75.000000   1.000      0.600   fosety
  Full comment: fosetyl-al
95003610 O    Sugar apple                       2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
95003620 O    Sugarcane, sugar                  2.000000   1.000      0.600   glypho
  Full comment: glyphosate;2,4-D
95003621 O    Sugarcane, sugar-babyfood         2.000000   1.000      0.600   glypho
  Full comment: glyphosate;2,4-D
95003630 O    Sugarcane, molasses              30.000000   1.000      0.600   glypho
  Full comment: glyphosate
95003631 O    Sugarcane, molasses-babyfood     30.000000   1.000      0.600   glypho
  Full comment: glyphosate
20003640 20   Sunflower, seed                   2.500000   1.000      0.600   alachl
  Full comment: alachlor
20003650 20   Sunflower, oil                    0.300000   1.000      0.600   lambda
  Full comment: lambda-cyhalothrin
20003651 20   Sunflower, oil-babyfood           0.300000   1.000      0.600   lambda
  Full comment: lambda-cyhalothrin
01033660 1CD  Sweet potato                     10.000000   1.000      0.600   phosme
  Full comment: phosmet
01033661 1CD  Sweet potato-babyfood            10.000000   1.000      0.600   phosme
  Full comment: phosmet
04023670 4B   Swiss chard                      100.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 4)
95003680 O    Tamarind                          2.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
10003690 10   Tangerine                        10.000000   1.000      0.600   azoxys
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  Full comment: azoxystrobin ( citrus CG)
10003700 10   Tangerine, juice                  10.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin ( citrus CG)
01033710 1CD  Tanier, corm                      1.000000   1.000      0.600   diuron
  Full comment: diuron [potato transl]
95003720 O    Tea, dried                       10.000000   1.000      0.600   propar
  Full comment: propargite
95003730 O    Tea, instant                      7.000000   1.000      0.600   glypho
  Full comment: glyphosate
08003740 8    Tomatillo                        10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08003750 8    Tomato                           10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08003751 8    Tomato-babyfood                  10.000000   1.000      0.600   carbar
  Full comment: carbaryl
08003760 8    Tomato, paste                     6.000000   1.000      0.600   imidac
  Full comment: imidacloprid
08003761 8    Tomato, paste-babyfood            6.000000   1.000      0.600   imidac
  Full comment: imidacloprid
08003770 8    Tomato, puree                     3.000000   1.000      0.600   imidac
  Full comment: imidacloprid
08003771 8    Tomato, puree-babyfood            3.000000   1.000      0.600   imidac
  Full comment: imidacloprid
08003780 8    Tomato, dried                    10.000000  14.300      0.600   carbar
  Full comment: carbaryl
08003781 8    Tomato, dried-babyfood           10.000000  14.300      0.600   carbar
  Full comment: carbaryl
08003790 8    Tomato, juice                    10.000000   1.000      0.600   carbar
  Full comment: carbaryl
95003800 O    Tomato, Tree                     10.000000   1.000      0.600   carbar
  Full comment: carbaryl [tomato]
15003810 15   Triticale, flour                  5.000000   1.000      0.600   glypho
  Full comment: glyphosate [wheat transl]
15003811 15   Triticale, flour-babyfood         5.000000   1.000      0.600   glypho
  Full comment: glyphosate [wheat transl]
50003820 P    Turkey, meat                      5.000000   1.000      0.600   carbar
  Full comment: carbaryl
50003821 P    Turkey, meat-babyfood             5.000000   1.000      0.600   carbar
  Full comment: carbaryl
50003830 P    Turkey, liver                     5.000000   1.000      0.600   iprodi
  Full comment: iprodione
50003831 P    Turkey, liver-babyfood            5.000000   1.000      0.600   iprodi
  Full comment: iprodione
50003840 P    Turkey, meat byproducts           1.000000   1.000      0.600   glypho
  Full comment: glyphosate
50003841 P    Turkey, meat byproducts-babyfood  1.000000   1.000      0.600   glypho
  Full comment: glyphosate
50003850 P    Turkey, fat                       5.000000   1.000      0.600   carbar
  Full comment: carbaryl
50003851 P    Turkey, fat-babyfood              5.000000   1.000      0.600   carbar
  Full comment: carbaryl
50003860 P    Turkey, skin                      5.000000   1.000      0.600   carbar
  Full comment: carbaryl
50003861 P    Turkey, skin-babyfood             5.000000   1.000      0.600   carbar
  Full comment: carbaryl
01033870 1CD  Turmeric                         1.000000   1.000      0.600   diuron
  Full comment: diuron [potato transl]
01013880 1AB  Turnip, roots                    15.000000   1.000      0.600   fosety
  Full comment: fosetyl-al
05023890 5B   Turnip, greens                   60.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (CG 5)
95003900 O    Vinegar                          25.000000   1.000      0.600   captan
  Full comment: captan [apple]
14003910 14   Walnut                            1.000000   1.000      0.600   glypho
  Full comment: glyphosate (tree nut)
86010000 O    Water, direct, all sources        0.100000   1.000      1.000   defaul
  Full comment: default 100 ppb
```

```
86020000 O    Water, indirect, all sources        0.100000   1.000      1.000   defaul
  Full comment: default 100 ppb
95003970 O    Water chestnut                      1.000000   1.000      0.600   carbar
  Full comment: carbaryl [pecan]
95003980 O    Watercress                          6.000000   1.000      0.600   methom
  Full comment: methomyl
09013990 9A   Watermelon                         15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
09014000 9A   Watermelon, juice                  15.000000   1.000      0.600   fosety
  Full comment: fosetyl-Al (curcurbits)
15004010 15   Wheat, grain                        5.000000   1.000      0.600   glypho
  Full comment: glyphosate
15004011 15   Wheat, grain-babyfood               5.000000   1.000      0.600   glypho
  Full comment: glyphosate
15004020 15   Wheat, flour                        5.000000   1.000      0.600   glypho
  Full comment: glyphosate
15004021 15   Wheat, flour-babyfood               5.000000   1.000      0.600   glypho
  Full comment: glyphosate
15004030 15   Wheat, germ                         5.000000   1.000      0.600   glypho
  Full comment: glyphosate
15004040 15   Wheat, bran                        20.000000   1.000      0.600   glypho
  Full comment: glyphosate
15004050 15   Wild rice                           5.000000   1.000      0.600   azoxys
  Full comment: azoxystrobin
01034060 1CD  Yam, true                          10.000000   1.000      0.600   phosme
  Full comment: phosmet
01034070 1CD  Yam bean                           10.000000   1.000      0.600   phosme
  Full comment: phosmet
```

Exhibit 8

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

MEMORANDUM Dated: 6/2/2009
To: Kerry Leifer (OPP)
From: Donna S. Davis, Kit Farwell, Alexandra LaMay, Matthew Lloyd, Christine L. Olinger, Sheila Piper, (OPP)

Re: Methyl Poly(Oxyethylene) C8 - C18 Alkylammonium Chlorides (MPOACs - JITF CST 7 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations (46 pages).

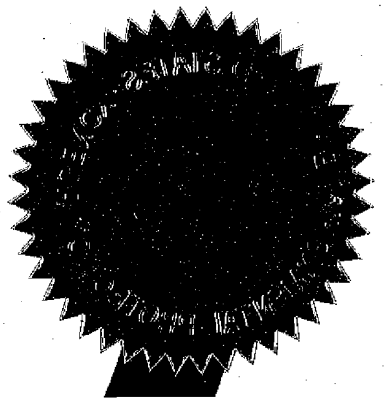
Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.



Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Date: June 2, 2009

MEMORANDUM

SUBJECT: **Methyl Poly(Oxyethylene) $C_8 - C_{18}$ Alkylammonium Chlorides (MPOACs - JITF CST 7 Inert Ingredients).** Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations.

PC Code: 869141
Decision No.: 411391
Petition No.: 9E7518

Risk Assessment Type: Single Chemical Aggregate
TXR No.: NA

DP Barcode: D365208
Registration No.: NA
Regulatory Action: Inert Tolerance Exemption
Case No.: NA
CAS No.: 3010-24-0, 18448-65-2, 70750-47-9, 22340-01-8, 60687-90-3, 64755-05-1, 61791-10-4, 28724-32-5, 28880-55-9, 68187-69-9, 68607-27-2 67784-77-4
40 CFR: 180.920

MRID No.: 47644401

FROM: Donna S. Davis, Risk Assessor, RAB VII
Kit Farwell, Toxicologist, RAB VII
Alexandra LaMay, Biologist, RAB VII
Matthew Lloyd, CIH, RAB VII
Christine L. Olinger, Chemist, RAB VII
Sheila Piper, Dietary Exposure Assessor, RAB VI
Health Effects Division (7509P)

THROUGH: Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

TO: Kerry Leifer, Team Leader
PV Shah, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

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1.0 Executive Summary

The Joint Inert Task Force (JITF) Cluster Support Team Number 7 (CST 7) has submitted a petition proposing to establish an exemption from the requirement of a tolerance under 40 CFR §180.920 for the "methyl poly(oxyethylene) $C_8 - C_{18}$ alkylammonium chlorides (MPOACs) when used as inert ingredients in pesticide formulations intended for pre-harvest application only at up to 10% in herbicide formulations and 5% in all other formulations".

The toxicology database is adequate to assess risk for this group of compounds when used as inert ingredients in pesticide formulations. The MPOACs are not acutely toxic in terms of lethality but are severe irritants for dermal, inhalation, and eye exposure. In the OECD Test Guideline 422 combined repeated dose toxicity study with reproductive/developmental toxicity screening in rats mortality occurred which was associated with forestomach inflammation. No developmental or reproductive toxicity occurred in this study and there are no concerns for sensitivity of offspring. No neurotoxicity was noted in this study. There are no carcinogenicity concerns based on structure activity modeling. Endpoints for chronic dietary and incidental oral exposure were selected from the OECD 422 study. The endpoint was forestomach inflammation and mortality associated with the forestomach inflammation.

Sufficient data were provided on the chemical identity of the MPOACs; however, limited data are available on the metabolism and environmental degradation of these compounds. The Agency relied collectively on information provided on the representative chemical structures, the submitted physicochemical EPI Suite™ data, structure-activity relationship information, as well as information on other surfactants and chemicals of similar size and functionality to determine the residues of concern for these inert ingredients. The residues of concern for risk assessment purposes are the parent compounds only.

No residue data were provided for the MPOACs. In the absence of data, the Agency has developed an approach that uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. No adverse effect attributable to a single exposure was identified for the MPOAC inerts; therefore an acute dietary risk assessment is not appropriate. Chronic dietary (food and water) risk assessments for the MPOACs did not identify any risks of concern.

Residential exposure is expected; however, since dermal and inhalation endpoints were not selected, only post-application incidental oral exposures to children were quantitatively assessed. Exposure and risk from indoor and outdoor incidental oral exposures to children was not of concern.

Since only oral endpoints were selected for the MPOAC inerts, aggregate risks for the MPOACs combined food and water exposures and incidental oral exposures (children only). Acute, short-term, intermediate-term and long-term (chronic) risks were not of concern.

A worker risk assessment is not appropriate for the MPOACs since dermal and inhalation endpoints were not selected for these inert ingredients.

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

This assessment does not rely on any studies in which human subjects were intentionally exposed to a pesticide.

Regulatory Recommendation

There are no human health exposure or risk issues that would preclude the approval of an exemption from the requirement of a tolerance for the MPOAC inerts when used as inert ingredients in pesticide products at no more than 10% by weight in herbicide formulations and 5% in all other formulations. HED has no objection to the establishment of exemptions from the requirement of a tolerance under 40 CFR §180.20 for:

> Methyl poly(oxyethylene) $C_8 - C_{18}$ alkylammonium chlorides where the poly(oxyethylene) content is POE n = 2-15 and where [the] C8 – C18 alkyl [group] is linear and may be saturated and or unsaturated. Concentration in formulated end-use products is not to exceed 10% by weight in herbicide products and 5% by weight in all other pesticide products.

2.0 Background

Inert ingredients are those ingredients that are added to end use products that are not active ingredients. The terms "active ingredient" and "inert ingredient" are defined under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). An active ingredient is one that prevents, destroys, repels or mitigates a pest, or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. The statute defines the term "inert ingredient" as an ingredient that is not active.

As mandated by the Food Quality Protection Act (FQPA) of 1996, EPA conducted a reassessment of tolerances and exemptions from the requirement of tolerances for inert ingredients used in pesticide products to determine if they met FFDCA's revised standard of safety. As a result of that reassessment, the Agency published a final rule in the Federal Register (FR Notice Volume 71, No. 153, p. 45422, Aug 9, 2006) proposing revocation of specific exemptions from the requirement of a tolerance due to insufficient data. The specific exemptions that are currently proposed for revocation relevant to this petition request were established under 40 CFR §180.920 and are as follows:

> Methyl bis (2-hydroxyethyl)alkyl ammonium chloride where the carbon chain ($C_8 - C_{18}$) is derived from coconut, cotton seed, soya, or tallow acids
>
> Methyl poly(oxyethylene) alkyl ammonium chloride where the poly(oxyethylene) content is 3 – 15 moles and the alkyl group ($C_8 - C_{18}$) is derived from coconut, cotton seed, soya, or tallow acids

In response to the proposed revocation, the JITF CST 7 has submitted a petition dated January 13, 2009 proposing to establish an exemption from the requirement of a tolerance under 40 CFR §180.20 for:

> Methyl poly(oxyethylene) $C_8 - C_{18}$ alkylammonium chlorides where the poly(oxyethylene) content is POE n = 2-15 and where [the] C8 – C18 alkyl [group] is linear and may be saturated and or unsaturated. Concentration in formulated end-use products is not to exceed 10% by weight in herbicide products and 5% by weight in all other pesticide products

The petitioner acknowledges that the revised descriptor serves to combine the previous descriptors into a single statement, but also expands the prior exemption from the requirement of a tolerance by deleting the source specification for the alkyl group. The Agency notes that the newly proposed descriptor specifies limits on the allowable concentrations in end-use products in contrast to the previously unlimited exemptions. Both the previously established and newly proposed exemptions are limited to use in pesticide formulations intended for pre-harvest application.

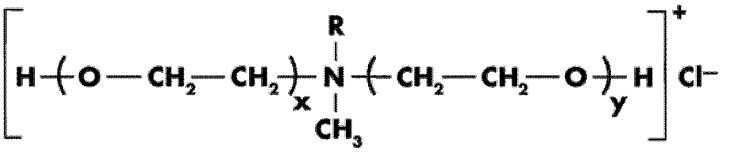
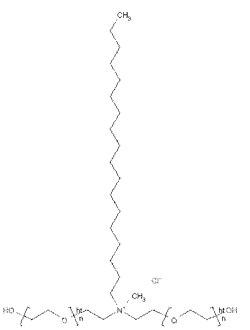
3.0 Ingredient Profile

3.1 Summary of Proposed Uses

The methyl poly(oxyethylene) $C_8 - C_{18}$ alkylammonium chlorides (MPOACs) are surfactants which are used in pesticide formulations intended for pre-harvest applications. The petitioner has proposed to limit the use in pesticide products to no more than 10% by weight in herbicide formulations and 5% by weight in all other pesticide formulations. Additionally, these cationic surfactants may be used as emulsifying and wetting agents in household products and personal care products.

3.2 Structural Information

The MPOACs included in this cluster may be mixtures or may be individual compounds. Information on the generic structures of these compounds is summarized in Table 3.2.1, below. The alkyl group is linear and may be unsaturated or saturated, and range in carbon chain length from eight to eighteen. A detailed listing of the chemicals included in this group may be found in Table 3.2.2.

Table 3.2.1. Methyl poly(oxyethylene) C_8-C_{18} alkylammonium chlorides (MPOAC) Chemical Structure	
Generic Chemical Structure [1]	
Structure of example compound, CAS No. 28724-32-5	

[1] Figure excerpted from petition, "*Petition Proposing An Exemption From The Requirement Of A Tolerance For Residues Of Joint Inerts Task Force Cluster 7: "Methyl Poly(Oxyethylene) C_8-C_{18} Alkylammonium Chlorides (MPOAC)" In Or On Raw Agricultural Products And Food Products"*, page 6, dated January 13, 2009.

Table 3.2.2 Listing of Chemicals included in the MPOAC Cluster	
CAS Number	**Descriptor**
3010-24-0	Octadecanaminium, N,N-bis(2-hydroxyethy1)-N-methyl-,chloride
18448-65-2	9-Octadecen-1-aminium, N,N-bis(2-hydroxyethy1)-N-methyl-, chloride, (9Z)-
70750-47-9	Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methy1, chlorides
22340-01-8	N-dodecyl, N,N-bis(2-hydroxyethy1)-N-methyl, chloride
60687-90-3	1-tetradecanammonium, N,N-bis(2-hydroxyethy1)-N-methyl, chloride
64755-05-1	Quaternary ammonium compounds, bis(hydroxyethyl)methyltallow alkyl,ethoxylated, chlorides
61791-10-4	Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methyl, ethoxylated, chlorides
28724-32-5	Poly(oxy-l,2-ethanediyl), α,α'-[(methyloctadecyliminio)di-2,1-ethanediyl]bis[ω-hydroxy-, chloride
28880-55-9	Poly(oxy- l,2-ethanediyl), α,α'-[[methyl-(9Z)-9-octadecenyliminio]di-2,1 - ethanediyl]bis[ω-hydroxy-, chloride
68187-69-9	Quaternary ammonium compounds, (hydrogenated tallow alkyl)bis(hydroxyethyl) methyl, ethoxylated, chlorides
68607-27-2	Quaternary ammonium compounds, (hydrogenated tallow alkyl) bis(hydroxyethy1) methyl, ethoxylated, chlorides
67784-77-4	Quaternary ammonium compounds, bis(hydroxyethy1) methyl, tallow alkyl), chlorides

3.3 Physical and Chemical Properties

Physicochemical data were estimated for the MPOAC cluster using publicly available Estimation Program Interface suite (EPI Suite™) modeling (http://www.epa.gov/opptintr/exposure/pubs/episuite.htm and are provided in Table 3.3. The basis for the estimated Estimation Program Interface suite (EPI Suite™) modeling physicochemical calculations and model capabilities are described in the EPA document titled The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program (EPA 1999). The EPA EPI Suite™ 3.2 model calculations for water solubility are based on K_{ow} (WSKOWWIN) and molecular fragments (WATERNT). EPA has cautioned in the publication OPPTS Pollution Prevention P2 Network (EPA, 2005), that EPI Suite™ 3.2 water solubility calculations are not reliable for dispersible compounds such as surfactants.

EPI Suite™ 3.2 generally calculates mixtures according to the major fatty acid component in the oleochemical source. For example, the OECD 422 test compound CAS RN 70750-47-9 coco is represented as its major fatty acid derived amine, linear saturated C12 dodecyl (also called lauryl) and CAS RN 67784-77-4 tallow is represented as its major fatty acid derived linear unsaturated amine C18:1 oleyl amine with unsaturation between 9 and 10 carbons. The average moles of polyethoxylation are either calculated as POE n=2 or POE n=12.

Overall, it is concluded the MPOAC compounds supported by CST 7 demonstrate similar physicochemical properties and predictable trends. As a general rule, increasing carbon chain length decreases the polarity of the molecule with resultant increases in MPOAC lipophilicity; whereas, increasing ethoxylation increases the polarity of the molecule with resultant increases in hydrophilicity.

Table 3.3. Physicochemical Properties of Representative MPOAC Compounds [1]

CAS No.	CX/Average POE n [2]	Log K_{OW}	Boiling Point (°C)	Melting Point (°C)	Vapor Pressure (mm Hg)	Water Solubility (mg/L) [3]
3010-24-0	C18/n=2	2.63	633.21	274.83	5.1×10^{-18}	15.6 0.0013885
18448-65-2	C18:1/n=2	2.41	636.79	276.49	3.7×10^{-18}	24.5 0.0030565
70750-47-9	C12/n=2	-0.32	547.26	234.68	1.02×10^{-14}	2.69×10^{4} 1.64
22340-01-8	C12/n=2	-0.32	547.26	234.68	1.02×10^{-14}	2.69×10^{4} 1.64
60687-90-3	C14/n=2	0.66	570.47	274.83	1.33×10^{-15}	2673 1.64
64755-05-1	C18/n=12	1.62	997.43	349.84	1.67×10^{-31}	0.1163 0.08633
61791-10-4	C12/n=12	-0.44	739.9	324.66	3.19×10^{-22}	886.8 31.076
28724-32-5	C18/n=12	1.62	997.43	349.84	1.67×10^{-31}	0.1163 0.08633
28880-55-9	C18:1/n=12	0.92	989.4	349.84	3.23×10^{-31}	0.6 [4]

Table 3.3. Physicochemical Properties of Representative MPOAC Compounds [1]						
CAS No.	**CX/Average POE n [2]**	**Log K_{OW}**	**Boiling Point (°C)**	**Melting Point (°C)**	**Vapor Pressure (mm Hg)**	**Water Solubility (mg/L) [3]**
68187-69-9	C18/n=2	2.63	633.21	274.83	5.1×10^{-18}	15.6 0.0013885
68607-27-2	C18/n=2	2.63	633.21	274.83	5.1×10^{-18}	15.6 0.0013885
67784-77-4	C18:1/n=12	0.92	989.4	349.84	3.23×10^{-31}	0.6 [4]

[1] Table values taken directly from submission entitled ""*Petition Proposing An Exemption From The Requirement Of A Tolerance For Residues Of Joint Inerts Task Force Cluster 7: "Methyl Poly(Oxyethylene) C_8-C_{18} Alkylammonium Chlorides (MPOAC)" In Or On Raw Agricultural Products And Food Products"*, page 16, dated January 13, 2009.

[2] CX = carbon number of R group modeled and POE represents average number of moles of polyethoxylation.

[3] The EPI Suite™ model calculates water solubility based on the octanol-water partition coefficient (Kow) (WSKOWWIN model) and molecular fragments (WATERNT model). The first value reflects the WSKOWWIN calculation and the second value reflects the WATERNT calculation.

4.0 Hazard Characterization/Assessment

4.1 Database Summary

The toxicity data available on the MPOACs consists of acute toxicity studies, mutagenicity studies, and an OECD Test Guideline 422 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test.

The OECD Test Guideline 422 study is a combined repeated dose toxicity study with reproduction/developmental toxicity test parameters. This study provides information on the possible health hazards likely to arise from repeated exposure over a relatively limited period of time. The method comprises the basic repeated dose toxicity study as well as a reproduction/developmental toxicity screening test and also places emphasis on neurological effects as a specific endpoint. Therefore, the study can provide information on general toxicity as well as possible developmental, reproductive, and neurological effects. It can also provide basic indications of immunological effects.

Table 4.1 summarizes the studies available for the MPOAC surfactants.

Table 4.1. MPOAC Inerts Supported by Cluster 7 (CST 7)		
Inert tested	**CAS No.**	**Studies available**
Ethoquad® C/12	CAS 70750-47-9	OECD 422 combined repeated dose toxicity study with reproduction/developmental toxicity screening test; Ames assay; acute data
C12	CAS 22340-01-8	Acute data
C18	CAS 3010-24-0	Acute data; Mutagenicity
C18:1	CAS 18448-65-2	Acute data; Mutagenicity
Coco	CAS 64755-05-1	Acute data
Tallow	CAS 61791-10-4	Acute data
Coco	CAS 28724-32-5	Acute data
C18	CAS 28880-55-9	Acute data; Mutagenicity
C18:1	CAS 68187-69-9	Acute data
Tallow, hydrogenated		Acute data

The Agency concurs with the determination that Ethoquad® (CAS RN 70750-47-9), the test material in the OECD 422 study, is an appropriate representative test compound.

The toxicity data for these MPOAC surfactants are adequate to support their use as inert ingredients in pesticide formulations.

4.2 Toxicological Effects

The majority of the MPOAC compounds are reported as "not acutely toxic" for lethality by the oral and dermal routes of exposure (Toxicity Category III). However, Ethoquad®, the representative test compound, is more toxic by the oral and dermal routes (Toxicity Category II). All MPOACs are severely irritating to the eye (Toxicity Category I), and the MPOAC identified by CAS no.70750-47-9 (Quaternary ammonium compounds, coco alkylbis(hydroxyethyl)methyl, chlorides) is severely irritating to the skin. Inhalation data on two of the MPOACs indicate irritation at high doses.

The OECD 422 study on the representative surfactant, Ethoquad® (CAS 70750-47-9) demonstrated severe toxicity in rats, as evidenced by deaths of all test subjects at 100 mg/kg/day after 5 days, and deaths of 5 out of 10 females at 50 mg/kg/day after 6-8 days of exposure. Given the extremely corrosive nature of the test material, the Agency believes that the high mortality rate is secondary to the forestomach lesions seen in the rats. Further, the Agency notes that the severity of the effects may be related to the unique anatomy of the rats. Humans do not have a forestomach which serves as a storage reservoir in rodents; therefore effects seen in the rat forestomach are likely to be significantly more severe than what would be expected from the compound in the glandular stomachs in humans and therefore, have less relevance to humans.

The NOAEL for developmental and reproductive toxicity is 25 mg/kg/day, the lowest dose tested. Although no reproductive or developmental effects were observed at the next higher dose of 50 mg/kg/day, the evaluation at this dose level included only five surviving female animals.

While the actual LOAEL for reproductive/developmental effects may be higher, or reproductive/developmental effects may not occur at all as a result of exposure to this chemical, in the absence of a sufficient number of animals to assess, the Agency has conservatively assumed that if more animals had been available at the mid-dose, developmental or reproductive toxicity might have been observed.

There was no evidence of neurotoxicity in this study; functional observational battery and motor activity data were similar in all the treatment groups. Liver enzymes were elevated but were not accompanied by microscopic lesions or increased organ weight and were not considered adverse.

4.2 Dermal Absorption

A dermal absorption value was not selected and is not required for the MPOACs since a dermal endpoint was not selected and a dermal risk assessment is not appropriate (see Section 4.5 Toxicity Endpoint section).

4.3 Carcinogenic potential

No carcinogenicity studies are available for the MPOACs. A qualitative structure activity relationship database, DEREK Version 11, identified no structural alerts suggestive of carcinogenicity.

4.4 FQPA Considerations

There was no evidence of increased sensitivity in young animals because no developmental or reproductive toxicity occurred in the lowest dose group in the OECD 422 study. Additionally, no developmental or reproductive toxicity was noted in the mid-dose group either; however, since there were only five surviving female animals in this group, which is considered an insufficient number of animals, the study LOAEL was set at the mid-dose level. There was no evidence of neurotoxicity in this study. Further, exposure estimates are not expected to underestimate risk. The FQPA safety factor can be reduced to 1x for this group of chemicals since regulation based on the forestomach lesions in rats, a very conservative hazard endpoint, coupled with the highly conservative exposure assessment and an absence of evidence of increased sensitivity, or neurotoxicity, supports the finding that the use of the standard 100X inter- and intra-species uncertainty facts are adequate to protect infants and children.

4.5 Toxicity Endpoint Selection and Levels of Concern

Points of departure for the MPOACs are shown in Table 4.5. An acute dietary point of departure was not selected because toxicity occurring from a single exposure was not identified.

The Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (MRID 47644401) was selected for the chronic dietary endpoint and the incidental oral endpoint. The point of departure was a NOAEL of 25 mg/kg/day. The LOAEL of 50 mg/kg/day was based on forestomach inflammation and mortality associated with the

forestomach inflammation. An uncertainty factor of 100X (10X for interspecies extrapolation from animals to humans and 10X for variation in sensitivity among humans) should be used. Using a 100X uncertainty factor is very conservative since we are regulating based on portal of entry effects for which inter-species differences as well as variability among humans are likely to be relatively small. This class of compounds is highly irritating and the toxicity was enhanced by the gavage dosing. Furthermore, humans lack a forestomach which serves as a storage reservoir in rodents.

Quantitative dermal or inhalation risk assessments will not be performed for occupational or residential exposures because the MPOACs are highly corrosive/irritating, and therefore, exposure will be self-limiting and will be regulated based on labeling of the formulations. There is not a significant concern for dermal or inhalation exposures due to expected low dermal and inhalation absorptions and the fact that the product is used in low percentages in household products (i.e., low exposure).

An aggregate assessment need only be conducted for food, water, and incidental oral exposures.

Table 4.5. Summary of Toxicological Doses and Endpoints

Exposure/ Scenario	Point of Departure	Uncertainty Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all populations)	Acute toxicity was not identified.			
Chronic Dietary (All Populations)	NOAEL= 25 mg/kg/day	UF_A = 10x UF_H =10x FQPA SF = 1X	Chronic RfD = 0.25 mg/kg/d cPAD = 0.25 mg/kg/d	LOAEL = 50 mg/kg/d based on stomach inflammation and mortality associated with the forestomach inflammation
Incidental Oral Short- and Intermediate-Term	NOAEL= 25 mg/kg/day	UF_A = 10x UF_H =10x	Residential LOC for MOE = 100	LOAEL = 50 mg/kg/d based on stomach inflammation and mortality associated with the forestomach inflammation
Dermal and Inhalation (All Durations)	Quantitative assessment not required: cluster is corrosive/irritating and exposure will be self limiting; expected low dermal and inhalation absorptions; product is used in low percentages in household products (i.e., low exposure).			
Cancer (oral, dermal, inhalation)	Classification: No animal toxicity data available for an assessment. Based on SAR analysis, not expected to be carcinogenic.			

4.6 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen

and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, the MPOACs may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

5.0 Dietary Exposure/Risk Characterization

5.1 Residues of Concern

Very limited information is available for MPOACs with respect to plant and animal metabolism or environmental degradation. The Agency considered the representative chemical structures, the generic cluster structures, the submitted physicochemical EPI Suite™ information as well as the structure-activity relationship analysis detailed in Appendix B of this review. Additionally, information on other surfactants and chemicals of similar size and functionality was considered as well.

The registrant selected Ethoquad® (CAS RN 70750-47-9), as the test compound because the coco alkyl encompasses the broad range of C_8-C_{18} alkyl chain included in the descriptor. The Agency concluded that the cluster grouping was appropriate. Further, the Agency also concluded that it is unlikely that any potential environmental degradates that would be found in food and water will be more toxic than the parent compound. Residue estimates used in the dietary risk assessment were chosen to represent an upper bound on the combined residues of parent and any potential metabolite or degradate of concern.

5.2 Drinking Water Residue Profile

No monitoring data or data reflecting the concentration of these inert ingredients in drinking water are available.

EFED conducted modeling runs on four surrogate inert chemicals using a range of physical chemical properties which bracket those expected for the MPOACs (email from D. Young to M. Metzger dated 1/15/09). EFED selected a North Carolina cotton scenario with an application date of July 1st as the scenario that would likely provide high end drinking water values for use in risk assessment. Percent crop area (PCA) factors were not applied. Simulations were run assuming a rate of 1 lb inert ingredient/A. Since degradation information was not available, three degradation scenarios were investigated: 1) chemically stable in water and soil; 2) a 100-day half-life in water and soil; and 3) a 10-day half life in water and soil. Further, two possible scenarios were investigated, one where all of the inert was applied as a single application, and

the second assuming that the inert was applied evenly over a growing season. Modeled acute drinking water values ranged from 0.001 ppb to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of the EFED analysis are contained in Appendix C of this document.

For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for the MPOAC inerts, a value of 100 ppb based on screening level modeling was used for both the acute and chronic dietary risk assessments for the parent compounds and for the metabolite of concern. HED considers the value of 100 ppb to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

5.3 Food Residue Profile

No residue data were submitted for the MPOAC inerts. In the absence of data, the Agency has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of 57 high use insecticides (22), herbicides (20), and fungicides (17). The 57 pesticides were selected based on an overall ranking scheme that included consideration of the 1999 data for active ingredients use. All herbicides at greater than 5 million lbs/yr and all fungicides and insecticides at greater than 1 million lbs/yr were included as candidate surrogate chemicals.

OPP assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

To summarize, the Agency believes the assumptions used to estimate dietary exposures lead to a very conservative assessment of dietary risk for the following reasons:

- the highest tolerance level from the surrogate pesticides for every food is used;
- 100% crop treated (%CT) is assumed for all crops (every food eaten by a person each day has tolerance-level residues);
- many of these high tolerances are based on very short pre-harvest intervals where there is little time for degradation, whereas actual pesticide applications occur throughout the growing season;
- no consideration was given to potential degradation between harvest and consumption (use of tolerance level residues which are typically one to two orders of magnitude higher than actual residues found in monitoring data);
- residue values were assigned to every commodity in DEEM™ with no consideration given to potential reduction in residues from washing or cooking.

Although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. OPP does not believe that this approach underestimates exposure in the absence of residue data.

5.4 Analytical Methodology

Since this request is for an exemption from the requirement of a tolerance, an analytical method for enforcement purposes is not required to support this action.

5.5 Dietary (Food and Water) Exposure and Risk

The model and inputs used for the MPOAC dietary risk assessments are described briefly in Section 5.3 and below. A complete description of the dietary exposure and risk assessment is provided in the memorandum for a different inert ingredient cluster entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09).

A chronic aggregate dietary (food and drinking water) exposure and risk assessments was conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

5.5.1. Acute Dietary Exposure and Risk

No adverse effects attributable to a single exposure to the MPOAC inerts were seen in the toxicity databases; therefore, an acute dietary risk assessment is not appropriate.

5.5.2. Chronic Dietary Exposure and Risk

A conservative screening level chronic dietary (food and water) exposure and risk assessment was conducted for the MPOACs using the highest tolerance level residue for all food forms, including meat, milk, poultry and eggs, default processing factors for dried commodities and 100% CT. In addition, a default concentration of 100 ppb was assumed for inert ingredient residues in drinking water.

The chronic dietary exposure estimates for food and drinking water are below HED's level of concern (<100% cPAD) for the U.S. population and all population subgroups. The petitioner has requested that the specific exemption from the requirement of a tolerance state that the MPOACs may be no more than 10% by weight in herbicide formulations and 5% in all other pesticide formulations. Since the screening level modeling developed to support inert ingredient risk assessments does not have the capability to accept differing caps for different classes of pesticides, the Agency ran the assessment using the highest requested cap in the final pesticide formulation of 10%. When the percentage of inert in the end use product for any class of pesticide was limited to no more than 10% by weight, the chronic dietary risk estimates for food

and drinking water were not of concern. MPOAC inert dietary exposure for food and drinking water is 16% of the cPAD for the U.S. population and 51% of the cPAD for children 1-2 yrs old, the most highly exposed population subgroup. See Table 5.4.4, below for a summary of results.

5.5.3. Cancer Dietary Exposure and Risk

HED has not identified any concerns for carcinogenicity relating to the MPOACs; therefore, a cancer dietary exposure assessment was not performed.

5.5.4. Summary of Dietary Exposure and Risk Assessment Results

The results of the chronic dietary risk assessment are shown in the summary table, below. The input and output files for the chronic dietary assessment are included in this memorandum as Appendix D.

Table 5.5.4. Summary of Dietary (Food and Drinking Water) Exposure and Risk for Alkyl Ammonium Chloride Salts (AACS) Cluster 7

Population Subgroup	Acute Dietary (95th Percentile)		Chronic Dietary	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	No acute endpoint selected		0.039988	16
All Infants (< 1 year old)			0.084945	34
Children 1-2 years old			**0.127305**	**51**
Children 3-5 years old			0.094736	38
Children 6-12 years old			0.052679	21
Youth 13-19 years old			0.030043	12
Adults 20-49 years old			0.030455	12
Adults 50+ years old			0.032072	13
Females 13-49 years old			0.030646	12

The most highly exposed subgroup is bolded.

6.0 Residential (Non-Occupational) Exposure/Risk Characterization

The MPOACs may be used as inert ingredients in pesticide formulations that are used in and around the home. Additionally, uses are possible in household cleaning products and in personal

care products. The Agency has not selected endpoints for dermal or inhalation risk assessment; therefore, only exposure scenarios which will result in oral exposures have been assessed for the MPOACs.

6.1 Residential Handler Exposure

Handler exposures to pesticide formulations and cleaning products are assessed for adults only and result in exposures by the dermal and inhalation routes only. Since dermal and inhalation endpoints have not been selected for the MPOACs; a residential handler assessment is not appropriate for these inert ingredients.

6.2 Residential Postapplication Exposure

Exposure Scenarios
Residential postapplication exposures result when bystanders, such as children come in contact with the MPOAC inerts in areas where end-use products have recently been applied (e.g., treated lawns, gardens or recently cleaned surfaces). The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. HED conducted an assessment to represent worst-case residential exposure by assessing post application exposures and risks from:

- MPOACs in pesticide formulations (fungicides/insecticides/herbicides); (Outdoor Scenarios)
- MPOACs in disinfectant-type uses; (Indoor Scenarios)

Only oral endpoints were selected for MPOAC inerts; therefore only incidental oral postapplication scenarios are assessed.

For all postapplication exposure scenarios, exposures are assessed at short- and intermediate-term exposure durations because residues may be present on treated lawns or indoor treated surfaces for lengths of time consistent with intermediate-term exposure.

Residential postapplication exposure can occur in commercially treated environments (e.g., schools, hospitals). If the products are used on a routine basis (i.e., daily) and the inert ingredient has a long indoor half-life, exposures may occur over an intermediate-term time duration (30 days – 6 months).

Postapplication High End Outdoor Exposure Scenarios
- Hand-to-Mouth activity for toddlers on treated lawns (children)
- Object-to-Mouth activity for toddlers on treated lawns (children)
- Soil ingestion from treated soil (children)

The exposures from these routes and scenarios were considered individually and were also added together, where appropriate, to determine a total dose for children exposure to treated lawns.

Residential postapplication exposure is assessed on the day of application, typically referred to as "Day 0".

Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the residential postapplication risk assessments. The assumptions and factors used in the risk calculations are consistent with current HED policy for completing residential exposure assessments (i.e., *SOPs for Residential Exposure Assessment [1997 and 2001 revision]*).

Exposures to adults/children after contact with treated lawns have been addressed using the latest approaches for this scenario including:

- For adult exposure, the mean for US males and females was used to estimate exposure (70 kg). For child exposure, the mean of median values for male and female 3 year olds was used to estimate exposure (15 kg).
- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2 (based on the surface area of three fingers of a toddler's hand). For short-term exposures, it is assumed that there were 20 events per hour (90th percentile, according to the SOP) and for intermediate-term exposures, it was assumed that there were 9.5 event/hour (mean value).
- The exposure time used is 4 hours a day (USEPA, 2000 and 2001).
- The saliva extraction efficiency used is 50% (USEPA, 2000 and 2001).
- Pesticidal products are assumed to contain a maximum of 10% MPOACs in herbicide products, 5% MPOACs in all other products.
- Residential risk assessments are based on estimates of what homeowners would typically treat. Per HED's Residential SOPs (1997 & 2001 revision), residential pesticide handlers are assumed to mix and use a volume of 5 gallons of product per day.
- For outdoor pesticide applications, residential handlers are assumed to use a total of 0.45 lbs MPOACs per day for herbicide products and 0.225 lbs MPOACs per day for all other products. This is also the amount used to estimate postapplication exposure. This estimate is based on the following assumptions:
    - Five (5) gallons of formulated pesticide solution are assumed to be used per day by a residential handler (Revised Residential SOPs Area Treated, February, 2001). Consistent with the residential SOPs, the density of the formulated pesticide solution are assumed to be 9 lbs/gallon. Per the JITF CST7 submission, the proposed limit to the amount of MPOAC inert in the pesticide products is 10% for herbicide products, 5% all other products. Therefore 10% of any herbicide product is assumed to be MPOACs, and all other products are assumed to be 5% MPOAC inerts. Product concentrates are assumed to be diluted at a 1 to 10 ratio with water.
- A dermal absorption factor is not relevant to this assessment as oral exposure was the only route of exposure assessed.

Postapplication High End Indoor Exposure Scenarios

Standard methodologies based on HED's Residential SOPs were used to assess residential postapplication exposure to hard surface cleaners.

Per the JITF CST7 submission, the proposed limit to the amount of MPOAC inert in the pesticide products is 10% for herbicide products, 5% all other pesticidal products. Additionally, HED has identified some residential use cleaning products that contain MPOAC that do not make antimicrobial claims. HED notes that inclusion of this scenario under FQPA in the aggregate risk assessment provides a conservative aggregate risk assessment. The amount of MPOAC in indoor cleaning products is not expected to exceed 5% as this reflects a high-end concentration based on an overall query of products that contain MPOAC. The residue of these indoor cleaning products can be available for residential postapplication exposure as children can be exposed in day care centers/schools.

Typically, the Agency assesses disinfectant-type products for the short-term exposure duration (1 to 30 days). This assumption is supported by the fact that the different residential scenarios (i.e. methods of application) are episodic, not daily. In addition, homeowners are assumed to use different cleaning products with varying active and inert ingredients. However, intermediate-term exposure is assessed for children because disinfectant products are used frequently in schools and day care centers where children can spend significant amounts of time. In those environments, cleaning products can be used on a daily basis.

The Agency used assumptions based on the Residential SOPs. The following key assumptions were used in this assessment:

- Toddlers (3 years old) were used to represent the 1 to 6 year old age group and are assumed to weigh 15 kg, the median for male and female toddlers (USEPA, 2000 and 2001).
- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2 (based on the surface area of three fingers of a toddler's hand. For short-term exposures, it is assumed that there were 20 events per hour (90th percentile, according to the SOP) and for intermediate-term exposures, it was assumed that there were 9.5 event/hour (mean value).
- The exposure time was 4 hours a day (USEPA, 2000 and 2001).
- The saliva extraction efficiency was 50% (USEPA, 2000 and 2001).
- No label information was available to represent the volume of disinfectant to be used for cleaning surfaces such as floors. It was assumed that the diluted treatment solution was applied at a rate of 1 gallon per 1,000 sq. ft^2.
- The maximum application rate on the product labels for application to hard surfaces is 8.34 lbs product/gal, based on the density of water. The amount of product used is assumed to be 0.5 gallons per day at a rate of 1 gallon/1000 ft^2, (i.e., 0.5 gallons for 500 ft^2). Therefore, the application rate used for the hard surface cleaner scenario in the post application scenario was $6.5x10^{-6}$ lbs inert/ft^2 [(1 gallon of product used * 8.34 lbs/gallon)/1000 ft^2 cleaned = 0.008 lb product/ft^2); (0.008 lb product/ ft^2 * 5% inert in a

given disinfectant formulation * 2 oz/128 oz dilution factor= $6.5x10^{-6}$ lb/ft^2 /per day)] (See Table 6.2: Indoor Cleaning Products)

- No data is available regarding the quantity of solution residue left on the floor after treatment. As a conservative measure, it was assumed that 25% of the cleaner remains after the final mopping. This assumption has been used by the AD for other Office of Pesticide Program risk assessments.
- No transferable residue data were available that could be used to estimate the transfer factor from the floor to skin. Therefore, it is assumed that 10% of the deposition rate is available for dermal transfer (USEPA, 2000 and 2001).
- A dermal absorption factor was utilized as incidental oral was the only route of exposure assessed.

Risks were calculated using the Margin of Exposure (MOE) approach, which compares a toxicological Point of Departure (PoD) to an exposure estimate. Exposure algorithms and additional information on calculating the risk estimates for residential postapplication exposure can be found in the memorandum entitled *JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations* (D364751, 5/7/09, Lloyd/LaMay)

Risk Summary

A summary of the residential postapplication exposure and risk estimates are presented in Table 6.2, below. Short- and intermediate-term post application risks for children are not of concern. The individual route-specific and combined non-dietary risks from incidental oral exposures for the outdoor scenarios and indoor scenarios do not demonstrate risks of concern for toddlers (i.e., the MOEs for the assessed scenarios are greater than 100).

Risk Characterization

At this time, residue dissipation data or reliable use pattern data are not available, including the frequency and duration of use of cleaning products in the residential setting. The Agency does not believe that the use patterns of many residential products result in intermediate-term exposure. However, the Agency notes that intermediate-term exposure to children may occur in areas where disinfecting products are used more frequently (i.e., schools and day care centers).

Table 6.2. Incidental Oral Residential Postapplication Short- and Intermediate-term Exposures and Risks for MPOACs				
Exposure Scenario	Application Rate[1]	Exposed Population & Exposure Duration[2]	Daily Dose (mg/kg/day)[3]	MOE[4]
Outdoor Lawn Products, Herbicides				
Hand-to-Mouth from Treated Lawn	0.45 lb/day	Child ST	0.0067	3,700
		Child IT	0.0032	7,800
Object-to-Mouth from Treated Lawn		Child ST	0.0017	15,000
		Child IT		
Soil Ingestion		Child ST	0.0000225	1,100,000
		Child IT		
Outdoor Lawn Products, Insecticides/ Fungicides				
Hand-to-Mouth from Treated Lawn	0.225 lb/day	Child ST	0.00336	7,400
		Child IT	0.0016	16,000
Object-to-Mouth from Treated Lawn		Child ST	0.00084	30,000
		Child IT		
Soil Ingestion		Child ST	0.0000113	2,200,000
		Child IT		
Indoor Cleaning Product				
Hand-to-Mouth from Treated Indoor Surface	6.5E-6 lb/ft^2	Child ST	0.0042	5,900
		Child IT	0.002	12,000

[1] Application rates for outdoor and indoor products are derived in Section 6.2.
[2] ST and IT indicate short- or intermediate-term exposure durations
[3] Daily Dose = Daily Dose algorithms for various residential postapplication scenarios outlined in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751," 5/7/09.
[4] MOE = PoD (NOAEL of 25 mg/kg/day)/ Daily dose (mg/kg/day)

7.0 Aggregate Risk Assessments and Risk Characterization

Endpoints for dermal and inhalation risk assessment were not selected for the MPOACs; therefore aggregate risks for this cluster of inert ingredients combine average dietary (food and water) exposures with post-application incidental oral exposures (children only).

7.1 Acute Aggregate Risk

There was no hazard attributable to a single exposure seen the in the toxicity database for the MPOAC inerts; therefore an acute aggregate risk assessment is not appropriate.

7.2 Short-Term/Intermediate-Term Aggregate Risk

Short-term and intermediate-term aggregate risk assessments for the MPOAC inert ingredients combine high end residential short- or intermediate-term exposures with average food and drinking water exposures, and compare this total to a short- or intermediate term PoD. Short- and intermediate-term aggregate risks for adults are limited to dietary exposure only, and as discussed in Section 5.5 are not of concern.

The residential exposure values used in the aggregate risk assessments for children are shown in Table 7.2.1., below.

Table 7.2.1. Residential Exposures for Use in the MPOAC Aggregate Risk Assessment

Population	Handler Exposure (mg/kg/day)[1]	Postapplication Exposure (mg/kg/day)[2]	Residential Exposure (mg/kg/day)[3]
Short-Term			
Child	N/A	0.0067 Source: Table 6.2 Hand-to-mouth from Treated Lawn (Herbicice)	0.0067
Intermediate-Term			
Child	N/A	0.0032 Source: Table 6.2 Hand-to-mouth from Treated Lawn (Herbicice)	0.0032

[1] Handler exposure, which is applicable to adult populations only, combines high end dermal and inhalation handler exposure. This exposure is included in the short-term aggregate assessment for adults only, as HED does not believe that residential handlers will have intermediate-term exposures.

[2] Postapplication exposure for adults, includes high end dermal exposure from: 1) treated turf or; 2) pets, whichever is higher. Postapplication exposure for children combines postapplication exposures from dermal and hand-to-mouth (oral) exposure to one of the following scenarios: 1) treated turf; 2) indoor cleaning surfaces; 3) or pets, whichever is highest. Both short- and intermediate-term durations are appropriate for post-application exposures.

[3] Residential exposure is the sum of the handler (adults only) and post application exposures.

Short- and intermediate-term aggregate risks are not of concern for the MPOACs. Short- and intermediate-term aggregate risks for adults are limited to dietary exposure only, and as discussed in Section 5.5, above, are not of concern. Table 7.2.2, below summarizes short- and intermediate-term aggregate risks for children.

Table 7.2.2. Short- and Intermediate-Term Aggregate Oral Risk Calculations for the MPOACs						
Population	**PoD mg/kg/day**	**LOC[1]**	**Max Allowable Exposure[2] mg/kg/day**	**Average Food & Water Exposure mg/kg/day**	**Residential Exposure[3] mg/kg/day**	**Aggregate MOE (food and residential)[4]**
Short-Term						
Child	25	100	0.25	0.127305	0.0067	190
Intermediate-Term						
Child	25	100	0.25	0.127305	0.0032	190

[1] The LOC (Level of Concern) is based on the standard inter- and intra-species uncertainty factors totaling 100.
[2] Maximum Allowable Exposure (mg/kg/day) = PoD (Point of Departure)/LOC
[3] Residential Exposure = Incidental Oral hand-to-mouth exposure for children only (Table 6.2).
[4] Aggregate MOE = [PoD/ (Avg Food & Water Exposure + Residential Exposure)]

7.3 Long-Term Aggregate Risk

For the MPOACs, the long-term aggregate risk includes dietary exposures to food and drinking water only. Dietary (food and water) exposures and risk are discussed in Section 5.5.4 of this memorandum. Long-Term (chronic) aggregate risks for the MPOAC inerts are not of concern.

7.4 Cancer Risk

HED has not identified any concerns for carcinogenicity for the MPOAC inerts; therefore, an aggregate cancer dietary exposure assessment is not appropriate.

8.0 Occupational Exposure/Risk Pathway

Quantitative dermal or inhalation risk assessments will not be performed for occupational workers because the MPOACs are highly corrosive/irritating, and therefore exposure will be self-limiting and will be regulated based on labeling of the end use product. There is not a significant concern for dermal or inhalation exposures due to expected low dermal and inhalation absorptions and the fact that the product is used in low percentages in household products (i.e., low exposure).

9.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the USDA under the Continuing Survey of Food Intake by Individuals (CSFII) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas postapplication are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

10.0 Human Studies

This assessment does not rely on any studies in which human subjects were intentionally exposed to a pesticide.

APPENDIX A. Toxicity Information for the MPOAC Inerts

Table A.2.2 Toxicity Profile			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
OECD 422	Subchronic/Repro	47644401 (2009) Acceptable/non-guideline 0, 25, 50, 100 mg/kg/d	**Parental NOAEL = 25** mg/kg/d **Parental LOAEL = 50** mg/kg/d based on forestomach inflammation and mortality in females **Repro/Devel NOAEL = 25** mg/kg/d **Repro/Devel LOAEL** could not be determined because of insufficient animals

EXECUTIVE SUMMARY: In a Combined Repeated Dose Toxicity Study using the Reproduction/Developmental Toxicity Screening Test (MRID 47644401), Quarternary ammonium compounds, coco alkylmethylbis(hydroxyethyl)methyl, chlorides (QACs, CAS # 70750-47-9; 75% purity) was administered by gavage to HanRcc: WIST(SPF) rats. There were 10 rats per sex per dose group. Males were dosed at 0, 25, 50 and 100 mg/kg bw/day for at least 28 days and females were dosed for 14 days prior to pairing, through the pairing and gestation periods until the F_1 generation reached lactation day 4. Dose levels were adjusted for 75% purity by applying a correction factor of 1.33. The test substance contains anhydrous isopropanol at a concentration of 23%, therefore the control animals were dosed with anhydrous isopropanol in water (IPA 23%) at the same dilution as the high-dose level formulation.

At 100 mg/kg/day, all animals were found dead or were sacrificed *in extremis* on day 5 of the pre-mating period. At 50 mg/kg/day, one female was found dead on day 6 of the pre-mating period and four females were sacrificed *in extremis* on day 8. Histopathology examination revealed that marked inflammatory lesions in the forestomach were associated with the cause of these deaths. The test material caused these lesions by severe local irritation following treatment with a bolus by gavage.

Food consumption in the mid-dose group was somewhat suppressed in both males and females at the end of the 14-day pre-mating period, though not statistically significant (-10.7% in males, -10.2% in females). Sporadic statistical significance in decreased body weight gain was observed in both sexes at 50 mg/kg/day between days 6 and 10 of the pre-mating period. There were no body weight or food consumption effects at the 25 mg/kg dose level.

Results of the FOB and motor activity testing were not indicative of any neurological effect caused by the test material. Pregnancy occurred in all female rats in the three test groups evaluated for reproductive performance (0, 25, and 50 mg/kg/day). No statistically significant or biologically meaningful differences were observed in fertility, gestation interval, or number of litters for the mated female rats from the low- and mid-dose groups. The number of females evaluated at the 50 mg/kg/day dose level was lower than the eight required by the OECD

guidelines. There was no mating within the high-dose group of rats, since all the females died or were terminated.

No treatment-related hematology effects were observed. Liver enzymes were increased in males at the low- and mid-dose levels and in females at the mid-dose level. These increases were not accompanied by histopathological findings in the liver and were are not considered adverse. No treatment-related effects on organ weight were observed. At necropsy, slight to marked forestomach lesions (primarily hyperkeratosis) were found in all rats examined microscopically, but was not considered advers. As noted above, marked inflammatory lesions in the forestomach was associated with deaths in the mid- and high-dose groups.

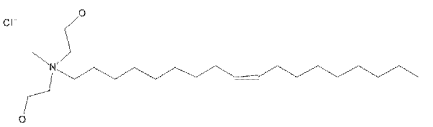
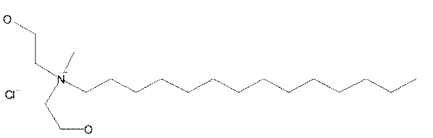
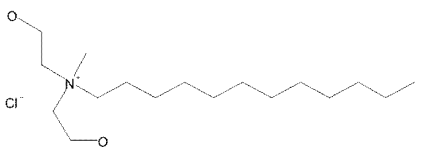
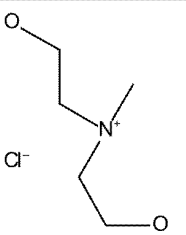
The repeated oral toxicity LOAEL for QACs in rats is 50 mg/kg/day based on mortality and forestomach inflammation. The NOAEL is 25 mg/kg/day.

A reproductive/developmental LOAEL for QACs in rats was not demonstrated in this study. The reproductive/developmental NOAEL in rats is 25 mg/kg/day (No reproductive or developmental effects were observed at 50 mg/kg/day, but the evaluation at this dose level included only five female animals.).

This study is classified **Acceptable (Guideline)** and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) in the rat.

APPENDIX B. Structure-Activity Relationship (SAR) Discussion

HED used DEREK for Windows (V. 11) to assess the potential toxicity of compounds in the inerts mixture as well as potential degradates. As described in Section 3 of this document these compounds are sodium salts of quaternary ammonium compounds. Five compounds were subjected to DEREK analysis: 1) a saturated C12 compound with POE =2; 2) a saturated C14 compound with POE =2; 3) an unsaturated C18 with POE =2; 4) a putative de-alkylated degradate, and 5) a putative de-ethoxylated degradate. The structures are shown in Figure 1 below.

Figure B-1. Structures of Compounds Subjected to Structure-Activity Analysis	
18448-65-2	
60687-90-3	
C12 Example	
De-alkylated	
De-ethoxylated structure	

Derek for Windows (LHASA Ltd.) is an expert system for the prediction of toxicity. It relies on a knowledge base of structural alerts and rules developed by scientists. When a test compound is inputted into the program, Derek for Windows scans the test compound for structural alerts contained within its database that are associated with specific toxicological endpoints and applies a series of reasoning rules to determine the likelihood of toxicity for the test compound. Information is provided on the rules used to make the prediction, along with descriptions of structural alerts identified, comments, available example compounds linked to the alerts and literature references.

APPENDIX C. Summary of Drinking Water Estimates of Four Surrogate Inert Chemicals

Notes:

1. Used a North Carolina cotton scenario with application date on July 1. This scenario should be a good representative of likely high-end drinking water residue estimates. Also varied application dates and weather files to ensure that there were no aberrations; these values look good in that regard.
2. PCA factors were not applied, but the impact of applying such factors (i.e., 0.5 to 0.9) would be insignificant in comparison to the vast uncertainties surrounding generation of concentrations from surrogate chemicals as well as uncertainties regarding the actual timing of applications.
3. All simulations were made at approximately 1 lb/A. Concentrations resulting from other application rates will be directly proportional to the application rate.
4. Table 1 gives the normalized concentration estimates for the case where all mass is applied on a single day. This should be the most conservative case.
5. Table 2 gives the normalized concentration estimates for the case where mass is distributed evenly over a 100-day period (April to June).
6. A range of degradation rates were used because degradation information was not available. 3 simulations were made 1) chemically stable in water and soil, 2) a 100 day half life in water and soil, and 3) a 10-day half life in water and soil. This should cover degradation.
7. Table 3 gives the chemical inputs used in the simulations.

Table 1. DW concentration for application lumped on a single day. (This maximizes the acute concentrations.) All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Estimates based on Stable Assumption				
Acute (ppb)	1.1	41	33	0.005
Chronic	0.69	15	19	0.003
Cancer	0.47	12	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
Acute (ppb)	0.74	36	22	0.003
Chronic	0.33	8.8	7.7	0.002
Cancer	0.25	6.4	6.4	0.001
Estimates based on assumption of a 10-day half life in soil and water				
Acute (ppb)	0.48	25	15	0.002
Chronic	0.04	1.1	0.96	0.0002
Cancer	0.03	0.65	0.60	0.0002

Table 2. DW concentration for applications spread out over a 100-day period. This simulates a more even distribution of pesticide over the growing season. All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Spread Out Values				
Estimates based on Stable Assumption				
Acute (ppb)	0.98	29	28	0.004
Chronic	0.70	13	18	0.003
Cancer	0.48	10	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
	0.57	21	17	0.003
	0.36	6.9	7.2	0.002
	0.27	5.3	6.4	0.001
Estimates based on assumption of a 10-day half life in soil and water				
	0.16	7.8	4.3	0.001
	0.04	0.79	0.77	0.0002
	0.03	0.61	0.63	0.0002

Table 3 Chemical Inputs used in Simulations.

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Chemical Inputs:				
MW	*928*	*274*	*302*	*1185*
Solubility (mg/L)	*382*	*299*	*19.5*	*6.69e-8*
V.P. (mmHg)	*5.8e-27*	*1.76e-8*	*3.86e-8*	*3.77e-33*
Koc (ml/g)	*9.44e6*	*152*	*1345*	*2.57e9*

APPENDIX D. Dietary Exposure and Risk Input/Outputs

D.1. MPOAC Chronic Dietary (Food and Water) Results

```
U.S. Environmental Protection Agency                                    Ver. 2.00
DEEM-FCID Chronic analysis for INERTS CST 7                          (1994-98 data)
Residue file name: C:\Deemfcid\inerts\Inerts_57active_10%_CST7_100ppbH2Orev2.R98
                                                    Adjustment factor #2 used.
Analysis Date 05-07-2009/10:02:19     Residue file dated: 05-07-2009/10:01:23/8
Reference dose (RfD, Chronic) = .25 mg/kg bw/day
COMMENT 1: Inert 57 active ingredients + drinking water (100ppb); 10% formulated product
================================================================================
                    Total exposure by population subgroup
--------------------------------------------------------------------------------
```

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.039988	16.0%
U.S. Population (spring season)	0.040774	16.3%
U.S. Population (summer season)	0.040558	16.2%
U.S. Population (autumn season)	0.039259	15.7%
U.S. Population (winter season)	0.039378	15.8%
Northeast region	0.043188	17.3%
Midwest region	0.039797	15.9%
Southern region	0.035898	14.4%
Western region	0.043815	17.5%
Hispanics	0.042254	16.9%
Non-hispanic whites	0.039190	15.7%
Non-hispanic blacks	0.038658	15.5%
Non-hisp/non-white/non-black	0.051461	20.6%
All infants (< 1 year)	0.084945	34.0%
Nursing infants	0.044592	17.8%
Non-nursing infants	0.100263	40.1%
Children 1-6 yrs	0.101523	40.6%
Children 7-12 yrs	0.049499	19.8%
Females 13-19 (not preg or nursing)	0.028974	11.6%
Females 20+ (not preg or nursing)	0.031541	12.6%
Females 13-50 yrs	0.032536	13.0%
Females 13+ (preg/not nursing)	0.034408	13.8%
Females 13+ (nursing)	0.040855	16.3%
Males 13-19 yrs	0.030879	12.4%
Males 20+ yrs	0.030339	12.1%
Seniors 55+	0.032141	12.9%
Children 1-2 yrs	0.127305	50.9%
Children 3-5 yrs	0.094736	37.9%
Children 6-12 yrs	0.052679	21.1%
Youth 13-19 yrs	0.030043	12.0%
Adults 20-49 yrs	0.030455	12.2%
Adults 50+ yrs	0.032072	12.8%
Females 13-49 yrs	0.030646	12.3%

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D2. MPOAC Chronic Dietary (Food and Water) Input File

```
U.S. Environmental Protection Agency                                  Ver. 2.00
DEEM-FCID Chronic analysis for INERTS CST 7                         1994-98 data
Residue file: C:\Deemfcid\inerts\Inerts_57active_10%_CST7_100ppbH2Orev2.R98
                                                                  Adjust. #2 used
Analysis Date 05-07-2009            Residue file dated: 05-07-2009/10:01:23/8
Reference dose (RfD) = 0.25 mg/kg bw/day
Comment:Inert 57 active ingredients + drinking water (100ppb); 10% formulated product
-------------------------------------------------------------------------------
Food Crop                                        Residue      Adj.Factors      Comment
EPA Code  Grp  Food Name                          (ppm)
                                                             #1        #2
-------- ---- -------------------------------   ---------- ------    ------   -------
95000010 O    Acerola                            2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
18000020 18   Alfalfa, seed                      0.500000   1.000      0.200   glypho
  Full comment: glyphosate
14000030 14   Almond                             1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
14000031 14   Almond-babyfood                    1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
14000040 14   Almond, oil                        1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
14000041 14   Almond, oil-babyfood               1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
04010050 4A   Amaranth, leafy                  100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
95000060 O    Amaranth, grain                    5.000000   1.000      0.200   glypho
  Full comment: glyphosate [wheat]
11000070 11   Apple, fruit with peel            25.000000   1.000      0.200   captan
11000080 11   Apple, peeled fruit               25.000000   1.000      0.200   captan
11000081 11   Apple, peeled fruit-babyfood      25.000000   1.000      0.200   captan
11000090 11   Apple, dried                      25.000000   8.000      0.200   captan
11000091 11   Apple, dried-babyfood             25.000000   8.000      0.200   captan
11000100 11   Apple, juice                      25.000000   1.000      0.200   captan
11000101 11   Apple, juice-babyfood             25.000000   1.000      0.200   captan
11000110 11   Apple, sauce                      25.000000   1.000      0.200   captan
11000111 11   Apple, sauce-babyfood             25.000000   1.000      0.200   captan
12000120 12   Apricot                           15.000000   1.000      0.200   TM
12000121 12   Apricot-babyfood                  15.000000   1.000      0.200   TM
12000130 12   Apricot, dried                    15.000000   6.000      0.200   TM
12000140 12   Apricot, juice                    15.000000   1.000      0.200   TM
12000141 12   Apricot, juice-babyfood           15.000000   1.000      0.200   TM
01030150 1CD  Arrowroot, flour                   1.000000   1.000      0.200   diuron
  Full comment: diuron (potato transl]
01030151 1CD  Arrowroot, flour-babyfood          1.000000   1.000      0.200   diuron
  Full comment: diuron (potato transl]
95000160 O    Artichoke, globe                   5.000000   1.000      0.200   permet
  Full comment: permethrin
01030170 1CD  Artichoke, Jerusalem               1.000000   1.000      0.200   diuron
  Full comment: diuron (potato transl]
04010180 4A   Arugula                          100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
95000190 O    Asparagus                         10.000000   1.000      0.200   carbar
  Full comment: carbaryl
95000200 O    Avocado                           25.000000   1.000      0.200   fosety
  Full comment: fosetyl-al
09020210 9B   Balsam pear                       15.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (curcurbits)
95000220 O    Bamboo, shoots                     0.200000   1.000      0.200   glypho
  Full comment: glyphosate
95000230 O    Banana                            10.000000   1.000      0.200   carbar
  Full comment: carbaryl
95000231 O    Banana-babyfood                   10.000000   1.000      0.200   carbar
  Full comment: carbaryl
95000240 O    Banana, dried                     10.000000   3.900      0.200   carbar
  Full comment: carbaryl
95000241 O    Banana, dried-babyfood            10.000000   3.900      0.200   carbar
  Full comment: carbaryl
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15000250 15	Barley, pearled barley	20.000000	1.000	0.200	glypho
Full comment: glyphosate					
15000251 15	Barley, pearled barley-babyfood	20.000000	1.000	0.200	glypho
Full comment: glyphosate					
15000260 15	Barley, flour	20.000000	1.000	0.200	glypho
Full comment: glyphosate					
15000261 15	Barley, flour-babyfood	20.000000	1.000	0.200	glypho
Full comment: glyphosate					
15000270 15	Barley, bran	30.000000	1.000	0.200	glypho
Full comment: glyphosate for bran					
19010280 19A	Basil, fresh leaves	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
19010281 19A	Basil, fresh leaves-babyfood	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
19010290 19A	Basil, dried leaves	260.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
19010291 19A	Basil, dried leaves-babyfood	260.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
06030300 6C	Bean, black, seed	7.000000	1.000	0.200	maneb
06020310 6B	Bean, broad, succulent	10.000000	1.000	0.200	maneb;
Full comment: maneb;carbaryl (CG 6)					
06030320 6C	Bean, broad, seed	7.000000	1.000	0.200	maneb
06020330 6B	Bean, cowpea, succulent	10.000000	1.000	0.200	maneb;
Full comment: maneb;carbaryl (CG 6)					
06030340 6C	Bean, cowpea, seed	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
06030350 6C	Bean, great northern, seed	7.000000	1.000	0.200	maneb
06030360 6C	Bean, kidney, seed	7.000000	1.000	0.200	maneb
06020370 6B	Bean, lima, succulent	10.000000	1.000	0.200	maneb;
Full comment: maneb;carbaryl (CG 6)					
06030380 6C	Bean, lima, seed	7.000000	1.000	0.200	maneb
06030390 6C	Bean, mung, seed	2.000000	1.000	0.200	triflu
Full comment: trifluralin					
06030400 6C	Bean, navy, seed	7.000000	1.000	0.200	maneb
06030410 6C	Bean, pink, seed	7.000000	1.000	0.200	maneb
06030420 6C	Bean, pinto, seed	7.000000	1.000	0.200	maneb
06010430 6A	Bean, snap, succulent	5.000000	1.000	0.200	chloro
Full comment: chlorothalonil					
06010431 6A	Bean, snap, succulent-babyfood	5.000000	1.000	0.200	chloro
Full comment: chlorothalonil					
21000440 M	Beef, meat	2.000000	1.000	0.200	endosu
Full comment: endosulfuran					
21000441 M	Beef, meat-babyfood	2.000000	1.000	0.200	endosu
Full comment: endosulfuran					
21000450 M	Beef, meat, dried	2.000000	1.920	0.200	endosu
Full comment: endosulfuran					
21000460 M	Beef, meat byproducts	1.000000	1.000	0.200	diuron
21000461 M	Beef, meat byproducts-babyfood	1.000000	1.000	0.200	diuron
21000470 M	Beef, fat	13.000000	1.000	0.200	endosu
Full comment: endosufuran					
21000471 M	Beef,fat-babyfood	13.000000	1.000	0.200	endosu
Full comment: endosufuran					
21000480 M	Beef, kidney	4.000000	1.000	0.200	glypho
Full comment: glyphosate; 2,4-D					
21000490 M	Beef, liver	5.000000	1.000	0.200	endosu
Full comment: endosulfuran					
21000491 M	Beef, liver-babyfood	5.000000	1.000	0.200	endosu
Full comment: endosulfuran					
01010500 1AB	Beet, garden, roots	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
01010501 1AB	Beet, garden, roots-babyfood	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
02000510 2	Beet, garden, tops	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin (CG 2)					
01010520 1A	Beet, sugar	15.000000	1.000	0.200	chlorp
Full comment: chlorpyrifos					
01010521 1A	Beet, sugar-babyfood	15.000000	1.000	0.200	chlorp
Full comment: chlorpyrifos					
01010530 1A	Beet, sugar, molasses	15.000000	1.000	0.200	chlorp
Full comment: chlorpyrifos					
01010531 1A	Beet, sugar, molasses-babyfood	15.000000	1.000	0.200	chlorp

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  Full comment: chlorpyrifos
95000540 O    Belgium endive                  100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
13010550 13A  Blackberry                       40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13010560 13A  Blackberry, juice                40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13010561 13A  Blackberry, juice-babyfood       40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13020570 13B  Blueberry                       40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13020571 13B  Blueberry-babyfood              40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13010580 13A  Boysenberry                     40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
14000590 14   Brazil nut                       1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
95000600 O    Breadfruit                       0.200000   1.000      0.200   glypho
  Full comment: glyphosate
05010610 5A   Broccoli                        60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
05010611 5A   Broccoli-babyfood               60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
05010620 5A   Broccoli, Chinese               60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
05020630 5B   Broccoli raab                   60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
05010640 5A   Brussels sprouts                60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
15000650 15   Buckwheat                        0.100000   1.000      0.200   metola
  Full comment: metolachlor
15000660 15   Buckwheat, flour                 0.100000   1.000      0.200   metola
  Full comment: metolachlor
01010670 1AB  Burdock                         10.000000   1.000      0.200   carbar
  Full comment: carbaryl (carrot)
14000680 14   Butternut                        1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
05010690 5A   Cabbage                         60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
05020700 5B   Cabbage, Chinese, bok choy      60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
05010710 5A   Cabbage, Chinese, napa          60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
05010720 5A   Cabbage, Chinese, mustard       60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
95000730 O    Cactus                           0.500000   1.000      0.200   glypho
  Full comment: glyphosate
95000740 O    Canistel                         2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
09010750 9A   Cantaloupe                      15.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (curcurbits)
04020760 4B   Cardoon                        100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
95000770 O    Carob                            0.050000   1.000      0.200   chloro
  Full comment: chlorothanil
01010780 1AB  Carrot                         10.000000   1.000      0.200   carbar
  Full comment: carbaryl
01010781 1AB  Carrot-babyfood                10.000000   1.000      0.200   carbar
  Full comment: carbaryl
01010790 1AB  Carrot, juice                  10.000000   1.000      0.200   carbar
  Full comment: carbaryl
09010800 9A   Casaba                          15.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (curcurbits)
14000810 14   Cashew                           1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
01030820 1CD  Cassava                         1.000000   1.000      0.200   diuron
  Full comment: diuron [potato transl]
01030821 1CD  Cassava-babyfood                1.000000   1.000      0.200   diuron
  Full comment: diuron [potato transl]
05010830 5A   Cauliflower                     60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
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01010840 1AB	Celeriac	10.000000	1.000	0.200	carbar
Full comment: carbaryl (carrot)					
04020850 4B	Celery	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
04020851 4B	Celery-babyfood	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
04020860 4B	Celery, juice	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
04020870 4B	Celtuce	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
09020880 9B	Chayote, fruit	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
95000890 O	Cherimoya	2.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
12000900 12	Cherry	50.000000	1.000	0.200	captan
12000901 12	Cherry-babyfood	50.000000	1.000	0.200	captan
12000910 12	Cherry, juice	50.000000	1.000	0.200	captan
12000911 12	Cherry, juice-babyfood	50.000000	1.000	0.200	captan
14000920 14	Chestnut	1.000000	1.000	0.200	glypho
Full comment: glyphosate (tree nut)					
40000930 P	Chicken, meat	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
40000931 P	Chicken, meat-babyfood	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
40000940 P	Chicken, liver	5.000000	1.000	0.200	iprodi
Full comment: iprodione					
40000950 P	Chicken, meat byproducts	1.000000	1.000	0.200	glypho
Full comment: glyphosate					
40000951 P	Chicken, meat byproducts-babyfoo	1.000000	1.000	0.200	glypho
Full comment: glyphosate					
40000960 P	Chicken, fat	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
40000961 P	Chicken, fat-babyfood	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
40000970 P	Chicken, skin	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
40000971 P	Chicken, skin-babyfood	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
06030980 6C	Chickpea, seed	7.000000	1.000	0.200	maneb
06030981 6C	Chickpea, seed-babyfood	7.000000	1.000	0.200	maneb
06030990 6C	Chickpea, flour	7.000000	1.000	0.200	maneb
01011000 1AB	Chicory, roots	10.000000	1.000	0.200	carbar
Full comment: carbaryl [carrot]					
02001010 2	Chicory, tops	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin (CG 2)					
09021020 9B	Chinese waxgourd	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
19011030 19A	Chive				
	110-Uncooked; Fresh or N/S; Cook Meth N/S	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
	210-Cooked; Fresh or N/S; Cook Meth N/S	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
	211-Cooked; Fresh or N/S; Baked	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
	212-Cooked; Fresh or N/S; Boiled	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
	213-Cooked; Fresh or N/S; Fried	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
	221-Cooked; Frozen; Baked	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
	240-Cooked; Canned; Cook Meth N/S	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
	242-Cooked; Canned; Boiled	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herbs]					
04011040 4A	Chrysanthemum, garland	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
19021050 19B	Cinnamon	38.000000	1.000	0.200	azoxys

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  Full comment: azoxystrobin [spice]
19021051 19B  Cinnamon-babyfood                38.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin [spice]
10001060 10   Citrus citron                    10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10001070 10   Citrus hybrids                   10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10001080 10   Citrus, oil                      10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
95001090 O    Cocoa bean, chocolate             0.050000   1.000      0.200   chloro
  Full comment: chlorothalonil
95001100 O    Cocoa bean, powder                0.050000   1.000      0.200   chloro
  Full comment: chlorothalonil
95001110 O    Coconut, meat                     0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95001111 O    Coconut- meat-babyfood            0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95001120 O    Coconut, dried                    0.100000   2.100      0.200   glypho
  Full comment: glyphosate
95001130 O    Coconut, milk                     0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95001140 O    Coconut, oil                      0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95001141 O    Coconut, oil-babyfood             0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95001150 O    Coffee, roasted bean              1.000000   1.000      0.200   glypho
  Full comment: glyphosate
95001160 O    Coffee, instant                   1.000000   1.000      0.200   glypho
  Full comment: glyphosate
05021170 5B   Collards                         60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
19011180 19A  Coriander, leaves                 30.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
19011181 19A  Coriander, leaves-babyfood       30.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
19021190 19B  Coriander, seed                  38.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin [spice]
19021191 19B  Coriander, seed-babyfood         38.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin [spice]
15001200 15   Corn, field, flour                0.150000   1.000      0.200   lambda
  Full comment: lambda-cyhalothrin
15001201 15   Corn, field, flour-babyfood       0.150000   1.000      0.200   lambda
  Full comment: lambda-cyhalothrin
15001210 15   Corn, field, meal                 1.000000   1.000      0.200   glypho
  Full comment: glyphosate
15001211 15   Corn, field, meal-babyfood        1.000000   1.000      0.200   glypho
  Full comment: glyphosate
15001220 15   Corn, field, bran                 1.000000   1.000      0.200   glypho
  Full comment: glyphosate
15001230 15   Corn, field, starch               1.000000   1.000      0.200   glypho
  Full comment: glyphosate
15001231 15   Corn, field, starch-babyfood      1.000000   1.000      0.200   glypho
  Full comment: glyphosate
15001240 15   Corn, field, syrup                1.000000   1.500      0.200   glypho
  Full comment: glyphosate
15001241 15   Corn, field, syrup-babyfood       1.000000   1.500      0.200   glypho
  Full comment: glyphosate
15001250 15   Corn, field, oil                  3.000000   1.000      0.200   chloro
  Full comment: chloropyrifos
15001251 15   Corn, field, oil-babyfood         3.000000   1.000      0.200   chloro
  Full comment: chloropyrifos
15001260 15   Corn, pop                         0.500000   1.000      0.200   mancoz
  Full comment: mancozeb
15001270 15   Corn, sweet                       5.000000   1.000      0.200   maneb;
  Full comment: maneb;carbaryl
15001271 15   Corn, sweet-babyfood              5.000000   1.000      0.200   maneb;
  Full comment: maneb;carbaryl
95001280 O    Cottonseed, oil                  35.000000   1.000      0.200   glypho
  Full comment: glyphosate
95001281 O    Cottonseed, oil-babyfood         35.000000   1.000      0.200   glypho
  Full comment: glyphosate
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11001290 11	Crabapple	20.000000	1.000	0.200	phosme
Full comment: phosmet					
95001300 O	Cranberry	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
95001301 O	Cranberry-babyfood	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
95001310 O	Cranberry, dried	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
95001320 O	Cranberry, juice	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
95001321 O	Cranberry, juice-babyfood	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
04011330 4A	Cress, garden	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
04011340 4A	Cress, upland	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
09021350 9B	Cucumber	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
13021360 13B	Currant	40.000000	1.000	0.200	fosety
Full comment: fosetyl-al (berries)					
13021370 13B	Currant, dried	40.000000	1.000	0.200	fosety
Full comment: fosetyl-al (berries)					
04011380 4A	Dandelion, leaves	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
01031390 1CD	Dasheen, corm	1.000000	1.000	0.200	diuron
Full comment: diuron [potato transl]					
02001400 2	Dasheen, leaves	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin (CG 2)					
95001410 O	Date	0.200000	1.000	0.200	glypho
Full comment: glyphosate					
13011420 13A	Dewberry	40.000000	1.000	0.200	fosety
Full comment: fosetyl-al (berries)					
19021430 19B	Dill, seed	38.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [spice]					
19011440 19A	Dillweed	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [herb]					
70001450 P	Egg, whole	1.500000	1.000	0.200	iprodi
Full comment: iprodione					
70001451 P	Egg, whole-babyfood	1.500000	1.000	0.200	iprodi
Full comment: iprodione					
70001460 P	Egg, white	1.500000	1.000	0.200	iprodi
Full comment: iprodione					
70001461 P	Egg, white (solids)-babyfood	1.500000	1.000	0.200	iprodi
Full comment: iprodione					
70001470 P	Egg, yolk	1.500000	1.000	0.200	iprodi
Full comment: iprodione					
70001471 P	Egg, yolk-babyfood	1.500000	1.000	0.200	iprodi
Full comment: iprodione					
08001480 8	Eggplant	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
13021490 13B	Elderberry	40.000000	1.000	0.200	fosety
Full comment: fosetyl-al (berries)					
04011500 4A	Endive	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
95001510 O	Feijoa	2.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
04021520 4B	Fennel, Florence	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
95001530 O	Fig	7.000000	1.000	0.200	maneb
95001540 O	Fig, dried	7.000000	1.000	0.200	maneb
14001550 14	Filbert	1.000000	1.000	0.200	glypho
Full comment: glyphosate (tree nut)					
14001560 14	Filbert, oil	1.000000	1.000	0.200	glypho
Full comment: glyphosate (tree nut)					
80001570 F	Fish-freshwater finfish	2.000000	1.000	0.200	diuron
Full comment: diuron [catfish]					
80001580 F	Fish-freshwater finfish, farm ra	2.000000	1.000	0.200	diuron
80001590 F	Fish-saltwater finfish, tuna	2.000000	1.000	0.200	diuron
Full comment: diuron [catfish]					
80001600 F	Fish-saltwater finfish, other	2.000000	1.000	0.200	diuron
Full comment: diuron [catfish]					

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80001610 F    Fish-shellfish, crustacean          3.000000   1.000      0.200   glypho
  Full comment: glyphosate [shellfish]
80001620 F    Fish-shellfish, mollusc             3.000000   1.000      0.200   glypho
  Full comment: glyphosate [shellfish]
20001630 20   Flaxseed, oil                       5.000000   1.000      0.200   carbar
  Full comment: carbaryl
03001640 3    Garlic                              0.200000   1.000      0.200   glypho
  Full comment: glyphosate (CG 3)
03001650 3    Garlic, dried                       0.200000   1.000      0.200   glypho
  Full comment: glyphosate (CG 3)
03001651 3    Garlic, dried-babyfood              0.200000   1.000      0.200   glypho
  Full comment: glyphosate (CG 3)
01031660 1CD  Ginger                              0.200000   1.000      0.200   glypho
  Full comment: glyphosate
01031661 1CD  Ginger-babyfood                     0.200000   1.000      0.200   glypho
  Full comment: glyphosate
01031670 1CD  Ginger, dried                       0.200000   1.000      0.200   glypho
  Full comment: glyphosate
01011680 1AB  Ginseng, dried                      4.000000   1.000      0.200   iprodi
  Full comment: iprodione
23001690 M    Goat, meat                          2.000000   1.000      0.200   endosu
  Full comment: endosulfan
23001700 M    Goat, meat byproducts               1.000000   1.000      0.200   diuron
  Full comment: diuron; propanil
23001710 M    Goat, fat                          13.000000   1.000      0.200   endosu
  Full comment: endosulfan
23001720 M    Goat, kidney                        4.000000   1.000      0.200   endosu
  Full comment: endosulfan; 2,4-D
23001730 M    Goat, liver                         5.000000   1.000      0.200   endosu
  Full comment: endosulfan
13021740 13B  Gooseberry                         40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
95001750 O    Grape                              25.000000   1.000      0.200   captan
95001760 O    Grape, juice                       25.000000   1.000      0.200   captan
95001761 O    Grape, juice-babyfood              25.000000   1.000      0.200   captan
95001770 O    Grape, leaves                      25.000000   1.000      0.200   captan
95001780 O    Grape, raisin                      25.000000   1.000      0.200   captan
95001790 O    Grape, wine and sherry             25.000000   1.000      0.200   captan
10001800 10   Grapefruit                         10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10001810 10   Grapefruit, juice                  10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
06031820 6C   Guar, seed                          7.000000   1.000      0.200   maneb
06031821 6C   Guar, seed-babyfood                7.000000   1.000      0.200   maneb
95001830 O    Guava                              2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95001831 O    Guava-babyfood                     2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
19011840 19A  Herbs, other
              110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              150-Uncooked; Cured etc; Cook Meth N/S
                                                50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              210-Cooked; Fresh or N/S; Cook Meth N/S
                                                50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              211-Cooked; Fresh or N/S; Baked   50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              212-Cooked; Fresh or N/S; Boiled
                                                50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              213-Cooked; Fresh or N/S; Fried   50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              215-Cooked; Fresh or N/S; Boiled/baked
                                                50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              221-Cooked; Frozen; Baked         50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
              230-Cooked; Dried; Cook Meth N/S
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                                          260.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
                232-Cooked; Dried; Boiled 260.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
                233-Cooked; Dried; Fried  260.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
                240-Cooked; Canned; Cook Meth N/S
                                          260.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
                242-Cooked; Canned; Boiled 260.000000  1.000      0.200   azoxys
  Full comment: azoxystrobin
                250-Cooked; Cured etc; Cook Meth N/S
                                          260.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
                252-Cooked; Cured etc; Boiled 260.000000 1.000     0.200   azoxys
  Full comment: azoxystrobin
                253-Cooked; Cured etc; Fried 260.000000 1.000      0.200   azoxys
  Full comment: azoxystrobin
19011841 19A  Herbs, other-babyfood        50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
14001850 14   Hickory nut                   1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
95001860 O    Honey                        30.000000   1.000      0.200   glypho
  Full comment: glyphosate[sugarcane mol trans]
95001861 O    Honey-babyfood               30.000000   1.000      0.200   glypho
  Full comment: glyphosate[sugarcane mol trans]
09011870 9A   Honeydew melon               15.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (curcurbits)
95001880 O    Hop                           1.000000   1.000      0.200   methyl
  Full comment: methyl parathion
24001890 M    Horse, meat                   2.000000   1.000      0.200   endosu
  Full comment: endosulfuran
01011900 1AB  Horseradish                   5.000000   1.000      0.200   carbar
  Full comment: carbaryl
13021910 13B  Huckleberry                  40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
95001920 O    Jaboticaba                    2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95001930 O    Jackfruit                     2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
05021940 5B   Kale                         60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
95001950 O    Kiwifruit                    25.000000   1.000      0.200   phosme
  Full comment: phosmet
05011960 5A   Kohlrabi                     60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
10001970 10   Kumquat                      10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
03001980 3    Leek                          3.000000   1.000      0.200   methom
  Full comment: methomyl
10001990 10   Lemon                        10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002000 10   Lemon, juice                 10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002001 10   Lemon, juice-babyfood        10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002010 10   Lemon, peel                  10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
19012020 19A  Lemongrass                   50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin [herb]
06032030 6C   Lentil, seed                 10.000000   1.000      0.200   carbar
  Full comment: carbaryl
04012040 4A   Lettuce, head               100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
04012050 4A   Lettuce, leaf               100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
10002060 10   Lime                         10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002070 10   Lime, juice                  10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002071 10   Lime, juice-babyfood         10.000000   1.000      0.200   azoxys
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  Full comment: azoxystrobin ( citrus CG)
13012080 13A  Loganberry                          40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
95002090 O    Longan                               3.000000   1.000      0.200   imidac
  Full comment: imidacloprid
11002100 11   Loquat                               2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95002110 O    Lychee                               3.000000   1.000      0.200   imidac
  Full comment: imidacloprid
95002120 O    Lychee, dried                        3.000000   1.850      0.200   imidac
  Full comment: imidacloprid
14002130 14   Macadamia nut                        1.000000   1.000      0.200   glypho
  Full comment: glyphosate (tree nut)
95002140 O    Mamey apple                          0.200000   1.000      0.200   glypho
  Full comment: glyphosate
95002150 O    Mango                                2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95002151 O    Mango-babyfood                       2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95002160 O    Mango, dried                         2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95002170 O    Mango, juice                         2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95002171 O    Mango, juice-babyfood                2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
95002180 O    Maple, sugar                        15.000000   1.000      0.200   chlorp
  Full comment: chlorpyrifos [sugarbeet]
95002190 O    Maple syrup                         15.000000   1.000      0.200   chlorp
  Full comment: chlorpyrifos [sugarbeet]
19012200 19A  Marjoram                            50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin [herb]
19012201 19A  Marjoram-babyfood                   50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin [herb]
28002210 M    Meat, game                           2.000000   1.000      0.200   endosu
  Full comment: endosulfan
27002220 D    Milk, fat                            2.000000   1.000      0.200   endosu
  Full comment: endosulfan
27002221 D    Milk, fat - baby food/infant for     2.000000   1.000      0.200   endosu
  Full comment: endosulfan
27012230 D    Milk, nonfat solids                  0.500000   1.000      0.200   iprodi
  Full comment: iprodione
27012231 D    Milk, nonfat solids-baby food/in     0.500000   1.000      0.200   iprodi
  Full comment: iprodione
27022240 D    Milk, water                          0.500000   1.000      0.200   iprodi
  Full comment: iprodione
27022241 D    Milk, water-babyfood/infant form     0.500000   1.000      0.200   iprodi
  Full comment: iprodione
27032251 D    Milk, sugar (lactose)-baby food/     0.500000   1.000      0.200   iprodi
  Full comment: iprodione
15002260 15   Millet, grain                        2.000000   1.000      0.200   carbar
  Full comment: carbaryl
95002270 O    Mulberry                            40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al [blueberry]
95002280 O    Mushroom                             5.000000   1.000      0.200   permet
  Full comment: permethrin
05022290 5B   Mustard greens                      60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
12002300 12   Nectarine                           25.000000   1.000      0.200   captan
15002310 15   Oat, bran                           20.000000   1.000      0.200   mancoz
  Full comment: mancozeb
15002320 15   Oat, flour                          20.000000   1.000      0.200   glypho
  Full comment: glyphosate
15002321 15   Oat, flour-babyfood                 20.000000   1.000      0.200   glypho
  Full comment: glyphosate
15002330 15   Oat, groats/rolled oats             20.000000   1.000      0.200   glypho
  Full comment: glyphosate
15002331 15   Oat, groats/rolled oats-babyfood    20.000000   1.000      0.200   glypho
  Full comment: glyphosate
08002340 8    Okra                                10.000000   1.000      0.200   carbar
  Full comment: carbaryl
95002350 O    Olive                               10.000000   1.000      0.200   carbar
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  Full comment: carbaryl
95002360 O    Olive, oil                          10.000000   1.000      0.200   carbar
  Full comment: carbaryl
03002370 3    Onion, dry bulb                      7.000000   1.000      0.200   maneb;
  Full comment: maneb; ziram
03002371 3    Onion, dry bulb-babyfood             7.000000   1.000      0.200   maneb;
  Full comment: maneb; ziram
03002380 3    Onion, dry bulb, dried               7.000000   9.000      0.200   maneb;
  Full comment: maneb; ziram
03002381 3    Onion, dry bulb, dried-babyfood      7.000000   9.000      0.200   maneb;
  Full comment: maneb; ziram
03002390 3    Onion, green                        10.000000   1.000      0.200   fosety
  Full comment: fosetyl-al
10002400 10   Orange                              10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002410 10   Orange, juice                       10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002411 10   Orange, juice-babyfood              10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10002420 10   Orange, peel                        10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
95002430 O    Palm heart, leaves                   0.200000   1.000      0.200   glypho
  Full comment: glyphosate
95002440 O    Palm, oil                            0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95002441 O    Palm, oil-babyfood                   0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95002450 O    Papaya                              15.000000   1.000      0.200   chloro
  Full comment: chlorothanil
95002451 O    Papaya-babyfood                     15.000000   1.000      0.200   chloro
  Full comment: chlorothanil
95002460 O    Papaya, dried                       15.000000   1.800      0.200   chloro
  Full comment: chlorothanil
95002470 O    Papaya, juice                       15.000000   1.000      0.200   chloro
  Full comment: chlorothanil
04012480 4A   Parsley, leaves                    100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
19012490 19A  Parsley, dried leaves              12.000000   1.000      0.200   carbar
  Full comment: carbaryl
19012491 19A  Parsley, dried leaves-babyfood     12.000000   1.000      0.200   carbar
  Full comment: carbaryl
01012500 1AB  Parsley, turnip rooted              2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
01012510 1AB  Parsnip                            5.000000   1.000      0.200   carbar
  Full comment: carbaryl
01012511 1AB  Parsnip-babyfood                   5.000000   1.000      0.200   carbar
  Full comment: carbaryl
95002520 O    Passionfruit                        3.000000   1.000      0.200   chloro
  Full comment: chlorothanil
95002521 O    Passionfruit-babyfood               3.000000   1.000      0.200   chloro
  Full comment: chlorothanil
95002530 O    Passionfruit, juice                 3.000000   1.000      0.200   chloro
  Full comment: chlorothanil
95002531 O    Passionfruit, juice-babyfood        3.000000   1.000      0.200   chloro
  Full comment: chlorothanil
95002540 O    Pawpaw                              2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
06022550 6B   Pea, succulent                     10.000000   1.000      0.200   carbar
  Full comment: carbaryl
06022551 6B   Pea, succulent-babyfood            10.000000   1.000      0.200   carbar
  Full comment: carbaryl
06032560 6C   Pea, dry                            8.000000   1.000      0.200   glypho
  Full comment: glyphosate
06032561 6C   Pea, dry-babyfood                   8.000000   1.000      0.200   glypho
  Full comment: glyphosate
06012570 6A   Pea, edible podded, succulent       3.000000   1.000      0.200   bentaz
  Full comment: bentazon
06032580 6C   Pea, pigeon, seed                   8.000000   1.000      0.200   glypho
  Full comment: glyphosate
06022590 6B   Pea, pigeon, succulent             10.000000   1.000      0.200   carbar
  Full comment: carbaryl
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12002600 12	Peach	15.000000	1.000	0.200	captan
12002601 12	Peach-babyfood	15.000000	1.000	0.200	captan
12002610 12	Peach, dried	15.000000	7.000	0.200	captan
12002611 12	Peach, dried-babyfood	15.000000	7.000	0.200	captan
12002620 12	Peach, juice	15.000000	1.000	0.200	captan
12002621 12	Peach, juice-babyfood	15.000000	1.000	0.200	captan
95002630 O	Peanut	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
95002640 O	Peanut, butter	5.000000	1.890	0.200	carbar
Full comment: carbaryl					
95002650 O	Peanut, oil	0.600000	1.000	0.200	azoxys
Full comment: azoxystrobin					
11002660 11	Pear	25.000000	1.000	0.200	captan
11002661 11	Pear-babyfood	25.000000	1.000	0.200	captan
11002670 11	Pear, dried	25.000000	6.250	0.200	captan
11002680 11	Pear, juice	25.000000	1.000	0.200	captan
11002681 11	Pear, juice-babyfood	25.000000	1.000	0.200	captan
14002690 14	Pecan	1.000000	1.000	0.200	glypho
Full comment: glyphosate (tree nut)					
08002700 8	Pepper, bell	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
08002701 8	Pepper, bell-babyfood	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
08002710 8	Pepper, bell, dried	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
08002711 8	Pepper, bell, dried-babyfood	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
08002720 8	Pepper, nonbell	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
08002721 8	Pepper, nonbell-babyfood	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
08002730 8	Pepper, nonbell, dried	10.000000	1.000	0.200	carbar
Full comment: carbaryl					
19022740 19B	Pepper, black and white	38.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [spice]					
19022741 19B	Pepper, black and white-babyfood	38.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [spice]					
95002750 O	Peppermint	200.000000	1.000	0.200	glypho
Full comment: glyphosate					
95002760 O	Peppermint, oil	200.000000	1.000	0.200	glypho
Full comment: glyphosate					
95002770 O	Persimmon	3.000000	1.000	0.200	imidac
Full comment: imidacloprid					
95002780 O	Pine nut	1.000000	1.000	0.200	glypho
Full comment: glyphosate					
95002790 O	Pineapple	2.000000	1.000	0.200	carbar
Full comment: carbaryl					
95002791 O	Pineapple-babyfood	2.000000	1.000	0.200	carbar
Full comment: carbaryl					
95002800 O	Pineapple, dried	2.000000	5.000	0.200	carbar
Full comment: carbaryl					
95002810 O	Pineapple, juice	2.000000	1.000	0.200	carbar
Full comment: carbaryl					
95002811 O	Pineapple, juice-babyfood	2.000000	1.000	0.200	carbar
Full comment: carbaryl					
14002820 14	Pistachio	1.000000	1.000	0.200	glypho
Full comment: glyphosate (tree nut)					
95002830 O	Plantain	10.000000	1.000	0.200	carbar
Full comment: carbaryl [banana]					
95002840 O	Plantain, dried	10.000000	3.900	0.200	carbar
Full comment: carbaryl [banana]					
12002850 12	Plum	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					
12002851 12	Plum-babyfood	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					
12002860 12	Plum, prune, fresh	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					
12002861 12	Plum, prune, fresh-babyfood	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					
12002870 12	Plum, prune, dried	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					

12002871 12	Plum, prune, dried-babyfood	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					
12002880 12	Plum, prune, juice	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					
12002881 12	Plum, prune, juice-babyfood	10.000000	1.000	0.200	captan
Full comment: captan;carbaryl					
95002890 O	Pomegranate	0.900000	1.000	0.200	imidac
Full comment: imidacloprid					
25002900 M	Pork, meat	2.000000	1.000	0.200	endosu
Full comment: endosulfan					
25002901 M	Pork, meat-babyfood	2.000000	1.000	0.200	endosu
Full comment: endosulfan					
25002910 M	Pork, skin	13.000000	1.000	0.200	endosu
Full comment: endosulfan					
25002920 M	Pork, meat byproducts	1.000000	1.000	0.200	diuron
25002921 M	Pork, meat byproducts-babyfood	1.000000	1.000	0.200	diuron
25002930 M	Pork, fat	13.000000	1.000	0.200	endosu
Full comment: endosulfan					
25002931 M	Pork, fat-babyfood	13.000000	1.000	0.200	endosu
Full comment: endosulfan					
25002940 M	Pork, kidney	4.000000	1.000	0.200	glypho
Full comment: glyphosate					
25002950 M	Pork, liver	5.000000	1.000	0.200	endosu
Full comment: endosulfan					
01032960 1C	Potato, chips	1.000000	1.000	0.200	imidac
Full comment: imidacloprid					
01032970 1C	Potato, dry (granules/ flakes)	1.000000	6.500	0.200	diuron
01032971 1C	Potato, dry (granules/ flakes)-b	1.000000	6.500	0.200	diuron
01032980 1C	Potato, flour	1.000000	1.000	0.200	diuron
01032981 1C	Potato, flour-babyfood	1.000000	1.000	0.200	diuron
01032990 1C	Potato, tuber, w/peel	1.000000	1.000	0.200	diuron
01032991 1C	Potato, tuber, w/peel-babyfood	1.000000	1.000	0.200	diuron
01033000 1C	Potato, tuber, w/o peel	1.000000	1.000	0.200	diuron
01033001 1C	Potato, tuber, w/o peel-babyfood	1.000000	1.000	0.200	diuron
60003010 P	Poultry, other, meat	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
60003020 P	Poultry, other, liver	5.000000	1.000	0.200	iprodi
Full comment: iprodione					
60003030 P	Poultry, other, meat byproducts	1.000000	1.000	0.200	glypho
Full comment: glyphosate					
60003040 P	Poultry, other, fat	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
60003050 P	Poultry, other, skin	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
95003060 O	Psyllium, seed	10.000000	1.000	0.200	propan
Full comment: propanil [rice]					
10003070 10	Pummelo	10.000000	1.000	0.200	azoxys
Full comment: azoxystrobin (citrus CG)					
09023080 9B	Pumpkin	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
09023090 9B	Pumpkin, seed	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
11003100 11	Quince	10.000000	1.000	0.200	mancoz
Full comment: mancozeb					
95003110 O	Quinoa, grain	5.000000	1.000	0.200	glypho
Full comment: glyphosate					
29003120 M	Rabbit, meat	2.000000	1.000	0.200	endosu
Full comment: endosulfan					
04013130 4A	Radicchio	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
01013140 1AB	Radish, roots	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
02003150 2	Radish, tops	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin (CG 2)					
01013160 1AB	Radish, Oriental, roots	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
02003170 2	Radish, Oriental, tops	50.000000	1.000	0.200	azoxys
Full comment: azoxystrobin (CG 2)					
05023180 5B	Rape greens	60.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 5)					
20003190 20	Rapeseed, oil	10.000000	1.000	0.200	glypho

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  Full comment: glyphosate
20003191 20   Rapeseed, oil-babyfood          10.000000   1.000      0.200   glypho
  Full comment: glyphosate
13013200 13A  Raspberry                      40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13013201 13A  Raspberry-babyfood            40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13013210 13A  Raspberry, juice              40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
13013211 13A  Raspberry, juice-babyfood     40.000000   1.000      0.200   fosety
  Full comment: fosetyl-al (berries)
04023220 4B   Rhubarb                      100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
15003230 15   Rice, white                   10.000000   1.000      0.200   propan
  Full comment: propanil
15003231 15   Rice, white-babyfood          10.000000   1.000      0.200   propan
  Full comment: propanil
15003240 15   Rice, brown                   10.000000   1.000      0.200   propan
  Full comment: propanil
15003241 15   Rice, brown-babyfood          10.000000   1.000      0.200   propan
  Full comment: propanil
15003250 15   Rice, flour                   10.000000   1.000      0.200   propan
  Full comment: propanil
15003251 15   Rice, flour-babyfood          10.000000   1.000      0.200   propan
  Full comment: propanil
15003260 15   Rice, bran                    40.000000   1.000      0.200   propan
  Full comment: propanil
15003261 15   Rice, bran-babyfood           40.000000   1.000      0.200   propan
  Full comment: propanil
01013270 1AB  Rutabaga                       5.000000   1.000      0.200   carbar
  Full comment: carbaryl
15003280 15   Rye, grain                     5.000000   1.000      0.200   mancoz
  Full comment: mancozeb
15003290 15   Rye, flour                     5.000000   1.000      0.200   mancoz
  Full comment: mancozeb
20003300 20   Safflower, oil                85.000000   1.000      0.200   glypho
  Full comment: glyphosate
20003301 20   Safflower, oil-babyfood       85.000000   1.000      0.200   glypho
  Full comment: glyphosate
01013310 1AB  Salsify, roots                 5.000000   1.000      0.200   carbar
  Full comment: carbaryl
02003320 2    Salsify, tops                 50.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin (CG 2)
95003330 O    Sapote, Mamey                  2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
19013340 19A  Savory                       38.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin [spice]
95003350 O    Seaweed                       60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
95003351 O    Seaweed-babyfood              60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
95003360 O    Sesame, seed                   0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95003361 O    Sesame, seed-babyfood          0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95003370 O    Sesame, oil                    0.100000   1.000      0.200   glypho
  Full comment: glyphosate
95003371 O    Sesame, oil-babyfood           0.100000   1.000      0.200   glypho
  Full comment: glyphosate
03003380 3    Shallot                        0.200000   1.000      0.200   pendim
  Full comment: pendimethalin
26003390 M    Sheep, meat                    2.000000   1.000      0.200   endosu
  Full comment: endosulfan
26003391 M    Sheep, meat-babyfood           2.000000   1.000      0.200   endosu
  Full comment: endosulfan
26003400 M    Sheep, meat byproducts         5.000000   1.000      0.200   endosu
  Full comment: endosulfan
26003410 M    Sheep, fat                    13.000000   1.000      0.200   endosu
  Full comment: endosulfan
26003411 M    Sheep, fat-babyfood           13.000000   1.000      0.200   endosu
  Full comment: endosulfan
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26003420 M	Sheep, kidney	4.000000	1.000	0.200	glypho
Full comment: glyphosate					
26003430 M	Sheep, liver	5.000000	1.000	0.200	glypho
Full comment: glyphosate					
15003440 15	Sorghum, grain	15.000000	1.000	0.200	glypho
Full comment: glyphosate					
15003450 15	Sorghum, syrup	15.000000	1.000	0.200	glypho
Full comment: glyphosate					
95003460 O	Soursop	2.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
06003470 6	Soybean, seed	20.000000	1.000	0.200	glypho
Full comment: glyphosate					
06003480 6	Soybean, flour	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
06003481 6	Soybean, flour-babyfood	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
06003490 6	Soybean, soy milk	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
06003491 6	Soybean, soy milk-babyfood or in	5.000000	1.000	0.200	carbar
Full comment: carbaryl					
06003500 6	Soybean, oil	0.300000	1.000	0.200	bifent
Full comment: bifenthrin					
06003501 6	Soybean, oil-babyfood	0.300000	1.000	0.200	bifent
Full comment: bifenthrin					
95003510 O	Spanish lime	3.000000	1.000	0.200	imidac
Full comment: imidacloprid					
95003520 O	Spearmint	200.000000	1.000	0.200	glypho
Full comment: glyphosate					
95003530 O	Spearmint, oil	200.000000	1.000	0.200	glypho
Full comment: glyphosate					
19023540 19B	Spices, other	38.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [spice]					
19023541 19B	Spices, other-babyfood	38.000000	1.000	0.200	azoxys
Full comment: azoxystrobin [spice]					
04013550 4A	Spinach	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
04013551 4A	Spinach-babyfood	100.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (CG 4)					
09023560 9B	Squash, summer	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
09023561 9B	Squash, summer-babyfood	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
09023570 9B	Squash, winter	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
09023571 9B	Squash, winter-babyfood	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
95003580 O	Starfruit	2.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
95003590 O	Strawberry	75.000000	1.000	0.200	fosety
Full comment: fosetyl-al					
95003591 O	Strawberry-babyfood	75.000000	1.000	0.200	fosety
Full comment: fosetyl-al					
95003600 O	Strawberry, juice	75.000000	1.000	0.200	fosety
Full comment: fosetyl-al					
95003601 O	Strawberry, juice-babyfood	75.000000	1.000	0.200	fosety
Full comment: fosetyl-al					
95003610 O	Sugar apple	2.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
95003620 O	Sugarcane, sugar	2.000000	1.000	0.200	glypho
Full comment: glyphosate;2,4-D					
95003621 O	Sugarcane, sugar-babyfood	2.000000	1.000	0.200	glypho
Full comment: glyphosate;2,4-D					
95003630 O	Sugarcane, molasses	30.000000	1.000	0.200	glypho
Full comment: glyphosate					
95003631 O	Sugarcane, molasses-babyfood	30.000000	1.000	0.200	glypho
Full comment: glyphosate					
20003640 20	Sunflower, seed	2.500000	1.000	0.200	alachl
Full comment: alachlor					
20003650 20	Sunflower, oil	0.300000	1.000	0.200	lambda
Full comment: lambda-cyhalothrin					
20003651 20	Sunflower, oil-babyfood	0.300000	1.000	0.200	lambda

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  Full comment: lambda-cyhalothrin
01033660 1CD  Sweet potato                    10.000000   1.000      0.200   phosme
  Full comment: phosmet
01033661 1CD  Sweet potato-babyfood           10.000000   1.000      0.200   phosme
  Full comment: phosmet
04023670 4B   Swiss chard                    100.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 4)
95003680 O    Tamarind                        2.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin
10003690 10   Tangerine                      10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
10003700 10   Tangerine, juice               10.000000   1.000      0.200   azoxys
  Full comment: azoxystrobin ( citrus CG)
01033710 1CD  Tanier, corm                     1.000000   1.000      0.200   diuron
  Full comment: diuron [potato transl]
95003720 O    Tea, dried                     10.000000   1.000      0.200   propar
  Full comment: propargite
95003730 O    Tea, instant                    7.000000   1.000      0.200   glypho
  Full comment: glyphosate
08003740 8    Tomatillo                      10.000000   1.000      0.200   carbar
  Full comment: carbaryl
08003750 8    Tomato                         10.000000   1.000      0.200   carbar
  Full comment: carbaryl
08003751 8    Tomato-babyfood                10.000000   1.000      0.200   carbar
  Full comment: carbaryl
08003760 8    Tomato, paste                   6.000000   1.000      0.200   imidac
  Full comment: imidacloprid
08003761 8    Tomato, paste-babyfood          6.000000   1.000      0.200   imidac
  Full comment: imidacloprid
08003770 8    Tomato, puree                   3.000000   1.000      0.200   imidac
  Full comment: imidacloprid
08003771 8    Tomato, puree-babyfood          3.000000   1.000      0.200   imidac
  Full comment: imidacloprid
08003780 8    Tomato, dried                  10.000000  14.300      0.200   carbar
  Full comment: carbaryl
08003781 8    Tomato, dried-babyfood         10.000000  14.300      0.200   carbar
  Full comment: carbaryl
08003790 8    Tomato, juice                  10.000000   1.000      0.200   carbar
  Full comment: carbaryl
95003800 O    Tomato, Tree                   10.000000   1.000      0.200   carbar
  Full comment: carbaryl [tomato]
15003810 15   Triticale, flour                5.000000   1.000      0.200   glypho
  Full comment: glyphosate [wheat transl]
15003811 15   Triticale, flour-babyfood       5.000000   1.000      0.200   glypho
  Full comment: glyphosate [wheat transl]
50003820 P    Turkey, meat                    5.000000   1.000      0.200   carbar
  Full comment: carbaryl
50003821 P    Turkey, meat-babyfood           5.000000   1.000      0.200   carbar
  Full comment: carbaryl
50003830 P    Turkey, liver                   5.000000   1.000      0.200   iprodi
  Full comment: iprodione
50003831 P    Turkey, liver-babyfood          5.000000   1.000      0.200   iprodi
  Full comment: iprodione
50003840 P    Turkey, meat byproducts         1.000000   1.000      0.200   glypho
  Full comment: glyphosate
50003841 P    Turkey, meat byproducts-babyfood  1.000000   1.000    0.200   glypho
  Full comment: glyphosate
50003850 P    Turkey, fat                     5.000000   1.000      0.200   carbar
  Full comment: carbaryl
50003851 P    Turkey, fat-babyfood            5.000000   1.000      0.200   carbar
  Full comment: carbaryl
50003860 P    Turkey, skin                    5.000000   1.000      0.200   carbar
  Full comment: carbaryl
50003861 P    Turkey, skin-babyfood           5.000000   1.000      0.200   carbar
  Full comment: carbaryl
01033870 1CD  Turmeric                        1.000000   1.000      0.200   diuron
  Full comment: diuron [potato transl]
01013880 1AB  Turnip, roots                  15.000000   1.000      0.200   fosety
  Full comment: fosetyl-al
05023890 5B   Turnip, greens                 60.000000   1.000      0.200   fosety
  Full comment: fosetyl-Al (CG 5)
```

95003900 O	Vinegar	25.000000	1.000	0.200	captan
Full comment: captan [apple]					
14003910 14	Walnut	1.000000	1.000	0.200	glypho
Full comment: glyphosate (tree nut)					
86010000 O	Water, direct, all sources	0.100000	1.000	1.000	defaul
Full comment: default 100 ppb					
86020000 O	Water, indirect, all sources	0.100000	1.000	1.000	defaul
Full comment: default 100 ppb					
95003970 O	Water chestnut	1.000000	1.000	0.200	carbar
Full comment: carbaryl [pecan]					
95003980 O	Watercress	6.000000	1.000	0.200	methom
Full comment: methomyl					
09013990 9A	Watermelon	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
09014000 9A	Watermelon, juice	15.000000	1.000	0.200	fosety
Full comment: fosetyl-Al (curcurbits)					
15004010 15	Wheat, grain	5.000000	1.000	0.200	glypho
Full comment: glyphosate					
15004011 15	Wheat, grain-babyfood	5.000000	1.000	0.200	glypho
Full comment: glyphosate					
15004020 15	Wheat, flour	5.000000	1.000	0.200	glypho
Full comment: glyphosate					
15004021 15	Wheat, flour-babyfood	5.000000	1.000	0.200	glypho
Full comment: glyphosate					
15004030 15	Wheat, germ	5.000000	1.000	0.200	glypho
Full comment: glyphosate					
15004040 15	Wheat, bran	20.000000	1.000	0.200	glypho
Full comment: glyphosate					
15004050 15	Wild rice	5.000000	1.000	0.200	azoxys
Full comment: azoxystrobin					
01034060 1CD	Yam, true	10.000000	1.000	0.200	phosme
Full comment: phosmet					
01034070 1CD	Yam bean	10.000000	1.000	0.200	phosme
Full comment: phosmet					

Exhibit 9

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

MEMORANDUM Dated: 5/28/2009
To: Kerry Leifer (OPP)
From: Donna S. Davis, Linda Taylor, Christine L. Olinger (OPP)

Re: Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates (SANFCs - JITF CST 11 Inert Ingredients). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations (14 pages).

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Date: May 28, 2009

MEMORANDUM

SUBJECT: **Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates (SANFCs - JITF CST 11 Inert Ingredients).** Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations.

PC Code: 790127
Decision No.: 411391
Petition No.: 9E7516
Risk Assessment Type: Single Chemical Aggregate
TXR No.: NA
MRID No.: 47643301

DP Barcode: D365205
Registration No.: NA
Regulatory Action: Inert Tolerance Exemption
Case No.: NA
CAS No.: 9008-63-3, 9069-80-1, 9084-06-4, 36290-04-7, 91078-68-1, 141959-43-5, 68425-94-5
40 CFR: 180.910

FROM: Donna S. Davis, Risk Assessor, RAB VII
Christine L. Olinger, Chemist, RAB VII
Linda Taylor, Toxicologist, RAB VII
Health Effects Division (7509P)

THROUGH: Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

TO: Kerry Leifer, Team Leader
PV Shah, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

Attached please find the HED Human Health Risk Assessment for the cluster of inert ingredients known as the "sodium and ammonium naphthalenesulfonate formaldehyde condensates" (SANFCs).

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1.0 Executive Summary

The Joint Inert Task Force (JITF) Cluster Support Team Number 11 (CST11) has submitted a petition proposing to establish an exemption from the requirement of a tolerance under 40 CFR §180.920 without limitation for a cluster of compounds known as the "sodium and ammonium naphthalenesulfonate formaldehyde condensates" (SANFCs) for use as inert ingredients in pesticide formulations applied to crops pre-harvest. Subsequently, the petitioner has requested to expand the exemption from the requirement of a tolerance to uses in pesticide formulations intended for use both pre- and post-harvest.

The toxicology database for the SANFC inerts is adequate to support their use as inert ingredients in pesticide formulations. The sodium and ammonium naphthalenesulfonate formaldehyde condensates have low acute oral toxicity and inhalation toxicity. There was no significant hazard identified in the OECD 422 combined repeated dose toxicity study with the reproduction/developmental toxicity screening test at the limit dose of 1000 mg/kg/day to either parental animals or their offspring. Thus, due to their low hazard potential for these inert compounds, a quantitative risk assessment is not required for the SANFC inerts. There is no concern for neurotoxicity, immunotoxicity or carcinogenicity for the SANFCs. A discussion of an FQPA SF is not germane to this risk assessment since a quantitative risk assessment is not required.

Based on the low hazard potential for the SANFC inerts, dietary (food and water) and non-dietary/non-occupational (residential) risks are not of concern. Further, aggregate risks are not of concern. Lastly, there are no concerns for worker risks from exposure to the SANFCs.

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf

No studies in which human subjects were intentionally exposed to pesticides were relied upon for this risk assessment.

Regulatory Recommendation

There are no human health exposure or risk issues that would preclude the approval of an exemption from the requirement of a tolerance for the SANFC inerts. HED has no objection to the establishment of an exemption from the requirement of a tolerance under 40 CFR §180.910 for sodium and ammonium naphthalenesulfonate formaldehyde condensates.

2.0 Background

Inert ingredients are those ingredients that are added to end use products that are not active ingredients. The terms "active ingredient" and "inert ingredient" are defined under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). An active ingredient is one that prevents, destroys, repels or mitigates a pest, or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. The statute defines the term "inert ingredient" as an ingredient that is not active.

As mandated by the Food Quality Protection Act (FQPA) of 1996, EPA conducted a reassessment of the tolerances or exemptions from tolerances for inert ingredients used in pesticide products to determine if they met the FFDCA's revised standard of safety. As a result of that reassessment, the Agency published a final rule in the Federal Register (FR Notice Volume 71, No. 153, p. 45422) proposing the revocation of certain inert ingredient specific tolerance exemptions under 40 CFR §180.910 (pre- and post-harvest uses), 40 CFR §180.920 (pre-harvest uses), 40 CFR §180.930 (animal uses), 40 CFR §180.940 (antimicrobial uses) and 40 CFR §180.960 (polymers).

In response to the proposed revocation, the JITF CST11 has submitted a petition dated 1/9/2009 proposing to establish specific exemptions from the requirement of a tolerance under 40 CFR §180.920 (pre-harvest only) without limitation for the following descriptor:

Sodium and ammonium naphthalenesulfonate formaldehyde condensates

Subsequently the petitioner has requested that this exemption from the requirement of a tolerance be expanded to include use in pesticide formulations intended for post-harvest application as well as pre-harvest application. The petitioner currently proposes to establish an exemption from the requirement of a tolerance under 40 CFR §180.910 for the SANFCs.

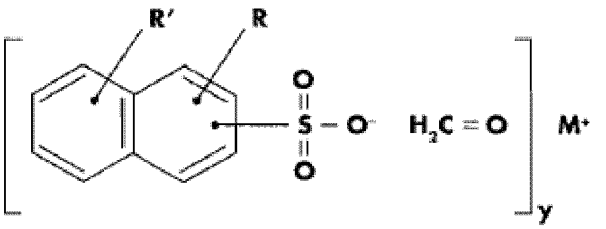
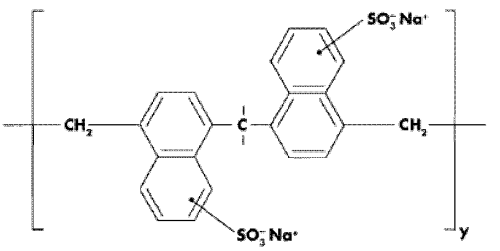
3.0 Ingredient Profile

3.1 Summary of Proposed Uses

The petitioner had indicated that the SANFC inerts are used as dispersants, defoamers and emulsifiers in pesticide formulations. This petition requests uses in pesticides intended for pre-harvest applications only. Additionally, the petitioner has noted that these surfactants have a wide range of industrial uses as well as serving as emulsifiers in personal care products and in food contact packaging.

3.2 Structural Information

The SANFCs are anionic surfactants that may be derived from naphthalene or methyl naphthalenesulfonic acids. The surfactants included in this group are complex mixtures and some constituents of these mixtures are likely to be very large molecules. Information on the generic structures of these compounds is summarized in Table 3.2.1, below. A detailed listing of the chemicals included in this group may be found in Table 3.2.2.

Table 3.2.1. Sodium And Ammonium Naphthalenesulfonate Formaldehyde Condensates (SANFC) Chemical Structure	
Generic Chemical Structure [1]	 M⁺ = Na⁺, NH_4^+ R, R' = H or CH_3 and combinations and H and CH_3 y = >> 1
Structure of Main Component of Test Material in the Toxicity Testing	 y = >>1

[1] Figures excerpted from petition, "*Petition Proposing An Exemption From The Requirement Of A Tolerance For Residues Of Joint Inerts Task Force Cluster 11 Sodium And Ammonium Naphthalenesulfonate Formaldehyde Condensates In Or On Raw Agricultural Products And Food Product*", pages 6-7, dated January 9, 2009.

Table 3.2.2. Listing of Chemicals included in the SANFC Cluster	
CAS Number	Descriptor
9008-63-3	Naphthalenesulfonic acid, sodium salt polymer with formaldehyde
9069-80-1	Naphthalenesulfonic acid, ammonium salt polymer with formaldehyde
9084-06-4	Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt
36290-04-7	2-Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt
91078-68-1	Naphthalenesulfonic acids, reaction products with formaldehyde, sodium salts
141959-43-5	Naphthalenesulfonic acid, methyl-sodium salt with formaldehyde
68425-94-5	Residues, petroleum, catalytic reformer fractionator, sulfonated, polymers with formaldehyde, sodium salts

3.3 Physical and Chemical Properties

Physicochemical data were estimated for the SANFC inerts using publicly available Estimation Program Interface suite (EPI Suite™) modeling (http://www.epa.gov/opptintr/exposure/pubs/episuite.htm and are provided in Table 3.3. The basis for the estimated Estimation Program Interface suite (EPI Suite™) modeling physicochemical calculations and model capabilities are described in the EPA document titled The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program (EPA 1999). The EPA EPI Suite™ 3.2 model calculations for water solubility are based on Kow (WSKOWWIN) and molecular fragments (WATERNT). EPA has cautioned in the publication OPPTS Pollution Prevention P2 Network (EPA, 2005), that EPI Suite™ 3.2 water solubility calculations are not reliable for dispersible compounds such as surfactants.

Table 3.3. Physicochemical Properties of Representative SSNA Compounds [1]

CAS No.	Modeled As	Log K_{OW}	Boiling Point (°C)	Melting Point (°C)	Vapor Pressure (mm Hg)	Water Solubility (mg/L) [2]
91078-68-1	Condensate Dimer	-0.32	854.3	349.8	1.01×10^{-18}	155.3 3.99×10^{-5}
Methyl example?	Methylnaphthalene sulfonate	0.78	877.5	349.8	1.53×10^{-15}	11.95 3.76×10^{-6}

[1] Table values taken from submission entitled "Petition Proposing An Exemption From The Requirement Of A Tolerance For Residues Of Joint Inerts Task Force Cluster 11 Sodium And Ammonium Naphthalenesulfonate Formaldehyde Condensates In Or On Raw Agricultural Products And Food Product", 1/29/2009, Table 2, p. 13.

[2] The EPI Suite™ model calculates water solubility based on the octanol-water partition coefficient (Kow) (WSKOWWIN) and molecular fragments (WATERNT). The first value reflects the WSKOWWIN calculation and the second value reflects the WATERNT calculation.

4.0 Hazard Characterization/Assessment

4.1 Database Summary

There are seven surfactants being supported in this inert assessment on the sodium and ammonium naphthalenesulfonate formaldehyde condensates (SANFCs). The representative test compound is naphthalenesulfonic acid, sodium salt polymer with formaldehyde (CAS 9084-06-4). The existing toxicology database for the SANFC consists of one OECD 422 combined repeated dose toxicity study with the reproduction/developmental toxicity screening in rats on the representative SANFC, and several studies from the scientific literature on acute toxicity and mutagenicity.

The OECD Test Guideline 422 study is a combined repeated dose toxicity study with reproduction/developmental toxicity test parameters. This study provides information on the possible health hazards likely to arise from repeated exposure over a relatively limited period of time. The method comprises the basic repeated dose toxicity study as well as a

reproduction/developmental toxicity screening test and also places emphasis on neurological effects as a specific endpoint. Therefore, the study can provide information on general toxicity as well as possible developmental, reproductive, and neurological effects. It can also provide basic indications of immunological effects.

4.2 Toxicological Effects and Metabolism

Toxicological Effects
The available toxicity data indicates that SANFC has low acute oral and inhalation toxicity. SANFC was not mutagenic in an Ames test.

In a repeated 28-42 day OECD Test Guideline 422 combined repeated dose toxicity study with the reproduction/developmental toxicity screening with the representative test compound, naphthalenesulfonic acid, sodium salt polymer with formaldehyde (CAS 9084-06-4), there was no evidence of increased susceptibility (MRID 47643301). Parental toxicity manifested as decrements in body-weight gain in both sexes at the limit dose (1000 mg/kg/day). No developmental or reproductive effects were observed at doses of 100, 300, and 1000 mg/kg/day.

There was no evidence of potential neurotoxicity or immunotoxicity in the adult animal in the OECD 422 study at the limit dose of 1000 mg/kg/day. There are no chronic data available on the SANFC surfactants; however, no structural alerts for cancer were identified in a qualitative structure activity relationship (SAR) database, DEREK Version 11.

Metabolism
As stated in the petition (JITF Cluster Support Team 11), the higher molecular weight polymeric SANFC surfactants (MW>1000) are not expected to be readily absorbed or metabolized, and should thus be rapidly excreted (likely in the feces) unchanged. By analogy to other classes of similar surfactants, the SANFC naphthalene ring sodium sulfonate group could provide a handle for conjugation and excretion. Additionally, lower molecular microsome cytochrome P-450 oxygenases may hydroxylate the naphthalene ring and/or methylene bridge to produce alternative metabolites that should also be readily conjugated and excreted.

4.3 Dermal Absorption

There are no dermal absorption data on the SANFCs; however, given the molecular weights and solubility characteristics of these polymers, dermal absorption is expected to be low.

4.4 Carcinogenic Potential

There is no evidence that the SANFCs are carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there

were structural alerts. No structural alerts were identified. In addition, there was little concern about any of the postulated metabolites having greater toxicity than the parent compounds.

4.5 Toxicity Endpoint Selection and FQPA Considerations

There was no significant hazard identified in the OECD 422 study at the limit dose of 1000 mg/kg/day to either parental animals or their offspring. Thus, due to their low potential hazard and the lack of a hazard endpoint, it was determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for the SANFCs. HED notes that there was no evidence of neurotoxicity or increased susceptibility to the offspring of rats following prenatal or postnatal exposure in the OECD 422 study. For the same reasons that a quantitative risk assessment based on a safety factor approach is not appropriate for the SANFCs, an FQPA SF is not needed to protect the safety of infants and children.

4.6 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, the sodium and ammonium naphthalenesulfonate formaldehyde condensates (SANFC) may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

5.0 Dietary Exposure/Risk Characterization

5.1 Residues of Concern

Very limited information is available for the SANFCs with respect to plant and animal metabolism or environmental degradation. The Agency has considered the representative

chemical structures, the generic cluster structures, the submitted physicochemical EPI Suite™ information as well as the structure-activity relationship analysis detailed in Appendix B of this review and information on other surfactants and chemicals of similar size and functionality. The Agency concurs that the cluster grouping was appropriate.

The residues of concern are the parent only. Considering the large size and polarity of the SANFC molecules, it is unlikely they would readily absorbed by livestock or taken up by plants for further metabolism.

5.2 Analytical Methodology

Since this request is for an exemption from the requirement of a tolerance, an analytical method for enforcement purposes is not required to support this action.

5.3 Dietary (Food and Water) Exposure and Risk

Since an endpoint for risk assessment was not identified, the Agency did not conduct a quantitative dietary risk assessment. Given the lack of concern for hazard posed by the SANFCs, HED concludes that there are no dietary risks of concern as a result of exposure to the SANFC inerts in food and water.

6.0 Residential (Non-Dietary/Non-Occupational) Exposure and Risk

The petitioner has indicated that these inert ingredients may be used in personal care products. Given the lack of concern for hazard posed by the SANFC inerts, the Agency concludes that there are no non-dietary/non-occupational (residential) risks of concern for these inert ingredients.

7.0 Aggregate Risk Assessments and Risk Characterization

Based on the low hazard associated with the SANFC inerts, the Agency concludes that aggregate risks are not of concern.

8.0 Occupational Exposure/Risk Pathway

Since no endpoints of concern were identified in the toxicity database for the SANFC inerts, a quantitative occupational risk assessment was not performed. Due to the low hazard associated with these inerts, worker risks are not of concern.

9.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the USDA under the Continuing Survey of Food Intake by Individuals (CSFII) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas postapplication are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

10.0 Human Studies

No studies in which human subjects were intentionally exposed to pesticides were relied upon for this risk assessment.

APPENDIX A. Toxicity Information for the SANFC Inerts

A.1 Acute Toxicity Profile for Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates

Table A.1. Acute Toxicity Profile of Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-1	Acute Oral – rat	as cited in JITF Cluster Support Team 11 petition	Naphthalenesulfonic acids, reaction products with formaldehyde, sodium salts CAS 91078-68-1 LD50 = 6168 mg/kg (rat) LD50 >5000 mg/kg (mouse)	IV
81-1	Acute Oral – rat	as cited in JITF Cluster Support Team 11 petition	Naphthalene (MW 128.1) CAS 91-20-3 LD50 = 2200-2400 mg/kg	III
81-1	Acute Oral – rat	MSDS; as cited in JITF Cluster Support Team 11 petition	1-methylnaphthalene (MW 142.2) CAS 90-12-0 LD50 = 1840 mg/kg	III
81-1	Acute Oral – rat	MSDS; as cited in JITF Cluster Support Team 11 petition	2-methylnaphthalene (MW 142.2) CAS 91-57-6 LD50 = 1630 mg/kg	III
81-3	Acute Inhalation	as cited in JITF Cluster Support Team 11 petition	Naphthalenesulfonic acids, reaction prouccts with formaldehyde, sodium salts CAS 91078-68-1 LC50 = 50 mg/L	IV

Table A.1. Acute Toxicity Profile of Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates				
Guideline No.	**Study Type**	**MRIDs #**	**Results**	**Toxicity Category**
81-5	Skin Irritation - rabbit	as cited in JITF Cluster Support Team 11 petition	Naphthalenesulfonic acid, sodium salt polymer with formaldehyde CAS 9084-06-4 Non-irritating	IV
81-4	Eye irritation - rabbit	as cited in JITF Cluster Support Team 11 petition	Slightly irritating	III

A.2. Toxicity Profile for the Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates (SANFC)

Table A.2. Toxicology Profile of Sodium and Ammonium Naphthalenesulfonate Formaldehyde Condensates (SANFC)		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
OECD 422 Repeat Dose Toxicity/Reproduction/ Developmental Screen (rat) Naphthalenesulfonic acid, polymer with fermaldehyde sodium salt CAS 9084-06-4	MRID 47643301 (2008) 0, 100, 300, 1000 mg/kg/day (Purity 94.1%) Acceptable/guideline	Parental NOAEL= 300 mg/kg/day Parental LOAEL = 1000 mg/kg/day, based on decrements in body-weight gains in both sexes. Reproductive/Developmental NOAEL = 1000 mg/kg/day

A.3. Toxicology Executive Summaries

EXECUTIVE SUMMARY: In a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (MRID 47643301*)* naphthalene sulfonic acid, polymer with formaldehyde sodium salt (94.1%, batch # 17320-L) was administered to 10 HanRcc:WIST(SPF) rats/sex/dose in water by gavage at dose levels of 0, 100, 300, or 1000 mg/kg bw/day. Parental animals were administered either the vehicle (controls) or the test substance solutions for 14 days prior to the cohabitation period with males receiving a total of at least 28 doses. Treatment for the females was continued through the day of sacrifice, which was lactation day (LD) 5. Five rats/sex/group were assigned for a functional observational battery (FOB) and motor activity assessment and the other five/sex/group were used for hematology, clinical chemistry and histopathological examination.

Treatment with the high-dose of napthalenesulfonic acid, polymer with formaldehyde sodium salt resulted in transient effects on body weight and food consumption in both males and females. Body weight was statistically decreased in high-dose males compared to controls on Days 2-5 of the pre-mating period; the rats lost weight on Day 2. Mean absolute body weight ranged from 94-96% of controls. No other statistically significant changes in absolute body weight were noted at any other time period in males or females. Summary body weight gain data were given only as mean values and did not include standard deviations; therefore, statistical analysis was not conducted. Evaluation of the data indicate that biologically significant reductions in mean body weight gain occurred during the pre-mating period in high-dose males over Days 1-8 (67% of controls) and in high-dose females over Days 1-14 (58% of controls). High-dose females did not gain any weight over Days 1-8. The decrements in body weight gain were accompanied by statistically reduced mean food consumption during Days 1-8 of the pre-mating period in both high-dose males (87% of controls) and high-dose females (86% of controls), but returned to control levels during Days 8-14 of the pre-mating period. No statistically significant changes in body weight or food consumption were noted in pregnant or nursing dams.

FOB and motor activity parameters were not affected by treatment. No other adverse effects, including reproductive effects, were observed in parental animals.

No adverse effects were observed in the offspring.

The parental toxicity LOAEL for napthalenesulfonic acid, polymer with formaldehyde sodium salt is 1000 mg/kg bw/day based on decrements in body weight gain in males and females, and the parental toxicity NOAEL is 300 mg/kg bw/day.

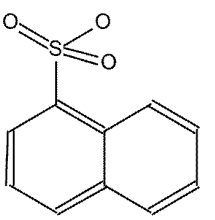
The reproductive/developmental NOAEL is 1000 mg/kg bw/day, and the reproductive/ developmental LOAEL could not be established.

This study is **Acceptable/Guideline** and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) in rats.

APPENDIX B. Structure-Activity Relationship (SAR) Discussion

HED used DEREK for Windows (V. 11) to assess the potential toxicity of compounds in the inerts mixture as well as potential degradates. As described in Section 3 the sodium and ammonium naphthalene sulfonate formaldehyde condensates (SANFC) are complex mixtures that may contain extensively crosslinked, very large molecules. DEREK is not designed to analyze these structures. Therefore, the precursor molecule, naphthalene sulfonate, was analyzed to give some indication of any potential structural alerts. The structure is shown in Figure 1 below.

Figure B-1. Structures of Compounds Subjected to Structure-Activity Analysis

Naphthalene sulfonates	

Derek for Windows (LHASA Ltd.) is an expert system for the prediction of toxicity. It relies on a knowledge base of structural alerts and rules developed by scientists. When a test compound is inputted into the program, Derek for Windows scans the test compound for structural alerts contained within its database that are associated with specific toxicological endpoints and applies a series of reasoning rules to determine the likelihood of toxicity for the test compound. Information is provided on the rules used to make the prediction, along with descriptions of structural alerts identified, comments, available example compounds linked to the alerts and literature references.

DEREK did not identify any structural alerts of concern for naphthalene sulfonate. DEREK has developed more alerts for genotoxicity and carcinogenicity than other endpoints in the system. Considering what is already known about these specific compounds and other long-chain fatty acid compounds, along with the lack of structural alerts for carcinogenicity, chronic toxicity, or genotoxicity, HED has no specific concerns regarding chronic exposures other than those identified in the subchronic toxicity study for this cluster.

Exhibit 10

[redacted]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

AUTHENTICATION

I, Delores Barber, attest that I am the Director of the Information Technology and Resources Management Division (ITRMD) of the United States Environmental Protection Agency (EPA or Agency) and that the attached documents are true, correct, and compared copies of the file copies in my legal custody, consisting of:

MEMORANDUM Dated: 7/14/2009
To: Kerry Leifer (OPP)
From: Donna S. Davis, Byong-Han Chin, Alexandra LaMay, Matthew Lloyd, Christine L. Olinger (OPP)

Re: Alkyl Alcohol Alkoxylates (AAA - JITF CST 1 Inert Ingredient). Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations (95 pages).

Subscribed under the penalty of perjury on this 7th day of June, 2018.

Delores Barber

Delores Barber, Director
Information Technology and Resources Management Division (ITRMD)

CERTIFICATION OF TRUE COPY

I, Wendy Blake, certify that I am the Associate General Counsel, General Law Office, Office of General Counsel, of the United States Environmental Protection Agency; that I am the designee of the General Counsel for the purpose of executing certifications under 40 C.F.R. sec. 2.406; that I have duties in Washington, District of Columbia; and that the official whose signature appears above has legal custody pursuant to 40 C.F.R. sec. 2.406 of the original documents, copies of which are attached, as witnessed by my signature and the official seal of the United States Environmental Protection Agency.

Wendy L. Blake
Associate General Counsel
General Law Office
Office of General Counsel

Date: 6/11/18

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Date: July 14, 2009

MEMORANDUM

SUBJECT: **Alkyl Alcohol Alkoxylates (AAA - JITF CST 1 Inert Ingredient).** Human Health Risk Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations.

PC Code: 911638, 900488
Decision No.: 389120
Petition No.: 9E7533
Risk Assessment Type: Single Chemical Aggregate
TXR No.: NA
MRID No.: 47067001, 47676801, 47050602, 47676803, 47676802

DP Barcode: D366020
Registration No.: NA
Regulatory Action: Inert Tolerance Exemption
Case No.: NA
CAS No.: 68551-12-2, 69227-21-0
40 CFR: 180.920, 180.930 & 180.940

FROM: Donna S. Davis, Risk Assessor, RAB VII
Byong-Han Chin, Toxicologist, RAB VII
Alexandra LaMay, Biologist, RAB VII
Matthew Lloyd, Industrial Hygienist, RAB VII
Christine L. Olinger, Chemist, RAB VII
Health Effects Division (7509P)

THROUGH: Michael S. Metzger, Chief
Risk Assessment Branch VII
Health Effects Division (7509P)

TO: Kerry Leifer, Team Leader
PV Shah, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

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1.0 Executive Summary

The Joint Inert Task Force (JITF) Cluster Support Team Number 1 (CST 1) has submitted a petition proposing to establish exemptions from the requirement of a tolerance under 40 CFR §180.910, §180.930, §180.940 and §180.960 for inert ingredients know as the "alkyl alcohol alkoxylates" (AAAs). The requested exemptions from the requirement of a tolerance would permit use of the smaller carbon chain inert ingredients in this grouping in pesticide products applied pre- and post-harvest, applied to livestock and used in antimicrobial formulations. Additionally, the larger inert ingredients in this grouping, which met the definition of a polymer in 40CFR §723.250 would be permitted for use in all pesticide formulations, including antimicrobial formulations. HED notes that review of inert polymers is the purview of the Registration Divison (RD); therefore HED defers to RD as to the appropriateness of the proposed exemption from the requirement of a tolerance under §180.960. The remaining exemptions under §180.910, §180.930, and §180.940 are addressed by this risk assessment.

The toxicology database is adequate to assess risk for this group of compounds when used as inert ingredients in pesticide formulations. The AAA inert ingredients are not acutely toxic by the oral and dermal routes of exposure under normal use conditions; however, concentrated materials are generally moderate to severe eye and skin irritants and may be skin sensitizers. Following subchronic exposure to rats and dogs, decreases in body weight and food consumption were observed, but no specific target organ toxicity or neurotoxicity was seen. No effects were detected in a functional observational battery (FOB) or motor activity assessment of the adult animals. No susceptibility was demonstrated in the offspring in the OECD Test Guideline 416, 421 and 422 studies with the AAAs following prenatal and post-natal exposure.

Reproductive toxicity was not observed in the OECD Test Guideline 416, 421 and 422 studies with the AAA surfactants; however, at the highest dose tested, microscopic changes in the testes and epididymides were observed in a few adult males in the OECD 421 study. Developmental/offspring toxicity was observed in this study also, as evidenced by decreased litter size and increased postimplantation loss. There is no evidence of mutagenciity in the Ames assay (bacterial strains). Further, there are no carcinogenicity concerns based on structure activity modeling. The points of departure (PoDs) for risk assessment for chronic dietary, incidental oral, dermal and inhalation exposure were taken from this OECD 421 reproduction/developmental toxicity screening tests in rats and are based on decreased litter size, increased postimplantation loss, and microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules).

Sufficient data were provided on the chemical identity of the AAAs; however, limited data are available on the metabolism and environmental degradation of these compounds. The Agency relied collectively on information provided on the representative chemical structures, the submitted physicochemical data, structure-activity relationship information, as well as information on other surfactants and chemicals of similar size and functionality to determine the residues of concern for these inert ingredients. The Agency has concluded that a risk assessment based on toxicity data for the parent compounds is not likely to underestimate risk.

No residue data were provided for AAAs. In the absence of data, the Agency has developed an approach that uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. No adverse effect attributable to a single exposure was identified for these inert ingredients; therefore an acute dietary risk assessment is not appropriate. Chronic dietary (food and water) risks are not of concern.

The Agency evaluated residential handler and post application risks for high-end residential exposure scenarios, assuming 50% AAAs in outdoor turf products, 10% AAAs in indoor cleaning products, and 6% AAAs in pet products. The combined dermal and inhalation margins of exposure (MOEs) for these scenarios were above 100 for residential handler scenarios, and therefore there are no risks of concern. The combined dermal and hand-to-mouth MOEs for these products were above 100 for residential postapplication scenarios, and therefore there are not risks of concern.

Aggregate risks which combine residential exposures with food and water exposures for the AAAs are not of concern.

The Agency evaluated occupational handler and postapplication risks for high-end occupational exposure scenarios. As there is no proposed limit to the amount of AAA inert in the pesticide products, HED has completed an occupational exposure assessment assuming any pesticidal product contains 50% AAAs (assuming that the inert ingredient would be in the formulation at a level equivalent to the active ingredient (50% active ingredient; 50% AAA). Occupational handler risks are of concern for workers using a low pressure handwand applying pesticides containing AAAs to ornamentals in greenhouse settings. Since MOEs for workers applying pesticides to ornamentals in greenhouses do not exceed an MOE of 100, HED has provided additional exposure and risk estimates reflecting reduced amounts of AAAs in all pesticide formulations; MOEs exceed 100 at a concentration of 20% AAAs as an inert ingredient in pesticide formulations. HED notes that the occupational handler assessment assumes that mixer/loaders who are handling pesticides containing AAAs for aerial and ground application on high acreage crops will wear chemical-resistant gloves. HED believes this is a reasonable assumption given the volume of pesticide handled for these applications. Occupational handler risk estimates exceeded MOEs of 100 when when mixer/loaders wore chemical-resistant gloves for application on high-acreage crops.

The occupational postapplication risk estimates for a number of the scenarios assessed demonstrate risks of concern on Day 0 for herbicides, insecticides, and fungicides; specifically, the hand-harvesting/detassling scenario for corn (short-term exposure duration). These scenarios have MOEs above 100 on Day 8 for herbicides, Day 8 for insecticides, and Day 1 for fungicides. The Agency notes that it is not expected to be typical agricultural practice to apply herbicides, insecticides or fungicides on the same day workers would be conducting hand harvesting and detassling activities.

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

This assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide. These studies have received the appropriate ethical review for use in risk assessment.

Regulatory Recommendation

There are no human health risk considerations that would preclude the establishment of the requested exemptions from the requirement of a tolerance as follows:

Under 40 CFR §180.910 for:

> α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of 6 carbons

Under 40 CFR §180.930 for:

> α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethene) polymers where the alkyl chain contains a minimum of 6 carbons

Under 40 CFR §180.940 for:

> α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethene) polymers where the alkyl chain contains a minimum of 6 carbons

HED defers to the Registration Division on the appropriateness of the proposed exemption under 40 CFR §180.960 as review of inert ingredient polymers is under the purview of that division.

2.0 Background

Inert ingredients are those ingredients that are added to end use products that are not active ingredients. The terms "active ingredient" and "inert ingredient" are defined under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). An active ingredient is one that prevents, destroys, repels or mitigates a pest, or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. The statute defines the term "inert ingredient" as an ingredient that is not active.

As mandated by the Food Quality Protection Act (FQPA) of 1996, EPA conducted a reassessment of tolerances and exemptions from the requirement of tolerances for inert ingredients used in pesticide products to determine if they met FFDCA's revised standard of safety. As a result of that reassessment, the Agency published a final rule in the Federal Register (FR Notice Volume 71, No. 153, p. 45422, Aug 9, 2006) proposing revocation of specific exemptions from the requirement of a tolerance due to insufficient data.

In response to the proposed revocation, the JITF CST 1 has submitted a petition dated February 13, 2009 proposing to establish an exemption from the requirement of a tolerance as follows:

Under 40 CFR §180.910 for:

> α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethene) polymers where the alkyl chain contains a minimum of 6 carbons

Under 40 CFR §180.930 for:

> α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethene) polymers where the alkyl chain contains a minimum of 6 carbons

Under 40 CFR §180.940 for:

> α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethene) polymers where the alkyl chain contains a minimum of 6 carbons

Under 40 CFR §180.960 for:

> α-alkyl-ω-hydroxypoly (oxypropylene) and/or poly (oxyethene) polymers where the alkyl chain contains a minimum of 6 carbons and meets the definition of a polyer in 40 CFR §723.250

Establishment of the requested exemption from the requirement of a tolerance would allow use of smaller chain AAAs in pesticide products applied pre- and post-harvest, applied to livestock and used in antimicrobial formulations. Under 40 CFR §180.960, inerts meeting the definition of a polymer under 40CFR §723.250 would be permitted for use in all pesticide formulations, including antimicrobial formulations. HED notes that review of inert polymers is the purview of the Registration Divison (RD); therefore HED defers to RD as to the appropriateness of the proposed exemption from the requirement of a tolerance under §180.960.

3.0 Ingredient Profile

3.1 Summary of Proposed Uses

The alkyl alcohol alkoxylates are used as inert ingredients in pesticide formulations, including antimicrobial products. The petitioner has indicated that they are also used in detergents, personal care products, cosmetics and as adjuvants in vitamin preparations. Lastly they are used in industrial chemicals, primarily adhesives and polymeric coatings.

3.2 Structural Information

The alkyl alcohol alkoxylates (AAA) are.non-ionic, surface active agents (surfactants) comprised of a hydrophobic aliphatic alcohol moiety and a hydrophilic polyalkoxylate backbone. The hydrophobic alkyl alcohol may include linear, branched saturated and unsaturated carbon chain groups. The AAA surfactants may also be comprised of either single alcohols, simple mixtures,

such as C_{12} - C_{14} or C_9 - C_{11} or complex mixtures of alcohols. The JITF CST 1 polyalkoxylate backbone may be comprised of polyethoxylates (POE) or polyethoxylates/polypropoxylates (POE/POP).

Information on the generic structures of these compounds is summarized in Table 3.2.1, below. A detailed listing of the chemicals included in this group may be found in Table 3.2.2.

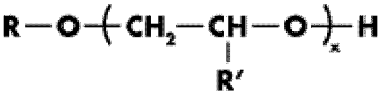
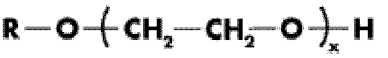
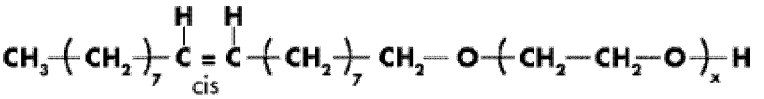
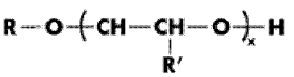
Table 3.2.1. Alkyl Alcohol Alkoxylates (AAA) Chemical Information	
Chemical Structure [1]	 R = Minimum C_6 linear or branched, saturated and/or unsaturated R' = H or H and CH_3 x = Minimum average 2 moles POE, minimum average 0 moles POP
Common name	Alkyl Alcohol Alkoxylates (AAA)
Test Compounds for Toxicity Testing	
Structure	 R = C_{12} – C_{14} branched, saturated x = Average moles polyethoxylation POE n = 12
CAS No.	84133-50-6
CAS Registry Nomenclature	Alcohols, C_{12} - C_{14} – secondary, ethoxylated
Tradename	Tergitol 15-S-12

Table 3.2.1. Alkyl Alcohol Alkoxylates (AAA) Chemical Information	
	Test Compound #2 (OECD 422 data): CAS RN 9004-98-2 is an unsaturated $C_{18:1}$ (average moles of POE n=10. **Figure 3. CAS RN 9004-98-2**  R = C18:1 (oleyl) linear unsaturated x = Average moles polyethoxylation POE n = 10 **CAS Registry Number** 9004-98-2 **CAS Registry Nomenclature** Poly(oxy-1,2-ethanediyl), . α-(9Z)-9-octadecen-1-yl-ω-hydroxy- **Alternate Nomenclature** 9-Octadecen-1-ol, monoether with polyethylene glycol, (Z)- (8CI) 9-Octadecen-1-ol-ethylene oxide copolymer **Tradename** AL-3037
	Test Compound #3 (OECD 422 data): CAS RN 103818-93-5 is a C_9-C_{11} linear and average moles of POE/POP n=9. **Figure 4. CAS RN 103818-93-5**  R = C_9 – C_{11} linear saturated R' = H or CH_3 x = Average moles polyethoxylation POE/POP n = 9 **CAS Registry Number** 103818-93-5 **CAS Registry Nomenclature** Alcohols, C_{9-11}, ethoxylated propoxylated **Tradename** AL-3347

[1] Figure excerpted from petition, "*Petition Proposing An Exemption From The Requirement Of A Tolerance For Residues Of Joint Inerts Task Force Cluster 1 "Alkyl Alcohol Alkoxylates" In Or On Raw Agricultural Products And Food Products*", page 6, dated February 13, 2009.

Table 3.2.2. Listing of Chemicals included in the NAPAAS Cluster	
CAS Number	**Descriptor**
AAA POE	
9002-92-0	Poly(oxy-1,2-ethanediyl), α-dodecyl-ω-hydroxy-
9004-95-9	Poly(oxy-1,2-ethanediyl), α-hexadecyl-ω-hydroxy-
9005-00-9	Poly(oxy-1,2-ethanediyl), α-octadecyl-ω-hydroxy-
26183-52-8	Poly(oxy-1,2-ethanediyl), α-decyl-ω-hydroxy-
34398-01-1	Poly(oxy-1,2-ethanediyl), α-undecyl-ω-hydroxy-
52292-17-8	Poly(oxy-1,2-ethanediyl), α-isooctadecyl-ω-hydroxy-
66455-14-9	Alcohols, C12-13, ethoxylated
66455-15-0	Alcohols, C10-14, ethoxylated
68002-97-1	Alcohols, C10-16, ethoxylated
68131-39-5	Alcohols, C12-15, ethoxylated
68131-40-8	Alcohols, C11-15-secondary, ethoxylated
68154-96-1	Alcohols, C14-18, ethoxylated
68213-23-0	Alcohols, C12-18, ethoxylated
68439-45-2	Alcohols, C6-12, ethoxylated
68439-46-3	Alcohols, C9-11, ethoxylated
68526-94-3	Alcohols, C12-20, ethoxylated
68439-50-9	Alcohols, C12-14, ethoxylated
68439-49-6	Alcohols, C11-15-secondary, ethoxylated
68551-12-2	Alcohols, C12-16, ethoxylated
68951-67-7	Alcohols, C14-15, ethoxylated
71243-46-4	Alcohols, C8-16, ethoxylated
97043-91-9	Alcohols, C9-16, ethoxylated
9043-30-5	Poly(oxy-1,2-ethanediyl), α-isotridecyl-ω-hydroxy-
60828-78-6	Poly(oxy-1,2-ethanediyl), α-[3,5-dimethyl-1-(2-methylpropyl)hexyl]- ω -hydroxy-
61827-42-7	Poly(oxy-1,2-ethanediyl), α-isodecyl-ω-hydroxy-
24938-91-8	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-
68439-54-3	Alcohols, C11-13-branched, ethoxylated
69011-36-5	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, branched
78330-20-8	Alcohols, C9-11-iso-, C10-rich, ethoxylated
78330-21-9	Alcohols, C11-14-iso-, C13-rich, ethoxylated
106232-83-1	Alcohols, C12-15-branched and linear, ethoxylated
127036-24-2	Poly(oxy-1,2-ethanediyl), α-undecyl-ω-hydroxy-, branched and linear
160875-66-1	Poly(oxy-1,2-ethanediyl), α -(2-propylheptyl)- ω -hydroxy-
9004-98-2	Poly(oxy-1,2-ethanediyl), α-(9Z)-9-octadecenyl-ω-hydroxy-
68920-66-1	Alcohols, C16-18 and C18-unsatd., ethoxylated
61804-34-0	Poly(oxy-1,2-ethanediyl), α-(9Z,12Z)-9,12-octadecadienyl-ω-hydroxy-
61791-28-4	Alcohols, tallow, ethoxylated
71060-57-6	Alcohols, C8-10, ethoxylated
26468-86-0	Poly(oxy-1,2-ethanediyl), α-(2-ethylhexyl)-ω-hydroxy-
31726-34-8	Poly(oxy-1,2-ethanediyl), α-hexyl-ω-hydroxy-
52609-19-5	Poly(oxy-1,2-ethanediyl), α-(2-hexyldecyl)-ω-hydroxy-
61791-20-6	Alcohols, lanolin, ethoxylated
68155-01-1	Alcohols, C16 and C18-unsatd., ethoxylated
69013-19-0	Alcohols, C8-22, ethoxylated
69364-63-2	Poly(oxy-1,2-ethanediyl), α-isohexadecyl-ω-hydroxy-
70879-83-3	Alcohols, C6-10, ethoxylated
78330-19-5	Alcohols, C7-9-iso-, C8-rich, ethoxylated
97953-22-5	Alcohols, C>30, ethoxylated
157627-86-6	Alcohols, C13-15-branched and linear, ethoxylated

Table 3.2.2. Listing of Chemicals included in the NAPAAS Cluster	
CAS Number	**Descriptor**
34398-05-5	Poly(oxy-1,2-ethanediyl), α-pentadecyl-ω-hydroxy-
72905-87-4	Alcohols, C13-18, ethoxylated
84133-50-6	Alcohols, C12-14-secondary, ethoxylated
61702-78-1	Poly(oxy-1,2-ethanediyl), α-[1,3-dimethyl-1-(2-methylpropyl)hexyl]-ω-hydroxy
27306-79-2	Poly(oxy-1,2-ethanediyl), α -tetradecyl- ω -hydroxy-
169107-21-5	Alcohols, C9-11-branched, ethoxylated
61791-13-7	Alcohols, coco, ethoxylated
39587-22-9	Poly(oxy-1,2-ethanediyl), α-nonyl-ω-hydroxy-
85422-93-1	Alcohols, C10-18, ethoxylated
AAA POP/POE	
68154-98-3	Alcohols, C14-18, ethoxylated propoxylated
61725-89-1	Oxirane, methyl-, polymer with oxirane, tridecyl ether
68002-96-0	Alcohols, C16-18, ethoxylated propoxylated
68154-97-2	Alcohols, C10-12, ethoxylated propoxylated
68439-51-0	Alcohols, C12-14, ethoxylated propoxylated
68551-13-3	Alcohols, C12-15, ethoxylated propoxylated
68603-25-8	Alcohols, C8-10, ethoxylated propoxylated
68937-66-6	Alcohols, C6-12, ethoxylated propoxylated
68987-81-5	Alcohols, C6-10, ethoxylated propoxylated
69227-21-0	Alcohols, C12-18, ethoxylated propoxylated
70750-27-5	Alcohols, C12-13, ethoxylated propoxylated
103818-93-5	Alcohols, C9-11, ethoxylated propoxylated
166736-08-9	Oxirane, methyl-, polymer with oxirane, mono(2-propylheptyl) ether
120313-48-6	Alcohols, C12-15-branched and linear, ethoxylated propoxylated
68213-24-1	Alcohols, C12-16, ethoxylated propoxylated
68458-88-8	Lanolin, ethoxylated propoxylated
68551-14-4	Alcohols, C11-15-secondary, ethoxylated propoxylated
69013-18-9	Alcohols, C8-18, ethoxylated propoxylated
69227-22-1	Alcohols, C10-16, ethoxylated propoxylated
72854-13-8	Alcohols, C14-18 and C16-18-unsatd., ethoxylated propoxylated
73049-34-0	Alcohols, C16-20, ethoxylated propoxylated
78330-23-1	Alcohols, C11-14-iso-, C13-rich, ethoxylated propoxylated
37311-02-7	Oxirane, 2-methyl-, polymer with oxirane, monooctyl ether
64366-70-7	Oxirane, 2-methyl-, polymer with oxirane, mono(2-ethylhexyl) ether
37251-67-5	Oxirane, 2-methyl-, polymer with oxirane, monodecyl ether
9087-53-0	Oxirane, 2-methyl-, polymer with oxirane, hexadecyl ether
196823-11-7	Oxirane, methyl-, polymer with oxirane, monoisotridecyl ether, block
57679-21-7	Oxirane, methyl-, polymer with oxirane, (9Z)-9-octadecenyl ether
111905-54-5	Alcohols, C13-15-branched and linear, ethoxylated propoxylated

3.3 Physical and Chemical Properties

Physicochemical data were estimated for the AAAs using publicly available Estimation Program Interface suite (EPI Suite™) modeling (http://www.epa.gov/opptintr/exposure/pubs/episuite.htm and are provided in Table 3.3. The basis for the estimated Estimation Program Interface suite (EPI Suite™) modeling physicochemical calculations and model capabilities are described in the EPA document titled The Use of Structure-Activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program (EPA 1999). The EPA EPI Suite™ 3.2 model calculations for water solubility are based on K_{ow} (WSKOWWIN model) and molecular fragments (WATERNT model). EPA has cautioned in the publication OPPTS Pollution

Prevention P2 Network (EPA, 2005), that EPI Suite™ water solubility calculations are not reliable for dispersible compounds such as surfactants.

The registrant provided EPI Suite™ estimates for all CAS numbers in the cluster. The properties are provided for representative products, including the products used in the toxicity testing and those with the highest molecular weights and Log K_{ow}s.

Table 3.3. Physicochemical Properties of Representative AAAS [1]

CAS No.	Descriptor[2]	Molecular Weight	Log K_{ow}	Vapor Pressure (mm Hg)	Water Solubility (mg/L) [3]
AAA POE					
9002-92-0	C12 POE n=5	406.61	3.4	7.5×10^{-11}	11.31 171.37
9004-95-9	C16 POE n=5	462.72	5.36	1.44×10^{-12}	0.1055 1.387
9005-00-9	C18 POE n=5	490.77	6.34	1.83×10^{-13}	0.01014 0.124
26183-52-8	C10 POE n=5	378.55	2.42	4.84×10^{-10}	116.2 1892.1
68131-39-5	C12-C15 POE n=5	406.61	3.4	7.54×10^{-11}	11.31 171.37
68439-45-2	C6-C12 POE n=5	350.5	1.43	3.64×10^{-9}	1188 20775
68526-94-3	C12-C20 POE n=1	326.61	9.89	2.09×10^{-5}	3.07×10^{-5} 4.52×10^{-5}
68951-67-7	C14-C15 POE n=1	242.45	6.94	4.66×10^{-3}	3.07×10^{-2} 0.056
106232-83-1	C12-C15 POE n = 4	348.53	2.96	2.84×10^{-8}	60.62 1500.41
9004-98-2	C18:1 POE n = 5	488.76	6.13	1.39×10^{-13}	1.59×10^{-2} 0.273
97953-22-5	C30 POE n=1	466.88	14.8	4.05×10^{-9}	2.67×10^{-10}
84133-50-6	C12-C14 POE n=1	406.61	3.32	1.26×10^{-10}	13.07 287.2
AAA POP/POE					
68002-96-0	C16-C18 POE n=1	270.5	7.92	7.05×10^{-4}	3.1×10^{-3} 5.26×10^{-3}
68603-25-8	C8-C10 POE n=1	158.29	4	9.82×10^{-1}	26.96 60.892
103818-93-5	C9-C11 POE n=3 POP n=2	392.58	2.76	9.25×10^{-10}	48.43 1600
57679-21-7	C16, C8-C18 olefin; POE n=3 POP n=2	490.77	6.2	7.63×10^{-13}	0.0135 0.348

[1] Table values taken from submission entitled "*Petition Proposing An Exemption From The Requirement Of A Tolerance For Residues Of Joint Inerts Task Force Cluster 1 "Alkyl Alcohol Alkoxylates" In Or On Raw Agricultural Products And Food Products*", page 6, dated February 13, 2009.

[2] Descriptor describes number of carbons assumed in the EPI Suite Model and the counter ions for the salts. POE denotes moles of ethoxylation.

[3] First value is generated using the WSKOWWIN model that calculates the solubility based on the Octanol/Water partition coefficient, and the second value was generated using the WATERNT model that calculates the value using molecular fragments.

4.0 Hazard Characterization/Assessment

4.1 Hazard and Dose-Response Characterization

4.1.1 Database Summary

The available toxicology database includes acute, subchronic (rat and dog), mutagenicity, three OECD 422 combined repeated dose toxicity studies with the reproduction/developmental toxicity screening tests, an OECD 421 reproduction/developmental toxicity screening test, an OECD 416 reproduction and fertility effects study, and reproduction and developmental effects studyies

The OECD Test Guideline 422 study is a combined repeated dose toxicity study with reproduction/developmental toxicity test parameters. This study provides information on the possible health hazards likely to arise from repeated exposure over a relatively limited period of time. The method comprises the basic repeated dose toxicity study as well as a reproduction/developmental toxicity screening test and also places emphasis on neurological effects as a specific endpoint. Therefore, the study can provide information on general toxicity as well as possible developmental, reproductive, and neurological effects. It can also provide basic indications of immunological effects.

The chemicals for which toxicity data were submitted are listed below:

Table 4.1. Representative AAA surfactants and Available Toxicological Data

Inert Tested	CAS No.	Studies Available
C9-11 AE_6	Not specified	Acute oral, acute dermal, primary skin irritation, and dermal sensitization (MRIDs 47041402A-47041402D)
C12-15 alkyl straight chain alcohols	68131-39-5	90-day oral toxicity in rats (MRID 47050601) 28-day oral toxicity in rats (MRID 47041001)
C12 Alkyl branched chain alcohols	60828-78-6	90-day oral toxicity in rats (MRID 46934102)
C12-15 Alkyl branched chain alcohols	106232-83-1	90-day oral toxicity in rats (MRID 46989501)
C18 Unsaturated Linear (oleyl) alcohol with average moles of POE n=10	9004-98-2	OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test in rats (MRID 47676802)
C12-14 Branched alcohol with average moles of POE n=12	84133-50-6	OECD 421 Reproduction/developmental toxicity screening test in rats (MRID 47676801), 90-day oral toxicity in dogs (MRIDs 46934101B, 46934103B, 46934104B, and 46934105B) 90-day oral toxicity in rats (MRID 46934101A, 46934103A, 46934104A, and 46934105A
C9-11 Linear alcohol with average moles of POE/POP n=9	103818-93-5	OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test in rats (MRID 47676803)

Table 4.1. Representative AAA surfactants and Available Toxicological Data		
Inert Tested	**CAS No.**	**Studies Available**
C14-15 Ethoxylated alcohols	68951-67-7	OECD 416 reproduction and fertility effects (MRID 47050602), reproduction and developmental effects study (MRID 47067001), mutagenicity (MRID 47041402F), 90-day dermal toxicity (MRID 47041402F)
C8 Alpha-Alkyl (C8)-o-hydroxypoly (oxypropylene) block copolymer with Polyoxyethylene	64366-70-7	OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test in rats (MRID 47361502)

The available toxicology data are adequate to support the requested exemption from the requirement of tolerance when used in pesticide formulations for the AAA inert ingredients.

4.1.2 Toxicological Effects and Metabolism

Toxicity
The AAAs are not acutely toxic by the oral and dermal routes of exposure under normal use conditions. Concentrated materials are generally moderate to severe eye and skin irritants and may be skin sensitizers. There is no evidence of mutagenicity in the Ames assay (bacterial strains).

Following subchronic exposure to rats and dogs, decreases in body weight and food consumption were observed, but no specific target organ toxicity or neurotoxicity was seen. No effects were detected in a functional observational battery (FOB) or motor activity assessment. In a 90-day dermal toxicity study with AAA surfactant, dermal toxicity was observed at 125 mg/kg/day (HDT), based on epidermal thickening and hyperkeratosis. No systemic toxicity was observed.

In an OECD 422 study with the AAA surfactant CAS No. 9004-98-2, parental toxicity observed at 110 mg/kg/day included decreased absolute and relative thymus weight, decreased body weight gain and decreased food consumption in females, and clinical signs in both sexes. The most common clinical signs were excess salivation and rales, soft or liquid feces, chromorhinorrhea, and red or clear perioral substance. These clinical signs may be attributed to local irritant effects. No reproductive or developmental/offspring toxicity was observed.

In the second OECD 422 study with the AAA surfactant CAS 103818-93-5, parental systemic toxicity was observed at 300 mg/kg/day (HDT), based on decreased body weight gain (in males) and clinical signs (orange/red perioral staining and moderate salivation) in both sexes. No reproductive or developmental/offspring toxicity was observed.

In the third OECD 422 study with the AAA surfactant CAS RN 64366-70-7, parental systemic toxicity was observed at 500 mg/kg/day (HDT), based on decreased body weight in males. No reproductive or developmental/offspring toxicity was observed.

In an OECD 421 study with the AAA surfactant CAS No. 84133-50-6, parental toxicity was observed at 470 mg/kg/day based on clinical signs (ptosis and hypoactivity), decreased absolute body weight, body weight gain, and food consumption. Reproductive toxicity was observed, as evidenced by the microscopic changes in the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules). Developmental/offspring toxicity was observed at 470 mg/kg/day, based on decreased litter size and increased postimplantation loss.

In a reproduction and developmental effects study with the AAA surfactant CAS 68951-67-7, the only significant effects observed in female rats were decreased body weight and body weight gain during premating at 400.8 mg/kg/day. At this maternally toxic dose, offspring toxicity observed was decreased body weight on lactation day (LD) 21 (both sexes in F_{1A}, F_{1B}, F_{2A}, and F2B). No treatment-related effects were observed on reproductive parameters.

In an OECD 416 study with AAA surfactant CAS 68951-67-7, clinical signs observed at 250 mg/kg/day were increased incidences of lachrymation, incidences of unkemptness, hunched posture, chromodacryorrhea and periocular swelling in F_0 and F_1 females. These effects may be attributed to local irritant effects. No treatment-related effects were observed on reproduction or the offspring at 250 mg/kg/day (HDT).

Metabolism
As stated in the petition, it is generally accepted that increased ethoxylation decreases lipophilicity resulting in decreased absorption and decreased toxicity. The lower molecular weight alkoxylates would be expected to be absorbed and distributed more readily than higher molecular weight alkoxylates and therefore to potentially be more toxic. The representative ethoxylated compounds tested have the lowest weight percent ethoxylation and lowest molecular weight of the series and are potentially the most bioavailable of the series.

Although metabolism data are not available, the major metabolic pathway for AAA POE or POE/POP surfactants is expected to include the hydrolysis of ether linkage to the corresponding alkyl alcohol and polyalkoxylate (POE or POE/POP) group which subsequently undergoes oxidative degradation and/or excretion (JITF CST 1 (2009).

4.2 Dermal Absorption

Available *in vivo* dermal absorption data in the rat show 50% dermal absorption.

4.3 Carcinogenic potential

There is no evidence that the AAA surfactants are carcinogenic. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Version 11, to determine if there were structural alerts. No structural alerts were identified. In addition, there was little concern about any of the postulated metabolites having greater toxicity than the parent compounds. See Appendix B for a complete description of the SAR analysis conducted for the AAA surfactants.

4.4 FQPA Considerations

The toxicity database consists of three OECD 422 studies, an OECD 421 study, an OECD 416 study, and reproduction and developmental effects studies. The executive summaries for these studies are presented in Appendix A.

In the case of the AAA surfactants, there was no increased susceptibility to the offspring of rats following prenatal and postnatal exposure in OECD reproductive/developmental screening studies on several representative AAA surfactants. Decreased litter size and increased postimplantation loss were observed in one OECD 421 study at 470 mg/kg/day where maternal/paternal toxicity was manifested as one maternal death (GD 22), decreased body weight, body-weight gain and food consumption and clinical signs (ptosis and hypoactivity) and microscopic changes in the testes (atrophy) and epididymides (increased intraluminal exfoliated spermatogenic cells) and dilated seminiferous tubules at 470 mg/kg/day. Since the rat reproduction/developmental study identified a clear NOAEL of 168 mg/kg/day for the offspring effects, and the selected point of departure of 168 mg/kg/day for the dietary, dermal, and inhalation risk assessments is protective of the offspring effects, there are no residual concerns.

There are no residual uncertainties identified in the exposure databases. The dietary and residential exposure assessments are considered to be conservative and are not likely to underestimate risk.

The FQPA factor can be reduced to 1X for the following reasons:

- The toxicology database is adequate for assessing the sensitivity of infants and children to the AAAs exposures.
- No susceptibility was demonstrated in the offspring in the OECD 416 study with the AAA surfactant CAS RN 68951-67-7.
- No susceptibility was demonstrated in the offspring in a dermal reproduction study with AAA surfactant CAS RN 68951-67-7.
- No susceptibility was demonstrated in the offspring in the OECD 422 studies with the AAA surfactants CAS RN103818-93-5, CAS RN 9004-98-2 and CAS RN 64366-70-7 following prenatal and post-natal exposure.
- No susceptibility was demonstrated in the offspring in the OECD 421 study with the AAA surfactant CAS RN 84133-50-6 following prenatal and post-natal exposure.
- No evidence of neurotoxicity was demonstrated.
- The endpoint and Point of Departure (POD) for offspring was used to quantify risks; a clear NOAEL was determined for these effects.
- Exposure values used in the dietary risk assessment are unlikely to underestimate risk.

4.5 Toxicity Endpoint Selection and Levels of Concern

The point of departure for risk assessment for all durations and routes of exposure was from the OECD 421 reproduction/developmental toxicity screening test (MRID 47676801). The NOAEL was 168 mg/kg/day, and the LOAEL was 470 mg/kg/day based on one maternal death (GD 22), decreased body weight, body weight gain, and food consumption, increased clinical signs (ptosis and hypoactivity), and microscopic changes of the testes and epididymides (testicular atrophy,

increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules) in parental animals, decreased litter size, and increased postimplantation loss. Although the chronic point of departure was selected from a subchronic study, longer-term studies are available that support the NOAEL selected. No additional uncertainty factor is needed for extrapolating from subchronic to chronic exposure.

While the petitioner submitted a dermal study, the Agency noted that effects seen in that study were limited to those related to the corrosive nature of these inert ingredients. No systemic toxicity was observed in the dermal study; however, systemic toxicity was seen at higher doses in the OECD 421 oral study. Therefore, the Agency considers it appropriate to select a dermal endpoint based on the findings in the oral study. The point of departure for dermal risk assessment is the oral NOAEL of 168 mg/kg/day. A dermal absorption factor of 50% was applied to the oral NOAEL based on the available dermal penetration study in rats. Additionally, to account for the difference in permeability between rat and human skin, the NOAEL was multiplied by a conservative factor of 3X. While at the present time it is not standard practice in HED to use the 3X rat to human skin correction factor, because this higher permeability to skin penetration in rats is well documented, and because of the numerous conservative inputs used in the risk assessment for the AAA inerts, the correction factor will be used in this case and is expected to result in a protective assessment of dermal risk.

A summary of the points of departure (PoDs) for all routes and durations of exposure may be found in Table 4.5. The residential, occupational and aggregate level of concern (LOC) is for MOEs that are less than 100 and is based on 10X for interspecies extrapolation from animals to humans and 10X for variation in sensitivity between humans.

An aggregate risk assessment across routes can be performed for the AAAs since common endpoints were selected for the oral, dermal and inhalation routes of exposure.

Table 4.5. Summary of Toxicological Doses and Endpoints for Alkyl Alcohol Alkoxylates for Use in Dietary, Non-Occupational, and Occupational Human Health Risk Assessments Human Health Risk Assessments

Exposure/ Scenario	Point of Departure	Uncertainty Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (all populations)	No appropriate endpoint was identified for acute dietary assessment			

Table 4.5. Summary of Toxicological Doses and Endpoints for Alkyl Alcohol Alkoxylates for Use in Dietary, Non-Occupational, and Occupational Human Health Risk Assessments Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Chronic Dietary (All Populations)	NOAEL = 168 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF = 1x	cRfD = 1.68 mg/kg/day cPAD= 1.68 mg/kg/day	**OECD 421** **reproduction/developmental toxicity screening test** MRID 47676801 (2009) LOAEL = 470 mg/kg/day based on one maternal death (GD 22), decreased body weight, body weight gain, and food consumption, increased clinical signs (ptosis and hypoactivity), and microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules) in parental animals, decreased litter size, and increased postimplantation loss.
Incidental Oral , and Inhalation (all durations)	NOAEL = 168 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF = 1x	Residential LOC for MOE = 100 Occupational LOC for MOE= 100	**OECD 421** **reproduction/developmental toxicity screening test** MRID 47676801 (2009) LOAEL = 470 mg/kg/day based on one maternal death (GD 22), decreased body weight, body weight gain, and food consumption, increased clinical signs (ptosis and hypoactivity), and microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules) in parental animals, decreased litter size, and increased postimplantation loss.

Table 4.5. Summary of Toxicological Doses and Endpoints for Alkyl Alcohol Alkoxylates for Use in Dietary, Non-Occupational, and Occupational Human Health Risk Assessments Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dermal (all durations)	Dermal NOAEL= 168 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF = 1x	Residential LOC for MOE = 100 Occupational LOC for MOE= 100	OECD 421 reproduction/developmental toxicity screening test MRID 47676801 (2009) Oral LOAEL = 470 mg/kg/day based on one maternal death (GD 22), decreased body weight, body weight gain, and food consumption, increased clinical signs (ptosis and hypoactivity), and microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules) in parental animals, decreased litter size, and increased postimplantation loss. The final dose used to quantify dermal risk must correct for 50% dermal absorption, and should be multiplied by 3 to take into account the differences in rat and human skin penetration. The resulting dose = 1000 mg/kg/day
Cancer (oral, dermal, inhalation)	Classification: Based on SAR analysis, AAA surfactants are not expected to be carcinogenic.			

Point of Departure (PoD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

4.6 Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When

additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed and vetted, the AAA may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

5.0 Dietary Exposure/Risk Characterization

5.1 Residues of Concern

Very limited information is available for the Alkyl Alcohol Alkoxylates (AAA) with respect to plant and animal metabolism or environmental degradation. The Agency considered the representative chemical structures, the generic cluster structures, the submitted physicochemical EPI Suite™ information as well as the structure-activity relationship analysis detailed in Appendix B of this review and information on other surfactants and chemicals of similar size and functionality.

Considering the large size and polarity of the AAA molecules, it is unlikely they would be readily absorbed by livestock or taken up by plants for further metabolism. Based on SAR analysis the AAA compounds are unlikely to degrade in the environment to compounds that are more toxic than the parent compounds; therefore, a risk assessment based on toxicity data from the parent compound would not likely underestimate dietary risk. Conservative food and drinking water residue estimates are used, as described below, which will be adequately protective for residues of the parent compound and any degradation product produced.

5.2 Drinking Water Residue Profile

No monitoring data or data reflecting the concentration of these inert ingredients in drinking water is available.

EFED conducted modeling runs on four surrogate inert chemicals using a range of physical chemical properties which represent a range of modeled drinking water exposure values expected to bracket that for AAA inert ingredients. EFED selected a North Carolina cotton scenario with an application date of July 1st as the scenario that would likely provide high end drinking water values for use in risk assessment. Percent crop area (PCA) factors were not applied. Simulations were run assuming a rate of 1 lb inert ingredient/A. Since degradation information was not available, three degradation scenarios were investigated: 1) chemically stable in water and soil; 2) a 100-day half-life in water and soil; and 3) a 10-day half life in water and soil. Further, two possible scenarios were investigated, one where all of the inert was applied as a single application, and the second assuming that the inert was applied evenly over a growing season. Modeled acute drinking water values ranged from 0.001 ppb to 41 ppb. Modeled chronic drinking water values ranged from 0.0002 ppb to 19 ppb. Further details of the EFED analysis are contained in Appendix C of this document.

For the purpose of the screening level dietary risk assessment to support the requested exemptions from the requirement of tolerances for the AAAs, a value of 100 ppb based on screening level modeling was used for the chronic dietary risk assessment for the parent

compound. HED considers the value of 100 ppb to be a high end, conservative assumption that is not likely to underestimate drinking water risks.

5.3 Food Residue Profile

No residue data were submitted for the AAAs. In the absence of data, the Agency has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of 57 high use insecticides (22), herbicides (20), and fungicides (17). The 57 pesticides were selected based on an overall ranking scheme that included consideration of the 1999 data for active ingredients use. All herbicides at greater than 5 million lbs/yr and all fungicides and insecticides at greater than 1 million lbs/yr were included as candidate surrogate chemicals.

OPP assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

To summarize, the Agency believes the assumptions used to estimate dietary exposures lead to a very conservative assessment of dietary risk for the following reasons:

- the highest tolerance level from the surrogate pesticides for every food is used;
- 100% crop treated (%CT) is assumed for all crops (every food eaten by a person each day has tolerance-level residues);
- many of these high tolerances are based on very short pre-harvest intervals where there is little time for degradation, whereas actual pesticide applications occur throughout the growing season;
- no consideration was given to potential degradation between harvest and consumption (use of tolerance level residues which are typically one to two orders of magnitude higher than actual residues found in monitoring data);
- residue values were assigned to every commodity in DEEM™ with no consideration given to potential reduction in residues from washing or cooking.

Although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. OPP does not believe that this approach underestimates exposure in the absence of residue data.

5.4 Analytical Methodology

Since this request is for an exemption from the requirement of a tolerance, an analytical method for enforcement purposes is not required to support this action.

5.5 Dietary (Food and Water) Exposure and Risk

The model and inputs used for the AAAs chronic dietary risk assessment are described in Section 5.3 and below. A complete description of the dietary exposure and risk assessment is provided in the memorandum for a different inert ingredient cluster entitled "Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts." (D361707, S. Piper, 2/25/09).

Chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model DEEM-FCID™, Version 2.03 which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

5.5.1. Acute Dietary Exposure and Risk

No adverse effects attributable to a single exposure of the AAAs were seen in the toxicity databases; therefore, an acute dietary risk assessment is not appropriate.

5.5.2. Chronic Dietary Exposure and Risk

A conservative screening level assessment was conducted for chronic dietary (food and drinking water) exposure using the highest tolerance level residue for all food forms, including meat, milk, poultry and eggs, default processing factors for dried commodities and 100% CT. In addition, a default concentration of 100 ppb was assumed for inert ingredient residues in drinking water.

Chronic dietary exposure estimates for food and drinking water are below HED's level of concern (<100% cPAD) for the U.S. population and all population subgroups. The AAA inert ingredient dietary exposure for food and drinking water is 11% of the cPAD for the U.S. population and 37% of the cPAD for children 1-2 yrs old, the most highly exposed population subgroup. See Table 5.5.4, below for a summary of results.

5.5.3. Cancer Dietary Exposure and Risk

HED has not identified any concerns for carcinogenicity relating to the AAA inert ingredients; therefore, a cancer dietary exposure assessment was not performed.

5.5.4. Summary of Dietary Exposure and Risk Assessment Results

The results of the chronic dietary risk assessment are shown in the summary table, below.

Table 5.5.4. Summary of Dietary (Food and Drinking Water) Exposure and Risk for the AAA Inert Ingredients

Population Subgroup	Acute Dietary (95th Percentile)	Chronic Dietary

	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
General U.S. Population	No acute endpoint selected		0.191509	11
All Infants (< 1 year old)			0.397082	23
Children 1-2 years old			**0.624005**	**37**
Children 3-5 years old			0.461958	27
Children 6-12 years old			0.255310	15
Youth 13-19 years old			0.144122	8
Adults 20-49 years old			0.144401	8
Adults 50+ years old			0.152076	9
Females 13-49 years old			0.145389	9

The most highly exposed subgroup is bolded.

6.0 Residential (Non-Occupational) Exposure/Risk Characterization

A screening level residential exposure and risk assessment was completed for products containing AAA inert ingredients. Details of the assumptions informing the residential exposure and risk assessment can be found in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09. A summary of the residential exposure and risk assessment is presented below.

The level of concern (LOC) for these risk assessments is an MOE of 100 based on the standard 10X inter-species and 10X intra-species extrapolation safety factors.

6.1 Residential Handler Exposure

Exposure Scenarios
The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. The AAA inerts are used in pesticide formulation that may be used around the home. These residential pesticide products are typically formulated as liquids in concentrates or as wettable powders. In addition, these inerts may be used in pesticide products applied to pets as aerosol sprays intended for flea control on carpeted surfaces and bedding, or as shampoo products applied to pets. Lastly, these inerts may be present in home cleaning products or paint products. HED conducted an assessment to represent high-end residential exposure scenarios by assessing:

- AAA in pesticide formulations (fungicides/insecticides/herbicides); (Outdoor Scenarios)
- AAA in disinfectant-type uses; (Indoor Scenarios)
- AAA in aerosol spray and shampoo pet products; (Pet Product Scenarios)
- AAA in paint applied by aerosol spray can, brush/roller, low-pressure sprayer, and airless sprayer; (Paint Product Scenarios)

Based on information contained in the petition, the AAA inerts can be present in cosmetics, personal care products, and consumer cleaning products. Therefore, HED assessed the disinfectant-type products containing the AAA inerts using exposure scenarios used by OPP's Antimicrobials Division to represent worst-case residential handler exposure.

Mixer/Loader/Applicator High Exposure Outdoor Scenarios:
The mixer/loader/applicator high exposure outdoor scenarios use data from the Outdoor Residential Exposure Task Force:

- Liquid products: Low Pressure Handwand (ORETF data)
- Liquid products: Hose End Sprayer (ORETF data)
- Ready to Use (RTU): Trigger Pump Sprayer Applications (ORETF data)

Exposure Data and Assumptions:
A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessments for the AAA inerts. Each assumption and factor is detailed below. In addition to these factors, unit exposures were used to calculate risk estimates.

The Agency used assumptions based on the Residential Exposure Assessment Standard Operating Procedures (Residential SOPs). Key assumptions used in this assessment are summarized below.

- The maximum application rate for the inert based on its use in a class of pesticide (herbicide/insecticide/fungicide) has been assessed for the short-term exposure duration.
- Residential risk assessments are based on high-end estimates of what homeowners would typically treat. Per HED's Residential SOPs (1997 & 2001 revision), residential pesticide handlers are assumed to mix and use a volume of 5 gallons of product per day.
- For adult exposure, the mean bodyweight for US males and females was used to estimate exposure (70 kg).

- Only adults (age 18+) are expected to apply pesticides.
- For outdoor pesticide applications, residential handlers are assumed to use a total of 2.25 lbs AAAs per day. This estimate is based on the following assumptions:
    - Five (5) gallons of formulated pesticide solution are assumed to be used per day by a residential handler (Revised Residential SOPs Area Treated, February, 2001). Consistent with the residential SOPs, the density of the formulated pesticide solution is assumed to be 9 lbs/gallon. The proposed limit to the amount of AAA inert in the pesticide products is 50%. Therefore 50% of any pesticidal product is assumed to be AAAs. Product concentrates are assumed to be diluted at a 1 to 10 ratio with water.

5 gallons formulated pesticide solution*(9 lbs/gallon)*(50% AAAs)*(1 part product concentrate/10 parts water) = 2.25 lbs AAAs in formulated pesticide solutions per day

- Residential exposure is assessed assuming clothing consisting of a short-sleeved shirt, short pants and no gloves or respiratory protection, the typical clothing for a home-owner applicator
- A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information.

The duration of exposure for most homeowner applications of home garden and lawn care products is best represented by the short-term duration (1 to 30 days). These exposure scenarios include the application of herbicides to lawns and insecticides/fungicides to gardens, ornamental plants, or lawns. While these types of applications may be applied on consecutive days, they are not likely to exceed 30 consecutive application days.

Mixer/Loader/Applicator High Exposure Indoor Scenarios:
The mixer/loader/applicator high exposure outdoor scenarios use data from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study, and the Pesticide Handlers Exposure Database:

- Liquid Products: Mopping Use (CMA data)
- Liquids Products: Wiping Use (CMA data)
- Aerosol Spray/Trigger pump/Air Deodorization Use (PHED data)

The Agency used assumptions based on methodology developed by the Antimicrobial Division (AD) of the Office of Pesticide Programs and the Residential SOPs to assess exposure and risk from indoor use of household cleaning products containing the AAA inerts. Based on information from RD, the Agency assumed that the maximum percentage by weight in indoor products would be 10% AAAs.

Unit Exposure Values: Unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642) or from the PHED data presented in HED's Residential SOPs (USEPA, 1997).

"**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and

Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09 contains additional information about the disinfectant-type exposure scenarios assessed in this document.

The following key assumptions were used in this assessment:

- For adult exposure, the mean for US male and female bodyweights was used to estimate exposure (70 kg).
- Only adults are assumed to apply pesticides.
- For the mopping scenario, the CMA dermal and inhalation unit exposure values for ungloved mopping were used (71.6 mg/lb inert. and 2.38 mg/lb inert, respectively). These values are based on data collected from six replicates mopping floors and receiving exposure via contact with the mop or with the bucket.
- For the wiping scenario, the CMA dermal and inhalation unit exposure values for ungloved wiping were used (2,870 mg/lb inert and 67.3 mg/lb inert, respectively). These values are based on data collected from six replicates that used a finger pump sprayer to apply cleaning products to restroom fixtures and dental fixtures and then wiped the surfaces with a paper towel.
- For aerosol spray, trigger pump and air deodorization scenarios, the PHED dermal and inhalation unit exposure values are 220 mg/lb inert and 2.4 mg/lb inert, respectively. The values are based on homeowners applying an aerosol insecticide to baseboards in kitchens and are representative of a handler wearing short pants and a short sleeve shirt, with no gloves.

The quantities handled/treated were estimated based on information from various sources and assumptions.

- For the mopping scenarios, it was assumed that 1 gallon of diluted solution is used. HED assumes that cleaning products are assumed to have the same density as water (8.34 lbs/gallon). While typical product concentrate directions indicate that 1 oz concentrated product per 1 gallon of water should be used, HED followed the AD SOP and assumed a dilution factor of 2 oz concentrated product/128 oz (1 gallon) of water for the residential handler risk assessment to represent heavy-duty cleaning formulations. Based on information from RD, the Agency assumed that the maximum percentage by weight in indoor products would be 10% AAAs.

1 gallon formulated pesticide solution*(8.34 lbs/gallon)*(10% AAAs)*(2 oz/ 128 oz dilution factor) = 0.013 lbs AAAs in formulated pesticide solutions per day

- For the wiping and trigger pump spray scenarios, it was assumed that 0.5 liter (0.13 gal) of ready-to-use (RTU) solution is used. For antimicrobial products, 10% AAAs in product is assumed.

0.13 gallon formulated pesticide solution*(8.34 lbs/gallon)*(10% AAAs) = 0.108 lbs AAAs in formulated pesticide solutions per day

- For the aerosol foam spray and air deodorization scenarios, it is assumed that one can of product is used. For the aerosol spray/trigger pump/air deodorization scenario, it is assumed that a 12 oz net weight product is used (0.094 gallons). 10% AAAs inert in antimicrobial and disinfectant-type products was assumed.
- A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information.

The duration of exposure for most homeowner applications of indoor cleaning products is believed to be best represented by the short-term duration (1 to 30 days) because the different scenarios (i.e. methods of application) are assumed to be episodic, not daily. In addition, homeowners are assumed to use different cleaning products with varying active and inert ingredients.

Mixer/Loader/Applicator High Exposure Pet Product Scenarios:

- Aerosol Spray scenario (Spray applications to pets and/or pet bedding)
- Pet Shampoo scenario (Shampoo application to pets)

Products intended for use on pets contain less than 6% AAAs in the formulation. Therefore, the residential handler exposure assessment assumed that products associated with the pet use scenarios contained up to 6% AAAs in pet products. Typically, HED would also assess a pet shampoo scenario to reflect a high-end dermal exposure scenario associated with pets.

The following key assumptions were used in this assessment:

- For adult exposure, the mean bodyweight for US males and females was used to estimate exposure (70 kg). Only adults are expected to apply pesticides.
- For aerosol spray scenario, the PHED dermal and inhalation unit exposure values are 220 mg/lb inert and 2.4 mg/lb inert, respectively. The values are based on homeowners applying an aerosol insecticide to baseboards in kitchens and are representative of a handler wearing short pants and a short sleeve shirt, with no gloves.
- For shampoo scenario, the carbaryl and MGK shampoo study (MRID 44658401 and MRID 46601001, respectively) dermal and inhalation unit exposure values are 1661 mg/lb inert and 0.06 mg/lb inert, respectively. These values are based on the geometric mean of the combined unit exposure values.

The quantities handled/treated were estimated based on information from various sources and assumptions.

- For the aerosol spray and air deodorization scenarios, it is assumed that one-half can of spray product is used. It is assumed that a 12 oz net weight product is used, so half of this can is 6 oz (0.047 gallons). The density of the product is assumed to be equivalent to water, 8.34 lbs/gallon.
- For the shampoo scenario, it is assumed that one-quarter of a bottle of shampoo is used. It is assumed that a 12 oz net weight product is used, so one quarter of a bottle is 3 oz (0.1875 lbs). Shampoo pet products were used to assess postapplication exposure to pet product as these types of products are used in large quantities on the pet. One-quarter of

a 12 oz shampoo product was assumed to be applied to the pet for short- and intermediate-term exposure durations. The pet shampoo application rate is a conservative estimate based on the amount of shampoo product applied in the Carbaryl and MGK shampoo studies (MRID 44658401 and MRID 46601001, respectively). According to the Carbaryl and MGK studies, the average amount of shampoo product applied to each animal was 27,240 mg and 33,900 mg, respectively. Our assessment assumes 85,000 mg of product applied in each application (one quarter of a 12 oz bottle), so this assumption is conservative.

- 6% AAA inert in pet product is assumed.
- A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information.

The duration of exposure for most homeowner applications of pet products is believed to be best represented by the short-term duration (1 to 30 days) because the pest pressure for these scenarios is assumed to be episodic, not daily.

Mixer/Loader/Applicator High Exposure Antimicrobial Paint Scenarios:

- Brush and roller paint application scenario
- Airless sprayer paint application scenario

As the AAA inert petition specifically made claims for 180.920, 180.930, and 180.940 (antimicrobial uses), HED also assessed exposure scenarios from paints with antimicrobial ingredients. This section describes assessing exposure for residential handlers applying paint containing antimicrobial ingredients. The HED document "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09 does not address the handler or postapplication paint-related exposure scenarios. However, all the inputs to calculate the relevant handler and postapplication dose (dermal, inhalation, and oral) are presented below.

These scenarios assume that paint aerosols containing antimicrobial ingredients may lead to inhalation or dermal exposure while spraying, brushing, and rolling. Spray paint aerosols are assumed to be similar to that of an insecticide pressurized spray can application. All brush and roller paints and stains are assumed to be similar regardless of the paint type (e.g. alkyd or latex paints and stains). The method for completing exposure assessments for this scenario relies on using surrogate PHED data. Information used to assess these scenarios can be found in HED's SOPs for Residential Exposure Assessments, 1997.

The following key assumptions were used in this assessment:

- For aerosol spray paints, the upper-percentile assumption for the amount handled is 3 cans (12 ounces each) used per event (the 90th percentile amount of spray paint used per event is 36.11 oz/use[1].
- For paints used with a brush or roller, the amount of paint used per event is 2 gallons (two 1-gallon cans) of paint. This is based on a 90th percentile value of 8 gallons of latex paint used per year divided by the mean frequency of 4 painting events per[1].
- For painting/staining with a low-pressure sprayer, it is assumed that residential users may use up to 5 gallons of finished spray prepared from a concentrated product and water. This is based on the experience and professional judgement of the OPP/HED staff by assuming that more product would be used with a low-pressure sprayer than with a roller or brush, but less than the used with a high-pressure sprayer.
- For painting/staining with an airless sprayer, a residential user is assumed to use three 5-gallon cans of ready-to-use product or of finished spray prepared from a concentrated product and water. This is based on a coverage rate of 200 ft^2/gallon and a house size of 40x30x20 ft (surface area of 2,800 ft^2). This is based on the experience and professional judgement of the OPP/HED staff and is assumed to be an upper-percentile input.
- All paint categories are considered similar for exposure assessment purposes (e.g. an exterior alkyd paint would be considered the same as a latex).
- The density of spray paint is 1.24 g/ml (10.34 lbs/gallon). This is based on the mean density for latex paint[2].
- For adult exposure, the mean bodyweight for US males and females was used to estimate exposure (70 kg). Only adults (18+) are expected to apply paints.
- For aerosol spray paint scenario, the PHED dermal and inhalation unit exposure values are 220 mg/lb inert and 2.4 mg/lb inert, respectively. The values are based on homeowners applying an aerosol insecticide to baseboards in kitchens and are representative of a handler wearing short pants and a short sleeve shirt, with no gloves.
- For the brush/roller painting scenario, the PHED dermal and inhalation unit exposure values are 230 mg/lb inert and 0.284 mg/lb inert, respectively. The values are based on using 1-gallon paint cans and typical brushes while engaged in painting a single, residential bathroom. The applicators were not professional painters. Each replicate used up to ½ gallon of paint for each bathroom painting.
- For the low-pressure sprayer scenario, the PHED dermal and inhalation unit exposures were 100 mg/lb inert and 0.0216 mg/lb inert, respectively. The values are based on using a typical low pressure handwand to treat low and mid-level targets generally below the waist.
- For the airless sprayer application scenario, the PHED dermal and inhalation unit exposures were 79 mg/lb inert and 0.83 mg/lb inert, respectively. The values are based on using an airless sprayer to apply paint or stain to building exteriors.

The duration of exposure for most homeowner applications of paint products is believed to be best represented by the short-term duration (1 to 30 days) because the activity of painting is

[1] U.S. Environmental Protection Agency. (1996) Exposure Factors Handbook [Draft]. National Center for Environmental Assessment, Washington D.C. EPA/600/P-95/002Ba.
[2] U.S. Environmental Protection Agency. (1986) Standard Scenarios for Estimating Exposure to Chemical Substances During Use of Consumer Products – Volume 1, Prepared for U.S. EPA, Ofice of Toxic Substances, Exposure Evaluation Division, by Versar, Inc. EPA Contract #68-02-3968.

assumed to be an episodic, not daily activity pattern for residential users. EPA's Exposure Factors Handbook [Draft, 1996] indicates a mean frequency of four painting events per year.

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Risk Summary

For all residential handler scenarios, risk estimates are not of concern (i.e., MOEs are all greater than 100) for both the route-specific (dermal or inhalation) assessment and for the total MOE (dermal and inhalation combined). A summary of the results are provided below in Tables 6.1, below.

The Agency believes that the handler scenarios assessed represent worse-case exposures and risks resulting from use of indoor and outdoor pesticide products, pet products and paint products containing the AAA inerts in residential environments.

Table 6.1. Short-term Exposure and Risks for AAAs Residential Handlers

Exposure Scenario (Formulation/ Application)	Application Rate[1] (lb inert/ gallon)	Quantity Handled/ Treated per day[2]	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (mg/ lb inert)[3]	Dermal Dose (mg/kg /day)[4]	Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Outdoor Products									
Liquids/ Low Pressure Handwand (ST) (ORETF data)	0.45 lb/gal	5 gallons	38	0.003	1.221	9.6E-5	820	1,700,000	820
Liquids/ Hose End Sprayer, Lawn (ST) (ORETF data)	0.45 lb/gal	5 gallons	11	0.017	0.354	0.00055	2,800	310,000	2,800
Liquids/ Trigger Sprayer/ Home Garden (ST) (ORETF data)	0.45 lb/gal	5 gallons	54	0.0019	1.736	6.11E-5	580	2,800,000	580
Indoor Products									
Indoor hard surface, Mopping (ST) (CMA data)	0.013 lb/gal	1 gallon	71.6	2.38	0.0133	0.00044	75,000	380,000	63,000
Indoor hard surface, Wiping (ST) (CMA data)	0.834 lb/gal	0.13 gallons	2870	67.3	4.445	0.104	220	1,600	200
Indoor hard surface, Aerosol spray (ST) (PHED data)	0.834 lb/gal	0.094 gallons (12 oz)	220	2.4	0.246	0.0027	4,100	63,000	3,800
Pet Products									
Pet Spray Product (ST) (PHED data)	0.5 lb/gal	0.047 gallons (6 oz)	220	2.4	0.0737	0.0008	14,000	210,000	13,000
Pet Shampoo Product (ST) (MRID 44658401 and 46601001)	0.01125 lbs	NA	1661	0.06	0.267	9.64E-6	3,700	17,000,000	3,700

Table 6.1. Short-term Exposure and Risks for AAAs Residential Handlers									
Exposure Scenario (Formulation/ Application)	Application Rate[1] (lb inert/ gallon)	Quantity Handled/ Treated per day[2]	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (mg/ lb inert)[3]	Dermal Dose (mg/kg /day)[4]	Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Paint Scenarios									
Paint Aerosol Spray can (ST) (PHED data)	0.2585	0.28125 gallons (36 oz)	220	2.4	0.2285	0.0025	4,400	67,000	4,100
Paint brush/roller (ST) (PHED data)	0.2585	2 gallons	230	0.284	1.699	0.0021	590	80,000	580
Paint low-pressure sprayer (ST) (PHED data)	0.2585	5 gallons	100	0.0216	1.846	0.0004	540	420,000	540
Paint airless sprayer (ST) (PHED data)	0.2585	15 gallons	79	0.83	4.376	0.046	230	3,700	220

[1]Application rates are based on maximum application rates of products containing AAA inerts multiplied by 50% for outdoor products, 10% for indoor products, 6% for pet products, and 2.5% for paint products to convert from product application rate to inert application rate.

[2]Quantity treated daily values are back-calculated from 5 gallons of product used per day (Revised Residential SOPs 2001) for outdoor products. Indoor products are assumed to be used at 1 gallon of solution for the mopping scenario, 0.5 L of solution for the wiping scenario, and a 12 oz can of spray for the aerosol spray/air deodorization scenario. Pet spray products are assumed to be used at a rate of half of a 12 oz can of product, pet shampoo products are assumed to be used at a rate of one quarter of a 12 oz bottle of product. Paint products are assumed to be used at a rate of 36 ounces for aerosol spray can application, 2 gallons for brush/roller application, 5 gallons for low-pressure sprayer application, and 15 gallons for airless sprayer application.

[3]Unit Exposure data sources are identified in the exposure scenario column. All exposure scenarios assess exposure reflecting applicators wearing short-sleeved shirts and shorts and no respiratory protection.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb /gal) * Quantity handled (gallons/day))/ Body Weight (70 kg)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (mg inert / lb inert) * Application Rate (lb /gal) * Quantity handled (gallons/day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.

[7] Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8] Total MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]

6.2 Residential Postapplication Exposure

Exposure Scenarios

Residential postapplication exposures result when bystanders, such as children come in contact with the AAA inerts in areas where end-use products have recently been applied (e.g., treated lawns, gardens or recently cleaned surfaces). The Agency selected representative scenarios, based on end-use product application methods and labeled application rates. HED conducted an assessment to represent worst-case residential exposure by assessing post application exposures and risks from:

- AAAs in pesticide formulations (fungicides/ insecticides/ herbicides); (Outdoor Scenarios)
- AAAs in disinfectant-type uses; (Indoor Scenarios)
- AAAs in shampoo pet treatments; (Pet Product Scenarios)
- AAAs in paint products; (Paint Product Scenarios)

The Agency considers dermal (adults and children) or incidental oral (children only) the primary exposure routes for the AAA inerts. Inhalation exposures are not typically calculated for

postapplication scenarios because inhalation exposures generally account for a negligible percentage of the overall body burden for most pesticide chemicals. Any inhalation exposure through the postapplication route will be less than the inhalation exposures assessed by residential handlers above in section 6.1.

For all postapplication exposure scenarios, exposures are assessed at short- and intermediate-term exposure durations because residues may be present on treated lawns, indoor treated surfaces, or on treated pets for lengths of time consistent with short- and intermediate-term exposure. Additionally, residential postapplication exposure can occur in commercially treated environments (e.g., schools, child care facilities, hospitals). If the products are used on a routine basis (i.e., daily), exposures may occur over an intermediate-term time duration (30 days – 6 months).

Postapplication High End Outdoor Exposure Scenarios

- Dermal exposure to treated lawns (adults/children)
- Hand-to-Mouth activity for toddlers on treated lawns (children)
- Object-to-Mouth activity for toddlers on treated lawns (children)
- Soil ingestion from treated soil (children)

The exposures from these routes and scenarios were considered individually and were also added together, where appropriate, to determine a total dose for children exposure to treated lawns. Residential postapplication exposure is assessed on the day of application, typically referred to as Day 0.

Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the residential postapplication risk assessments. The assumptions and factors used in the risk calculations are consistent with current HED policy for completing residential exposure assessments (i.e., *SOPs for Residential Exposure Assessment [1997 and 2001 revision]*).

Exposures to adults/children after contact with treated lawns have been addressed using the latest approaches for this scenario including:

- For adult exposure, the mean bodyweight for US males and females was used to estimate exposure (70 kg). For child exposure, the mean of median values for male and female 3 year olds was used to estimate exposure (15 kg).
- HED has developed standard transfer coefficient (TC) values for residential postapplication scenarios to ensure consistency in exposure assessments. For the short-term assessment, TC values of 14,500 cm^2/hr (adults) and 5,200 cm^2/hr (children) were used. For intermediate-term risk assessment, TC values of 7,300 cm^2/hr (adults) and 2,600 cm^2/hr (children) were used. These default transfer coefficients, found in the 2001 Residential SOPs, were used to calculate postapplication exposures.
- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2 (based on the surface area of three fingers of a toddler's hand). For short-term exposures, it is assumed that there were 20 events per hour (90th percentile, according to the SOP) and for intermediate-term exposures, it was assumed that there were 9.5 event/hour (mean value).

- The exposure time used is 4 hours a day (USEPA, 2000 and 2001).
- The saliva extraction efficiency used is 50% (USEPA, 2000 and 2001).
- Pesticidal products are assumed to contain a maximum of 50% AAAs by weight in the end use products.
- The relevant application rates for AAAs containing products are derived above in Section 6.1
- A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information.

Postapplication High End Indoor Exposure Scenarios

Standard methodologies based on HED's Residential SOPs were used to assess residential postapplication exposure to hard surface cleaners.

The Agency assumed that the maximum percentage by weight in indoor products would be 10% AAAs. Based on an overall query of products that contain AAAs, this reflects a high-end concentration.

Typically, the Agency assesses disinfectant-type products for the short-term exposure duration (1 to 30 days). This assumption is supported by the fact that the different scenarios (i.e. methods of application) are episodic, not daily. In addition, homeowners are assumed to use different cleaning products with varying active and inert ingredients. However, intermediate-term exposure is assessed for children because disinfectant products are used frequently in schools and day care centers where children can spend significant amounts of time. In those environments, cleaning products can be used on a daily basis.

The Agency used assumptions based on the Residential SOPs. The following key assumptions were used in this assessment:

- For child exposure, the mean of median values for male and female 3 year olds was used to estimate exposure (15 kg).
- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2 (based on the surface area of three fingers of a toddler's hand). For short-term exposures, it is assumed that there were 20 events per hour (90th percentile, according to the SOP) and for intermediate-term exposures, it was assumed that there were 9.5 event/hour (mean value).
- The exposure time used is 4 hours a day (USEPA, 2000 and 2001).
- The saliva extraction efficiency was 50% (USEPA, 2000 and 2001).
- No label information was available to represent the volume of disinfectant to be used for cleaning surfaces such as floors. It was assumed that the diluted treatment solution was applied at a rate of 1 gallon per 1,000 sq. ft^3.
- The maximum application rate on the product labels for application to hard surfaces is 8.34 lbs product/gal, based on the density of water. The amount of product used is assumed to be 0.5 gallons per day at a rate of 1 gallon/1000 ft^2, (i.e., 0.5 gallons for 500

ft^2). Therefore, the application rate used for the hard surface cleaner scenario in the post application scenario was $1.3x10^{-5}$ lbs inert/ft^2 [(1 gallon of product used * 8.34 lbs/gallon)/1000 ft^2 cleaned = 0.008 lb product/ft^2); (0.008 lb product/ ft^2 * 10% inert in a given disinfectant formulation * 2 oz/128 oz dilution factor= $1.3x10^{-5}$ lb/ft^2 /per day)] (See Table 6.2: Indoor Cleaning Products)

- No data is available regarding the quantity of solution residue left on the floor after treatment. As a conservative measure, it was assumed that 25% of the cleaner remains after the final mopping. This assumption has been used by the AD for other Office of Pesticide Program risk assessments.
- No transferable residue data were available that could be used to estimate the transfer factor from the floor to skin. Therefore, it is assumed that 10% of the deposition rate is available for dermal transfer (USEPA, 2000 and 2001).
- A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information.

Postapplication High End Pet Product Exposure Scenarios

Standard methodologies based on HED's Residential SOPs were used to assess residential postapplication exposure to pesticidal products used on pets. Shampoo products were assessed as these products are applied in large quantities to the pet for flea control, and thus are the most readily available for postapplication residential exposure.

The Agency assumed that the maximum percentage by weight in pet products would be 6% AAAs. Based on an overall query of products that contain AAAs, this reflects a high-end concentration.

Shampoo pet products were used to assess postapplication exposure to pet product as these types of products are used in large quantities on the pet. One-quarter of a 12 oz shampoo product was assumed to be applied to the pet for short- and intermediate-term exposure durations. The pet shampoo application rate is a conservative estimate based on the amount of shampoo product applied in the Carbaryl and MGK shampoo studies (MRID 44658401 and MRID 46601001, respectively). According to the Carbaryl and MGK studies, the average amount of shampoo product applied to each animal was 27,240 mg and 33,900 mg, respectively. This assessment assumes 85,000 mg of product applied in each application (one quarter of a 12 oz bottle), so this assessment is conservative.

The residue of pesticidal shampoo treatments on pets is expected to remain available for transfer and exposures are expected to occur over a short- and intermediate-term time duration (1- 30 days, 30 days – 6 months, respectively).

The Agency used assumptions based on the Residential SOPs. The following key assumptions were used in this assessment:

- For adult exposure, the mean for US males and females was used to estimate exposure (70 kg). For child exposure, the mean of median values for male and female 3 year olds was used to estimate exposure (15 kg).
- Application rate is based on the size of shampoo treatment. Short- and intermediate-term

exposures were estimated assuming one quarter the size of a 12 ounce shampoo bottle, or 3 ounces per day for the exposure duration. This means for AAAs, 5,100 mg of inert are used for short- and intermediate-term exposure durations [3 ounces * (2,8350 mg/oz) * 6% inert in product = 5,100 mg inert]. This assumption of the amount of shampoo used varies from that in the current residential SOPs, but is consistent with proposed updated methodologies.

- It is assumed that one pet is contacted per day.
- On the day of application, it may be assumed that 5% (0.05) of the maximum application rate is available on the pet's body and transferred to the adult/toddler as a dislodgeable residue. This value is believed to be an upper-percentile assumption based on the properties of the AAAs. The assumption of 5% transfer varies from the current SOPs, but is consistent with proposed updated methodologies.
- Postapplication activities are assed on the same day that the pesticide is applied because it is assumed that individuals could come in contact with the pet immediately after application.
- The surface animal of a dog is determined using a representative (average) animal, or a medium-sized (30 lb) dog. Estimated risks are based on an even loading of residues across the entire surface of a 30 lb dog, where Surface area (cm^2) = ((12.3 * (BW (lb)*454)^0.65)) = 2490 cm^2 from HED's 1993 Wildlife Exposure Factors Handbook.

Pet Product Postapplication Dermal Exposure Assumptions:

- HED's default value for the surface area of an adult hug is 5,625 cm^2; surface area for a toddler hug is 1,875 cm^2 (US EPA, 1999 SAP).
- A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information.

Pet Product Postapplication HTM Exposure Assumptions:

- Based on HED's Residential SOPs, it was assumed that the surface area used for each hand-to-mouth event is 20 cm^2, representing the surface area of the child's hands entering the mouth (assumed to be 3 fingers).
- Saliva extraction efficiency is assumed to be 50% (i.e., every time the hand goes in the mouth approximately half of the residues on the hand are removed).
- The approach used to address the hand-to-mouth exposure pathway has been modified since 1999 Draft Policy 13, "Postapplication Exposure Assessment for Children from Treated Pets." In the revised approach, the frequency term has been modified to an equilibrium approach analogous to the dermal exposure component (i.e., the frequency = 1 event/day). This approach was revised since the data from which the transferable residues concentrations were determined rely on a continuous contact (grooming) technique that would lead to concentrations on the hands which are anticipated to be significantly higher than would result from petting/hugging.

Postapplication High End Paint Product Exposure Scenarios

This section describes assessing postapplication exposure among children from ingestion of paint chips containing pesticide residues. This scenario assumes that pesticide containing paint chips are ingested by children.

The residue of pesticidal paint treatments is expected to remain available for transfer and exposures are expected to occur over a short- and intermediate-term time duration (1- 30 days, 30 days – 6 months, respectively).

The Agency used assumptions based on HED's Residential SOPs. The following key assumptions were used in this assessment:

- The assumed ingestion rate for paint chips containing pesticides is 0.04 gram/day for children (age 6 months to 1-1/2 year). This assumes that child ingests a paint chip with an overall size of 1 in^2 (6.25 cm^2) and an average weight of 6.5 mg/cm^2 for a paint chip that is one layer thick (US EPA, 1994). This is believed to be an upper-percentile value.
- Infants (age 6 months to 1-1/2 year) are assumed to weight 10 kg. This is the mean of the median value for male and female children in the 6-11 month and 1 year age groups. (US EPA, 1996).
- It is assumed that 20 percent of the residue is remaining in paint and is available for ingestion via paint chip. This is believed to be an upper-percentile assumption, based on the experience and professional judgement of the OPP/HED staff.

Potential dose rates from ingestion are calculated as follows:

$$PDR = \frac{IgR * (P/100) * F * CF1}{BW}$$

Where:

PDR = potential dose rate (mg/kg/day)
IgR = ingestion rate of paint chips containing pesticide residues (g/day)
P = percent of inert in paint
F = fraction of inert available for ingestion (unitless)
CF1 = weight unit conversion factor (1,000 mg/g)
BW = body weight (kg)

Risks were calculated using the Margin of Exposure (MOE) approach, which compares a toxicological PoD to an exposure estimate. Exposure algorithms and additional information on calculating the risk estimates for residential postapplication exposure can be found in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751," 5/7/09.

Risk Summary

A summary of the residential postapplication exposure and risk estimates are presented in Table 6.2, below. Short- and intermediate-term post application risks for children are not of concern. The individual route-specific and combined non-dietary risks from dermal exposure and hand-to-mouth exposure for the outdoor scenarios and indoor scenarios do not demonstrate risks of concern for toddlers (i.e., the MOEs for the assessed scenarios are greater than 100) for both the short- and intermediate-term exposure durations. Incidental oral exposure to infants of paint chips does not demonstrate a risk of concern for short-term exposure durations.

Risk Characterization

At this time, residue dissipation data or reliable use pattern data are not available, including the frequency and duration of use of antimicrobial products in the residential setting. The Agency does not believe that the use patterns of many residential products result in intermediate-term exposure. However, the Agency notes that intermediate-term exposure to children may occur in areas where disinfecting products are used more frequently (i.e., schools and day care centers).

Table 6.2. Residential Postapplication Short- and Intermediate-term Exposures and Risks for AAAs

Exposure Scenario	Application Rate[1]	Exposed Population & Exposure Duration[2]	Daily Dose (mg/kg/day)[3]	MOE[4]
Outdoor Lawn Products				
Dermal Exposure to Treated Lawns	2.25 lb/day	Adult ST	0.5226	1,900
		Adult IT	0.263	3,800
		Child ST	0.8747	1,100
		Child IT	0.437	2,300
Hand-to-Mouth from Treated Lawn		Child ST	0.0336	5,000
		Child IT	0.016	11,000
Object-to-Mouth from Treated Lawn		Child ST	0.0084	20,000
		Child IT		
Soil Ingestion		Child ST	0.000113	1,500,000
		Child IT		
Total Lawn Combined Exposures*		Child ST	NA	930
		Child IT	NA	1,900
Indoor Cleaning Product				
Dermal Exposure to Treated Indoor Surface	1.3E-5 lb/ft^2	Child ST	0.0698	14,000
		Child IT		
Hand-to-Mouth from Treated Indoor Surface		Child ST	0.0085	20,000
		Child IT	0.004	42,000
Total Surface Combined Exposures*		Child ST	NA	8,200
		Child IT	NA	11,000
Pet Product				
Dermal Exposure to Treated Pet	5,100 mg/day	Adult ST	3.428	290
		Adult IT		
	5,100 mg/day	Child ST	5.333	190

Table 6.2. Residential Postapplication Short- and Intermediate-term Exposures and Risks for AAAs				
Exposure Scenario	Application Rate[1]	Exposed Population & Exposure Duration[2]	Daily Dose (mg/kg/day)[3]	MOE[4]
		Child IT		
Hand-to-Mouth from Treated Pet	5,100 mg/day	Child ST	0.028	5,900
		Child IT		
Total Pet Combined Exposures*	5,100 mg/day	Child ST	NA	180
		Child IT		
Paint Products				
Incidental Oral Exposure to Paint Chips	NA	Infant ST	0.02	8,400

[1] Application rates for outdoor products are derived in Section 6.1 Application rates for indoor and pet products are derived in Section 6.2.
[2] ST and IT indicate short- or intermediate-term exposure durations.
[3] Daily Dose = Daily Dose algorithms for various residential postapplication scenarios outlined in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751, 5/7/09.
[4] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin. Oral MOE = PoD (NOAEL of 168 mg/kg/day) / Daily dose (mg/kg/day).
[5] Combined exposures reflect the aggregation of dermal exposure to treated areas and HTM exposure from treated areas (for children). Total Combined Exposures = 1/ [(1/ Dermal MOE) + (1/ HTM MOE)]

7.0 Aggregate Risk Assessments and Risk Characterization

7.1 Acute Aggregate Risk

There was no hazard attributable to a single exposure seen the in the toxicity database for the AAAs; therefore, an acute aggregate risk assessment is not required.

7.2 Short-Term/Intermediate-Term Aggregate Risk

Short-term and intermediate-term aggregate risk assessments for the AAA inert ingredients combine high end residential short- or intermediate-term exposures with average food and drinking water exposures, and compare this total to a short- or intermediate term PoD. Short- and intermediate term residential exposures are summarized in Table 7.2.1.

Table 7.2.1. Short- and Intermediate-Term Residential Risks for the AAA Aggregate Risk Calculations			
Population	**Handler Risk (MOE)[1]**	**Postapplication Risk (MOE)[2]**	**Residential Risk (MOE)[3]**
Short-Term			
Adult Male	200 Source: Table 6.1 Indoor hard surface, Wiping (ST)	290 Source: Table 6.2 ST Dermal Exposure to Treated Pet	120
Adult Female	200 Source: Table 6.1 Indoor hard surface, Wiping (ST)	290 Source: Table 6.2 ST Dermal Exposure to Treated Pet	120
Child	N/A	180 Source: Table 6.2 ST Total Pet Combined Exposures	180
Intermediate-Term			
Adult Male	N/A	290 Source: Table 6.2 IT Dermal Exposure to Treated Pet	290
Adult Female	N/A	290 Source: Table 6.2 IT Dermal Exposure to Treated Pet	290
Child	N/A	180 Source: Table 6.2 IT Total Pet Combined Exposures	180

1 – Handler exposure combines high end dermal and inhalation handler exposure, where the exposure duration is appropriate to assess

2 – Postapplication exposure combines high end dermal exposure to outdoor lawn products or indoor cleaning products with high end dermal and incidental oral exposure to pet products for the relevant exposure duration

3 - Residential exposure combines high end dermal and inhalation handler exposure for short-term (Table 6.1) with high end post application dermal and incidential oral exposure (Table 6.2).

Short- and intermediate-term aggregate risks are summarized in Table 7.2.2. Short- and intermediate-term aggregate risks are not of concern for adults or children.

Table 7.2.2 Short-Term and Intermediate-Term Aggregate Risk Calculations				
Population	LOC for Aggregate Risk[1]	MOE food & water[2]	MOE residential[3]	Aggregate MOE (food and residential)[4]
Short-Term				
Adult Male	100	1100	120	110
Adult Female	100	1200	120	110
Child	100	270	180	110
Intermediate-Term				
Adult Male	100	1100	290	230
Adult Female	100	1200	290	230
Child	100	270	180	110

[1] The LOC is base don the standard 100X safety factor for inter- and intra-species extrapolation.
[2] MOE food = [(short- or intermediate-term oral NOAEL)/(chronic dietary exposure)]. Chronic dietary exposure values from Table 5.5.4.
[3] MOE residential from Table 7.2.1.
[4] Aggregate MOE (food and residential) = 1[[(1MOE food) + (1MOE residential)]]

7.3 Long-Term Aggregate Risk

For the AAAs, the long-term aggregate risk includes dietary exposures to food and drinking water only. Dietary (food and water) exposures and risk are discussed in Section 5.5.4 of this memorandum. Long-Term (chronic) aggregate risks for the AAAs are not of concern.

7.4 Cancer Risk

HED has not identified any concerns for carcinogenicity; therefore, an aggregate cancer dietary exposure assessment was not performed.

8.0 Occupational Exposure/Risk Pathway

Based on examination of product labels which may contain the AAAs as inert ingredients, HED has determined that exposure to handlers can occur in a variety of occupational environments. Details of the occupational exposure assessment for the AAA inerts can be found in the document "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751," 5/7/09.

The representative occupational scenarios selected by the Agency for assessment were evaluated based on likely maximum application rates for products which may contain the AAA inerts for the short-term exposure assessment, and average application rates for products likely to contain AAAs as inerts for the intermediate- and long-term exposure durations. Active ingredient application rates were corrected for the maximum amount of AAAs likely to be in the final formulations to determine exposure and risk from exposure to AAAs grouped by fungicide/insecticide or herbicide. A summary of the occupational assessment is presented below.

The level of concern (LOC) for these risk assessments is an MOE of 100 based on the standard 10X inter and 10X intra species uncertainty safety factors.

8.1 Handler Risk

Exposure Scenarios

Exposure to pesticide handlers is likely during the occupational use of pesticides containing the AAA inert ingredients. Dermal and inhalation exposure was estimated using PHED and ORETF data. The quantitative exposure/risk assessment developed for occupational handlers to support the requested exemption from the requirement of a tolerance for the AAAs is based on the following scenarios. HED notes that these scenarios were selected to represent the scenarios with the highest potential exposure.

Mixer/Loader/Applicators:

1) Mixer/Loader for aerial application- high acreage field crops (liquids)
2) Mixer/Loader for airblast application- tree nuts crops (both liquid and wettable powder)
3) Mixer/Loader for groundboom application- high acreage field crops and turf (liquids and wettable powder)
4) Applicators for aerial application- high acreage field crops (liquid)
5) Applicators for airblast- tree nut crops
6) Applicators for groundboom- high acreage field crops and turf
7) Mixer/Loader/Applicator- low pressure handwand (liquids and wettable powders)*
8) High pressure handwand- greenhouse (wettable powders)
9) Flagging- high acreage field crops (liquids)

* Uses ORETF unit exposure data. All others use PHED data.

- Risk estimates were calculated using the Margin of Exposure (MOE) which is a ratio of the toxicological PoD to the daily dose. Daily dose values are calculated by first calculating exposures by considering application parameters (i.e., rate and area treated) along with unit exposures. Exposures are then normalized by body weight to calculate dose levels. Dermal short- and intermediate-term exposure is compared to the dermal PoD of 168 mg/kg/day. A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information. Inhalation short- and intermediate-term exposure is compared to the inhalation PoD of 168 mg/kg/day (same PoD for short- and intermediate-term exposure durations). A combined dermal and

inhalation MOE was also calculated for each exposure duration for the AAA inerts since common toxicity endpoints were identified for both the dermal and inhalation routes of exposure. The route-specific MOEs were compared to their respective PoDs; the dermal and inhalation doses were not combined and compared to a single PoD. To assess handler risks, the Agency used surrogate unit exposure data from the Pesticide Handlers Exposure Database (PHED), and ORETF data.

The following assumptions and factors were used in order to complete the exposure and risk assessment for occupational handlers/applicators:

- All worker scenarios were assumed to be short- and intermediate-term in exposure durations (i.e., 1-30 days and 1-6 months) except the greenhouse/hothouse scenario.
- For scenarios where greenhouse/hothouse applications are possible, long-term exposure (6+ months) was assessed.
- The exposure assessment assumes an 8 hour work day.
- The maximum application rate per pesticide group (herbicide/insecticide/fungicide) has been assessed for the short-term exposure duration.
- The average application rate per pesticide group (herbicide/insecticide/fungicide) has been assessed for the intermediate-term exposure duration.
- For adult exposure, the mean for US male and female bodyweights was used to estimate exposure (70 kg).
- The baseline clothing level for occupational exposure scenarios is considered to be an individual wearing long pants, a long-sleeved shirt, shoes, socks, no chemical-resistant gloves, and no respiratory protection.
- For high acreage crops (e.g. corn, soybeans) where applicators can mix/load large quantities of pesticide, exposure assessments have also been completed for baseline dermal PPE (Personal Protective Equipment) plus chemical-resistant gloves, and no respiratory protection.
- Per the JITF CST1 submission, there is no proposed limit to the amount of AAA inert in the pesticide products. Therefore 50% of any pesticidal product is assumed to be AAA (assuming that the inert ingredient would be in the formulation at a level equivalent to the active ingredient (50% active ingredient; 50% AAA).

Risk Characterization:

HED initially assessed handler exposure and risks for the AAA inerts in fungicides, herbicides and insecticides at baseline PPE (long pants, a long-sleeved shirt, shoes, socks, no chemical-resistant gloves, and no respiratory protection) which HED considers to be standard agricultural worker clothing. When these assessments indicated that there was potential risks of concern for scenarios where workers would be handling large quantities of pesticide for high volume operations typically involving aerial applications to high acreage crops, HED repeated the assessments and included additional PPE (i.e., chemical-resistant gloves for pesticide handlers). See Table 8.1.2 for herbicide products, Table 8.1.5 for insecticide products, and Table 8.1.8 for fungicide products. HED has included an assessment for workers handling high volumes of chemicals, which includes gloves, as the Agency believes workers handling these volumes of pesticides will be wearing chemical-resistant gloves.

When handlers are wearing standard worker clothing (i.e., baseline PPE) the majority of occupational handler scenarios do not indicate risks of concern. For the occupational handler scenarios which involve the handling of large volumes of pesticides, those which EPA believes that handlers will be wearing chemical-resistant gloves, occupational handler scenarios do not indicate risks of concern with the addition of chemical-resistant gloves to baseline PPE (i.e., minimum dermal PPE).

For the occupational scenarios that involve mixer loader applicators applying pesticides containing the AAA inerts in pesticides formulated as a wettable powder with a low pressure handwand to ornamentals in a greenhouse environment, calculated risks resulted in MOEs below 100 when baseline PPE is assessed. Since the Agency does not believe that it is routine for these workers to wear gloves for these scenarios, an assessment was provided showing MOEs when the percent of AAAs in the final formulation was reduced. For herbicides, insecticides, and fungicides, the assessments were provided reducing the cap from the proposed maximum of 50% to 30%, 25%, and 20% (Table 8.1.3 for herbicides products, Table 8.1.6 for insecticide products, and Table 8.1.9 for fungicide products). MOEs for applicators applying liquids by low pressure handwand to ornamentals in a greenhouse/hothouse setting exceed the LOC of 100 when the percentages of AAA in the herbicide, insecticide and fungicide formulations are limited to 20%.

For the mixer/loader/applicator scenarios described in the occupational handler tables (below), the ORETF handler studies have no data for baseline dermal exposure because the handlers in the study wore gloves and no respiratory protection. HED believes baseline exposure is relevant to assess for these exposure scenarios (i.e., baseline dermal PPE and no respiratory protection). Therefore, both ORETF and PHED scenarios are shown in the mixer/loader/applicator section of the occupational handler tables. Baseline inhalation MOEs are reported "as is" because ORETF study participants did not wear respiratory protection. Additional explanation of the ORETF studies, as well as additional information concerning the exposure scenarios assessed, is available in "**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations", D364751," 5/7/09.

Table 8.1.1. Exposure and Risks for Occupational Handlers of AAAs in Herbicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	5.2	1200	2.9	1.2	258.5	0.107	**4**	1,600	**4**
Liquids/ Aerial Application/ High Acreage Crops (IT)	1				49.7	0.02	**20**	8,200	**20**
Liquids/ Airblast/ Nut Tree (ST)	3.6	40			5.966	0.002	170	68,000	170
Liquids/ Airblast/ Nut Tree (IT)	1.6				2.65	0.0011	380	150,000	380

Table 8.1.1. Exposure and Risks for Occupational Handlers of AAAs in Herbicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Liquids/ Groundboom/ High Acreage Crops (ST)	5.2	200			43.09	0.017	**23**	9,400	**23**
Liquids/ Groundboom/ High Acreage Crops (IT)	1				8.29	0.0034	120	49,000	120
Liquids/ Groundboom/ Turf (ST)	5.2	40			8.617	0.0036	120	47,000	120
Liquids/ Groundboom/ Turf (IT)	1				1.657	0.0007	600	250,000	600
Liquids/ Low Pressure Handwand/ Turf (ST)	3.6	5			0.746	0.0003	1,300	540,000	1,300
Liquids/ Low Pressure Handwand/ Turf (IT)	3.6				0.746	0.0003	1,300	540,000	1,300
Wettable Powder/ Airblast/ Nut Tree (ST)	0.8	40	3.7	43	1.69	0.0197	590	8,500	550
Wettable Powder/ Airblast/ Nut Tree (IT)	0.8				1.69	0.0197	590	8,500	550
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.8	200			8.457	0.0983	120	1,700	110
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.5				5.286	0.0614	190	2,700	180
Wettable Powder/ Groundboom/ Turf (ST)	0.8	40			1.69	0.0197	590	8,500	550
Wettable Powder/ Groundboom/ Turf (IT)	0.5				1.057	0.0123	950	14,000	880
Wettable powder/ Low Pressure Handwand/ Turf (ST)	3.6	5			0.951	0.011	1,100	15,000	980
Wettable powder/ Low Pressure Handwand/ Turf (IT)	3.6				0.951	0.011	1,100	15,000	980
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	5.2	1200	Eng control only: 0.0055	Eng control only: 0.068	0.49	0.0061	2,000	28,000	1,900
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	1				0.094	0.0012	11,000	140,000	9,900
Airblast/ Nut Tree (ST)	0.8	40	0.36	4.5	0.1646	0.0021	6,100	82,000	5,700
Airblast/ Nut Tree (IT)	0.8				0.1646	0.0021	6,100	82,000	5,700
Groundboom/ High Acreage Crops (ST)	5.2	200	0.014	0.74	0.208	0.011	4,800	15,000	3,700
Groundboom/ High Acreage Crops (IT)	1				0.04	0.0021	25,000	79,000	19,000
Groundboom/ Turf (ST)	5.2	40			0.042	0.0022	24,000	76,000	18,000
Groundboom/ Turf (IT)	1				0.008	0.00042	130,000	400,000	95,000
Mixer/Loader/Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	3.6	5	No Data	6.6	NA	0.0017	NA	99,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	3.6				NA	0.0017	NA	99,000	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	3.6	5	No Data	1100	NA	0.2829	NA	590	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	3.6				NA	0.2829	NA	590	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	3.6				NA	0.2829	NA	590	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	3.6	5	100	30	25.7	0.0077	**39**	22,000	**39**
Liquid/ Low Pressure Handwand/ Ornamentals	3.6				25.7	0.0077	**39**	22,000	**39**

Table 8.1.1. Exposure and Risks for Occupational Handlers of AAAs in Herbicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
(IT)									
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	3.6				25.7	0.0077	**39**	22,000	**39**
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	5.2	1200	0.011	0.35	0.981	0.0312	1,000	5,400	860
Liquid/ Flagger/ High Acreage Crops (IT)	1				0.189	0.006	5,300	28,000	4,500

[1]Application rates are based on maximum application rates of products containing inerts in AAAs multiplied by 50% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 50% inert AAAs). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Baseline Dermal PPE is single layer clothing, no gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.

[7]ST Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]

[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline dermal (no gloves) plus baseline inhalation exposure.

[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed has a higher unit exposure at baseline dermal exposure than either of the two scenarios shown at baseline PPE plus gloves dermal exposure.

Table 8.1.2. Exposure and Risks for Occupational Handlers of AAAs in Herbicide Products (All Exposure Durations) with Baseline Dermal PPE and Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Min PPE Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Min PPE Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)[9]	5.2	1200	0.023	1.2	2.05	0.107	490	1,600	370
Liquids/ Aerial Application/ High Acreage Crops (IT)[9]	1				0.394	0.0201	2,500	8,200	1,900
Liquids/ Groundboom/ High Acreage Crops (ST)[9]	5.2	200			0.3417	0.0178	2,900	9,400	2,200
Liquids/ Groundboom/ High Acreage Crops (IT)[9]	1				0.066	0.004	15,000	49,000	12,000

[1]Application rates are based on maximum application rates of products containing inerts in AAAs multiplied by 50% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 50% inert AAAs). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-

term (IT) and long-term (LT) exposures are based on average application rates. Scenarios shown are with Baseline Dermal PPE plus gloves.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess minimum dermal PPE (with gloves) plus baseline inhalation exposure.
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.
[7] Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]
[9] Exposure scenarios assess minimum dermal PPE (baseline PPE plus gloves) plus baseline inhalation exposure.

Table 8.1.3: Exposure and Risks for Occupational Handlers of AAAs in Herbicide Products Used in Low Pressure Handwand Applications to Ornamentals in Greenhouses (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader/Applicator for Herbicide Products with 30% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	2.16	5	100	30	15.429	0.0046	**65**	36,000	**65**
Mixer/Loader/Applicator for Herbicide Products with 25% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	1.8	5	100	30	12.857	0.00386	**78**	44,000	**78**
Mixer/Loader/Applicator for Herbicide Products with 20% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	1.44	5	100	30	10.286	0.00309	**97**	54,000	**97**

[1]Application rates are based on maximum application rates of products containing inerts in the AAA cluster multiplied by variable % AAAs in formulation to convert to application rate of just inert in an herbicide product. Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE (single layer no gloves) plus baseline inhalation exposure
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.
[7] Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]
[9] Exposure scenarios assess baseline dermal PPE (baseline PPE no gloves) plus baseline inhalation exposure.

Table 8.1.4. Exposure and Risks for Occupational Handlers of AAAs in Insecticide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	1	1200	2.9	1.2	49.7	0.021	**20**	8,200	**20**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.35				17.4	0.0072	**57**	23,000	**57**
Liquids/ Airblast/ Nut Tree (ST)	4.5	40			7.457	0.0031	130	54,000	130
Liquids/ Airblast/ Nut Tree (IT)	1.25				2.07	0.00086	480	200,000	480
Liquids/ Groundboom/ High Acreage Crops (ST)	1	200			8.286	0.0034	120	49,000	120
Liquids/ Groundboom/ High Acreage Crops (IT)	0.35				2.9	0.0012	340	140,000	340
Liquids/ Groundboom/ Turf (ST)	1	40			1.657	0.00069	600	250,000	600
Liquids/ Groundboom/ Turf (IT)	0.35				0.58	0.00024	1,700	700,000	1,700
Liquids/ Low Pressure Handwand/ Turf (ST)	3.6	5			0.746	0.00031	1,300	540,000	1,300
Liquids/ Low Pressure Handwand/ Turf (IT)	3.6				0.746	0.00031	1,300	540,000	1,300
Wettable Powder/ Airblast/ Nut Tree (ST)	3	40	3.7	43	6.34	0.0737	160	2,300	150
Wettable Powder/ Airblast/ Nut Tree (IT)	1.5				3.17	0.037	320	4,600	290
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.8	200			8.457	0.098	120	1,700	110
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.35				3.7	0.043	270	3,900	250
Wettable Powder/ Groundboom/ Turf (ST)	0.8	40			1.69	0.0197	590	8,500	550
Wettable Powder/ Groundboom/ Turf (IT)	0.35				0.74	0.0086	1,400	20,000	1,300
Wettable powder/ Low Pressure Handwand/ Turf (ST)	3.6	5			0.951	0.011	1,100	15,000	980
Wettable powder/ Low Pressure Handwand/ Turf (IT)	3.6				0.951	0.011	1,100	15,000	980
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	1	1200	Eng control only: 0.0055	Eng control only: 0.068	0.094	0.0012	11,000	140,000	9,900
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.35				0.033	0.0004	30,000	410,000	28,000
Airblast/ Nut Tree (ST)	4.5	40	0.36	4.5	0.9257	0.0116	1,100	15,000	1,000
Airblast/ Nut Tree (IT)	1.25				0.257	0.0032	3,900	52,000	3,600
Groundboom/ High Acreage Crops (ST)	1	200	0.014	0.74	0.04	0.00211	25,000	79,000	19,000
Groundboom/ High Acreage Crops (IT)	0.35				0.014	0.00074	71,000	230,000	54,000
Groundboom/ Turf (ST)	1	40			0.008	0.00042	130,000	400,000	95,000
Groundboom/ Turf (IT)	0.35				0.0028	0.00015	360,000	1,100,000	270,000
Mixer/Loader/Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	3.6	5	NA	6.6	NA	0.0017	NA	99,000	NA
Low Pressure Handwand/	3.6				NA	0.0017	NA	99,000	NA

Table 8.1.4. Exposure and Risks for Occupational Handlers of AAAs in Insecticide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Turf (ORETF data) (IT)[10]									
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	3.6	5	NA	1100	NA	0.2829	NA	590	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	3.6				NA	0.2829	NA	590	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	3.6				NA	0.2829	NA	590	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	3.6	5	100	30	25.7	0.0077	**39**	22,000	**39**
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	3.6				25.7	0.0077	**39**	22,000	**39**
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	3.6				25.7	0.0077	**39**	22,000	**39**
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	1	1200	0.011	0.35	0.1886	0.006	5,300	28,000	4,500
Liquid/ Flagger/ High Acreage Crops (IT)	0.35				0.066	0.0021	15,000	80,000	13,000

[1]Application rates are based on maximum application rates of products containing inerts in AAAs multiplied by 50% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 50% inert AAAs). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Baseline Dermal PPE is single layer clothing, no gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.

[7] ST Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]

[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline dermal (no gloves) plus baseline inhalation exposure.

[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed has a higher unit exposure at baseline dermal exposure than either of the two scenarios shown at baseline PPE plus gloves dermal exposure.

Table 8.1.5. Exposure and Risks for Occupational Handlers of AAAs in Insecticide Products (All Exposure Durations) with Baseline Dermal PPE and Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Min PPE Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Min PPE Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)[9]	1	1200	0.023	1.2	0.394	0.0206	2,500	8,200	1,900
Liquids/ Aerial Application/ High Acreage Crops (IT)[9]	0.35				0.138	0.0072	7,200	23,000	5,500

[1]Application rates are based on maximum application rates of products containing inerts in the AAAs multiplied by 50% to convert to application rate of just inert in an insecticide product (Insecticide products assumed to contain maximum of 50% AAA inert). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess minimum dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.

[7] Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]

[9] Exposure scenarios assess minimum dermal PPE (baseline PPE plus gloves) plus baseline inhalation exposure.

Table 8.1.6: Exposure and Risks for Occupational Handlers of AAAs in Insecticde Products Used in Low Pressure Handwand Applications to Ornamentals in Greenhouses (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader/Applicator for Insecticide Products with 30% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	2.16	5	100	30	15.429	0.0046	**65**	36,000	**65**
Mixer/Loader/Applicator for Insecticide Products with 25% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	1.8	5	100	30	12.857	0.00386	**78**	44,000	**78**
Mixer/Loader/Applicator for Insecticide Products with 20% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	1.44	5	100	30	10.286	0.00309	**97**	54,000	**97**

[1]Application rates are based on maximum application rates of products containing inerts in the AAA cluster multiplied by variable % AAAs in formulation to convert to application rate of just inert in an insecticide product.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE (single layer no gloves) plus baseline inhalation exposure

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.
[7] Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]
[9] Exposure scenarios assess baseline dermal PPE (baseline PPE no gloves) plus baseline inhalation exposure.

Table 8.1.7. Exposure and Risks for Occupational Handlers of AAAs in Fungicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)	2.5	1200	2.9	1.2	124.29	0.0514	**8**	3,300	**8**
Liquids/ Aerial Application/ High Acreage Crops (IT)	0.35				17.4	0.0072	**57**	23,000	**57**
Liquids/ Airblast/ Nut Tree (ST)	5.5	40			9.11	0.0038	110	45,000	110
Liquids/ Airblast/ Nut Tree (IT)	1.5				2.49	0.00103	400	160,000	400
Liquids/ Groundboom/ High Acreage Crops (ST)	2.5	200			20.7	0.0086	**48**	20,000	**48**
Liquids/ Groundboom/ High Acreage Crops (IT)	0.35				2.9	0.0012	340	140,000	340
Liquids/ Groundboom/ Turf (ST)	2.5	40			4.14	0.0017	240	98,000	240
Liquids/ Groundboom/ Turf (IT)	0.35				0.58	0.00024	1,700	700,000	1,700
Liquids/ Low Pressure Handwand/ Turf (ST)	3.6	5			0.746	0.0003	1,300	540,000	1,300
Liquids/ Low Pressure Handwand/ Turf (IT)	3.6				0.746	0.0003	1,300	540,000	1,300
Wettable Powder/ Airblast/ Nut Tree (ST)	3.5	40	3.7	43	7.4	0.086	140	2,000	130
Wettable Powder/ Airblast/ Nut Tree (IT)	1				2.11	0.025	470	6,800	440
Wettable Powder/ Groundboom/ High Acreage Crops (ST)	0.5	200			5.29	0.0614	190	2,700	180
Wettable Powder/ Groundboom/ High Acreage Crops (IT)	0.3				3.17	0.0369	320	4,600	290
Wettable Powder/ Groundboom/ Turf (ST)	0.5	40			1.057	0.0123	950	14,000	880
Wettable Powder/ Groundboom/ Turf (IT)	0.3				0.634	0.0074	1,600	23,000	1,500
Wettable powder/ Low Pressure Handwand/ Turf (ST)	3.6	5			0.95	0.011	1,100	15,000	980
Wettable powder/ Low Pressure Handwand/ Turf (IT)	3.6				0.95	0.011	1,100	15,000	980
Applicator Scenarios									
Liquid/ Aerial Application/ High Acreage Crops (ST)[9]	2.5	1200	Eng control only: 0.0055	Eng control only: 0.068	0.236	0.0029	4,200	58,000	4,000
Liquid/ Aerial Application/ High Acreage Crops (IT)[9]	0.35				0.033	0.0004	30,000	410,000	28,000
Airblast/ Nut Tree (ST)	3.5	40	0.36	4.5	0.72	0.009	1,400	19,000	1,300
Airblast/ Nut Tree (IT)	1.5				0.309	0.0039	3,200	44,000	3,000

Table 8.1.7. Exposure and Risks for Occupational Handlers of AAAs in Fungicide Products (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Groundboom/ High Acreage Crops (ST)	2.5	200	0.014	0.74	0.1	0.0053	10,000	32,000	7,600
Groundboom/ High Acreage Crops (IT)	0.35				0.014	0.0007	71,000	230,000	54,000
Groundboom/ Turf (ST)	2.5	40			0.02	0.0011	50,000	160,000	38,000
Groundboom/ Turf (IT)	0.35				0.0028	0.00015	360,000	1,100,000	270,000
Mixer/Loader/Applicator Scenarios									
Low Pressure Handwand/ Turf (ORETF data) (ST)[10]	3.6	5	No Data	6.6	NA	0.0017	NA	99,000	NA
Low Pressure Handwand/ Turf (ORETF data) (IT)[10]	3.6				NA	0.0017	NA	99,000	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (ST)[10]	3.6	5	No Data	1100	NA	0.2829	NA	590	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (IT)[10]	3.6				NA	0.2829	NA	590	NA
Wettable Powder/ Low Pressure Handwand/ Ornamentals (LT)[10]	3.6				NA	0.2829	NA	590	NA
Liquid/ Low Pressure Handwand/ Ornamentals (ST)	3.6	5	100	30	25.7	0.0077	**39**	22,000	**39**
Liquid/ Low Pressure Handwand/ Ornamentals (IT)	3.6				25.7	0.0077	**39**	22,000	**39**
Liquid/ Low Pressure Handwand/ Ornamentals (LT)	3.6				25.7	0.0077	**39**	22,000	**39**
Flagger Scenarios									
Liquid/ Flagger/ High Acreage Crops (ST)	2.5	1200	0.011	0.35	0.47	0.015	2,100	11,000	1,800
Liquid/ Flagger/ High Acreage Crops (IT)	0.35				0.066	0.0021	15,000	80,000	13,000

[1]Application rates are based on maximum application rates of products containing inerts in AAAs multiplied by 50% to convert to application rate of just inert in a product (Pesticide products assumed to contain a maximum of 50% inert AAA). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) and long-term (LT) exposures are based on average application rates. Baseline Dermal PPE is single layer clothing, no gloves.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.

[7]ST Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]

[9]Aerial applicators do not have baseline exposure: only engineering control exposure can be assessed. All other exposure scenarios assess baseline dermal (no gloves) plus baseline inhalation exposure.

[10]These scenarios have baseline inhalation unit exposures, but not baseline dermal unit exposures. The M/L/A scenario assessed has a higher unit exposure at baseline dermal exposure than either of the two scenarios shown at baseline PPE plus gloves dermal exposure.

Table 8.1.8. Exposure and Risks for Occupational Handlers of AAAs in Fungicide Products (All Exposure Durations) with Baseline Dermal PPE and Gloves for High Acreage Mixer/ Loader Scenarios

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Min PPE Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Min PPE Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader Scenarios									
Liquids/ Aerial Application/ High Acreage Crops (ST)[9]	2.5	1200	0.023	1.2	0.9857	0.0514	1,000	3,300	770
Liquids/ Aerial Application/ High Acreage Crops (IT)[9]	0.35				0.138	0.0072	7,200	23,000	5,500
Liquids/ Groundboom/ High Acreage Crops (ST)[9]	2.5	200			0.164	0.0086	6,100	20,000	4,600
Liquids/ Groundboom/ High Acreage Crops (IT)[9]	0.35				0.023	0.0012	43,000	140,000	33,000

[1]Application rates are based on maximum application rates of products containing inerts in the AAAs multiplied by 50% to convert to application rate of just inert in a fungicide product (Fungicide products assumed to contain maximum of 50% inert from the AAAs). Application rates for Short-term (ST) exposure risk estimates are based on maximum application rates. Application rates for Intermediate-term (IT) exposures are based on average application rates.

[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.

[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess minimum dermal PPE plus baseline inhalation exposure except for aerial applicator scenarios, which assess inhalation and dermal exposures with engineering controls.

[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)

[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)

[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.

[7] Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)

[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]

[9] Exposure scenarios assess minimum dermal PPE (baseline PPE plus gloves) plus baseline inhalation exposure.

Table 8.1.9: Exposure and Risks for Occupational Handlers of AAAs in Fungicide Products Used in Low Pressure Handwand Applications to Ornamentals in Greenhouses (All Exposure Durations) at Baseline Dermal PPE

Exposure Scenario (Formulation/ Application/ Crop)	Application Rate[1] (lb inert/ A)	Area Treated Daily[2] (acres)	Dermal Unit Exposure (mg/lb inert)[3]	Inhalation Unit Exposure (ug/ lb inert)[3]	Baseline Dermal Dose (mg/kg /day)[4]	Baseline Inhalation Dose (mg/kg/ day)[5]	Baseline Dermal MOE[6]	Baseline Inhalation MOE[7]	Total MOE[8]
Mixer/Loader/Applicator for Fungicide Products with 30% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	2.16	5	100	30	15.429	0.0046	**65**	36,000	**65**
Mixer/Loader/Applicator for Fungicide Products with 25% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	1.8	5	100	30	12.857	0.00386	**78**	44,000	**78**
Mixer/Loader/Applicator for Fungicide Products with 20% AAAs in formulation									
Liquids/ Low Pressure Handwand/ Ornamentals (IT)[9]	1.44	5	100	30	10.286	0.00309	**97**	54,000	**97**

[1]Application rates are based on maximum application rates of products containing inerts in the AAA cluster multiplied by variable % AAAs in formulation to convert to application rate of just inert in an fungicide product.
[2]Area treated daily values are from the EPA HED estimates of acreage treated in a single day for each exposure scenario of concern.
[3]Unit Exposure values are reported in PHED Surrogate Exposure Guide dated August 1998 or from ORETF data. All exposure scenarios assess baseline dermal PPE (single layer no gloves) plus baseline inhalation exposure
[4]Daily Dermal Dose = (Dermal Unit Exposure (mg inert /lb inert) * Application Rate (lb inert /A) * Area Treated (A /day))/ Body Weight (70 kg)
[5] Daily Inhalation Dose = (Inhalation Unit Exposure (µg inert / lb inert) * Conversion Factor (1 mg /1000 µg) * Application Rate (lb inert /A) * Area Treated (A /day)) / Body Weight (70 kg)
[6] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.
[7] Inhalation MOE = PoD (NOAEL of 168 mg/kg/day) / Daily inhalation dose (mg/kg/day)
[8]Total Combined MOE = 1/ [(1/ Dermal MOE) + (1/ inhalation MOE)]
[9] Exposure scenarios assess baseline dermal PPE (baseline PPE no gloves) plus baseline inhalation exposure.

8.2 Occupational Postapplication Risk

HED uses the term postapplication to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Postapplication exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for postapplication exposure.

Inhalation exposures are not typically calculated for postapplication scenarios because inhalation exposures generally account for a negligible percentage of the overall body burden for most pesticide chemicals. This is particularly true for chemicals with a low vapor pressure such as the AAA cluster.

Exposure Scenarios

This assessment is considered to be a screening level estimate, demonstrating that there are minimal potential risks to workers re-entering fields treated with pesticides containing the AAAs as inert ingredients. While the AAAs are present in formulations designated for crops besides those assessed in this document, risk estimates for those occupational postapplication scenarios are expected to be less than those scenarios assessed in this document (i.e., calculated MOEs will be higher). The three occupational postapplication scenarios assessed are for postapplication activities associated with:

- Tall field/row crops (including scouting, weeding, hand harvesting sweet corn)
- Turf (golf course/sod farm) (including mowing, transplanting, hand weeding)
- Vine/Trellis crops (including scouting, training, tying, thinning, and grape girding and cane turning)

Exposure Data and Assumptions

Key assumptions used in the postapplication risk assessment calculations are detailed as follows:

- The average occupational workday is assumed to be 8 hours.
- For adult exposure, the mean for US male and female bodyweights was used to estimate exposure (70 kg).
- HED has developed standard transfer coefficient values for occupational postapplication scenarios to ensure consistency in exposure assessments. These standard values were used to calculate postapplication exposures.
- Anticipated postapplication activities and their respective dermal transfer coefficients (TCs) are summarized in Table 8.2. The TC information is based on the Science Advisory Council for Exposure Policy Number 3.1.
- TC for sod transplanting, hand weeding is from data using Agriculture Re-entry Task Force (ARF) Study ARF-035 (MRID 45432303).
- Calculations of postapplication exposures are completed using maximum application rates of the products of that type of pesticide (herbicide, insecticide, or fungicide) for short-term exposures and average application rates of products for intermediate-term exposures.
- Herbicides/insecticides/fungicides assessed can contain a maximum of 50% AAAs in any product formulation.
- No postapplication data were submitted for the AAAs cluster; a default 20% of the application rate (for agricultural crops) and 5% (for turf) is considered available as a transferrable residue with a 10% default daily dissipation rate.
- A 50% dermal absorption value was used, as well as a 3X factor to account for the increased permeability of rat versus human skin. See hazard characterization section 4.1 for additional information.

Risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of the body burden to the toxicological PoD.

"**JITF Inert Ingredients.** Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations",

D364751, 5/7/09 contains additional information about the exposure scenarios assessed in this document.

A variety of pesticide formulations may potentially contain AAAs as an inert ingredient. PPE is usually not required for worker re-entry, and therefore these postapplication risk estimates are based on baseline PPE (no gloves). Typically, HED characterizes the risk estimate in relation to the restricted entry interval (REI) for a particular active ingredient. However, since this assessment is to support an exemption from the requirement of a tolerance without a requirement for an REI, MOEs have been calculated on the day of application (Day 0).

Risk Summary

Occupational postapplication risk estimates are presented in Table 8.2. The risk estimates for a number of the scenarios assessed demonstrate risks of concern (i.e., MOEs > 100) for any of the assessed scenarios on Day 0. Those scenarios include:

1) the short-term worker postapplication activities involving herbicides on corn, specifically the hand-harvesting / detassling scenario. That scenario resulted in an MOE of **44** on the day of application (Day 0). Assuming an herbicide application at the maximum application rate, the MOE would exceed 100 for this scenario at day 8 after application. The Agency notes that it is not expected to be typical agricultural practice to apply herbicides on the same day workers would be conducting hand harvesting and detassling activities. As noted earlier in this assessment, herbicides are typically applied relatively early in a growing season.
2) the short-term worker postapplication activities involving insecticides on corn, specifically the hand-harvesting / detassling scenario. That scenario resulted in an MOE of **46** on the day of application (Day 0). Assuming an insecticide application at the maximum application rate, the MOE would exceed 100 for this scenario at day 8 after application. The Agency notes that it is not expected to be typical agricultural practice to apply insecticides on the same day workers would be conducting hand harvesting and detassling activities.
3) the short-term worker postapplication activities involving fungicides on corn, specifically the hand-harvesting / detassling scenario. That scenario resulted in an MOE of **92** on the day of application (Day 0). Assuming an insecticide application at the maximum application rate, the MOE would exceed 100 for this scenario at day 1 after application. The Agency notes that it is not expected to be typical agricultural practice to apply insecticides on the same day workers would be conducting hand harvesting and detassling activities.

Table 8.2. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for MOTs							
Crop & Exposure Duration	**Application Rate (lb inert /A)**	**Work Activity**	**Transfer Coefficient[1] (cm^2/hr)**	**Day after Treatment[2]**	**DFR_t (µg/cm^2)[3]**	**Daily Dose (mg/kg/day)[4]**	**MOE[5]**
Herbicide Products							
Corn (ST)	5.2	Scout, weed low foliage	100	0	11.668	0.1333	7,500
		Scout, weed high foliage	400	0		0.5334	1,900
		Scout, irrigate, weed high foliage	1,000	0		1.3335	750
		Harvesting/ detassling	17,000	0		22.669	**44**
Days after Treatment where MOE > 100							**8**
Corn (IT)	0.6	Scout, weed low foliage	100	0	1.346	0.0154	65,000
		Scout, weed high foliage	400	0		0.0615	16,000
		Scout, irrigate, weed high foliage	1,000	0		0.1539	6,500
		Harvesting/ detassling	17,000	0		2.616	380
Grapes (Table) (ST)	2.4	Hedge, irrigate, weed, scout, train, tie	500	0	5.385	0.3077	3,200
		Scout, train, tie	1,000	0		0.6154	1,600
		Harvest, pull, thin, prune, train, tie	5,000	0		3.077	320
		Cane turning, girdle	10,000	0		6.154	160
Grapes (Table) (IT)	1.4	Hedge, irrigate, weed, scout, train, tie	500	0	3.141	0.1795	5,600
		Scout, train, tie	1,000	0		0.359	2,800
		Harvest, pull, thin, prune, train, tie	5,000	0		1.795	560
		Cane turning, girdle	10,000	0		3.59	280
Turf/ sod (ST)	5.2	Mowing	500	0	2.917	0.167	6,000
		Transplant, weed, harvest	6,800	0		2.267	440
Turf/ Sod (IT)	0.6	Mowing	500	0	0.337	0.019	52,000
		Transplant, weed, harvest	6,800	0		0.262	3,800
Insecticide Product							
Corn (ST)	5	Scout, weed low foliage	100	0	11.219	0.1282	7,800
		Scout, weed	400	0		0.5129	1,900

Table 8.2. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for MOTs							
Crop & Exposure Duration	**Application Rate (lb inert /A)**	**Work Activity**	**Transfer Coefficient[1] (cm^2/hr)**	**Day after Treatment[2]**	**DFR_t (µg/cm^2)[3]**	**Daily Dose (mg/kg/day)[4]**	**MOE[5]**
		high foliage					
		Scout, irrigate, weed high foliage	1,000	0		1.2822	780
		Harvesting/ detassling	17,000	0		21.797	**46**
Days after treatment when MOE > 100							**8**
Corn (IT)	0.5	Scout, weed low foliage	100	0	1.122	0.0128	78,000
		Scout, weed high foliage	400	0		0.0513	19,000
		Scout, irrigate, weed high foliage	1,000	0		0.1282	7,800
		Harvesting/ detassling	17,000	0		2.1797	460
Grapes (Table) (ST)	3.5	Hedge, irrigate, weed, scout, train, tie	500	0	7.853	0.4488	2,200
		Scout, train, tie	1,000	0		0.8975	1,100
		Harvest, pull, thin, prune, train, tie	5,000	0		4.4876	220
		Cane turning, girdle	10,000	0		8.9752	110
Grapes (Table) (IT)	1.5	Hedge, irrigate, weed, scout, train, tie	500	0	3.366	0.1923	5,200
		Scout, train, tie	1,000	0		0.3846	2,600
		Harvest, pull, thin, prune, train, tie	5,000	0		1.9232	520
		Cane turning, girdle	10,000	0		3.8465	260
Turf/ sod (ST)	5	Mowing	500	0	2.805	0.16	6,200
		Transplant, weed, harvest	6,800	0		2.18	460
Turf/ Sod (IT)	0.5	Mowing	500	0	0.28	0.016	62,000
		Transplant, weed, harvest	6,800	0		0.218	4,600
Fungicide Products							
Corn (ST)	2.5	Scout, weed low foliage	100	0	5.609	0.0641	16,000
		Scout, weed high foliage	400	0		0.2564	3,900
		Scout, irrigate, weed high	1,000	0		0.6411	1,600

Table 8.2. Short- and Intermediate-Term Occupational Postapplication Dermal Exposures and Risks for MOTs

Crop & Exposure Duration	Application Rate (lb inert /A)	Work Activity	Transfer Coefficient[1] (cm^2/hr)	Day after Treatment[2]	DFR_t (µg/cm^2)[3]	Daily Dose (mg/kg/day)[4]	MOE[5]
		foliage					
		Harvesting/ detassling	17,000	0		10.898	**92**
Days after treatment when MOE > 100							**1**
Corn (IT)	0.5	Scout, weed low foliage	100	0	1.122	0.0128	78,000
		Scout, weed high foliage	400	0		0.0513	19,000
		Scout, irrigate, weed high foliage	1,000	0		0.1282	7,800
		Harvesting/ detassling	17,000	0		2.1797	460
Grapes (Table) (ST)	2.5	Hedge, irrigate, weed, scout, train, tie	500	0	5.609	0.3205	3,100
		Scout, train, tie	1,000	0		0.6411	1,600
		Harvest, pull, thin, prune, train, tie	5,000	0		3.205	310
		Cane turning, girdle	10,000	0		6.411	160
Grapes (Table) (IT)	1	Hedge, irrigate, weed, scout, train, tie	500	0	2.244	0.1282	7,800
		Scout, train, tie	1,000	0		0.256	3,900
		Harvest, pull, thin, prune, train, tie	5,000	0		1.282	780
		Cane turning, girdle	10,000	0		2.56	390
Turf/ sod (ST)	2.5	Mowing	500	0	1.402	0.08	12,000
		Transplant, weed, harvest	6,800	0		1.09	920
Turf/ Sod (IT)	0.5	Mowing	500	0	0.28	0.016	62,000
		Transplant, weed, harvest	6,800	0		0.218	4,600

[1] Transfer coefficient from Science Advisory Council for Exposure: Policy Memo #003 "Agricultural Transfer Coefficients" 05/07/98.

2 DAT = Day After Treatment

[3] DFR = Application rate (lbs inert/acre) * fraction of active ingredient that remains on foliage (0.2 for crop, 0.05 for turf)* (1-D(10% dissipation))$^{(t=0)}$ * 4.54 µg/lb * 24.7 x10-9 acre/cm^2

[4] Daily Dose = DFR (µg/cm^2) * Tc (cm^2/hr) * (1 mg/1000 µg) * ET (8 hrs/day) * DA (5% dermal absorption) / body weight (70 kg)

[5] Dermal MOE = PoD (NOAEL of 168 mg/kg/day)/ Daily dermal dose (mg/kg/day) corrected for 50% dermal absorption in rats, and a 3X factor to account for the increased permeability of rat vs. human skin.

9.0 Environmental Justice

Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," http://www.eh.doe.gov/oepa/guidance/justice/eo12898.pdf).

As a part of every pesticide risk assessment, OPP considers a large variety of consumer subgroups according to well-established procedures. In line with OPP policy, HED estimates risks to population subgroups from pesticide exposures that are based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the USDA under the Continuing Survey of Food Intake by Individuals (CSFII) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age, season of the year, ethnic group, and region of the country. Additionally, OPP is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas postapplication are evaluated. Further considerations are currently in development as OPP has committed resources and expertise to the development of specialized software and models that consider exposure to bystanders and farm workers as well as lifestyle and traditional dietary patterns among specific subgroups.

10.0 Human Studies

This assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide. These studies, listed below, have received the appropriate ethical review for use in risk assessment.

> The PHED Task Force, 1998. The Pesticide Handler Exposure Database (PHED), Version 1.1. Task Force members: Health Canada, U.S. Environmental Protection Agency, the California Department of Pesticide regulation, and the American Crop Protection Association; released August 1998.
>
> ORETF Handler Studies (MRID 44972201): Outdoor Residential Exposure Task
>
> MRID 466010-01: Human Exposure During and Following Use of a Pyrethrins/Piperonyl Butoxide/MGK-264 Shampoo Formulation on Dogs – Volume I & II
>
> MRID # 446584-01: Dermal Exposure and Inhalation Exposure to Carbaryl by Commercial Pet Groomers During Applications of Adams™ Carbaryl Shampoo.
>
> Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999: DP Barcode D247642).

APPENDIX A. Toxicity Data

A.1. Toxicity Profiles for the Alkyl Alcohol Alkoxylate (AAA) Inerts

Table A.1.1. Acute Toxicity Profile of the Alkyl Alcohol Ethoxylates

Guideline No.	Study Type	MRIDs #	Results	Toxicity Category
81-1	Acute Oral – rat	47041402A	$C_{9\text{-}11}AE_6$ LD50 = 1378 mg/kg (combined sex)	III
81-2	Acute Dermal -rabbit	47041402B	$C_{9\text{-}11}AE_6$ LD50 = >2000 mg/kg	III
81-3	Acute Inhalation - rat	Not available		
81-4	Primary Eye Irritation Rabbit	Not available		
81-5	Primary Skin Irritation - rabbit	47041402C	$C_{9\text{-}11}AE_6$ Moderately irritating Primary Irritation Index (PII) = 5.3	III
81-6	Dermal Sensitization Guinea pig	47041402D	$C_{9\text{-}11}AE_6$ not a dermal sensitizer	

Table A.1.2. Toxicology Profile of Alkyl Alcohol Ethoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3050 28-day oral toxicity in rats (SD) WITCO C-6147 CAS 68131-39-5	MRID 47041001 (2000) by gavage in distilled water at dose levels of 0, 10, 50, 150 or 600 mg/kg/day. acceptable/guideline (purity not reported)	NOAEL = 150 mg/kg/day LOAEL = 600 mg/kg/day, based on decreases in body weight gain and food consumption in females.
870.3100 90-day oral toxicity rats (diet) Wistar strain Dobanol 45-7 NEODOL 45-7 CAS 68131-39-5	MRID 47050601 (1982) 0, 300, 1000, 3000, or 10,000 ppm (equivalent to 0, 15, 50, 150 or 500 mg/kg/day based on 1 ppm = 0.05 mg/kg/day) 99 % Purity acceptable/nonguideline	NOAEL = 150 mg/kg/day LOAEL = 500 mg/kg/day based on decreased body weight gain (both sexes), decreased food consumption and absolute body weight in males
870.3100 90-Day oral toxicity (Diet) Wistar rats Tergitol nonionic 15-S-7 CAS 84133-50-6	MRID 46934101A (1967) 0, 62.5, 125, 250, or 500 mg/kg/ day acceptable/nonguideline	NOAEL = 62.5 mg/kg/day LOAEL = 125 mg/kg/day, based on decreased body-weight gain (males 15%; females 17%).
870.3100 90-day oral toxicity rats (Wistar) Tergitol 15-S-9 CAS 68131-40-8	MRID 46934105A (1967) M --0, 67.3, 132, 262 or 500 mg/kg/day F -- 0, 64.2, 128, 258 or 490 mg/kg/day (purity not reported) acceptable/nonguideline	NOAEL = 67.3 mg/kg/day in males 128 mg/kg/day in females. LOAEL = 132 mg/kg/day in males, based on decrease in body weight gain (-15.7%) 258 mg/kg/day in females based on decreases in body weight gain (-20%) and food consumption.
870.3100 90-Day oral toxicity (CFE albino rats) Tergitol TMN-3/10 CAS 60828-78-6	MRID 46934102 (1962) 0, 8, 40, 200, or 1000 mg/kg/day acceptable/nonguideline	NOAEL = ≥1000 mg/kg/day (HDT) in males 200 mg/kg/day in females LOAEL = 1000 mg/kg/day, based on decreased body-weight gain (15%) and food consumption (13%) in females.

Table A.1.2. Toxicology Profile of Alkyl Alcohol Ethoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3100 90-Day oral toxicity Rat (Wistar) Tergitol 15-S-12 CAS 84133-50-6	MRID 46934103A (1967) 0, 67.1, 137, 269 and 500 mg/kg/day in males 0, 63.2, 126, 260 and 480 mg/kg/day in females. (purity not reported) acceptable/nonguideline	NOAEL = 125 mg/kg/day in males 250 mg/kg/day in females. LOAEL = 250 mg/kg/day based on decrease in body weight gain in males 500 mg/kg/day based on decreases in body weight gain and food consumption in females.
870.3100 90-Day oral (gavage) toxicity in rats (SD strain) CAS 106232-83-1	MRID 46989501 (1986) 0, 100, 500, or 1000 mg/kg 100 % Purity: assumed acceptable/nonguideline	NOAEL = 100 mg/kg/day LOAEL = 500 mg/kg/day, based on decreased body weight, increased absolute and relative liver weights, and increased relative kidney weight.
870.3100 90-day oral toxicity rats (Wistar) Tergitol 15-S-12 CAS 84133-50-6	MRID 46934104A (1967) 0, 270, 540, 1050 and 2080 mg/kg/day in males 0, 260, 510, 1080 and 2100 mg/kg/day in females. (purity not reported) acceptable/nonguideline	NOAEL = 540 mg/kg/day in males 510 mg/kg/day in females. LOAEL = 1050 mg/kg/day in males, based on 13% decreases in body weight gain and food consumption 1080 mg/kg/day in females based on 21% decrease in body weight gain.
870.3100 90-Day oral toxicity dog Tergitol nonionic 15-8-7 CAS 84133-50-6	MRID 46934101B (1967) 0, 76, 158 or 276 mg/kg/day (computed for combined sexes) acceptable/nonguideline	NOAEL = 158 mg/kg/day LOAEL = 276 mg/kg/day, based on 17% decrease in body weight.
870.3100 90-Day oral toxicity dog Tergitol 15-S-12 CAS 84133-50-6	MRID 46934103B (1967) 0, 148 and 245 mg/kg/day (computed for combined sexes) (purity not reported) acceptable/nonguideline	NOAEL = 148 mg/kg/day LOAEL = 245 mg/kg/day, based on a decrease (-27.5%) in food consumption

Table A.1.2. Toxicology Profile of Alkyl Alcohol Ethoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3100 90-day oral toxicity dog Tergitol 15-S-12 CAS 84133-50-6	MRID 46934104B (1967) 0, 315, 688 and 955 mg/kg/day (computed for combined sexes) (purity not reported) acceptable/nonguideline	NOAEL = 688 mg/kg/day LOAEL = 955 mg/kg/day, based on decreases in body weight (9.4%) and food consumption (-37.7%).
870.3100 90-day oral toxicity dog Tergitol 15-S-9 CAS 84133-50-6	MRID 46934105B (1967) 0, 82, 154 and 354 mg/kg/day (computed for combined sexes) (purity not reported) acceptable/nonguideline	NOAEL = 154 mg/kg/day LOAEL = 354 mg/kg/day, based on a decrease (-8.6%) in food consumption.
OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test gavage SD strain CAS 9004-98-2 AL-3037 (Trade name) Unsaturated Linear C18:1 (oleyl) and average moles of POE n=10	MRID 47676802 (2009) 0, 50, 110, or 242 mg/kg/day 98% pure Acceptable/Guideline	Parental systemic NOAEL = 50 mg/kg/day Parental systemic LOAEL = 110 mg/kg/day based on decreased absolute and relative thymus weight (-33 to -36%), decreased body weight gain and decreased food consumption in females, and clinical signs in both sexes. The thymus/lymph node effects are a result of an overall stress response to treatment and not a direct immunotoxicity effect of the chemical. The effects are secondary effects caused by an overall stress response to the irritation properties of this chemical, not an immunotoxic effect. In mid- and high-dose animals of both sexes, most common clinical signs were excess salivation and rales which were seen intermittently (earliest onset on study day 4). In addition, soft or liquid feces, chromorhinorrhea, and red or clear perioral substance were seen sporadically. These clinical signs may be due to local irritant effects. Reproductive/developmental/offspring NOAEL ≥ 242 mg/kg/day. Reproductive/developmental/offspring LOAEL = not identified

Table A.1.2. Toxicology Profile of Alkyl Alcohol Ethoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
OECD 421 reproduction/developmental toxicity screening test gavage SD strain CAS 84133-50-6 TERGITOL™ 15-S-12 Surfactant (Trade name) Alcohols, C_{12-14}-secondary, ethoxylated	MRID 47676801 (2009) 0, 60, 168, or 470 mg/kg/day 99% pure Acceptable/Guideline	Parental systemic NOAEL = 168 mg/kg bw/day Parental systemic LOAEL = 470 mg/kg bw/day, based on decreased body weight and body weight gain, decreased food consumption, and clinical signs (ptosis and hypoactivity). Reproductive toxicity NOAEL = 168 mg/kg/day Reproductive toxicity LOAEL = 470 mg/kg/day, based on microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules). Developmental/offspring NOAEL = 168 mg/kg bw/day. Developmental/offspring LOAEL = 470 mg/kg bw/day, based on decreased litter size and increased postimplantation loss
870.3800 Reproduction and developmental effects (CD rats) UDL-700 CAS 68951-67-7 C14-15 ethoxylated alcohols	MRID 47067001 (1976) 0, 500, 1000, 5000 ppm 0, 36.0, 71.6, or 354.7 mg/kg/day for F_0 males; 0, 41.3, 80.9, or 400.8 mg/kg /day for F_0 females; 0, 41.9, 82.6, or 403.0 mg/kg /day for F_1 males; 0, 47.6, 95.0, or 466.6 mg/kg/day for F_1 females. Acceptable/nonguideline	Males Systemic NOAEL = ≥354.7 mg/kg/day Systemic LOAEL = not identified Females Systemic NOAEL = 80.9 mg/kg/day Systemic LOAEL = 400.8 mg/kg/day based on decreased body weight (6%) and body weight gain (11%) during premating, Offspring NOAEL = 80.9 mg/kg/day Offspring LOAEL = 400.8 mg/kg/day, based on decreased body weight (-9 to -16%) on LD 21 (both sexes in F_{1A}, F_{1B}, F_{2A}, F_{2B}). decreased body weight on LD 21 F1A males/females: -16%/-12%; F1B males/females: -13%/-14%; F2A males/females: -14%/-13%; F2B males/females: -13%/-9%; Reproductive toxicity NOAEL = 400.8 mg/kg/day Reproductive toxicity LOAEL = not identified.

Table A.1.2. Toxicology Profile of Alkyl Alcohol Ethoxylates

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test gavage SD strain CAS 103818-93-5 AL-3347 (Trade name) Linear and average moles of POE/POP n=9	MRID 47676803 (2009) 0, 48, 120 or 300 mg/kg/day. 99% pure Acceptable/Guideline	Parental systemic NOAEL = 120 mg/kg/day. Parental systemic LOAEL = 300 mg/kg/day based on decreased body weight gain (in males) and clinical signs (orange/red perioral staining and moderate salivation) in both sexes. Reproductive/developmental NOAEL = 300 mg/kg/day (HDT). Reproductive/developmental LOAEL= could not be determined Offspring NOAEL = 300 mg/kg/day (HDT). Offspring LOAEL = could not be determined
870.3800 Reproduction and fertility effects (Fischer 344 rats) DERMAL STUDY OECD 416 NEODOL® 91-6 ethoxylate CAS 68951-67-7 C14-15 ethoxylated alcohols	MRID 47050602 (1985) MRID 47041402 (1991)--JOURNAL ARTICLE dose levels: 0, 1, 10, or 25% (equivalent to 0, 10, 100 or 250 mg/kg/day based on dosing volume of 1.0 mL/kg) Treated three times/week except during the mating periods. % purity not specified Acceptable/guideline	Parental systemic NOAEL = 250 mg/kg/day Parental systemic LOAEL = not established Clinical signs (increased incidences of lachrymation, incidences of unkemptness, hunched posture, chromodacryorrhea and periocular swelling) observed in F_0 and F_1 females at 250 mg/kg/day might be due to local irritant effects. Reproductive toxicity NOAEL = 250 mg/kg/day Reproductive toxicity LOAEL = not identified. Offspring NOAEL = 250 mg/kg/day Offspring LOAEL = not identified.
OECD 422 Combined repeated dose toxicity study with a reproduction/developmental toxicity screening test Wistar rat CAS NO. 64366-70-7 alpha-Alkyl (C8)-o-hydroxypoly(oxypropylene) block copolymer with polyoxyethylene	MRID 47361502 (2007) 20, 100, or 500 mg/kg/day % purity N/A (mixture of polymers of varying length) Acceptable/guideline	Parental systemic NOAEL= 100 mg/kg/day Parental systemic LOAEL = 500 mg/kg/day, based on decreased body weight in males. Reproductive/developmental toxicity NOAEL = ≥500 mg/kg/day

Table A.1.2. Toxicology Profile of Alkyl Alcohol Ethoxylates		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3100 90-Day DERMAL toxicity in rats (Fischer 344) NEODOL® 91-6 ethoxylate CAS 68951-67-7 C14-15 ethoxylated alcohols	MRID 47041402E (1991) JOURNAL ARTICLE dose levels: 0, 1, 10, or 25% (equivalent to 0, 5, 50 or 125 mg/kg/day based on dosing volume of 0.5 mL/kg) % purity not specified Acceptable/nonguideline	Dermal toxicity NOAEL = 50 mg/kg/day Dermal toxicity LOAEL = 125 mg/kg/day, based on epidermal thickening and hyperkeratosis. Systemic LOAEL is not identified. Systemic NOAEL ≥ 125 mg/kg/day.
870.5100 *In vitro* Bacterial Gene Mutation- *Salmonella typhimurium*/mammalian activation gene mutation assay CAS 68951-67-7 C14-15 ethoxylated alcohols	MRID 47041402F (1991) JOURNAL ARTICLE % purity not specified Acceptable/nonguideline	. There was no evidence of induced mutant colonies over background.

A.2. Executive Summaries

EXECUTIVE SUMMARY: In OECD 416 reproduction and fertility effects study (MRID 47067001), UDL-700 (% a.i. and batch/lot # not reported) was administered in the diet to groups of 25 male and 25 female CD rats at dose levels of 0 ppm (one group), 500 (two groups), 1000 ppm (two groups), or 5000 ppm (two groups). Dosing of the treated groups was carried out according to two different treatment regimens: *continuous treatment*, in which the animals of both sexes were given the treated diets throughout pre-mating, mating, gestation, the rest periods, and until sacrifice; and the *GD 6-15 treatment regimen*, in which females were treated on presumptive GD 6-15, and males were left untreated. Pre-mating doses for the *continuously treated animals* were as follows: 0, 36.0, 71.6, or 354.7 mg/kg bw/day for F_0 males; 0, 41.3, 80.9, or 400.8 mg/kg bw/day for F_0 females; 0, 41.9, 82.6, or 403.0 mg/kg bw/day for F_1 males; and 0, 47.6, 95.0, or 466.6 mg/kg bw/day for F_1 females. From animals on each treatment regimen, three litters (A, B, and C) were produced in each generation (F_1 and F_2). Interim sacrifices of 5 animals/sex/group were done at the conclusion of pre-mating. Dams were killed on gestation day (GD) 13 or 21 of the C litters for collection of intrauterine data, and the fetuses from dams killed on GD 21 (or pups from dams that littered) were subjected to external, visceral, and skeletal examinations, as a developmental toxicity study. Pre-mating intervals for the F_0 and F_1 parental animals were 91 and 60 days long, respectively. Pre-mating doses for the continuously treated animals were as follows: 0, 36.0, 71.6, or 354.7 mg/kg bw/day for F_0 males; 0, 41.3, 80.9, or 400.8 mg/kg bw/day for F_0 females; 0, 41.9, 82.6, or 403.0 mg/kg bw/day for F_1 males; and 0, 47.6, 95.0, or 466.6 mg/kg bw/day for F_1 females.

Systemic toxicity was evident in continuously treated high-dose females as decreased body weight and decreased body weight gain during pre-mating. In continuously treated high-dose F_0 females, weight gain over weeks 0-13 was 11% less than controls, and absolute body weight during week 13 was 6% less than controls ($p<0.05$). Mean body weight of continuously treated high-dose F_1 females was decreased at the beginning of pre-mating as the continuation of an offspring effect and remained decreased (9-13% less than controls) and this group gained 14% less weight than controls. Continuous treatment did not result in any biologically significant effects on mortality, clinical signs, food consumption, hematology, organ weights, gross or microscopic pathology, or body weight in males.

In mated females treated on presumptive GD 6-15, no treatment-related effects on mortality, clinical signs, body weight, food consumption, organ weights, or gross or microscopic pathology were seen.

Following continuous treatment, the parental systemic LOAEL for UDL-700 in CD rats is 400.8 mg/kg/day in females, based on decreased body weight and body weight gain during premating. The LOAEL is not identified in males. The parental systemic NOAEL is 80.9 mg/kg bw/day in females and is greater than or equal to 354.7 mg/kg/day in males.

High-dose pups from the continuously treated parental animals had decreased body weight on LD 21 (F_{1A} males/females: -16%/-12%; F_{1B} males/females: -13%/-14%; F_{2A} males/females: -14%/-13%; F_{2B} males/females: -13%/-9%; $p<0.01$ for all). There was no treatment-related altered growth during gestation or decreased survival during gestation or lactation. No increased

total fetal or litter incidences of malformations or other structural alterations were seen, and all individual malformations and other alterations occurred at very low incidences.

In mated females treated on presumptive GD 6-15, pup body weight was not affected and no definite offspring toxicity was seen.

Following continuous treatment, the offspring LOAEL for UDL-700 in CD rats is 400.8 mg/kg/day, based on decreased body weight on LD 21 (both sexes). The offspring NOAEL is 80.9 mg/kg/day.

No evidence of reproductive toxicity was observed on either treatment regimen.

Following continuous treatment, the reproductive toxicity LOAEL for UDL-700 in CD rats is not identified. The reproductive toxicity NOAEL is greater than or equal to 400.8 mg/kg/day.

This study is **Acceptable/Non-guideline** and does not satisfy the guideline requirement for a reproduction and fertility effects study (OPPTS 870.3800; OECD 416) in the rat. The study satisfies the intent for which it was designed but was conducted prior to implementation of GLP standards and current guidelines. See deficiency section for the full list of deficiencies.

EXECUTIVE SUMMARY: In OECD 421 Reproduction/Developmental Toxicity Screening Test (MRID 47676801), "secondary Alcohol Ethoxylate" (98.73% a.i.; lot/batch #UI0501N7B1) was administered to ten Crl:CD(SD) rats/sex/dose by gavage in reverse osmosis membrane processed deionized water at dose levels of 0, 60, 168, or 470 mg/kg bw/day for at least 14 days prior to mating, throughout mating, and up to and including the day prior to sacrifice. Terminal sacrifices took place on study day (SD) 47 for males, on postnatal day (PND) 5 for females that littered, or on presumptive gestation day (GD) 25 for mated females that did not litter.

One pregnant high-dose female was found dead prior to dosing on GD 22, and the death was attributed to treatment. On SD 2 and/or 3, ptosis was seen in 4 high-dose males and 4 high-dose females, and hypoactivity was seen in 5 high-dose males and 7 high-dose females. One mid-dose female had hypoactivity and dehydration on GD 16-17 followed by a head tilt beginning on GD 20 and persisting through PND 4. Rales were noted in both sexes at all treated dose levels (males: 0/10, 4/10, 6/10, and 9/10; females: 0/10, 2/10, 8/10, and 10/10; in ascending dose order), with earliest onset on day 1 of dosing. Excess salivation was seen in 4 mid-dose and 10 high-dose males and in 1 mid-dose and 5 high-dose females, with earliest onset on day 4.

High-dose males had significant decreases in mean body weight throughout the study (9-16% less than controls; $p<0.01$), which increased in magnitude over time. This was due to weight loss during SD 1-8 (-5.8 g vs. +29.9 g for controls; $p<0.01$) and decreased weekly weight gain thereafter (-10% to -34%; n.s.). Mid-dose males had decreased weight gain during all measuring intervals except study days (SD) 43-47, with resultant decreases in cumulative weight gain (-19%; $p<0.05$) and decreased mean absolute body weight on SDs 43 and SD 47 (both -7%; $p<0.05$). Food consumption (g/rat/day) of high-dose males was 31% less than controls during the first week and 16-25% less than controls during the subsequent weeks ($p<0.01$ for all). Mean

food consumption of the mid-dose males was 11% less than controls during SD 1-8 and 8-15% less than controls during SD 29-47 ($p<0.05$). High-dose females had a treatment-related decrease in body weight gain during the first week of pre-mating (-53%; n.s.), which was followed by a compensatory increase during the second week (+68%; $p<0.01$), and this group also had a correlated transient treatment-related decrease in mean food consumption during the first week of the study (-22%; $p<0.01$).

Therefore, the parental systemic LOAEL for secondary alcohol ethoxylate in rats is 470 mg/kg/day based on decreased body weight and body weight gain, decreased food consumption, and clinical signs (ptosis and hypoactivity). The parental systemic NOAEL is 168 mg/kg/day.

Reproductive toxicity was evident at the highest dose level tested as a slightly increased incidence of microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules). There were no treatment-related effects on estrus cycle length and periodicity, the reproductive indices, mean numbers of implantation sites, precoital interval, or gestation length. There were no treatment-related effects on numbers of stillborn pups, pup sex ratio, pup survival to PND 5, pup body weight, or offspring clinical signs or macroscopic changes. Mean live litter size of the high-dose group was slightly decreased (12.5 pups vs. 14.2 for controls; n.s.). Along with this, the high-dose litters had slightly increased postimplantation losses (13.04% vs. 5.96% for controls), and the percentage of litters with at least one postimplantation loss was also slightly increased (87.5% vs. 60.0%). Considered together, these findings are consistent with increased resorptions.

The developmental/offspring LOAEL for secondary alcohol ethoxylate in rats is 470 mg/kg bw/day, based on decreased litter size, increased postimplantation loss, and microscopic changes of the testes and epididymides. The developmental/offspring NOAEL is 168 mg/kg bw/day.

The reproductive toxicity LOAEL for secondary alcohol ethoxylate in rats is 470 mg/kg bw/day, based on a slightly increased incidence of microscopic changes of the testes and epididymides (testicular atrophy, increased intraluminal exfoliated spermatogenic cells in epididymides, and dilated seminiferous tubules). The reproductive toxicity NOAEL **is 168 mg/kg/day.**

This study is classified as **Acceptable / Guideline** and satisfies the guideline requirement for a Reproduction/Developmental Toxicity Screening Test (OECD 421) in the rat.

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EXECUTIVE SUMMARY: In OECD 416 Dermal Reproduction and Fertility Effects Study (MRID 47050602), NEODOL 91-6 Ethoxylate (NE) (% a.i. not reported; batch/lot number WRC TOX. Sample No. 423E) in distilled water was administered dermally to male and female Fischer 344 rats at dose levels of 0, 1, 10, or 25% (equivalent to 0, 10, 100 or 250 mg/kg/day). On day 0 of treatment, the hair on the back of each rat was shaved and the appropriate dosing solution was applied evenly on the shaved area (2" X 2") using a Pipetman automatic micropipette. The exact volume (1.0 mL/kg bw) administered to

each rat was based on its weekly body weight. Parental rats were treated three times per week except during the mating periods. Fertility, gestation, lactation, pup growth, and pup survival were monitored during two generations. Each generation littered once. Daily clinical observations, weekly body weight determinations, and weekly skin irritation scorings were done. At necropsy, postmortem observations were made and body and organ weights were measured.

No mortalities were observed in the F_0 generation. However, five deaths occurred in the F_1 generation. One control male, one 10% female, and one male and two females at 25% died. All deaths were attributed to asphyxiation and were not considered to be compound-related. No evidence of skin irritation was observed at the application site. An increased incidence of brown or tan skin at the treatment site in parental animals of both generations at 10% and 25% was considered compound related but not adverse.

In the F_0 males, no treatment-related clinical signs were observed. In the F_0 females, there was a dose-related increase in lachrymation, with 6/30, 9/30, 11/30, and 16/30 animals affected in the control, low-, mid-, and high-dose groups, respectively. The F_1 males showed an increase in the number that appeared unkempt at 25% NE (11/20 vs. 1/20 controls). The F_1 females in the control, low-, mid-, and high-dose groups had increased incidences of unkemptness (1/40, 0/40, 6/40, and 23/40, respectively), hunched posture (1/40, 0/40, 6/40, and 22/40, respectively), chromodacryorrhea (7/40, 8/40, 13/40, and 14/40, respectively) and periocular swelling (2/40, 4/40, 11/40, 11/40, respectively).

Food consumption was not measured. For the F_0 males, a significant decrease ($p<0.05$) was observed in mean body weight at the 25% dose beginning on day 56 and continuing to day 105. Overall body weight gain by the high-dose F_0 males was decreased 7% from the control group. A statistically significant decrease ($p< 0.05$ or 0.01) in body weight was observed in the 25% dose group F_1 females on day 119. Overall weight gain by the high-dose F_1 females was decreased 21% relative to controls. No significant, treatment-related differences in overall mean body weight were seen in the F_0 females or F_1 males.

Gross necropsy of adult animals was unremarkable. No clear effects on organ weight were seen and microscopic lesions were limited to the testes.

The LOAEL is not established in this study. Clinical signs (increased incidences of lachrymation, incidences of unkemptness, hunched posture, chromodacryorrhea and periocular swelling) observed in F_0 and F_1 females at 250 mg/kg/day might be due to local irritant effects. The parental systemic NOAEL is 250 mg/kg/day (HDT).

The fertility indices for the control, low-, mid-, and high-dose groups were 77.3%, 64.0%, 84.0%, and 53.6%, respectively, for the F_0 generation and 88.5%, 67.9%, 84.5%, and 77.4%, respectively, for the F_1 generation. In the F_0 generation, there was an increase at 25% NE in the number of males that mated (produced plugs) but produced no litters. The number of pups per litter at birth was 8.2, 9.6, 7.9, and 6.4, respectively, in the F_1 litters and 6.8, 8.3, 8.0, and 8.4, respectively, in the F_2 litters. Lower gestation body weight of the high-dose F_0 dams correlated with the fewer number of pups/litter at birth.

EXECUTIVE SUMMARY: In a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (MRID 47676803), CAS No. 103818-93-5 (99% a.i.; Batch no. 2110FD4449) was administered to ten Crl:CD(SD) rats/sex/dose in reverse osmosis deionized water orally by gavage at dose levels of 0, 48, 120 or 300 mg/kg/day. Parental animals were administered either the vehicle (controls) or the test substance solutions for 14 days prior to the cohabitation period with males receiving a total of at least 46 doses. Treatment for the females was continued through the day of sacrifice which was gestation day (GD) 4 for rats not delivering a litter, lactation day (LD) 4 for rats delivering a litter or study day (SD) 52 for rats with no confirmed day of mating. Females received between 38-52 doses. Five rats/sex/group were assigned for a functional observational battery (FOB) and motor activity assessment and the other five/sex/group were used for hematology, clinical chemistry and histopathological examination.

There were no treatment-related effects in the parental animals on mortality, organ weight, fertility indices, FOB and motor activity assessment, hematology parameters or gross and histopathological examinations. One 300 mg/kg female died, but lesions at necropsy indicated that death was caused by a gavage error. Clinical signs observed in the 300 mg/kg/day male and female rats included orange/red perioral staining and moderate salivation. During pre-mating (days 1-14), the total body weight gain of the 300 mg/kg males was decreased 33% when compared to controls. For the entire treatment period (days 1-46), body weight gain was decreased compared to controls by 15% in the 120 mg/kg males and 27% in the 300 mg/kg males. All treated females during pre-mating had decreased body weight and body weight gain, when compared to the controls, but the values were similar to each other and the controls appeared to be slightly higher than typical, indicating no dose-dependent decrease. Food consumption was decreased in the males and females (within 10% of controls) during the pre-mating period but the males were similar to controls by the time of their sacrifice. Females during gestation and lactation had similar changes in body weight and body weight gain in all the treated groups when compared to controls. Food consumption in the females during gestation and lactation was similar to controls. No treatment-related effects in clinical chemistry were observed in the females.

The parental systemic LOAEL for CAS No. 103818-93-5 in rats is 300 mg/kg/day based on decreased body weight gain (males only) and clinical signs (orange/red perioral staining and moderate salivation in both sexes). The parental systemic NOAEL is 120 mg/kg/day.

There were no treatment-related effects observed in any of the reproductive/developmental parameters measured. The number of implantations, corpora lutea, live births, gestation index, lactation index, fertility index and lactation index were all similar between the control and treated groups.

The reproductive/developmental LOAEL for CAS No. 103818-93-5 in rats could not be determined and the reproductive/developmental NOAEL is 300 mg/kg/day (the highest dose tested).

The offspring toxicity LOAEL for CAS No. 103818-93-5 in rats could not be determined and the offspring toxicity NOAEL is 300 mg/kg/day (the highest dose tested).

This study is **Acceptable/Guideline** and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) in rats.

EXECUTIVE SUMMARY: In a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (MRID 47676802), CAS # 9004-98-2 (98.0% a.i.; Lot No. 59622) was administered to ten Crl:CD(SD) rats/sex/dose by gavage in reverse osmosis membrane processed deionized water at dose levels of 0, 50, 110, or 242 mg/kg bw/day for at least 14 days prior to mating, throughout mating, and up to and including the day prior to sacrifice. Terminal sacrifices took place on study day (SD) 47 for males, on postnatal day (PND) 5 for females that littered, or on presumptive gestation day (GD) 25 for females that did not litter.

One high-dose male was found dead on SD 24 after exhibiting gasping during SD 19-20 and scant, soft or liquid feces, ungroomed coat, and dehydration during SD 21-23. Rales were noted in both sexes at all treated dose levels (males: 0/10, 3/10, 5/10, and 10/10; females: 0/10, 1/10, 7/10, and 9/10; in ascending dose order), with earliest onset on day 4 of dosing. Excess salivation was seen in 2 low-dose, 6 mid-dose, and 10 high-dose males and in 2 mid-dose and 8 high-dose females, with earliest onset also on SD 4. Other treatment-related clinical signs included increased incidences of soft or liquid feces, chromorhinorrhea, and red or clear perioral substance in mid- and/or high-dose animals of both sexes. These clinical signs might be due to local irritant effects.

High-dose males had decreased cumulative body weight gain (-17%; n.s.) due to decreased body weight gain during the first three weeks of the study (-22%, -17%, -43%, respectively; n.s.), but absolute body weight and food consumption of the treated males were not affected. High-dose females had decreased mean absolute body weight beginning on GD 10 and continuing through PND 1 (-8% to -10%; $p<0.05$) and gained significantly less weight than controls during the first week of pre-mating (-48%; $p<0.05$) and throughout gestation (-16%; n.s.) with recovery seen during lactation as a weight gain rather than weight loss during PND 1-2 (+3.8 g vs. -6.1 g for controls) and increased body weight gain thereafter. High-dose females also had decreased food consumption during premating (-13% to -15%; $p<0.05$) and throughout gestation (GD 0-20: -14%; $p<0.01$). Mid-dose females had decreased body weight gain and decreased food consumption during GD 0-7 (-12% and -11%, respectively). Mid- and high-dose females had markedly decreased absolute and relative (to body and brain) thymus weights (high-dose: -55 to -58%, $p<0.01$; mid-dose: -33% to -36%, $p<0.05$ or n.s.). There were no treatment-related effects on hematology, clinical chemistry, coagulation, or FOB parameters, motor activity, bone marrow cellularity or composition, or gross or microscopic pathology.

The parental systemic LOAEL for CAS No. 9004-98-2 in rats is 110 mg/kg bw/day, based on decreased absolute and relative thymus weight, decreased body weight gain, and decreased food consumption in females and clinical signs in both sexes. The parental systemic NOAEL is 50 mg/kg bw/day. The thymus/lymph node effects are considered secondary effects caused by an overall stress response to the irritant properties of this chemical, not an immunotoxic effect.

No evidence of reproductive toxicity was seen. There were no treatment-related effects on estrus cyclicity, reproductive indices, mean numbers of corpora lutea, implantations, or pups per dam, pre- or postimplantation loss, or pup external anomalies, survival, clinical signs, or macroscopic findings. Evaluation of the testes did not reveal any treatment-related microscopic changes. **The reproductive/developmental LOAEL for CAS No. 9004-98-2 in rats is not identified, and the reproductive/developmental NOAEL is greater than or equal to 242 mg/kg bw/day.**

This study is classified as **Acceptable/Guideline** and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test [OPPTS 870.3650; OECD 422] in the rat.

In a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (MRID 47361502) Agnique KE 3551 (purity, N/A; batch/lot # E362470004) was administered to12 Wistar Hanover rats/sex/dose in water by oral gavage at dose levels of 0, 20, 100, or 500 mg/kg bw/day) for 6 weeks (males) or 6-8 weeks (females), including pre-mating: 2 weeks, mating: 2 weeks, gestation: approximately 22 days, and lactation: up to Day 4. Examined parameters included clinical observation, mortality and moribundity checks, body weights, food consumption, function observation battery (FOB), motor activity, clinical pathology, gross pathology, organ weights, microscopic pathology, and reproductive performance.

The only clinical sign noted was a significantly increased incidence of oral staining in males at 500 mg/kg (incidence: 0/12, 0/12, 1/12, 10/12* for 0, 20, 100, and 500 mg/kg groups, respectively). Males at 500 mg/kg had lower body weight (92% of control) on day 28. Females at 500 mg/kg had reduced food consumption during pre-mating (77-88% of control; $p<0.05$ or 0.01) with the most pronounced effect during the first week of treatment. A corresponding effect on body weight was not seen. No other effects were observed in females on body weight or food consumption during premating, gestation, and lactation.

Spleen weight was increased in females at 100 mg/kg (125% of control) and 500 mg/kg (129% of control). Extramedullary hematopoiesis in the spleen and liver of 100- and 500- mg/kg females was noted. The increased spleen weights and hematopoiesis are not considered toxicologically significant. There was increased cholesterol concentration in 500 mg/kg females. There were no treatment-related changes observed with respect to the FOB, motor activity, or gross pathology in either sex at any dose level tested.

The parental systemic LOAEL is 500 mg/kg bw/day based on decreased body weight in males. The parental systemic NOAEL is 100 mg/kg bw/day.

Treatment-related effects on reproductive performance or on F_1 offspring litter size, viability, body weight, or clinical observations were not observed at any dose level tested. Thus, **the reproductive/developmental NOAEL is 500 mg/kg bw/day in males and females and the LOAEL was not identified.**

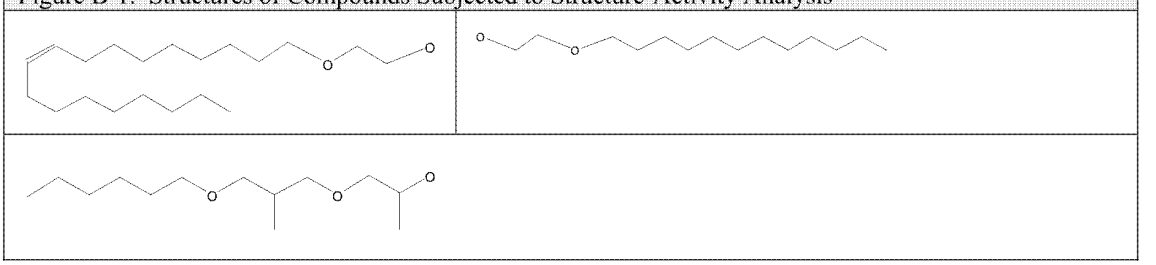
This study is classified acceptable (guideline) and satisfies the guideline requirement for a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD 422) in the rat.

APPENDIX B. SAR

B.1. Structure-Activity Relationship (SAR) Discussion

HED used DEREK for Windows (V. 11) to assess the potential toxicity of compounds in the inerts mixture. As described in Section 3 of this document these compounds are alkyl alcohol alkoxylates (AAA), comprised of a hydrophobic aliphatic alcohol moiety and a hydrophilic polyalkoxylate backbone. Three compounds were subjected to DEREK are analysis and are shown in Figure B-1 below. Only smaller molecules were selected for DEREK analysis, as the larger ones are likely to be poorly absorbed and less likely to cause significant toxicity.

Figure B-1. Structures of Compounds Subjected to Structure-Activity Analysis



Derek for Windows (LHASA Ltd.) is an expert system for the prediction of toxicity. It relies on a knowledge base of structural alerts and rules developed by scientists. When a test compound is inputted into the program, Derek for Windows scans the test compound for structural alerts contained within its database that are associated with specific toxicological endpoints and applies a series of reasoning rules to determine the likelihood of toxicity for the test compound. Information is provided on the rules used to make the prediction, along with descriptions of structural alerts identified, comments, available example compounds linked to the alerts and literature references.

DEREK did not identify any structural alerts of concern for of the chemicals screened. DEREK has developed more alerts for genotoxicity and carcinogenicity than other endpoints in the system. Considering what is already known about these specific compounds and other long-chain fatty acid compounds, along with the lack of structural alerts for carcinogenicity, chronic toxicity, or genotoxicity, HED has no specific concerns regarding chronic exposures other than those identified in the toxicity studies for this cluster.

APPENDIX C. Drinking Water Surrogate Analysis

Summary of Drinking Water Estimates of Four Surrogate Inert Chemicals

Notes:

1. Used a North Carolina cotton scenario with application date on July 1. This scenario should be a good representative of the numbers that you can expect from EFED. Also tried manipulation of application dates and weather files to ensure that there are no aberrations; these values look good in that regard.

2. PCA factors were not applied, but the impact of applying such factors (i.e., 0.5 to 0.9) would be insignificant in comparison to the vast uncertainties surrounding generation of concentrations from surrogate chemicals as well as uncertainties regarding the actual timing of applications.

3. All simulations were made at approximately 1 lb/A. Concentrations resulting from other application rates will be directly proportional to the application rate.

4. Table 1 gives the normalized concentration estimates for the case where all mass is applied on a single day. This should be the most conservative case.

5. Table 2 gives the normalized concentration estimates for the case where mass is distributed evenly over a 100-day period (April to June).

6. A range of degradation rates were used because degradation information was not available. 3 simulations were made 1) chemically stable in water and soil, 2) a 100 day half life in water and soil, and 3) a 10-day half life in water and soil. This should cover degradation.

7. Table 3 gives the chemical inputs used in the simulations.

Table 1. DW concentration for application lumped on a single day. (This maximizes the acute concentrations.) All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Estimates based on Stable Assumption				
Acute (ppb)	1.1	41	33	0.005
Chronic	0.69	15	19	0.003
Cancer	0.47	12	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
Acute (ppb)	0.74	36	22	0.003
Chronic	0.33	8.8	7.7	0.002
Cancer	0.25	6.4	6.4	0.001
Estimates based on assumption of a 10-day half life in soil and water				
Acute (ppb)	0.48	25	15	0.002
Chronic	0.04	1.1	0.96	0.0002
Cancer	0.03	0.65	0.60	0.0002

Table 2. DW concentration for applications spread out over a 100-day period. This simulates a more even distribution of pesticide over the growing season. All concentrations are normalized to a yearly application of 1 kg/hA (1.12 lb/acre).

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Spread Out Values				
Estimates based on Stable Assumption				
Acute (ppb)	0.98	29	28	0.004
Chronic	0.70	13	18	0.003
Cancer	0.48	10	15	0.002
Estimates based on assumption of a 100-day half life in soil and water				
	0.57	21	17	0.003
	0.36	6.9	7.2	0.002
	0.27	5.3	6.4	0.001
Estimates based on assumption of a 10-day half life in soil and water				
	0.16	7.8	4.3	0.001
	0.04	0.79	0.77	0.0002
	0.03	0.61	0.63	0.0002

Table 3 Chemical Inputs used in Simulations.

	Chemical 1	Chemical 2	Chemical 3	Chemical 4
Chemical Inputs:				
MW	*928*	*274*	*302*	*1185*
Solubility (mg/L)	*382*	*299*	*19.5*	*6.69e-8*
V.P. (mmHg)	*5.8e-27*	*1.76e-8*	*3.86e-8*	*3.77e-33*
Koc (ml/g)	*9.44e6*	*152*	*1345*	*2.57e9*

APPENDIX D. Dietary Risk Assessment

D.1. Chronic Dietary Exposure and Risk Assessment Results

```
U.S. Environmental Protection Agency                                    Ver. 2.00
DEEM-FCID Chronic analysis for INERTS CST 1                          (1994-98 data)
Residue file name: C:\Documents and Settings\colinger\My Documents\Inerts\Cst1\CST1.R98
                                                Adjustment factor #2 NOT used.
Analysis Date 06-16-2009/12:00:43     Residue file dated: 06-16-2009/12:00:05/8
Reference dose (RfD, Chronic) = 1.7 mg/kg bw/day
COMMENT 1: Inert 57 active ingredients + drinking water (100ppb); no adjustment for % in
formulation
================================================================================
                    Total exposure by population subgroup
--------------------------------------------------------------------------------
```

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.191509	11.3%
U.S. Population (spring season)	0.195512	11.5%
U.S. Population (summer season)	0.193733	11.4%
U.S. Population (autumn season)	0.188144	11.1%
U.S. Population (winter season)	0.188739	11.1%
Northeast region	0.208249	12.2%
Midwest region	0.190460	11.2%
Southern region	0.171478	10.1%
Western region	0.209414	12.3%
Hispanics	0.201698	11.9%
Non-hispanic whites	0.187723	11.0%
Non-hispanic blacks	0.185288	10.9%
Non-hisp/non-white/non-black	0.246967	14.5%
All infants (< 1 year)	0.397082	23.4%
Nursing infants	0.212711	12.5%
Non-nursing infants	0.467077	27.5%
Children 1-6 yrs	0.495834	29.2%
Children 7-12 yrs	0.239839	14.1%
Females 13-19 (not preg or nursing)	0.138939	8.2%
Females 20+ (not preg or nursing)	0.149292	8.8%
Females 13-50 yrs	0.154523	9.1%
Females 13+ (preg/not nursing)	0.163842	9.6%
Females 13+ (nursing)	0.192592	11.3%
Males 13-19 yrs	0.148194	8.7%
Males 20+ yrs	0.144142	8.5%
Seniors 55+	0.152430	9.0%
Children 1-2 yrs	0.624005	36.7%
Children 3-5 yrs	0.461958	27.2%
Children 6-12 yrs	0.255310	15.0%
Youth 13-19 yrs	0.144122	8.5%
Adults 20-49 yrs	0.144401	8.5%
Adults 50+ yrs	0.152076	8.9%
Females 13-49 yrs	0.145389	8.6%

D.2. Chronic Dietary Assessment Input Parameters

```
Filename: C:\Documents and Settings\colinger\My Documents\Inerts\Cst1\CST1.R98
Chemical: Inerts CST 1
RfD(Chronic): 1.7 mg/kg bw/day  NOEL(Chronic): 168 mg/kg bw/day
RfD(Acute): 1.7 mg/kg bw/day  NOEL(Acute):  168 mg/kg bw/day
Date created/last modified: 06-16-2009/12:00:05/8          Program ver. 2.03
Comment: Inert 57 active ingredients + drinking water (100ppb); no adjustment for % in
formulation
```

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
95000010	O	Acerola	2.000000	1.000	1.000	azoxys
		Full comment: azoxystrobin				
18000020	18	Alfalfa, seed	0.500000	1.000	1.000	glypho
		Full comment: glyphosate				
14000030	14	Almond	1.000000	1.000	1.000	glypho
		Full comment: glyphosate (tree nut)				
14000031	14	Almond-babyfood	1.000000	1.000	1.000	glypho
		Full comment: glyphosate (tree nut)				
14000040	14	Almond, oil	1.000000	1.000	1.000	glypho
		Full comment: glyphosate (tree nut)				
14000041	14	Almond, oil-babyfood	1.000000	1.000	1.000	glypho
		Full comment: glyphosate (tree nut)				
04010050	4A	Amaranth, leafy	100.000000	1.000	1.000	fosety
		Full comment: fosetyl-Al (CG 4)				
95000060	O	Amaranth, grain	5.000000	1.000	1.000	glypho
		Full comment: glyphosate [wheat]				
11000070	11	Apple, fruit with peel	25.000000	1.000	1.000	captan
11000080	11	Apple, peeled fruit	25.000000	1.000	1.000	captan
11000081	11	Apple, peeled fruit-babyfood	25.000000	1.000	1.000	captan
11000090	11	Apple, dried	25.000000	8.000	1.000	captan
11000091	11	Apple, dried-babyfood	25.000000	8.000	1.000	captan
11000100	11	Apple, juice	25.000000	1.000	1.000	captan
11000101	11	Apple, juice-babyfood	25.000000	1.000	1.000	captan
11000110	11	Apple, sauce	25.000000	1.000	1.000	captan
11000111	11	Apple, sauce-babyfood	25.000000	1.000	1.000	captan
12000120	12	Apricot	15.000000	1.000	1.000	TM
12000121	12	Apricot-babyfood	15.000000	1.000	1.000	TM
12000130	12	Apricot, dried	15.000000	6.000	1.000	TM
12000140	12	Apricot, juice	15.000000	1.000	1.000	TM
12000141	12	Apricot, juice-babyfood	15.000000	1.000	1.000	TM
01030150	1CD	Arrowroot, flour	1.000000	1.000	1.000	diuron
		Full comment: diuron (potato transl]				
01030151	1CD	Arrowroot, flour-babyfood	1.000000	1.000	1.000	diuron
		Full comment: diuron (potato transl]				
95000160	O	Artichoke, globe	5.000000	1.000	1.000	permet
		Full comment: permethrin				
01030170	1CD	Artichoke, Jerusalem	1.000000	1.000	1.000	diuron
		Full comment: diuron (potato transl]				
04010180	4A	Arugula	100.000000	1.000	1.000	fosety
		Full comment: fosetyl-Al (CG 4)				
95000190	O	Asparagus	10.000000	1.000	1.000	carbar
		Full comment: carbaryl				
95000200	O	Avocado	25.000000	1.000	1.000	fosety
		Full comment: fosetyl-al				
09020210	9B	Balsam pear	15.000000	1.000	1.000	fosety
		Full comment: fosetyl-Al (curcurbits)				
95000220	O	Bamboo, shoots	0.200000	1.000	1.000	glypho
		Full comment: glyphosate				
95000230	O	Banana	10.000000	1.000	1.000	carbar
		Full comment: carbaryl				
95000231	O	Banana-babyfood	10.000000	1.000	1.000	carbar
		Full comment: carbaryl				
95000240	O	Banana, dried	10.000000	3.900	1.000	carbar
		Full comment: carbaryl				
95000241	O	Banana, dried-babyfood	10.000000	3.900	1.000	carbar

```
          Full comment: carbaryl
15000250 15   Barley, pearled barley            20.000000   1.000  1.000  glypho
          Full comment: glyphosate
15000251 15   Barley, pearled barley-babyfood   20.000000   1.000  1.000  glypho
          Full comment: glyphosate
15000260 15   Barley, flour                     20.000000   1.000  1.000  glypho
          Full comment: glyphosate
15000261 15   Barley, flour-babyfood            20.000000   1.000  1.000  glypho
          Full comment: glyphosate
15000270 15   Barley, bran                      30.000000   1.000  1.000  glypho
          Full comment: glyphosate for bran
19010280 19A  Basil, fresh leaves               50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
19010281 19A  Basil, fresh leaves-babyfood      50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
19010290 19A  Basil, dried leaves              260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
19010291 19A  Basil, dried leaves-babyfood     260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
06030300 6C   Bean, black, seed                 7.000000   1.000  1.000  maneb
06020310 6B   Bean, broad, succulent           10.000000   1.000  1.000  maneb;
          Full comment: maneb;carbaryl (CG 6)
06030320 6C   Bean, broad, seed                 7.000000   1.000  1.000  maneb
06020330 6B   Bean, cowpea, succulent          10.000000   1.000  1.000  maneb;
          Full comment: maneb;carbaryl (CG 6)
06030340 6C   Bean, cowpea, seed                5.000000   1.000  1.000  carbar
          Full comment: carbaryl
06030350 6C   Bean,  great northern, seed       7.000000   1.000  1.000  maneb
06030360 6C   Bean, kidney, seed                7.000000   1.000  1.000  maneb
06020370 6B   Bean, lima, succulent            10.000000   1.000  1.000  maneb;
          Full comment: maneb;carbaryl (CG 6)
06030380 6C   Bean, lima, seed                  7.000000   1.000  1.000  maneb
06030390 6C   Bean, mung, seed                  2.000000   1.000  1.000  triflu
          Full comment: trifluralin
06030400 6C   Bean, navy, seed                  7.000000   1.000  1.000  maneb
06030410 6C   Bean, pink, seed                  7.000000   1.000  1.000  maneb
06030420 6C   Bean, pinto, seed                 7.000000   1.000  1.000  maneb
06010430 6A   Bean, snap, succulent             5.000000   1.000  1.000  chloro
          Full comment: chlorothalonil
06010431 6A   Bean, snap, succulent-babyfood    5.000000   1.000  1.000  chloro
          Full comment: chlorothalonil
21000440 M    Beef, meat                        2.000000   1.000  1.000  endosu
          Full comment: endosulfuran
21000441 M    Beef, meat-babyfood               2.000000   1.000  1.000  endosu
          Full comment: endosulfuran
21000450 M    Beef, meat, dried                 2.000000   1.920  1.000  endosu
          Full comment: endosulfuran
21000460 M    Beef, meat byproducts             1.000000   1.000  1.000  diuron
21000461 M    Beef, meat byproducts-babyfood    1.000000   1.000  1.000  diuron
21000470 M    Beef, fat                        13.000000   1.000  1.000  endosu
          Full comment: endosufuran
21000471 M    Beef,fat-babyfood                13.000000   1.000  1.000  endosu
          Full comment: endosufuran
21000480 M    Beef, kidney                      4.000000   1.000  1.000  glypho
          Full comment: glyphosate; 2,4-D
21000490 M    Beef, liver                       5.000000   1.000  1.000  endosu
          Full comment: endosulfuran
21000491 M    Beef, liver-babyfood              5.000000   1.000  1.000  endosu
          Full comment: endosulfuran
01010500 1AB  Beet, garden, roots               5.000000   1.000  1.000  carbar
          Full comment: carbaryl
01010501 1AB  Beet, garden, roots-babyfood      5.000000   1.000  1.000  carbar
          Full comment: carbaryl
02000510 2    Beet, garden, tops               50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin (CG 2)
01010520 1A   Beet, sugar                      15.000000   1.000  1.000  chlorp
          Full comment: chlorpyrifos
01010521 1A   Beet, sugar-babyfood             15.000000   1.000  1.000  chlorp
          Full comment: chlorpyrifos
01010530 1A   Beet, sugar, molasses            15.000000   1.000  1.000  chlorp
          Full comment: chlorpyrifos
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01010531 1A   Beet, sugar, molasses-babyfood    15.000000   1.000  1.000  chlorp
         Full comment: chlorpyrifos
95000540 O    Belgium endive                   100.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 4)
13010550 13A  Blackberry                        40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al (berries)
13010560 13A  Blackberry, juice                40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al (berries)
13010561 13A  Blackberry, juice-babyfood        40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al (berries)
13020570 13B  Blueberry                        40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al (berries)
13020571 13B  Blueberry-babyfood               40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al (berries)
13010580 13A  Boysenberry                      40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al (berries)
14000590 14   Brazil nut                        1.000000   1.000  1.000  glypho
         Full comment: glyphosate (tree nut)
95000600 O    Breadfruit                        0.200000   1.000  1.000  glypho
         Full comment: glyphosate
05010610 5A   Broccoli                         60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
05010611 5A   Broccoli-babyfood                60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
05010620 5A   Broccoli, Chinese                60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
05020630 5B   Broccoli raab                    60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
05010640 5A   Brussels sprouts                 60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
15000650 15   Buckwheat                         0.100000   1.000  1.000  metola
         Full comment: metolachlor
15000660 15   Buckwheat, flour                  0.100000   1.000  1.000  metola
         Full comment: metolachlor
01010670 1AB  Burdock                          10.000000   1.000  1.000  carbar
         Full comment: carbaryl (carrot)
14000680 14   Butternut                         1.000000   1.000  1.000  glypho
         Full comment: glyphosate (tree nut)
05010690 5A   Cabbage                          60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
05020700 5B   Cabbage, Chinese, bok choy       60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
05010710 5A   Cabbage, Chinese, napa           60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
05010720 5A   Cabbage, Chinese, mustard        60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
95000730 O    Cactus                            0.500000   1.000  1.000  glypho
         Full comment: glyphosate
95000740 O    Canistel                          2.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
09010750 9A   Cantaloupe                       15.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (curcurbits)
04020760 4B   Cardoon                         100.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 4)
95000770 O    Carob                             0.050000   1.000  1.000  chloro
         Full comment: chlorothanil
01010780 1AB  Carrot                          10.000000   1.000  1.000  carbar
         Full comment: carbaryl
01010781 1AB  Carrot-babyfood                 10.000000   1.000  1.000  carbar
         Full comment: carbaryl
01010790 1AB  Carrot, juice                   10.000000   1.000  1.000  carbar
         Full comment: carbaryl
09010800 9A   Casaba                           15.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (curcurbits)
14000810 14   Cashew                            1.000000   1.000  1.000  glypho
         Full comment: glyphosate (tree nut)
01030820 1CD  Cassava                           1.000000   1.000  1.000  diuron
         Full comment: diuron [potato transl]
01030821 1CD  Cassava-babyfood                  1.000000   1.000  1.000  diuron
         Full comment: diuron [potato transl]
05010830 5A   Cauliflower                      60.000000   1.000  1.000  fosety
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          Full comment: fosetyl-Al (CG 5)
01010840 1AB  Celeriac                          10.000000   1.000  1.000  carbar
          Full comment: carbaryl (carrot)
04020850 4B   Celery                          100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
04020851 4B   Celery-babyfood                 100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
04020860 4B   Celery, juice                   100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
04020870 4B   Celtuce                         100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
09020880 9B   Chayote, fruit                   15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
95000890 O    Cherimoya                         2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
12000900 12   Cherry                          50.000000   1.000  1.000  captan
12000901 12   Cherry-babyfood                 50.000000   1.000  1.000  captan
12000910 12   Cherry, juice                   50.000000   1.000  1.000  captan
12000911 12   Cherry, juice-babyfood          50.000000   1.000  1.000  captan
14000920 14   Chestnut                         1.000000   1.000  1.000  glypho
          Full comment: glyphosate (tree nut)
40000930 P    Chicken, meat                    5.000000   1.000  1.000  carbar
          Full comment: carbaryl
40000931 P    Chicken, meat-babyfood           5.000000   1.000  1.000  carbar
          Full comment: carbaryl
40000940 P    Chicken, liver                   5.000000   1.000  1.000  iprodi
          Full comment: iprodione
40000950 P    Chicken, meat byproducts         1.000000   1.000  1.000  glypho
          Full comment: glyphosate
40000951 P    Chicken, meat byproducts-babyfoo 1.000000   1.000  1.000  glypho
          Full comment: glyphosate
40000960 P    Chicken, fat                     5.000000   1.000  1.000  carbar
          Full comment: carbaryl
40000961 P    Chicken, fat-babyfood            5.000000   1.000  1.000  carbar
          Full comment: carbaryl
40000970 P    Chicken, skin                    5.000000   1.000  1.000  carbar
          Full comment: carbaryl
40000971 P    Chicken, skin-babyfood           5.000000   1.000  1.000  carbar
          Full comment: carbaryl
06030980 6C   Chickpea, seed                   7.000000   1.000  1.000  maneb
06030981 6C   Chickpea, seed-babyfood          7.000000   1.000  1.000  maneb
06030990 6C   Chickpea, flour                  7.000000   1.000  1.000  maneb
01011000 1AB  Chicory, roots                  10.000000   1.000  1.000  carbar
          Full comment: carbaryl [carrot]
02001010 2    Chicory, tops                   50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin (CG 2)
09021020 9B   Chinese waxgourd                15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
19011030 19A  Chive
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                              50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                              50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
                 211-Cooked; Fresh or N/S; Baked
                                              50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
                 212-Cooked; Fresh or N/S; Boiled
                                              50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
                 213-Cooked; Fresh or N/S; Fried
                                              50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
                 221-Cooked; Frozen; Baked    50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
                 240-Cooked; Canned; Cook Meth N/S
                                              50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
                 242-Cooked; Canned; Boiled   50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herbs]
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04011040 4A   Chrysanthemum, garland          100.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 4)
19021050 19B  Cinnamon                         38.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin [spice]
19021051 19B  Cinnamon-babyfood                38.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin [spice]
10001060 10   Citrus citron                    10.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin ( citrus CG)
10001070 10   Citrus hybrids                   10.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin ( citrus CG)
10001080 10   Citrus, oil                      10.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin ( citrus CG)
95001090 O    Cocoa bean, chocolate             0.050000   1.000  1.000  chloro
         Full comment: chlorothalonil
95001100 O    Cocoa bean, powder                0.050000   1.000  1.000  chloro
         Full comment: chlorothalonil
95001110 O    Coconut, meat                     0.100000   1.000  1.000  glypho
         Full comment: glyphosate
95001111 O    Coconut- meat-babyfood            0.100000   1.000  1.000  glypho
         Full comment: glyphosate
95001120 O    Coconut, dried                    0.100000   2.100  1.000  glypho
         Full comment: glyphosate
95001130 O    Coconut, milk                     0.100000   1.000  1.000  glypho
         Full comment: glyphosate
95001140 O    Coconut, oil                      0.100000   1.000  1.000  glypho
         Full comment: glyphosate
95001141 O    Coconut, oil-babyfood             0.100000   1.000  1.000  glypho
         Full comment: glyphosate
95001150 O    Coffee, roasted bean              1.000000   1.000  1.000  glypho
         Full comment: glyphosate
95001160 O    Coffee, instant                   1.000000   1.000  1.000  glypho
         Full comment: glyphosate
05021170 5B   Collards                         60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
19011180 19A  Coriander, leaves                 30.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
19011181 19A  Coriander, leaves-babyfood       30.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
19021190 19B  Coriander, seed                  38.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin [spice]
19021191 19B  Coriander, seed-babyfood         38.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin [spice]
15001200 15   Corn, field, flour                0.150000   1.000  1.000  lambda
         Full comment: lambda-cyhalothrin
15001201 15   Corn, field, flour-babyfood       0.150000   1.000  1.000  lambda
         Full comment: lambda-cyhalothrin
15001210 15   Corn, field, meal                 1.000000   1.000  1.000  glypho
         Full comment: glyphosate
15001211 15   Corn, field, meal-babyfood        1.000000   1.000  1.000  glypho
         Full comment: glyphosate
15001220 15   Corn, field, bran                 1.000000   1.000  1.000  glypho
         Full comment: glyphosate
15001230 15   Corn, field, starch               1.000000   1.000  1.000  glypho
         Full comment: glyphosate
15001231 15   Corn, field, starch-babyfood      1.000000   1.000  1.000  glypho
         Full comment: glyphosate
15001240 15   Corn, field, syrup                1.000000   1.500  1.000  glypho
         Full comment: glyphosate
15001241 15   Corn, field, syrup-babyfood       1.000000   1.500  1.000  glypho
         Full comment: glyphosate
15001250 15   Corn, field, oil                  3.000000   1.000  1.000  chloro
         Full comment: chloropyrifos
15001251 15   Corn, field, oil-babyfood         3.000000   1.000  1.000  chloro
         Full comment: chloropyrifos
15001260 15   Corn, pop                         0.500000   1.000  1.000  mancoz
         Full comment: mancozeb
15001270 15   Corn, sweet                       5.000000   1.000  1.000  maneb;
         Full comment: maneb;carbaryl
15001271 15   Corn, sweet-babyfood              5.000000   1.000  1.000  maneb;
         Full comment: maneb;carbaryl
95001280 O    Cottonseed, oil                  35.000000   1.000  1.000  glypho
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          Full comment: glyphosate
95001281 O    Cottonseed, oil-babyfood          35.000000   1.000  1.000  glypho
          Full comment: glyphosate
11001290 11   Crabapple                         20.000000   1.000  1.000  phosme
          Full comment: phosmet
95001300 O    Cranberry                         10.000000   1.000  1.000  carbar
          Full comment: carbaryl
95001301 O    Cranberry-babyfood                10.000000   1.000  1.000  carbar
          Full comment: carbaryl
95001310 O    Cranberry, dried                  10.000000   1.000  1.000  carbar
          Full comment: carbaryl
95001320 O    Cranberry, juice                  10.000000   1.000  1.000  carbar
          Full comment: carbaryl
95001321 O    Cranberry, juice-babyfood         10.000000   1.000  1.000  carbar
          Full comment: carbaryl
04011330 4A   Cress, garden                    100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
04011340 4A   Cress, upland                    100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
09021350 9B   Cucumber                          15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
13021360 13B  Currant                          40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
13021370 13B  Currant, dried                   40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
04011380 4A   Dandelion, leaves                100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
01031390 1CD  Dasheen, corm                     1.000000   1.000  1.000  diuron
          Full comment: diuron [potato transl]
02001400 2    Dasheen, leaves                   50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin (CG 2)
95001410 O    Date                               0.200000   1.000  1.000  glypho
          Full comment: glyphosate
13011420 13A  Dewberry                          40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
19021430 19B  Dill, seed                        38.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [spice]
19011440 19A  Dillweed                         50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herb]
70001450 P    Egg, whole                         1.500000   1.000  1.000  iprodi
          Full comment: iprodione
70001451 P    Egg, whole-babyfood                1.500000   1.000  1.000  iprodi
          Full comment: iprodione
70001460 P    Egg, white                         1.500000   1.000  1.000  iprodi
          Full comment: iprodione
70001461 P    Egg, white (solids)-babyfood       1.500000   1.000  1.000  iprodi
          Full comment: iprodione
70001470 P    Egg, yolk                          1.500000   1.000  1.000  iprodi
          Full comment: iprodione
70001471 P    Egg, yolk-babyfood                 1.500000   1.000  1.000  iprodi
          Full comment: iprodione
08001480 8    Eggplant                          10.000000   1.000  1.000  carbar
          Full comment: carbaryl
13021490 13B  Elderberry                        40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
04011500 4A   Endive                           100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
95001510 O    Feijoa                             2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
04021520 4B   Fennel, Florence                 100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
95001530 O    Fig                                7.000000   1.000  1.000  maneb
95001540 O    Fig, dried                         7.000000   1.000  1.000  maneb
14001550 14   Filbert                            1.000000   1.000  1.000  glypho
          Full comment: glyphosate (tree nut)
14001560 14   Filbert, oil                       1.000000   1.000  1.000  glypho
          Full comment: glyphosate (tree nut)
80001570 F    Fish-freshwater finfish            2.000000   1.000  1.000  diuron
          Full comment: diuron [catfish]
80001580 F    Fish-freshwater finfish, farm ra   2.000000   1.000  1.000  diuron
80001590 F    Fish-saltwater finfish, tuna       2.000000   1.000  1.000  diuron
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          Full comment: diuron [catfish]
80001600 F    Fish-saltwater finfish, other      2.000000   1.000  1.000  diuron
          Full comment: diuron [catfish]
80001610 F    Fish-shellfish, crustacean         3.000000   1.000  1.000  glypho
          Full comment: glyphosate [shellfish]
80001620 F    Fish-shellfish, mollusc            3.000000   1.000  1.000  glypho
          Full comment: glyphosate [shellfish]
20001630 20   Flaxseed, oil                      5.000000   1.000  1.000  carbar
          Full comment: carbaryl
03001640 3    Garlic                             0.200000   1.000  1.000  glypho
          Full comment: glyphosate (CG 3)
03001650 3    Garlic, dried                      0.200000   1.000  1.000  glypho
          Full comment: glyphosate (CG 3)
03001651 3    Garlic, dried-babyfood             0.200000   1.000  1.000  glypho
          Full comment: glyphosate (CG 3)
01031660 1CD  Ginger                             0.200000   1.000  1.000  glypho
          Full comment: glyphosate
01031661 1CD  Ginger-babyfood                    0.200000   1.000  1.000  glypho
          Full comment: glyphosate
01031670 1CD  Ginger, dried                      0.200000   1.000  1.000  glypho
          Full comment: glyphosate
01011680 1AB  Ginseng, dried                     4.000000   1.000  1.000  iprodi
          Full comment: iprodione
23001690 M    Goat, meat                         2.000000   1.000  1.000  endosu
          Full comment: endosulfan
23001700 M    Goat, meat byproducts              1.000000   1.000  1.000  diuron
          Full comment: diuron; propanil
23001710 M    Goat, fat                         13.000000   1.000  1.000  endosu
          Full comment: endosulfan
23001720 M    Goat, kidney                       4.000000   1.000  1.000  endosu
          Full comment: endosulfan; 2,4-D
23001730 M    Goat, liver                        5.000000   1.000  1.000  endosu
          Full comment: endosulfan
13021740 13B  Gooseberry                        40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
95001750 O    Grape                             25.000000   1.000  1.000  captan
95001760 O    Grape, juice                      25.000000   1.000  1.000  captan
95001761 O    Grape, juice-babyfood             25.000000   1.000  1.000  captan
95001770 O    Grape, leaves                     25.000000   1.000  1.000  captan
95001780 O    Grape, raisin                     25.000000   1.000  1.000  captan
95001790 O    Grape, wine and sherry            25.000000   1.000  1.000  captan
10001800 10   Grapefruit                        10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10001810 10   Grapefruit, juice                 10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
06031820 6C   Guar, seed                         7.000000   1.000  1.000  maneb
06031821 6C   Guar, seed-babyfood                7.000000   1.000  1.000  maneb
95001830 O    Guava                              2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
95001831 O    Guava-babyfood                     2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
19011840 19A  Herbs, other
                 110-Uncooked; Fresh or N/S; Cook Meth N/S
                                                50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 150-Uncooked; Cured etc; Cook Meth N/S
                                                50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 210-Cooked; Fresh or N/S; Cook Meth N/S
                                                50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 211-Cooked; Fresh or N/S; Baked
                                                50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 212-Cooked; Fresh or N/S; Boiled
                                                50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 213-Cooked; Fresh or N/S; Fried
                                                50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 215-Cooked; Fresh or N/S; Boiled/baked
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                                          50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 221-Cooked; Frozen; Baked      50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 230-Cooked; Dried; Cook Meth N/S
                                         260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 232-Cooked; Dried; Boiled     260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 233-Cooked; Dried; Fried      260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 240-Cooked; Canned; Cook Meth N/S
                                         260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 242-Cooked; Canned; Boiled    260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 250-Cooked; Cured etc; Cook Meth N/S
                                         260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 252-Cooked; Cured etc; Boiled 260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
                 253-Cooked; Cured etc; Fried  260.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
19011841 19A  Herbs, other-babyfood             50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
14001850 14   Hickory nut                        1.000000   1.000  1.000  glypho
          Full comment: glyphosate (tree nut)
95001860 O    Honey                            30.000000   1.000  1.000  glypho
          Full comment: glyphosate[sugarcane mol trans]
95001861 O    Honey-babyfood                   30.000000   1.000  1.000  glypho
          Full comment: glyphosate[sugarcane mol trans]
09011870 9A   Honeydew melon                   15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
95001880 O    Hop                               1.000000   1.000  1.000  methyl
          Full comment: methyl parathion
24001890 M    Horse, meat                       2.000000   1.000  1.000  endosu
          Full comment: endosulfuran
01011900 1AB  Horseradish                       5.000000   1.000  1.000  carbar
          Full comment: carbaryl
13021910 13B  Huckleberry                      40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
95001920 O    Jaboticaba                        2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
95001930 O    Jackfruit                         2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
05021940 5B   Kale                             60.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 5)
95001950 O    Kiwifruit                        25.000000   1.000  1.000  phosme
          Full comment: phosmet
05011960 5A   Kohlrabi                         60.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 5)
10001970 10   Kumquat                          10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
03001980 3    Leek                              3.000000   1.000  1.000  methom
          Full comment: methomyl
10001990 10   Lemon                            10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10002000 10   Lemon, juice                     10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10002001 10   Lemon, juice-babyfood            10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10002010 10   Lemon, peel                      10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
19012020 19A  Lemongrass                       50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [herb]
06032030 6C   Lentil, seed                     10.000000   1.000  1.000  carbar
          Full comment: carbaryl
04012040 4A   Lettuce, head                   100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
04012050 4A   Lettuce, leaf                   100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
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10002060 10   Lime                              10.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin ( citrus CG)
10002070 10   Lime, juice                       10.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin ( citrus CG)
10002071 10   Lime, juice-babyfood              10.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin ( citrus CG)
13012080 13A  Loganberry                        40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al (berries)
95002090 O    Longan                             3.000000   1.000  1.000  imidac
         Full comment: imidacloprid
11002100 11   Loquat                             2.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
95002110 O    Lychee                             3.000000   1.000  1.000  imidac
         Full comment: imidacloprid
95002120 O    Lychee, dried                      3.000000   1.850  1.000  imidac
         Full comment: imidacloprid
14002130 14   Macadamia nut                      1.000000   1.000  1.000  glypho
         Full comment: glyphosate (tree nut)
95002140 O    Mamey apple                        0.200000   1.000  1.000  glypho
         Full comment: glyphosate
95002150 O    Mango                              2.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
95002151 O    Mango-babyfood                     2.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
95002160 O    Mango, dried                       2.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
95002170 O    Mango, juice                       2.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
95002171 O    Mango, juice-babyfood              2.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin
95002180 O    Maple, sugar                      15.000000   1.000  1.000  chlorp
         Full comment: chlorpyrifos [sugarbeet]
95002190 O    Maple syrup                       15.000000   1.000  1.000  chlorp
         Full comment: chlorpyrifos [sugarbeet]
19012200 19A  Marjoram                          50.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin [herb]
19012201 19A  Marjoram-babyfood                 50.000000   1.000  1.000  azoxys
         Full comment: azoxystrobin [herb]
28002210 M    Meat, game                         2.000000   1.000  1.000  endosu
         Full comment: endosulfan
27002220 D    Milk, fat                          2.000000   1.000  1.000  endosu
         Full comment: endosulfan
27002221 D    Milk, fat - baby food/infant for   2.000000   1.000  1.000  endosu
         Full comment: endosulfan
27012230 D    Milk, nonfat solids                0.500000   1.000  1.000  iprodi
         Full comment: iprodione
27012231 D    Milk, nonfat solids-baby food/in   0.500000   1.000  1.000  iprodi
         Full comment: iprodione
27022240 D    Milk, water                        0.500000   1.000  1.000  iprodi
         Full comment: iprodione
27022241 D    Milk, water-babyfood/infant form   0.500000   1.000  1.000  iprodi
         Full comment: iprodione
27032251 D    Milk, sugar (lactose)-baby food/   0.500000   1.000  1.000  iprodi
         Full comment: iprodione
15002260 15   Millet, grain                      2.000000   1.000  1.000  carbar
         Full comment: carbaryl
95002270 O    Mulberry                          40.000000   1.000  1.000  fosety
         Full comment: fosetyl-al [blueberry]
95002280 O    Mushroom                           5.000000   1.000  1.000  permet
         Full comment: permethrin
05022290 5B   Mustard greens                    60.000000   1.000  1.000  fosety
         Full comment: fosetyl-Al (CG 5)
12002300 12   Nectarine                         25.000000   1.000  1.000  captan
15002310 15   Oat, bran                         20.000000   1.000  1.000  mancoz
         Full comment: mancozeb
15002320 15   Oat, flour                        20.000000   1.000  1.000  glypho
         Full comment: glyphosate
15002321 15   Oat, flour-babyfood               20.000000   1.000  1.000  glypho
         Full comment: glyphosate
15002330 15   Oat, groats/rolled oats           20.000000   1.000  1.000  glypho
         Full comment: glyphosate
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15002331 15   Oat, groats/rolled oats-babyfood  20.000000   1.000  1.000  glypho
          Full comment: glyphosate
08002340 8    Okra                              10.000000   1.000  1.000  carbar
          Full comment: carbaryl
95002350 O    Olive                             10.000000   1.000  1.000  carbar
          Full comment: carbaryl
95002360 O    Olive, oil                        10.000000   1.000  1.000  carbar
          Full comment: carbaryl
03002370 3    Onion, dry bulb                    7.000000   1.000  1.000  maneb;
          Full comment: maneb; ziram
03002371 3    Onion, dry bulb-babyfood           7.000000   1.000  1.000  maneb;
          Full comment: maneb; ziram
03002380 3    Onion, dry bulb, dried             7.000000   9.000  1.000  maneb;
          Full comment: maneb; ziram
03002381 3    Onion, dry bulb, dried-babyfood    7.000000   9.000  1.000  maneb;
          Full comment: maneb; ziram
03002390 3    Onion, green                      10.000000   1.000  1.000  fosety
          Full comment: fosetyl-al
10002400 10   Orange                            10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10002410 10   Orange, juice                     10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10002411 10   Orange, juice-babyfood            10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10002420 10   Orange, peel                      10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
95002430 O    Palm heart, leaves                 0.200000   1.000  1.000  glypho
          Full comment: glyphosate
95002440 O    Palm, oil                          0.100000   1.000  1.000  glypho
          Full comment: glyphosate
95002441 O    Palm, oil-babyfood                 0.100000   1.000  1.000  glypho
          Full comment: glyphosate
95002450 O    Papaya                            15.000000   1.000  1.000  chloro
          Full comment: chlorothanil
95002451 O    Papaya-babyfood                   15.000000   1.000  1.000  chloro
          Full comment: chlorothanil
95002460 O    Papaya, dried                     15.000000   1.800  1.000  chloro
          Full comment: chlorothanil
95002470 O    Papaya, juice                     15.000000   1.000  1.000  chloro
          Full comment: chlorothanil
04012480 4A   Parsley, leaves                  100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
19012490 19A  Parsley, dried leaves             12.000000   1.000  1.000  carbar
          Full comment: carbaryl
19012491 19A  Parsley, dried leaves-babyfood    12.000000   1.000  1.000  carbar
          Full comment: carbaryl
01012500 1AB  Parsley, turnip rooted            2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
01012510 1AB  Parsnip                           5.000000   1.000  1.000  carbar
          Full comment: carbaryl
01012511 1AB  Parsnip-babyfood                  5.000000   1.000  1.000  carbar
          Full comment: carbaryl
95002520 O    Passionfruit                      3.000000   1.000  1.000  chloro
          Full comment: chlorothanil
95002521 O    Passionfruit-babyfood             3.000000   1.000  1.000  chloro
          Full comment: chlorothanil
95002530 O    Passionfruit, juice               3.000000   1.000  1.000  chloro
          Full comment: chlorothanil
95002531 O    Passionfruit, juice-babyfood      3.000000   1.000  1.000  chloro
          Full comment: chlorothanil
95002540 O    Pawpaw                            2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
06022550 6B   Pea, succulent                    10.000000   1.000  1.000  carbar
          Full comment: carbaryl
06022551 6B   Pea, succulent-babyfood           10.000000   1.000  1.000  carbar
          Full comment: carbaryl
06032560 6C   Pea, dry                           8.000000   1.000  1.000  glypho
          Full comment: glyphosate
06032561 6C   Pea, dry-babyfood                  8.000000   1.000  1.000  glypho
          Full comment: glyphosate
06012570 6A   Pea, edible podded, succulent      3.000000   1.000  1.000  bentaz
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          Full comment: bentazon
06032580 6C   Pea, pigeon, seed                  8.000000   1.000  1.000  glypho
          Full comment: glyphosate
06022590 6B   Pea, pigeon, succulent            10.000000   1.000  1.000  carbar
          Full comment: carbaryl
12002600 12   Peach                             15.000000   1.000  1.000  captan
12002601 12   Peach-babyfood                    15.000000   1.000  1.000  captan
12002610 12   Peach, dried                      15.000000   7.000  1.000  captan
12002611 12   Peach, dried-babyfood             15.000000   7.000  1.000  captan
12002620 12   Peach, juice                      15.000000   1.000  1.000  captan
12002621 12   Peach, juice-babyfood             15.000000   1.000  1.000  captan
95002630 O    Peanut                             5.000000   1.000  1.000  carbar
          Full comment: carbaryl
95002640 O    Peanut, butter                     5.000000   1.890  1.000  carbar
          Full comment: carbaryl
95002650 O    Peanut, oil                        0.600000   1.000  1.000  azoxys
          Full comment: azoxystrobin
11002660 11   Pear                              25.000000   1.000  1.000  captan
11002661 11   Pear-babyfood                     25.000000   1.000  1.000  captan
11002670 11   Pear, dried                       25.000000   6.250  1.000  captan
11002680 11   Pear, juice                       25.000000   1.000  1.000  captan
11002681 11   Pear, juice-babyfood              25.000000   1.000  1.000  captan
14002690 14   Pecan                              1.000000   1.000  1.000  glypho
          Full comment: glyphosate (tree nut)
08002700 8    Pepper, bell                      10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08002701 8    Pepper, bell-babyfood             10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08002710 8    Pepper, bell, dried               10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08002711 8    Pepper, bell, dried-babyfood      10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08002720 8    Pepper, nonbell                   10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08002721 8    Pepper, nonbell-babyfood          10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08002730 8    Pepper, nonbell, dried            10.000000   1.000  1.000  carbar
          Full comment: carbaryl
19022740 19B  Pepper, black and white           38.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [spice]
19022741 19B  Pepper, black and white-babyfood  38.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [spice]
95002750 O    Peppermint                       200.000000   1.000  1.000  glypho
          Full comment: glyphosate
95002760 O    Peppermint, oil                  200.000000   1.000  1.000  glypho
          Full comment: glyphosate
95002770 O    Persimmon                          3.000000   1.000  1.000  imidac
          Full comment: imidacloprid
95002780 O    Pine nut                           1.000000   1.000  1.000  glypho
          Full comment: glyphosate
95002790 O    Pineapple                          2.000000   1.000  1.000  carbar
          Full comment: carbaryl
95002791 O    Pineapple-babyfood                 2.000000   1.000  1.000  carbar
          Full comment: carbaryl
95002800 O    Pineapple, dried                   2.000000   5.000  1.000  carbar
          Full comment: carbaryl
95002810 O    Pineapple, juice                   2.000000   1.000  1.000  carbar
          Full comment: carbaryl
95002811 O    Pineapple, juice-babyfood          2.000000   1.000  1.000  carbar
          Full comment: carbaryl
14002820 14   Pistachio                          1.000000   1.000  1.000  glypho
          Full comment: glyphosate (tree nut)
95002830 O    Plantain                          10.000000   1.000  1.000  carbar
          Full comment: carbaryl [banana]
95002840 O    Plantain, dried                   10.000000   3.900  1.000  carbar
          Full comment: carbaryl [banana]
12002850 12   Plum                              10.000000   1.000  1.000  captan
          Full comment: captan;carbaryl
12002851 12   Plum-babyfood                     10.000000   1.000  1.000  captan
          Full comment: captan;carbaryl
12002860 12   Plum, prune, fresh                10.000000   1.000  1.000  captan
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          Full comment: captan;carbaryl
12002861 12   Plum, prune, fresh-babyfood       10.000000   1.000  1.000  captan
          Full comment: captan;carbaryl
12002870 12   Plum, prune, dried                10.000000   1.000  1.000  captan
          Full comment: captan;carbaryl
12002871 12   Plum, prune, dried-babyfood       10.000000   1.000  1.000  captan
          Full comment: captan;carbaryl
12002880 12   Plum, prune, juice                10.000000   1.000  1.000  captan
          Full comment: captan;carbaryl
12002881 12   Plum, prune, juice-babyfood       10.000000   1.000  1.000  captan
          Full comment: captan;carbaryl
95002890 O    Pomegranate                        0.900000   1.000  1.000  imidac
          Full comment: imidacloprid
25002900 M    Pork, meat                         2.000000   1.000  1.000  endosu
          Full comment: endosulfan
25002901 M    Pork, meat-babyfood                2.000000   1.000  1.000  endosu
          Full comment: endosulfan
25002910 M    Pork, skin                        13.000000   1.000  1.000  endosu
          Full comment: endosulfan
25002920 M    Pork, meat byproducts              1.000000   1.000  1.000  diuron
25002921 M    Pork, meat byproducts-babyfood     1.000000   1.000  1.000  diuron
25002930 M    Pork, fat                         13.000000   1.000  1.000  endosu
          Full comment: endosulfan
25002931 M    Pork, fat-babyfood                13.000000   1.000  1.000  endosu
          Full comment: endosulfan
25002940 M    Pork, kidney                       4.000000   1.000  1.000  glypho
          Full comment: glyphosate
25002950 M    Pork, liver                        5.000000   1.000  1.000  endosu
          Full comment: endosulfan
01032960 1C   Potato, chips                      1.000000   1.000  1.000  imidac
          Full comment: imidacloprid
01032970 1C   Potato, dry (granules/ flakes)     1.000000   6.500  1.000  diuron
01032971 1C   Potato, dry (granules/ flakes)-b   1.000000   6.500  1.000  diuron
01032980 1C   Potato, flour                      1.000000   1.000  1.000  diuron
01032981 1C   Potato, flour-babyfood             1.000000   1.000  1.000  diuron
01032990 1C   Potato, tuber, w/peel              1.000000   1.000  1.000  diuron
01032991 1C   Potato, tuber, w/peel-babyfood     1.000000   1.000  1.000  diuron
01033000 1C   Potato, tuber, w/o peel            1.000000   1.000  1.000  diuron
01033001 1C   Potato, tuber, w/o peel-babyfood   1.000000   1.000  1.000  diuron
60003010 P    Poultry, other, meat               5.000000   1.000  1.000  carbar
          Full comment: carbaryl
60003020 P    Poultry, other, liver              5.000000   1.000  1.000  iprodi
          Full comment: iprodione
60003030 P    Poultry, other, meat byproducts    1.000000   1.000  1.000  glypho
          Full comment: glyphosate
60003040 P    Poultry, other, fat                5.000000   1.000  1.000  carbar
          Full comment: carbaryl
60003050 P    Poultry, other, skin               5.000000   1.000  1.000  carbar
          Full comment: carbaryl
95003060 O    Psyllium, seed                    10.000000   1.000  1.000  propan
          Full comment: propanil [rice]
10003070 10   Pummelo                           10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
09023080 9B   Pumpkin                           15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
09023090 9B   Pumpkin, seed                     15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
11003100 11   Quince                            10.000000   1.000  1.000  mancoz
          Full comment: mancozeb
95003110 O    Quinoa, grain                      5.000000   1.000  1.000  glypho
          Full comment: glyphosate
29003120 M    Rabbit, meat                       2.000000   1.000  1.000  endosu
          Full comment: endosulfan
04013130 4A   Radicchio                        100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
01013140 1AB  Radish, roots                      5.000000   1.000  1.000  carbar
          Full comment: carbaryl
02003150 2    Radish, tops                      50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin (CG 2)
01013160 1AB  Radish, Oriental, roots            5.000000   1.000  1.000  carbar
          Full comment: carbaryl
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02003170 2    Radish, Oriental, tops              50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin (CG 2)
05023180 5B   Rape greens                         60.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 5)
20003190 20   Rapeseed, oil                       10.000000   1.000  1.000  glypho
          Full comment: glyphosate
20003191 20   Rapeseed, oil-babyfood              10.000000   1.000  1.000  glypho
          Full comment: glyphosate
13013200 13A  Raspberry                          40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
13013201 13A  Raspberry-babyfood                 40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
13013210 13A  Raspberry, juice                   40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
13013211 13A  Raspberry, juice-babyfood          40.000000   1.000  1.000  fosety
          Full comment: fosetyl-al (berries)
04023220 4B   Rhubarb                           100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
15003230 15   Rice, white                         10.000000   1.000  1.000  propan
          Full comment: propanil
15003231 15   Rice, white-babyfood                10.000000   1.000  1.000  propan
          Full comment: propanil
15003240 15   Rice, brown                         10.000000   1.000  1.000  propan
          Full comment: propanil
15003241 15   Rice, brown-babyfood                10.000000   1.000  1.000  propan
          Full comment: propanil
15003250 15   Rice, flour                         10.000000   1.000  1.000  propan
          Full comment: propanil
15003251 15   Rice, flour-babyfood                10.000000   1.000  1.000  propan
          Full comment: propanil
15003260 15   Rice, bran                          40.000000   1.000  1.000  propan
          Full comment: propanil
15003261 15   Rice, bran-babyfood                 40.000000   1.000  1.000  propan
          Full comment: propanil
01013270 1AB  Rutabaga                             5.000000   1.000  1.000  carbar
          Full comment: carbaryl
15003280 15   Rye, grain                           5.000000   1.000  1.000  mancoz
          Full comment: mancozeb
15003290 15   Rye, flour                           5.000000   1.000  1.000  mancoz
          Full comment: mancozeb
20003300 20   Safflower, oil                      85.000000   1.000  1.000  glypho
          Full comment: glyphosate
20003301 20   Safflower, oil-babyfood             85.000000   1.000  1.000  glypho
          Full comment: glyphosate
01013310 1AB  Salsify, roots                       5.000000   1.000  1.000  carbar
          Full comment: carbaryl
02003320 2    Salsify, tops                       50.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin (CG 2)
95003330 O    Sapote, Mamey                        2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
19013340 19A  Savory                             38.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [spice]
95003350 O    Seaweed                             60.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 5)
95003351 O    Seaweed-babyfood                    60.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 5)
95003360 O    Sesame, seed                         0.100000   1.000  1.000  glypho
          Full comment: glyphosate
95003361 O    Sesame, seed-babyfood                0.100000   1.000  1.000  glypho
          Full comment: glyphosate
95003370 O    Sesame, oil                          0.100000   1.000  1.000  glypho
          Full comment: glyphosate
95003371 O    Sesame, oil-babyfood                 0.100000   1.000  1.000  glypho
          Full comment: glyphosate
03003380 3    Shallot                              0.200000   1.000  1.000  pendim
          Full comment: pendimethalin
26003390 M    Sheep, meat                          2.000000   1.000  1.000  endosu
          Full comment: endosulfan
26003391 M    Sheep, meat-babyfood                 2.000000   1.000  1.000  endosu
          Full comment: endosulfan
26003400 M    Sheep, meat byproducts               5.000000   1.000  1.000  endosu
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          Full comment: endosulfan
26003410 M    Sheep, fat                          13.000000   1.000  1.000  endosu
          Full comment: endosulfan
26003411 M    Sheep, fat-babyfood                 13.000000   1.000  1.000  endosu
          Full comment: endosulfan
26003420 M    Sheep, kidney                        4.000000   1.000  1.000  glypho
          Full comment: glyphosate
26003430 M    Sheep, liver                         5.000000   1.000  1.000  glypho
          Full comment: glyphosate
15003440 15   Sorghum, grain                      15.000000   1.000  1.000  glypho
          Full comment: glyphosate
15003450 15   Sorghum, syrup                      15.000000   1.000  1.000  glypho
          Full comment: glyphosate
95003460 O    Soursop                              2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
06003470 6    Soybean, seed                       20.000000   1.000  1.000  glypho
          Full comment: glyphosate
06003480 6    Soybean, flour                       5.000000   1.000  1.000  carbar
          Full comment: carbaryl
06003481 6    Soybean, flour-babyfood              5.000000   1.000  1.000  carbar
          Full comment: carbaryl
06003490 6    Soybean, soy milk                    5.000000   1.000  1.000  carbar
          Full comment: carbaryl
06003491 6    Soybean, soy milk-babyfood or in     5.000000   1.000  1.000  carbar
          Full comment: carbaryl
06003500 6    Soybean, oil                         0.300000   1.000  1.000  bifent
          Full comment: bifenthrin
06003501 6    Soybean, oil-babyfood                0.300000   1.000  1.000  bifent
          Full comment: bifenthrin
95003510 O    Spanish lime                         3.000000   1.000  1.000  imidac
          Full comment: imidacloprid
95003520 O    Spearmint                          200.000000   1.000  1.000  glypho
          Full comment: glyphosate
95003530 O    Spearmint, oil                     200.000000   1.000  1.000  glypho
          Full comment: glyphosate
19023540 19B  Spices, other                       38.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [spice]
19023541 19B  Spices, other-babyfood              38.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin [spice]
04013550 4A   Spinach                            100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
04013551 4A   Spinach-babyfood                   100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
09023560 9B   Squash, summer                      15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
09023561 9B   Squash, summer-babyfood             15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
09023570 9B   Squash, winter                      15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
09023571 9B   Squash, winter-babyfood             15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
95003580 O    Starfruit                            2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
95003590 O    Strawberry                          75.000000   1.000  1.000  fosety
          Full comment: fosetyl-al
95003591 O    Strawberry-babyfood                 75.000000   1.000  1.000  fosety
          Full comment: fosetyl-al
95003600 O    Strawberry, juice                   75.000000   1.000  1.000  fosety
          Full comment: fosetyl-al
95003601 O    Strawberry, juice-babyfood          75.000000   1.000  1.000  fosety
          Full comment: fosetyl-al
95003610 O    Sugar apple                          2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
95003620 O    Sugarcane, sugar                     2.000000   1.000  1.000  glypho
          Full comment: glyphosate;2,4-D
95003621 O    Sugarcane, sugar-babyfood            2.000000   1.000  1.000  glypho
          Full comment: glyphosate;2,4-D
95003630 O    Sugarcane, molasses                 30.000000   1.000  1.000  glypho
          Full comment: glyphosate
95003631 O    Sugarcane, molasses-babyfood        30.000000   1.000  1.000  glypho
          Full comment: glyphosate
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20003640 20   Sunflower, seed                    2.500000   1.000  1.000  alachl
          Full comment: alachlor
20003650 20   Sunflower, oil                     0.300000   1.000  1.000  lambda
          Full comment: lambda-cyhalothrin
20003651 20   Sunflower, oil-babyfood            0.300000   1.000  1.000  lambda
          Full comment: lambda-cyhalothrin
01033660 1CD  Sweet potato                      10.000000   1.000  1.000  phosme
          Full comment: phosmet
01033661 1CD  Sweet potato-babyfood            10.000000   1.000  1.000  phosme
          Full comment: phosmet
04023670 4B   Swiss chard                     100.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 4)
95003680 O    Tamarind                           2.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
10003690 10   Tangerine                         10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
10003700 10   Tangerine, juice                  10.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin ( citrus CG)
01033710 1CD  Tanier, corm                       1.000000   1.000  1.000  diuron
          Full comment: diuron [potato transl]
95003720 O    Tea, dried                        10.000000   1.000  1.000  propar
          Full comment: propargite
95003730 O    Tea, instant                       7.000000   1.000  1.000  glypho
          Full comment: glyphosate
08003740 8    Tomatillo                         10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08003750 8    Tomato                            10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08003751 8    Tomato-babyfood                   10.000000   1.000  1.000  carbar
          Full comment: carbaryl
08003760 8    Tomato, paste                      6.000000   1.000  1.000  imidac
          Full comment: imidacloprid
08003761 8    Tomato, paste-babyfood             6.000000   1.000  1.000  imidac
          Full comment: imidacloprid
08003770 8    Tomato, puree                      3.000000   1.000  1.000  imidac
          Full comment: imidacloprid
08003771 8    Tomato, puree-babyfood             3.000000   1.000  1.000  imidac
          Full comment: imidacloprid
08003780 8    Tomato, dried                     10.000000  14.300  1.000  carbar
          Full comment: carbaryl
08003781 8    Tomato, dried-babyfood            10.000000  14.300  1.000  carbar
          Full comment: carbaryl
08003790 8    Tomato, juice                     10.000000   1.000  1.000  carbar
          Full comment: carbaryl
95003800 O    Tomato, Tree                      10.000000   1.000  1.000  carbar
          Full comment: carbaryl [tomato]
15003810 15   Triticale, flour                   5.000000   1.000  1.000  glypho
          Full comment: glyphosate [wheat transl]
15003811 15   Triticale, flour-babyfood          5.000000   1.000  1.000  glypho
          Full comment: glyphosate [wheat transl]
50003820 P    Turkey, meat                       5.000000   1.000  1.000  carbar
          Full comment: carbaryl
50003821 P    Turkey, meat-babyfood              5.000000   1.000  1.000  carbar
          Full comment: carbaryl
50003830 P    Turkey, liver                      5.000000   1.000  1.000  iprodi
          Full comment: iprodione
50003831 P    Turkey, liver-babyfood             5.000000   1.000  1.000  iprodi
          Full comment: iprodione
50003840 P    Turkey, meat byproducts            1.000000   1.000  1.000  glypho
          Full comment: glyphosate
50003841 P    Turkey, meat byproducts-babyfood   1.000000   1.000  1.000  glypho
          Full comment: glyphosate
50003850 P    Turkey, fat                        5.000000   1.000  1.000  carbar
          Full comment: carbaryl
50003851 P    Turkey, fat-babyfood               5.000000   1.000  1.000  carbar
          Full comment: carbaryl
50003860 P    Turkey, skin                       5.000000   1.000  1.000  carbar
          Full comment: carbaryl
50003861 P    Turkey, skin-babyfood              5.000000   1.000  1.000  carbar
          Full comment: carbaryl
01033870 1CD  Turmeric                          1.000000   1.000  1.000  diuron
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          Full comment: diuron [potato transl]
05023890 5B   Turnip, greens                    60.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (CG 5)
01013880 1AB  Turnip, roots                     15.000000   1.000  1.000  fosety
          Full comment: fosetyl-al
95003900 O    Vinegar                           25.000000   1.000  1.000  captan
          Full comment: captan [apple]
14003910 14   Walnut                             1.000000   1.000  1.000  glypho
          Full comment: glyphosate (tree nut)
86010000 O    Water, direct, all sources         0.100000   1.000  1.000  defaul
          Full comment: default 100 ppb
86020000 O    Water, indirect, all sources       0.100000   1.000  1.000  defaul
          Full comment: default 100 ppb
95003970 O    Water chestnut                     1.000000   1.000  1.000  carbar
          Full comment: carbaryl [pecan]
95003980 O    Watercress                         6.000000   1.000  1.000  methom
          Full comment: methomyl
09013990 9A   Watermelon                        15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
09014000 9A   Watermelon, juice                 15.000000   1.000  1.000  fosety
          Full comment: fosetyl-Al (curcurbits)
15004010 15   Wheat, grain                       5.000000   1.000  1.000  glypho
          Full comment: glyphosate
15004011 15   Wheat, grain-babyfood              5.000000   1.000  1.000  glypho
          Full comment: glyphosate
15004020 15   Wheat, flour                       5.000000   1.000  1.000  glypho
          Full comment: glyphosate
15004021 15   Wheat, flour-babyfood              5.000000   1.000  1.000  glypho
          Full comment: glyphosate
15004030 15   Wheat, germ                        5.000000   1.000  1.000  glypho
          Full comment: glyphosate
15004040 15   Wheat, bran                       20.000000   1.000  1.000  glypho
          Full comment: glyphosate
15004050 15   Wild rice                          5.000000   1.000  1.000  azoxys
          Full comment: azoxystrobin
01034060 1CD  Yam, true                         10.000000   1.000  1.000  phosme
          Full comment: phosmet
01034070 1CD  Yam bean                          10.000000   1.000  1.000  phosme
          Full comment: phosmet
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