RALLIS AGROCHEMICAL RESEARCH STATION
Peenya, II Phase, Bangalore-560 058

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS

TEST COMPOUND : GLYPHOSATE TECHNICAL
(FSG 03090 H/05 MARCH 1990)

STUDY No. TOXI:890-MUT-CH.AB.

SPONSORED BY

M/s FEINCHEMIE SCHWEBDA GmbH.,
BAHNHOF-2, D-3446, MEINHARD-SCHWEBDA,
GERMANY.

REPORT PREPARED BY

RALLIS INDIA LIMITED
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DATE: 22-01-1994

REPORT CONTENTS **PAGE**

REPORT CONTENTS CONTINUED

LIST OF TABLES

LIST OF APPENDICES

RALLIS AGROCHEMICAL RESEARCH STATION
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QUALITY ASSURANCE STATEMENT

To the best of my knowledge the Study No.TOXI: 890-MUT-CH.AB has been conducted in compliance with Good Laboratory Practice Regulations with accurate reflection of supportive raw data. Dates of Inspection: 11-01-1993, 26-01-1993, 27-01-1993, 7-02-1993, 8-02-1993 and 27-07-1993.

Date: 20.1.1994

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SCIENTIFIC STATEMENT

To the best of my knowledge the Study No.TOXI: 890-MUT-CH.AB was conducted in compliance with Good Laboratory Practice Regulations and this report represents true and accurate record of the results obtained and interpretation.

Date: 19/01/1994

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Study Director and
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MANAGEMENT STATEMENT

This is to certify that Study No. TOXI: 890-MUT-CH.AB Genetic Toxicology - In Vivo Mammalian Bone Marrow Cytogenetic Test - Chromosomal analysis sponsored by M/s Feinchemie Schwebda GmbH., Bahnhof 2, D-3446, Meinhard Schwebda, Germany was carried out at the Toxicology Department of Rallis Agrochemical Research Station, Bangalore-560058 in compliance with Good Laboratory Practice Regulations and mutually agreed protocol.

Date: 26/01/1994

[redacted]
General Manager Research (AGRO)
Rallis Agrochemical Research Station
Plot Nos. 21 & 22, Post Box No. 5813
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INDIA

STUDY DETAILS

TITLE : GENETIC TOXICOLOGY-IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS.

TEST COMPOUND : GLYPHOSATE TECHNICAL

STUDY NUMBER : TOXI:890-MUT-CH.AB

STUDY DIRECTOR :

SPONSOR : M/s FEINCHEMIE SCHWEBDA GmbH., BAHNHOF 2, D-3446 MEINHARD SCHWEBDA, GERMANY.

MONITORING SCIENTIST :

NOMINEE :

BAHNHOF 2, D-3446, MEINHARD SCHWEBDA GERMANY.

TEST FACILITY : TOXICOLOGY DEPARTMENT,
RALLIS INDIA LIMITED,
RALLIS AGROCHEMICAL RESEARCH STATION,
POST BOX No. 5813, PLOT NOS. 21 & 22,
PEENYA II PHASE, BANGALORE 560058,
INDIA.

STUDY PERIOD : START : 11-01-1993
END : 09-02-1993

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PROJECT STAFF		SIGNATURE
STUDY DIRECTOR	:	19/01/1994
TECHNICAL COORDINATOR	:	19/1/94.
COORDINATOR	:	19/1/94
STUDY VETERINARIAN	:	19/1/94
aa DOCUMENTATION AND DATA ANALYSIS	:	19/1/94

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GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS WITH GLYPHOSATE TECHNICAL

SUMMARY

The genotoxic effect of Glyphosate technical manufactured by M/s Epic Schwebda Chemicals Pvt. Ltd., 514 Persipolis, Vashi, New Bombay - 400 705, INDIA. and supplied by M/s Feinchemie Schwebda GmbH., Bahnhof 2, D-3446, Meinhard Schwebda, GERMANY was studied using chromosomal aberration test in bone marrow cells of Swiss albino mice.

The test compound, suspended in refined groundnut oil was administered as gavage to 4 groups (G1 , G3 , G4 and G5) of young Swiss albino mice at the dosages of 0 (vehicle control), 50 (low dose), 500 (mid dose) and 5000 (high dose /limit dose) mg/kg body weight (Bwt) for two consecutive days. Another group (G2) was treated with a positive control substance -Cyclophosphamide at 50 mg/kg Bwt. Twenty four hours after the second dose each animal was injected intraperitoneally with a spindle inhibitor - Colchicine (0.04 % solution ; 10 mL/kg Bwt) and sacrificed 90 minutes later. The femur bone marrow was flushed out with 0.56 % KCl for hypotonic treatment for 15 minutes and centrifuged at 1500 rpm for 5 minutes. Slides were prepared from the cell suspension after fixation in methanol and glacial acetic acid (3:1) mixture and stained with 2 % Giemsa stain.

The slides were screened for 50 analyzable metaphases per animal and scored for aberrations such as chromatid and chromosome types of gaps, breaks, acentric fragments , ring chromosomes, multiple chromatid breaks, pulverization, polyploidy, exchange figures and total number of cells with aberrations including gaps and excluding gaps. For the calculation of mitotic index the number of metaphases per hundred blast cells per slide were counted. In this study the low and mid dose treatment effects were not evaluated as the high dose treatment effect was not significantly different from the control value.

The data were statistically analyzed using 'Z' test for the incidence of aberrations and the number of metaphases with aberrations for the intergroup comparison with control group . The results indicate that Glyphosate technical causes :

1) at the highest dose tested (5000 mg/kg Bwt.) mild pharmacotoxic symptoms in few animals and a significant reduction in the body weight in females.
2) no significant change in the number of metaphases and incidence of individual aberrations (except for a significant increase in the incidence of gaps in females) in both males and females at high dose and
3) a significant reduction in the mitotic index in males,females and for combined sex at high dose.

Cyclophosphamide positive control signifcantly increased the number of metaphases and incidence of individual aberrations scored both in males and females and for combined sex. There was also a significant reduction in the mitotic index in females and for combined sex.

Thus the study performed to find out if Glyphosate technical induces chromosomal aberrations in Swiss albino mice has indicated that the test compound is not mutagenic in Swiss albino mice by in vivo chromosomal aberration test upto 5000 mg/kg Bwt under the testing conditions adopted. At the tested dose it caused a significant reduction in the mitotic index indicative of toxicity to test animal.

Date: 19/01/1994

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GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST -CHROMOSOMAL ANALYSIS WITH GLYPHOSATE TECHNICAL

INTRODUCTION

Mutagenicity is the property of the test compound that causes structural chromosomal aberrations in the mitotically active tissue. In vivo chromosomal analysis and mitotic index of bone marrow cells is to assess the mutagenic profile of the test compound when administered to a test species. The study of cells obtained from mitotically active tissue such as the bone marrow offers a convenient and sensitive system for the investigation of chemical induced chromosome damage. This study will provide rational basis for risk assessment in man.

The study was conducted as per OECD guidelines for testing of chemicals, Section 4, No. 475 "Genetic Toxicology - in vivo Mammalian Bone Marrow Cytogenetic test, Chromosomal Analysis" adopted from 4th April 1984, in compliance with Good Laboratory Practice Regulations / Standards and mutually agreed protocol.

MATERIALS AND METHODS

TEST SYSTEM	: Swiss Albino Mice
SOURCE	: Bred at Toxicology Department, Rallis Agrochemical Research Station, Bangalore - 560 058, INDIA.
NUMBER OF GROUPS*	: 5 - 1 vehicle control 1 positive control and 3 treatment groups.
NUMBER OF ANIMALS PER GROUP	: 10 mice (5 males + 5 females)/group
AGE AT THE START OF STUDY	: 10 - 12 weeks
BODY WEIGHT AT START OF STUDY	: Males : 32 to 38 g. Females : 28 to 32 g.
IDENTIFICATION	: By unique animal number and cage cards.
ACCLIMATIZATION	: At least one week under experimental conditions after veterinary examination.
RANDOMIZATION	: Animals randomly assigned to 5 treatment groups after acclimatization and veterinary examination.

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*: Vehicle control and positive control groups were common with other studies conducted during the period.

GROUPING

TEST GROUP	DOSE LEVEL# (mg/kg) TEST MATERIAL		NUMBER OF ANIMALS		ANIMAL NUMBERS FROM	TO	DOSE VOLUME mL/kg
G1*	0	Vehicle control	M	5	M 691	-M 695	10
			F	5	M 696	-M 700	
G2*	50	Endoxan @	M	5	M 701	-M 705	10
			F	5	M 706	-M 710	
G3	50	ES-GPT	M	5	M 711	-M 715	10
			F	5	M 716	-M 720	
G4	500	ES-GPT	M	5	M 721	-M 725	10
			F	5	M 726	-M 730	
G5	5000	ES-GPT	M	5	M 731	-M 735	15
			F	5	M 736	-M 740	

* : Common for a group of studies; M: Male ; F: Female
\# : These doses were selected after the dose range study.
@ : Positive control - Endoxan-ASTA (Cyclophosphamide, M/s Khandelwal Lab, Bombay in collaboration with ASTA-WERKE A.G, Germany)

DOSE RANGE STUDY : The range finding study was done using doses of 2000 and 3000 mg/kg Bwt.in 2 M + 2 F. There was no effect on body weight and pharmacotoxic symptoms.

The maximum tolerable dose (MTD) was > 3000 mg/kg Bwt. Hence for the final study the dosages of 50, 500 and 5000 mg/kg Bwts. were chosen.

HUSBANDRY

ROOM NUMBER : Toxicology Laboratory Room - A 6

CONDITIONS : Standard Laboratory Conditions with temperature 22 ± 3 degrees Celsius, relative humidity 40 - 70 % ; natural light supplemented with fluorescent light - 12 hours light/ dark cycle.

ACCOMMODATION : Housed in standard polypropylene mice cages (size L 290 x H 220 x W 140 mm) with stainless steel top grill having facilities for feed and drinking water in glass bottles. Clean paddy husk bedding changed thrice a week.

Pre-treatment period-in groups of five mice of same sex.
Treatment period - individually in mice cages.

FEED : Maintained on ad libitum pelletted mice feed (Gold Mohur brand, manufactured by M/s Lipton India Ltd., Bangalore, a subsidiary of Unilever of England). Declared mice feed composition enclosed as Appendix 5, analysis report of mice feed enclosed as Appendix 6 and Contaminant analysis report - mice feed as Appendix 7.

WATER : Deep borewell water, passed through activated charcoal filter and exposed to UV rays in Aquaguard on-line water filter-cum-purifier (manufactured by M/s Eureka Forbes Ltd., Bombay in collaboration with Electrolux of Sweden) is provided in glass bottles, ad libitum. Analysis report of water sample is enclosed as Appendix 8 and a report of chemical contaminants analysis in water is given as Appendix 9.

TEST COMPOUND

COMMON NAME : Glyphosate

CHEMICAL NAME : N-(Phosphomethyl) glycine

CAS No. : 1071-83-6

CODE : FSG 03090 H/05, MARCH 1990

MANUFACTURED BY : M/s Epic Schwebda Chemicals Pvt. Ltd.
514 Persipolis, Vashi,
New Bombay - 400 705
INDIA.

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Peenya, II Phase, Bangalore-560 058.

SUPPLIED BY	: M/s Feinchemie Schwebda GmbH., Bahnhof 2, D-3446, Meinhard Schwebda GERMANY.
BATCH NUMBER	: 046
DATE OF MANUFACTURE	: AUGUST 1990
DATE OF RECEIPT at RARS	: FEBRUARY 22, 1992.
DATE OF EXPIRY	: JULY 1994
PURITY (DECLARED)	: 96.8 %
DESCRIPTION	: Odourless, white crystals
DECLARED STABILITY	: More than 2 yrs. at ambient temperature
SOLUBILITY	: Not soluble in water
PACKING	: Packed in plastic drums
STORAGE CONDITIONS	: Stored at ambient temperature in its original container in our laboratory.
TEST COMPOUND ANALYSIS CERTIFICATE	: Appendix 10

SPINDLE INHIBITOR

COMMON NAME	: COLCHICINE
CHEMICAL NAME	: $C_{22}\ H_{25}\ NO_6$
LOT No.	: 2910
MANUFACTURED BY	: Loba Chemie P.B No. 2042 Bombay-400 002, India.
BATCH NUMBER	: 25809-A
DATE OF RECEIPT at RARS	: 22-10-1992
PURITY (DECLARED)	: 98.5 %

DESCRIPTION : Pale yellow amorphous powder.

PACKING : Packed in white bottle.

STORAGE CONDITIONS : Stored at (2-8 degrees Celsius) in its original container

VEHICLE

COMMON NAME : Postman brand refined groundnut (peanut) oil

PHYSICAL PROPERTY : Clear, odorless

MANUFACTURED BY : Faruk Anwar Co.
Raichur, Karnataka, India
Under license from Ahmed Mills
Bombay 400 008, INDIA

BATCH No. : L-26

DATE OF MANUFACTURE : November 1992

STORAGE : Stored in its original container at room temperature.

TEST COMPOUND PREPARATION : Just prior to treatment known amounts of the test compound were weighed, ground using mortar and pestle and suspended in known volumes of refined groundnut oil to get concentrations of 50 and 500 mg in 10 mL and 5000 mg in 15 mL of the vehicle. Gavage solution thus prepared were analyzed for a.i. concentration of the test compound. The actual concentrations were :

5.1 mg/mL
51.5 mg/mL
334.0 mg/mL

Gavage suspension was administered at 10 mL/kg body weight for low and mid doses and 15 mL/kg Bwt. for high dose. Homogeneity of the test compound suspension was maintained by constant stirring/mixing in mortar during treatment.

TREATMENT

ROUTE OF ADMINISTRATION	: Oral, as gavage
NUMBER OF TREATMENTS	: 2 : One daily for two consecutive days.
METHOD	: The test compound was administered daily for two consecutive days. Twenty four hours after the second dose each animal was injected intraperitoneally with 10 mL/kg Bwt of 0.04 % solution of Colchicine. The animals were sacrificed 90 minutes later to obtain cell suspension from the femur bone marrow.

OBSERVATIONS

1. **PHARMACOTOXIC SYMPTOMS AND MORTALITY** : Twice a day. Dead animals if any were immediately necropsied.

2. **BODY WEIGHT** : Daily -on treatment day one, two and at sacrifice.

3. **NECROPSY AND BONE MARROW SLIDE PREPARATION**

i) Animals were sacrificed by cervical dislocation.

ii) Femur bones from both sides were removed after clearing the musculature.

iii) The femur heads were trimmed to expose marrow canal.

iv) The bone marrow from the shaft of femur was flushed with 0.56 % KCl solution and collected in a centrifuge tube.

v) Hypotonic treatment : Cell suspension was incubated at 37 degrees Celsius for 15 minutes and centrifuged at 1500 rpm. Supernatant was discarded and the cell button dispersed.

vi) Fixation : was achieved by the dropwise addition of freshly prepared cold methanol and glacial acetic acid (3:1) fixative with two changes of 10 minutes each. The third change was for one hour in the refrigerator. The fixative was changed for the last time just prior to slide preparation.

vii) Slide preparation : The cell suspension was dropped onto a clean chilled slide and flame dried. The slides were coded immediately after.

viii) Staining : The slides were stained 24 hours after preparation with 2 % Giemsa in phosphate buffer (pH 6.8) for 10 minutes, rinsed in distilled water, blow dried, immersed in xylene and cover slip mounted with DPX.

4. MICROSCOPIC ANALYSIS OF METAPHASES:

A. The frequency of mitotic divisions (mitotic index) was estimated by counting the number of metaphase plates per 100 blast cells per slide.

B. Slides were screened for 50 analyzable metaphases per animal and scored for aberrations classified as chromatid or chromosome gaps, breaks, acentric fragments, ring chromosomes, multiple chromatid breaks, pulverization, polyploidy and exchange figures. For drawing conclusion gaps were not considered as true aberrations though for statistical analysis total aberrations with and without gaps have been carried out.

STATISTICAL ANALYSIS

The intra group body weight changes during the treatment period were compared by Paired 't' test.

The data from the positive control and the treatment groups were statistically compared with the control group for individual and combined sex for by 'Z' test for the following observations:

i) chromatid/chromosome gaps
ii) chromatid/chromosome breaks
iii) acentric fragments
iv) ring chromosomes
v) multiple chromatid breaks
vi) pulverization
vii) polyploidy
viii) exchange figures

ix) Total no. of metaphases with one or more aberrations

a) including gaps

b) excluding gaps

x) Mitotic Index (%)

The statistical significance is designated with a superscript as follows :

+/- : Significantly higher (+) / lower (-) than the control group value at ($P \leq 0.05$).

ARCHIVING

The protocol, stained slides, raw data, draft and final reports are stored in the Archives of Rallis Agrochemical Research Station, Peenya II Phase, Bangalore 560 058, INDIA.

RESULTS AND DISCUSSION

A. A brief outline of the Experimental layout and treatment schedule is presented in Table 1.

B. **INDIVIDUAL BODY WEIGHT, PHARMACOTOXIC SYMPTOMS, MORTALITY AND NECROPSY FINDINGS** Tables 2 & 3; Appendix 1

At high dose (5000 mg/kg Bwt.) there was significant ($P \leq 0.05$) decrease in the body weight of females. There were no treatment related pharmacotoxic symptoms and necropsy findings in the treatment groups except for two males in the high dose group which were dull and had soft stool and one animal in the positive control group with petechial haemorrhage in the lungs.

C **MICROSCOPIC ANALYSIS OF METAPHASES** ; Tables 4 & 5 Appendices 2-4.

1. Vehicle Control group: In males 12 metaphases out of 250 analyzed showed aberrations such as chromatid breaks (6), acentric fragments (4) and ring chromosomes (2). There were also 5 metaphases with chromatid gaps and 1 with chromosome gap.

   In females 10 metaphases out of 250 evaluated had only chromatid breaks and 5 metaphases had chromatid gap.

   In combined sex totally 22 out of 500 metaphases showed aberrations such as chromatid break (16), acentric fragment (4) and ring chromosomes (2).

   There were 10 metaphases with chromatid gap.

2. Treatment group: At the highest dose (5000 mg/kg Bwt.) tested the incidence of individual aberrations (except for a significant increase in the incidence of gaps in females) and the total number of metaphases with aberrations both in males and females and for combined sex did not differ significantly from the control value. In both males and females there was one incidence each of chromosome exchange figure, however this incidence is not statistically significant as compared to the control group. The mitotic index in this group was significantly lowered as compared to the controls indicating the toxicity of the test compound at this dosage.

3. Positive control group: The total number of metaphases with aberrations and the incidence of various types of aberrations were significantly high in males, females and for combined sex as compared to the controls. Majority of the metaphases showed aberrations such as chromatid breaks, pulverization and chromosome exchange figures. The mitotic index in females and for combined sex was also significantly less as compared to the controls.

CONCLUSIONS

A study was performed to test the mutagenic potency, if any, of Glyphosate technical by in vivo chromosomal aberration test in Swiss albino mice. The test compound was suspended in refined groundnut oil and administered as a gavage for two consecutive days at doses of 0 (vehicle control), 50 (low dose), 500 (mid dose) and 5000 (high dose) mg/kg Bwt. A positive control group (Cyclophosphamide, 50 mg/kg Bwt. on two consecutive days) was also included in the study. Each study group had 5 males and 5 females. The treated groups were sacrificed 24 hours (after treating with colchicine, 0.04 % solution, 10 mL/kg Bwt. i.p., 90 minutes before sacrifice) after the second treatment. Chromosomal preparations were made from the femoral bone marrow cells and 50 scorable metaphases were scored for aberrations like chromatid or chromosome gaps, breaks, acentric fragments, ring chromosomes, multiple chromatid breaks, pulverization, polyploidy and exchange figures. Mitotic index was calculated. The data was statistically analyzed by 'Z' test.

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The study has shown that Glyphosate technical is not mutagenic in Swiss albino mice upto the dose of 5000 mg/kg Bwt. under the test conditions adopted.

Date: 19/01/94

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REFERENCES

1. Adler .I.D. 1984., Cytogenetics test in mammals. In: Mutagenicity testing - A Practical Approach. Ed. S.Venitt and J.M. Parry, IRL Press, Oxford, Washington D.C pp 275-306.
2. Bartlett, M.S.1937.,J Royal Statist Soc.Suppl., 4:137-170.
3. Scheffe, H. 1953., Biometrika 40:87-104.
4. Snedecor,B.W and Cochran, W.G. 1980.,Statistical Methods. Iowa State University Press, Ames, Iowa , USA.

TABLE 1

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST-CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

DETAILS OF EXPERIMENTAL LAYOUT AND TREATMENT SCHEDULE

Dosage: mg/kg body weight Route: Oral

Group	Dose	Chemical	No. of animals		Duration of Treatment (2 consecutive days)	Sacrifice 24 hrs. after II dose
			M	F		
G1	0	Vehicle control	5	5	+	+
G2 control	50	Positive	5	5	+	+
G3	50	ES-GPT	5	5	+	+
G4	500	ES-GPT	5	5	+	+
G5	5000	ES-GPT	5	5	+	+

+: Yes ; M: Male ; F: Female;

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TABLE 2

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

SUMMARY OF BODY WEIGHTS, PHARMACOTOXIC SYMPTOMS AND NECROPSY FINDINGS SEX-WISE

DOSAGE : mg/kg Bwt. VALUES : MEAN ± SD Ref. App. 1

GROUP & DOSE	SEX	BODY WEIGHTS (g) ON DAY 1	DAY 2	DAY 3	PHARMACOTOXIC SYMPTOMS	NECROPSY FINDINGS
G1 (0)	M	35.2 2.04	35.6 1.49	36.0 1.79	NAD	NAD
	F	28.8 0.98	29.2 0.98	26.8 1.60	NAD	NAD
G2@ (50)	M	36.8 1.60	36.8 1.60	35.4 2.30	NAD	Lungs-petechiae (1)
	F	29.6 1.49	29.6 1.49	29.2 1.60	NAD	NAD
G3 (50)	M	36.0 1.26	35.6 0.80	35.2 1.60	NAD	NAD
	F	28.4 0.80	27.6 1.96	26.4 1.96	NAD	NAD
G4 (500)	M	34.8 1.60	34.0 1.79	32.3 2.13	NAD	NAD
	F	29.6 0.80	28.8 0.98	29.2 0.98	NAD	NAD
G5 (5000)	M	34.8 1.60	36.0 1.26	35.2 1.60	Dull,loose stool (2)	NAD
	F	30.8 0.98	28.8 1.60	26.8 0.98	NAD	NAD

- :Significantly less than control by Paired 't' test.
@ :Positive control ; NAD : No Abnormality Detected

TABLE 3

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

SUMMARY OF BODY WEIGHTS, PHARMACOTOXIC SYMPTOMS AND NECROPSY FINDINGS
COMBINED SEX

DOSAGE : mg/kg Bwt. VALUES : MEAN ± SD Ref. App. 1

GROUP & DOSE	BODY WEIGHTS (g) ON DAY 1	DAY 2	DAY 3	PHARMACOTOXIC SYMPTOMS	NECROPSY FINDINGS
G1 (0)	32.0 3.80	32.4 3.60	31.4 5.20	NAD	NAD
G2@ (50)	33.2 4.13	33.2 4.13	32.4 3.90	NAD	Lungs-petechiae (1)
G3 (50)	32.2 4.20	31.6 4.50	30.8 5.00	NAD	NAD
G4 (500)	32.2 3.00	31.4 3.10	31.0 2.50	NAD	NAD
G5 (5000)	32.8 2.50	32.4 4.10	31.0 4.60	Dull, loose stool (2)	NAD

- :Significantly less than control by Paired 't' test.
@ :Positive control ; NAD : No Abnormality Detected

TABLE 4

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

SUMMARY OF CHROMOSOMAL ABERRATIONS (SEX-WISE)

Dosage: mg/kg Bwt — Route: Oral

Group (Dose)	No. of Animals	SEX	No.of MPs scored	No. of metaphases with aberrations: Gaps Ct	Gaps Cs	Breaks Ct	Breaks Cs	Acentric fragments	Ring Chromosomes	Multiple chromatid breaks	Pulverisation	Polyploidy	Exchange figures Ct	Exchange figures Cs	Total no.of MPs with aberrations Incl. gaps	Total no.of MPs with aberrations Excl. gaps	MITOTIC INDEX (%)
G1 (0)	5	M	250	5	1	6	0	4	2	0	0	0	0	0	18	12	13.34
	5	F	250	5	0	10	0	0	0	0	0	0	0	0	15	10	17.42
G2 @ (50)	5	M	251	19+	6	68+	14+	15+	11+	6+	87+	2	0	24+	164+	139+	14.68
	5	F	250	14+	2	103+	13+	16+	6+	14+	60+	0	0	20+	171+	155+	5.53 -
G5 (5000)	5	M	250	5	0	6	0	5	1	0	0	1	0	1	15	10	8.87 -
	5	F	250	16+	0	6	0	3	2	0	0	1	0	1	27	11	9.54

MP: Metaphase plate; Ct: Chromatid; Cs: Chromosome; @: Positive control;
*: Metaphase plates with one or more than one aberrations was considered as one Metaphase plate with aberrations;
Mitotic index = Number of Metaphase plates per 100 Blast cells;
+: Significantly higher than control by 'Z' test.

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TABLE 5

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

SUMMARY OF CHROMOSOMAL ABERRATIONS (COMBINED SEX)

Dosage: mg/kg Bwt

Route: Oral

Group (Dose)	No. of Animals	No.of MPs scored	No. of metaphases with aberrations: Gaps Ct	Gaps Cs	Breaks Ct	Breaks Cs	Acentric fragments	Ring Chromosomes	Multiple chromatid breaks	Pulverisation	Polyploidy	Exchange figures Ct	Exchange figures Cs	Total no.of MPs with aberrations* Incl. gaps	Total no.of MPs with aberrations* Excl. gaps	MITOTIC INDEX (%)
G1 (0)	10	500	10	1	16	0	4	2	0	0	0	0	0	33	22	15.3
G2 @ (50)	10	501	33+	8+	171+	27+	31+	17+	20+	147+	2	0	44+	335+	294+	10.1-
G5 (5000)	10	500	21+	0	12	0	8	3	0	0	2	0	2	42	21	9.2-

MP: Metaphase plate; Ct: Chromatid; Cs: Chromosome; @: Positive control;
*: Metaphase plates with one or more than one aberrations was considered as one Metaphase plate with aberrations;
Mitotic index = Number of Metaphase plates per 100 Blast cells;
+: Significantly higher than control by 'Z' test.

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APPENDIX 1

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST-CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL BODY WEIGHT, PHARMACOTOXIC SYMPTOMS AND NECROPSY FINDINGS

Dosage : mg/kg body weight

Group (Dose)	Sl. No.	ANIMAL No.	SEX	BODY WEIGHT (g)-Day 1	2	3	PHAR. SYMP.	NECROPSY FINDINGS
G1 (0)	1.	M691	M	32	34	34	NAD	NAD
	2.	M692	M	38	38	38	NAD	NAD
	3.	M693	M	36	36	38	NAD	NAD
	4.	M694	M	36	36	36	NAD	NAD
	5.	M695	M	34	34	34	NAD	NAD
	6.	M696	F	30	30	28	NAD	NAD
	7.	M697	F	28	28	26	NAD	NAD
	8.	M698	F	28	28	24	NAD	NAD
	9.	M699	F	30	30	28	NAD	NAD
	10.	M700	F	28	30	28	NAD	NAD
G2 @ (50)	1.	M701	M	38	38	38	NAD	NAD
	2.	M702	M	36	36	34	NAD	NAD
	3.	M703	M	38	38	36	NAD	Lungs-petechiae
	4.	M704	M	38	38	38	NAD	NAD
	5.	M705	M	34	34	32	NAD	NAD
	6.	M706	F	32	32	32	NAD	NAD
	7.	M707	F	28	28	28	NAD	NAD
	8.	M708	F	30	30	30	NAD	NAD
	9.	M709	F	30	30	28	NAD	NAD
	10.	M710	F	28	28	28	NAD	NAD
G3 (50)	1.	M711	M	36	36	36	NAD	NAD
	2.	M712	M	34	34	32	NAD	NAD
	3.	M713	M	36	36	36	NAD	NAD
	4.	M714	M	38	36	36	NAD	NAD
	5.	M715	M	36	36	36	NAD	NAD
	6.	M716	F	30	30	30	NAD	NAD
	7.	M717	F	28	28	26	NAD	NAD
	8.	M718	F	28	28	24	NAD	NAD
	9.	M719	F	28	28	26	NAD	NAD
	10.	M720	F	28	28	26	NAD	NAD

NAD: No Abnormality Detected; M: Male; F: Female; @:Positive control

Contd ...

APPENDIX 1 Contd.

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST-CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL BODY WEIGHT, PHARMACOTOXIC SYMPTOMS AND NECROPSY FINDINGS

Dosage : mg/kg body weight

Group (Dose)	Sl. No.	ANIMAL No.	SEX	BODY WEIGHT (g)-Day 1	2	3	PHAR. SYMP.	NECROPSY FINDINGS
G4 (500)	1.	M721	M	34	32	32	NAD	NAD
	2.	M722	M	36	36	36	NAD	NAD
	3.	M723	M	36	32	30	NAD	NAD
	4.	M724	M	36	36	34	NAD	NAD
	5.	M725	M	32	34	32	NAD	NAD
	6.	M726	F	30	30	28	NAD	NAD
	7.	M727	F	28	28	28	NAD	NAD
	8.	M728	F	30	28	30	NAD	NAD
	9.	M729	F	30	30	30	NAD	NAD
	10.	M730	F	30	28	30	NAD	NAD
G5 (5000)	1.	M731	M	34	36	34	NAD	NAD
	2.	M732	M	34	36	34	NAD	NAD
	3.	M733	M	34	36	36	Dull, loose stools	NAD
	4.	M734	M	38	38	38	Dull, loose stools	NAD
	5.	M735	M	34	34	34	NAD	NAD
	6.	M736	F	30	28	26	NAD	NAD
	7.	M737	F	30	28	28	NAD	NAD
	8.	M738	F	30	28	26	NAD	NAD
	9.	M739	F	32	32	26	NAD	NAD
	10.	M740	F	32	28	28	NAD	NAD

NAD: No Abnormality Detected; M: Male; F: Female;

APPENDIX 2

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA

Group : G1 Dose : 0 mg/kg - (Vehicle control) Route : Oral

Sl. No.	Animal No.	SEX	No.of MPs scored	No. of metaphases with aberrations: Gaps Ct	Gaps Cs	Breaks Ct	Breaks Cs	Acentric fragments	Ring Chromosomes	Multiple chromatid breaks	Pulverisation	Polyploidy	Exchange figures Ct	Exchange figures Cs	Total no.of MPs with aberrations* Incl. gaps	Total no.of MPs with aberrations* Excl. gaps	MITOTIC INDEX MP	MITOTIC INDEX BC
1	M691	M	50	2	0	0	0	1	0	0	0	0	0	0	3	1	76	515
2	M692	M	50	0	0	1	0	1	1	0	0	0	0	0	3	3	76	483
3	M693	M	50	1	0	0	0	0	0	0	0	0	0	0	1	0	59	575
4	M694	M	50	0	1	1	0	1	1	0	0	0	0	0	4	3	55	474
5	M695	M	50	2	0	4	0	1	0	0	0	0	0	0	7	5	70	471
6	M696	F	50	1	0	0	0	0	0	0	0	0	0	0	1	0	68	444
7	M697	F	50	0	0	3	0	0	0	0	0	0	0	0	3	3	80	449
8	M698	F	50	1	0	2	0	0	0	0	0	0	0	0	3	2	77	514
9	M699	F	50	1	0	2	0	0	0	0	0	0	0	0	3	2	82	458
10	M700	F	50	2	0	3	0	0	0	0	0	0	0	0	5	3	101	475

MP: Metaphase plate; Ct: Chromatid; Cs: Chromosome; BC: Blast cells
*: Metaphase plates with one or more than one aberrations was considered as one Metaphase plate with aberrations;
Mitotic index = Number of Metaphase plates per 100 Blast cells.

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APPENDIX 3

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA

Group : G2 Dose : 50 mg/kg (+ve control-Cyclophosphamide) Route : Oral

Sl. No.	Animal No.	SEX	No.of MPs scored	No. of metaphases with aberrations: Gaps Ct	Gaps Cs	Breaks Ct	Breaks Cs	Acentric fragments	Ring Chromosomes	Multiple chromatid breaks	Pulverisation	Polyploidy	Exchange figures Ct	Exchange figures Cs	Total no.of MPs with aberrations* Incl. gaps	Total no.of MPs with aberrations* Excl. gaps	MITOTIC INDEX MP	MITOTIC INDEX BC
1	M701	M	50	6	1	15	3	4	3	1	12	2	0	6	33	26	72	485
2	M702	M	50	4	3	14	4	3	1	0	3	0	0	2	21	14	69	472
3	M703	M	51	2	1	8	3	2	1	1	38	0	0	3	44	41	70	459
4	M704	M	50	5	1	16	1	1	3	2	13	0	0	7	30	24	63	473
5	M705	M	50	2	0	15	3	5	3	2	21	0	0	6	36	34	74	481
6	M706	F	50	2	1	16	2	4	5	5	8	0	0	1	39	36	32	463
7	M707	F	50	4	0	26	6	7	1	4	11	0	0	6	38	34	12	499
8	M708	F	50	3	0	16	1	2	0	2	18	0	0	2	35	32	25	490
9	M709	F	50	3	0	23	3	2	0	1	1	0	0	3	25	22	42	474
10	M710	F	50	2	1	22	1	1	0	2	12	0	0	8	34	31	20	435

MP: Metaphase plate; Ct: Chromatid; Cs: Chromosome; BC: Blast cells
*: Metaphase plates with one or more than one aberrations was considered as one Metaphase plate with aberrations;
Mitotic index = Number of Metaphase plates per 100 Blast cells.

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APPENDIX 4

GENETIC TOXICOLOGY - IN VIVO MAMMALIAN BONE MARROW CYTOGENETIC TEST - CHROMOSOMAL ANALYSIS IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA

Group : G5 Dose : 5000 mg/kg (High dose) Route : Oral

Sl. No.	Animal No.	SEX	No.of MPs scored	No. of metaphases with aberrations: Gaps Ct	Gaps Cs	Breaks Ct	Breaks Cs	Acentric fragments	Ring Chromosomes	Multiple chromatid breaks	Pulverisation	Polyploidy	Exchange figures Ct	Exchange figures Cs	Total no.of MPs with aberrations* Incl. gaps	Total no.of MPs with aberrations* Excl. gaps	MITOTIC INDEX MP	MITOTIC INDEX BC
1	M731	M	50	0	0	0	0	1	0	0	0	1	0	0	2	2	63	443
2	M732	M	50	0	0	1	0	1	1	0	0	0	0	0	2	2	33	428
3	M733	M	50	0	0	3	0	1	0	0	0	0	0	0	3	3	40	471
4	M734	M	50	3	0	2	0	1	0	0	0	0	0	1	5	2	28	430
5	M735	M	50	2	0	0	0	1	0	0	0	0	0	0	3	1	34	460
6	M736	F	50	5	0	0	0	0	0	0	0	1	0	0	6	1	51	444
7	M737	F	50	4	0	3	0	2	0	0	0	0	0	0	8	4	36	445
8	M738	F	50	3	0	1	0	0	1	0	0	0	0	1	5	2	44	437
9	M739	F	50	1	0	1	0	1	0	0	0	0	0	0	3	2	46	420
10	M740	F	50	3	0	1	0	0	1	0	0	0	0	0	5	2	32	443

MP: Metaphase plate; Ct: Chromatid; Cs: Chromosome; BC: Blast cells
*: Metaphase plates with one or more than one aberrations was considered as one Metaphase plate with aberrations;
Mitotic index = Number of Metaphase plates per 100 Blast cells.

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APPENDIX 5

DECLARED MICE FEED COMPOSITION
(AS REPORTED BY MANUFACTURERS)

M/s LIPTON INDIA LIMITED, BANGALORE-560 052

Sl. No.	Contents	Values
1	Moisture Content (Max %)	10.0
2	Crude Protein (Min. %)	20.0
3	Ether Extract (Min. %)	4.0
4	Crude Fibre (Max. %)	4.0
5	Ash (Max. %)	8.0
6	Calcium (Min. %)	1.0
7	Phosphorus (Min. %)	0.6
8	Nitrogen Free Extract (%)	54.0
	MINERALS	
9	Fe (mg/kg)	123 to 125
10	Cu (mg/kg)	19 to 21
11	Mn (mg/kg)	92 to 95
12	Zn (mg/kg)	35 to 38
13	Co (mcg/kg)	576 to 580
	VITAMINS	
14	Vitamin A (IU)	16500 to 22000
15	Vitamin D-3 (IU)	3300 to 4000
16	Vitamin B-1 (mg)	6 to 8
17	Vitamin B-2 (mg)	8 to 12
18	Vitamin B-6 (mg)	6 to 8
19	Vitamin B-12 (mg)	1 to 2
20	Vitamin E (mg)	70 to 80
21	Vitamin K (mg)	5 to 7
22	Pantothenic Acid (mg)	4 to 6
23	Niacin (mg)	10 to 13
24	Folic Acid (mg)	2 to 3
25	Choline Chloride (mg)	100 to 120

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Peenya, II Phase, Bangalore-560 058.

APPENDIX 6

RALLIS AGROCHEMICAL RESEARCH STATION
21 & 22, PEENYA INDUSTRIAL AREA, II PHASE
BANGALORE 560 058
ANALYSIS REPORT - ANIMAL DIET SAMPLE

FROM: Soil Science Department, RARS, Bangalore-560 058
TO: Toxicology Department, RARS, Bangalore 560 058

Our Ref. No. SS/TF/113 Date: 22.2.1993

Sample Details : Name : Mice Feed Sampling Date: 30.1.1993
Batch No. : LAF 004625
Supplier : M/s Kamadhenu Agencies, Bangalore 560 042
Manufacturer : M/s Lipton India Limited, Bangalore 560 052

ANALYSIS RESULTS
(Analysis on "as is basis")

Sl. No.	PARAMETER	CONTENT (%)	Sl. No.	PARAMETER	CONTENT (ppm)
1.	Moisture	13.0	13.	Iron (Fe)	680
2.	Crude protein (Nx6.25)	20.5	14.	Manganese (Mn)	120
3.	Crude fat (Ether extract)	4.1	15.	Copper (Cu)	30
4.	Crude fibre	3.8	16.	Zinc (Zn)	20
5.	Total ash	5.6	17.	*Cobalt (Co)	<0.1
6.	Acid insoluble ash	1.0	18.	*Arsenic (As)	<0.8
7.	Nitrogen free extract	53.0	19.	*Cadmium (Cd)	<0.1
8.	Calcium (Ca)	1.03	20.	*Mercury (Hg)	<0.6
9.	Phosphorus (P)	0.66	21.	*Lead (Pb)	<0.4
10.	Magnesium (Mg)	0.24	22.	*Selenium (Se)	<0.1
11.	Sodium (Na)	-----			
12.	Potassium (K)	-----			

* From Cosmic Industrial Laboratories Pvt. Ltd., Bangalore 560 076.

sd/-
Soil Chemist
for RALLIS INDIA LIMITED

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RALLIS AGROCHEMICAL RESEARCH STATION
Peenya, II Phase, Bangalore-560 058.

APPENDIX 7

TOXICOLOGY DEPARTMENT
FEED CONTAMINANT ANALYSIS REPORT FOR MICE FEED

ANALYSED BY: LANDWIRTSCHAFTLICHE UNTERSUCHUNGS UND FORSCHUNGSANSTALT INSTITUT FUR TIERGESUNDHEIT UND LEBENSMITTELQUALITAT KIEL, GERMANY

AGRICULTURAL EXPERIMENTAL RESEARCH STATION AND INSTITUTE FOR ANIMAL HEALTH AND FOOD STUFF QUALITY KIEL, GERMANY

REFERENCE: MICE-FEED

Date of Receipt: 10.03.1993
Batch No. : LAF No. 018682
Sampling Date : 02.04.1993
Sample No. : F-5(M)

ANALYSIS REPORT

Date of Receipt: 06.04.1993
Reference No. : 92/Schu/Fr
Code No. : SO 12190
Report No. QVM 1146/92/19/04/1993

I. POLYCHLORINATED BIPHENYLS (PCB)

		mg/kg
a. PCB EK 28	n.b.	< 0.005
b. PCB EK 52	n.b.	< 0.005
c. PCB EK 101	n.b.	< 0.005
d. PCB EK 138	n.b.	< 0.005
e. PCB EK 153	n.b.	< 0.005
f. PCB EK 180	n.b.	< 0.005

II. CHLORINATED HYDROCARBONS

		mg/kg
a. Hexachlorbenzol (HCB)	n.b.	< 0.002
b. alpha-HCH		0.626
c. beta-HCH		0.056
d. gamma-HCH (Lindan)		0.117
e. delta-HCH		0.052
f. Quintozen	n.b.	< 0.002
g. Heptachlor	n.b.	< 0.002
h. Heptachlorepoxid	n.b.	< 0.002
i. alpha-Chlordan	n.b.	< 0.002
j. gamma-Chlordan	n.b.	< 0.002
k. alpha-Endosulfan	n.b.	< 0.002
l. beta-Endosulfan	n.b.	< 0.002
m. Aldrin	n.b.	< 0.002
n. Dieldrin	n.b.	< 0.002
o. Endrin	n.b.	< 0.002
p. p.p-DDE	n.b.	< 0.002
q. o.p-DDT		0.009
r. p.p-DDD	n.b.	< 0.002
s. p.p-DDT		0.034

III. PHOSPHORIC ACID ESTERS

		mg/kg
a. Chlorthion	n.b.	< 0.010
b. Disulfoton	n.b.	< 0.010
c. Malathion	n.b.	< 0.010
d. Parathion (-methyl)	n.b.	< 0.010
e. Parathion (-ethyl)	n.b.	< 0.010
f. Sulfotepp	n.b.	< 0.010
g. Fenthion	n.b.	< 0.010
h. Diazinon	n.b.	< 0.010
i. Dimethoate	n.b.	< 0.010
j. Mecarbam	n.b.	< 0.010
k. Fenitrothion	n.b.	< 0.010
l. Bromophos (-methyl)	n.b.	< 0.010
m. Bromophos (-ethyl)	n.b.	< 0.010
n. Chlorfenvinphos	n.b.	< 0.010
o. Chlorpyriphos (-ethyl)	n.b.	< 0.010
p. Chlorpyriphos (-methyl)	n.b.	< 0.010
q. Pirimiphos (-methyl)	n.b.	< 0.010
r. Methidathion	n.b.	< 0.010
s. Ethion	n.b.	< 0.010

n.b.: Not determinable

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APPENDIX 8

RALLIS AGROCHEMICAL RESEARCH STATION
21 & 22, PEENYA INDUSTRIAL AREA, II PHASE
BANGALORE 560 058
ANALYSIS REPORT - WATER SAMPLE

FROM: Soil Science Department, RARS, Bangalore-560 058
TO: Toxicology Department, RARS, Bangalore 560 058

Our Ref. No. SS/TW/28 Date: 12/01/1993

Sample Details: Source of Collection: Outlet of the Aquaguard (At use point)

Date of Collection : 28/12/1992

ANALYSIS RESULTS

Sl. No.	PARAMETER	CONTENT	Sl. No.	PARAMETER	CONTENT (ppm)
1.	Colour	Colour-less	11.	Chemical Oxygen Demand	24.0
2.	Odour	Odour-less	12.	Total hardness as CaCO	427
3.	Turbidity	Clear	13.	Calcium as Ca	87
4.	pH	7.8	14.	Magnesium as Mg	51
5.	Electrical Conductivity mmho/cm	1.2	15.	Chlorides as Cl	152
6.	Total Solids, (ppm)	709	16.	Sulphate as SO	24
7.	Suspended Solids, (ppm)	18	17.	Carbonates as CO	Nil
8.	Dissolved Solids, (ppm)	691	18.	Bicarbonates as HCO	420
9.	Dissolved Oxygen, (ppm)	6.2	19.	Sulphides as S	---
10.	Biochemical Oxygen Demand 5 days at 20 C, (ppm)	1.1	20.	Fluorides as F	0.1

-Sd/
Soil Chemist
for RALLIS INDIA LIMITED

RALLIS AGROCHEMICAL RESEARCH STATION
Peenya, II Phase, Bangalore-560 058.

APPENDIX 9
TOXICOLOGY DEPARTMENT
CONTAMINANT ANALYSIS REPORT FOR WATER SAMPLE

ANALYSED BY: [redacted] **ANALYTIK,**
EUPENER STRASSE, 150
5000 KOLN 41, GERMANY

REFERENCE: WATER SAMPLE
Sample No. W-4
Date of Sampling: 29.03.1993

ANALYSIS REPORT
Reference No.93/1917
Dated : 16.04.1993

Sl. No.	PARAMETERS	VALUES	Sl. No.	PARAMETERS	VALUES
	ORGANOHALOGENS				
1.	1,3,5-Tribrombenzol	n.n.	16.	2,4'-DDE	n.n.
2.	1,2,4-Trichlorbenzol	n.n.	17.	2,2',4,5,5'-pentachlobiphenyl (Bal 101)	n.n.
3.	1,2,3,4-Tetrachlorbenzol	n.n.	18.	alpha-Endosulfan	n.n.
4.	Pentachlorbenzol	n.n.	19.	Dieldrin	n.n.
5.	alpha-HCH	n.n.	20.	4,4'-DDE	n.n.
6.	Hexachlorbenzol	n.n.	21.	Endrin	n.n.
7.	beta-HCH	n.n.	22.	beta-Endosulfan	n.n.
8	gamma-HCH	n.n.	23.	4,4'-DDD	n.n.
9.	delta-HCH	n.n.	24.	2,4'-DDT	n.n.
10.	Pentachlornitrobenzol (Quintozen)	n.n.	25.	2,2',4,4',5,5'-Hexachlorbiphenyl (Bal 153)	n.n.
11.	2,4,4'-Trichlorbiphenyl (Bal 28)	n.n.	26.	4,4'-DDT	n.n.
12.	Heptachlor	n.n.	27.	2,2',3,4,4',5'-Hexachlorbiphenyl (Bal 138)	n.n.
13.	2,2',5,5'-Tetrachlorbiphenyl (Bal 52)	n.n.	28.	Methoxychlor	n.n.
14.	Aldrin	n.n.	29.	2,2',3,4,4',5,5' -Heptachlorbiphenyl (Bal 180)	n.n.
15.	Heptachlorepoxid	n.n.			

(Proof levels per each component is approximately 1 mcg/L)

Dated: 15.04.1993

Sd/-
Dr.N.Bertram
Koln

POLYCHLORINATED BIPHENYLS		PROOF LEVEL/DIMENSION						
30.	Bal 28	0.05	mcg/L	n.n.	36.	Nitrite	mg/L	0.11
31.	Bal 52	0.05	mcg/L	n.n.	37.	Nitrate	mg/L	19.60
32.	Bal 101	0.05	mcg/L	n.n.	38.	Lead	mg/L	< 0.001
33.	Bal 138	0.05	mcg/L	n.n.	39.	Cadmium	mg/L	< 0.0002
34.	Bal 153	0.05	mcg/L	n.n.	40.	Mercury	mg/L	< 0.00002
35.	Bal 180	0.05	mcg/L	n.n.	41.	Arsenic	mg/L	< 0.001
					42.	Selenium	mg/L	< 0.001

n.n.: Traces
Dated: 16.04.1993

Sd/-
[redacted]

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Peenya, II Phase, Bangalore-560 058.

APPENDIX 10

RESIDUE/ANALYTICAL DEPARTMENT

CERTIFICATE OF ANALYSIS
ON
AUTHENTICITY OF TEST COMPOUND

Lab Ref: AUTH/6

TEST COMPOUND DETAILS DECLARED BY SPONSOR M/S FEINCHEMIE

Test Compound (Common name)	:	Glyphosate Technical	Batch No.	: 046
Test Compound Code:		ES-GPT	Mfd.Date	: January, 1992
Declared Purity	:	96.0 % m/m (min.)	Expiry Date	: January, 1995

TEST COMPOUND RECEIPT AND ANALYSIS

Date of Receipt : 22.02.1992

Date of Analysis : 08.09.1992

METHOD OF ANALYSIS

Reference Compound: Using Certified Analytical standard Glyphosate Analytical Standard Purity 99.0%.

Qualitative : The presence of the main active ingredient (Glyphosate) in the test compound was checked by Spectrophotometric Method.

Quantitative : Purity of the test compound as Glyphosate was determined by Spectrophotometric Method.

RESULTS

The active ingredient content (purity) as Glyphosate is 96.8 % m/m.

AUTHENTICITY

The results conform to the declared value within permissible limits.

for Residue/Analytical Dept.

sd/-
(Signature)

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Bundesgesundheitsamt

- GLP-Bundesstelle -

GUTE LABORPRAXIS
GOOD LABORATORY PRACTICE

GLP-Bescheinigung / Statement of Compliance

(gemäß / according to § 19b Abs.2 Nr.3 Chemikaliengesetz)

Eine GLP-Inspektion wurde durchgeführt in / A GLP inspection was carried out at

Prüfeinrichtung / Test facility

RALLIS INDIA LIMITED
Agrochemical Research Station
Bangalore 560 058
India

Prüfkategorien / Area of Expertise

Prüfungen auf toxikologische Eigenschaften an Ratte, Maus, Kaninchen und Vogel
Toxicity studies with rat, mouse, rabbit and bird

Datum der Inspektion / Date of Inspection

30.03.-02.04.1992

Auf der Grundlage des Inspektionsberichtes und der Besprechung über zu erfolgende Maßnahmen wird hiermit bestätigt, daß in dieser Prüfeinrichtung die obengenannten Prüfungen zum Zeitpunkt der Inspektion unter Einhaltung der GLP-Grundsätze durchgeführt wurden.

Based on the inspection report and the discussion of follow up activities it can be confirmed, that at time of inspection the test facility were conducting the aforementioned studies in compliance with the Principles of Good Laboratory Practice.

27. October 1992

Im Auftrag

[redacted]

Leiter GLP-Bundesstelle