RALLIS AGROCHEMICAL RESEARCH STATION
Peenya, Bangalore-560 058.

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE

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

STUDY No. TOXI: 889-MUT.MN

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QUALITY ASSURANCE STATEMENT

To the best of my knowledge the Study No.TOXI:889-MUT.MN has been conducted in compliance with Good Laboratory Practice Regulations with accurate reflection of supportive raw data.
Dates of Inspection: 03.07.1991, 08.10.1991, 11.10.1991 and 12.12.1991.

Date: 4th May 1993

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SCIENTIFIC STATEMENT

To the best of my knowledge the Study No.TOXI:889-MUT.MN was conducted in compliance with Good Laboratory Practice Regulations and this report represents true and accurate record of the results obtained and interpretation.

Date: 3/5/93

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MANAGEMENT STATEMENT

This is to certify that Study No.TOXI:889-MUT.MN (Mutagenicity -Micronucleus Test in Swiss Albino Mice) 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: 4/05/93

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STUDY DETAILS

TITLE	: MUTAGENICITY- MICRONUCLEUS TEST IN SWISS ALBINO MICE
TEST COMPOUND	: GLYPHOSATE TECHNICAL
STUDY NUMBER	: TOXI:889-MUT.MN
REPORT SUBMISSION	:
STUDY DIRECTOR	: [redacted]
SPONSOR	: M/s FEINCHEMIE SCHWEBDA GmbH., BAHNHOF 2, D-3446., MEINHARD-SCHWEBDA., GERMANY
MONITORING SCIENTIST	: [redacted]
NOMINEE :	[redacted]
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 : 08-10-91 END : 12-10-91

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STUDY VETERINARIAN	:	[redacted]
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MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

SUMMARY

The genotoxic effect of GLYPHOSATE TECHNICAL manufactured by M/s Epic Schwebda Chemicals Pvt. Limited ., 514 Persipolis, Vashi, New Bombay-400705., INDIA and supplied by M/s Feinchemie Schwebda, GmbH., Bahnhof 2, D-3446, Meinhard, GERMANY was studied using Micronucleus Test in bone marrow cells of Swiss Albino Mice.

The test compound, suspended in refined groundnut oil was administered as gavage to four groups (G1,G2,G3 and G4) of young Swiss albino mice at the dosages of 0 (Vehicle control), 50 (low dose), 500 (mid dose) and 5000 (high dose) mg/kg body weight for two consecutive days. A similar group was administered with a positive control substance - **Cyclophosphamide** at 100 mg/kg dose. The mice were sacrificed 24 hours after second administration and bone marrow cell smears from femur were prepared and stained by a combination of May-Gruenwald and Giemsa staining. A minimum of two thousand erythrocytes (RBCs) were scored and differentiated for Polychromatic (PCE), Normochromatic (NCE) Erythrocytes and micronuclear incidences. The results were analyzed by one way Anova and 't' test for unequal number of observations.

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The study has shown that GLYPHOSATE TECHNICAL at the dosages of 0, 50, 500 and 5000 mg/kg Bwt causes:

1. no compound and dose related pharmacotoxic symptoms but reduced body weight marginally in higher doses.
2. no significant increase in the incidence of micronuclei at doses tested except in female mice at high dose.
3. a dose related increase in micronuclear incidence in females.

   Cyclophosphamide - positive control produced significant and many fold increase in the micronuclear incidence.

CONCLUSIONS

The study has shown that Glyphosate technical at the doses tested and the conditions adapted is not mutagenic by Micronucleus Test in mice. However at 5000 mg/kg dose it may significantly increase the incidence of Micronuclei in female mice.

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MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INTRODUCTION

"Micronuclei" are small particles consisting of acentric fragments of chromosomes or entire chromosomes which lag behind at anaphase stage of cell division. After telophase, these fragments may not be included in the nuclei of daughter cells and form single or multiple micronuclei in the cytoplasm.

The Mutagenicity - Micronucleus Test is designed to determine the potential of the test substance to induce chromosomal damage or damage of mitotic apparatus which leads to an increase in micronuclei in the polychromatic erythrocytes . This study will provide a rational basis for risk assessment in man.

The study was conducted as per OECD guidelines for testing of chemicals, Section 4, number 474, "Genetic Toxicology - Micronucleus Test " adopted on 4th April 1984 and in compliance with Good Laboratory Practice regulations and mutually agreed protocol .

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MATERIALS AND METHODS

TEST SYSTEM	: Swiss Albino Mice
SOURCE	: Bred at Toxicology Department, Rallis Agrochemical Research Station, Bangalore - 560058, INDIA.
NUMBER OF GROUPS	: Five - one vehicle control; three treatment groups and one positive control group.
NUMBER OF ANIMALS PER GROUP	: Control - 20 (10 males + 10 females) : Treatment Groups - 10 (5 males + 5 females)
AGE AT THE START OF STUDY	: 8 - 10 Weeks
BODY WEIGHT AT START OF STUDY	: 25 - 35 g
IDENTIFICATION	: By unique animal numbers and cage tags.
RANDOMIZATION	: Animals are randomized and assigned to 5 treatment groups after acclimatization and veterinary examination.
ACCLIMATIZATION	: At least one week under experimental conditions after veterinary examination.

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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 10	M 491 M 601	-M 495 -M 605	10
			F 10	M 496 M 606	-M 500 -M 610	
G2	50	ES-GPT	M 5 F 5	M 501 M 506	-M 505 -M 510	10
G3	500	ES-GPT	M 5 F 5	M 511 M 516	-M 515 -M 520	10
G4	5000	ES-GPT	M 5 F 5	M 521 M 526	-M 525 -M 530	10
G5	100	@	M 5 F 5	M 531 M 536	-M 535 -M 540	10

* 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, West Germany)

HUSBANDRY

ROOM NUMBER : Toxicology Acute Laboratory - A 9

CONDITIONS : Standard Laboratory Conditions { air conditioned with filtered air (12-15 air changes per hour) in monitored environment with temperature 22 ± 3 degrees Celsius, relative humidity 40 - 70 %}; natural light supplemented with fluorescent light : 12 hours light/ dark cycle.

ACCOMMODATION : Pre-treatment period-in groups of five mice/sex placed in sterilized 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 sterilized paddy husk bedding provided; changed thrice a week.

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Treatment period - individually in mice cages.

DIET	: 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 is in Appendix 7 and feed analysis report is enclosed as Appendix 8.
WATER	: Protected, 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 9.

TEST COMPOUND

COMMON NAME	: GLYPHOSATE
CHEMICAL NAME	: N-(Phosphonomethyl) 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
SUPPLIED BY	: M/s Feinchemie Schwebda GmbH., Bahnhof 2, D-3446 Meinhard-Schwebda, GERMANY
BATCH NUMBER	: 60
DATE OF MANUFACTURE	: August 1990
DATE OF RECEIPT at R.A.R.S	: September 11, 1990
DATE OF EXPIRY	: July 1992

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PURITY (DECLARED)	:	96.8 %
DESCRIPTION	:	Odorless , white crystals
DECLARED STABILITY	:	More than two years at ambient temperature
SOLUBILITY	:	Not soluble in water
PACKING	:	Packed in plastic drums
STORAGE CONDITIONS	:	Stored at ambient temperature in its original container
TEST COMPOUND ANALYSIS CERTIFICATE	:	Ref. App. 10

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-5
DATE OF MANUFACTURE	:	5/91
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 0, 50, 500 and 5000 mg/kg in 10 mL of the vehicle. Gavage suspension was administered at an equivolume dose of 10 mL/kg body weight .

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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 : Two: One daily for two consecutive days.

TERMINATION : The treated mice were sacrificed 24 hours after second treatment.

OBSERVATIONS

1. **PHARMACOTOXIC SYMPTOMS AND MORTALITY** : Twice a day -including time of onset, degree and duration. Dead animals were immediately necropsied.

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

3. **NECROPSY AND BONE MARROW CELL 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 was flushed with sterile physiological saline and collected into a centrifuge tube.

v) The cell suspension was centrifuged at 1000g (2750 rpm) for 10 minutes and the supernatant discarded. The cell button was resuspended in 50 microlitre (mcL) of physiological saline.

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vi) Slide preparation : Approximately 10 mcL of cell suspension was spread evenly on microscopic slide and air dried. Four to six slides were prepared from each animal. The slides were fixed in methanol 4 hours later by immersing them in a coplin jar for 30 minutes. Slides were stained 24 hours later by a combination of May-Gruenwald and Giemsa stain in succession. The slides were blow dried, immersed in xylene and cover slips mounted with DPX.

4. MICROSCOPIC ANALYSIS OF ERYTHROCYTES:

A. From each animal a minimum of 2000 erythrocytes were scored from four slides for : polychromatic (PCE) and normochromatic (NCE) erythrocytes and incidence of micronuclei.

B. The following were derived for each animal from the above observations :

i) Total RBCs / erythrocytes scored

ii) No. of PCEs differentiated

iii) No. and percentage of PCE with micronuclei

iv) No. of NCEs differentiated

v) No. and percentage of NCE with micronuclei

vi) No. and percentage of total RBCs with micronuclei

vii) Ratio of PCE:NCE

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STATISTICAL ANALYSIS

The data was analyzed group wise and sex-wise using one way Anova and 't' test for unequal number of observations for the percentage of micronucleated cells in the treated and control groups at $P \leq 0.05$ level and significant findings have been superscribed as +: significantly higher (+) than control group value; 't' test will be used for dose-effect relationship (when required at $P \leq 0.05$ and 0.10)

ARCHIVING

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

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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 AND NECROPSY FINDINGS** Appendix 1

At the doses tested there were no compound and dose related pharmacotoxic symptoms and mortality in the treatment groups. At sacrifice many animals in mid and high dose treatment groups and all mice in positive control group had lost body weight marginally.

C. **MICRONUCLEAR ASSAY IN ERYTHROCYTES** :

Tables 2 and 3; Appendices 2 to 6

1. Control group : The percentage of micronucleated polychromatic erythrocytes (PCE), normochromatic erythrocytes (NCE) and total erythrocytes (RBCs) were 0.69, 0.62 and 0.65 in males ; 0.51, 0.39 and 0.44 in females and 0.6, 0.5 and 0.54 for combined sex respectively.

2. Incidence of micronucleated erythrocytes in low (50 mg/kg) and mid dose (500 mg/kg) treatment groups were statistically similar ($P \leq 0.05$) to control group in both the sexes and combined sex.

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3. In high dose (5000 mg/kg) group males and combined sex data did not differ from control group, however in females the incidence of micronucleated PCE and total RBCs were significantly higher ($P \leq 0.05$) than in control.

   Dose effect relationship was evident in female mice.

4. Under similar testing conditions positive control (Cyclophosphamide, 100 mg/kg) group produced manyfold increase (significant $P \leq 0.05$) in the incidence of micronuclei in both types of RBCs and in both sexes. The ratio of PCE:NCE was 1:1.9 indicating a high degree of cytotoxicity.

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CONCLUSIONS

The study was conducted to assess possible mutagenic property of Glyphosate technical by micronuclear test in mice. The test compound was administered as gavage at 50, 500 and 5000 mg/kg body weight for two consecutive days. Vehicle control and Positive control groups (Cyclophosphamide 100 mg/kg) were treated similarly. The bone marrow erythrocytes were evaluated for incidence of micronuclei in PCE, NCE and total RBCs. Statistical comparison of treatment groups with control group has shown that at the doses tested and the conditions adopted Glyphosate technical is not mutagenic by Micronucleus test in mice. However at 5000 mg/kg it may significantly increase the incidence of micronuclei in female mice. Cyclophosphamide produced significant and manyfold increase in the incidence of micronucleated RBCs.

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TABLE 1

MUTAGENICITY-MICRONUCLEUS TEST 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 M	No. of animals F	Duration of Treatment (2 consecutive days)	Sacrifice 24 hrs. after II dose
G1	0	Vehicle control	10	10	+	+
G2	50	ES-GPT	5	5	+	+
G3	500	ES-GPT	5	5	+	+
G4	5000	ES-GPT	5	5	+	+
G5	100	Positive control	5	5	+	+

+ : Yes; M : Male; F : Female

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TABLE 2

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

SUMMARY OF MICRONUCLEAR INCIDENCE and PCE:NCE RATIO (SEX-WISE)

Ref. App. : 2-6

Group Dose (mg/kg)	No.of Animals	Sex	Total RBCs scored	Erythrocytes Differentiated						Total RBCs		Ratio
				Polychromatic(PCE)			Normochromatic(NCE)					
				No.	No.with MN	%	No.	No.with MN	%	No.with MN	%	PCE:NCE
G1 (0)	10	M	19974	9337	65	0.69	10637	66	0.62	131	0.65	1:1.1
	10	F	21799	9971	51	0.51	11828	47	0.39	98	0.44	1:1.2
G2 (50)	5	M	9606	4513	38	0.84	5093	33	0.64	71	0.73	1:1.1
	5	F	10351	4597	13	0.28	5754	9	0.15	22	0.21	1:1.3
G3 (500)	5	M	11016	4904	36	0.73	6112	14	0.22	50	0.45	1:1.2
	5	F	11165	5112	27	0.52	6049	14	0.23	41	0.36	1:1.2
G4 (5000)	5	M	12152	5388	48	0.89	6764	32	0.47	80	0.65 +	1:1.3
	5	F	11424	5028	53	1.05 + c	6396	30	0.46	83	0.72 +	1:1.3
G5 @ (100)	5	M	13086	4532	106	2.33 +	8554	101	1.18 +	207	1.58 +	1:1.9
	5	F	10734	3668	88	2.39 +	7066	117	1.65 +	205	1.90 +	1:1.9

MN : Micronuclei ; RBC : Red Blood Corpuscles;@: Positive Control; M : Male ; F : Female
Significantly higher (+) than control group by contingency test
c: 't' test for dose-response relationship significant ($P \leq 0.10$)

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TABLE 3

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

SUMMARY OF MICRONUCLEAR INCIDENCE and PCE:NCE RATIO (COMBINED SEX)

Ref. App.: 2-6

Group Dose (mg/kg)	No.of Animals	Total RBCs scored	Erythrocytes Differentiated						Total RBCs		Ratio PCE:NCE
			Polychromatic(PCE)			Normochromatic(NCE)					
			No.	No.with MN	%	No.	No.with MN	%	No.with MN	%	
G1 (0)	20	41773	19308	116	0.60	22465	113	0.50	229	0.54	1:1.2
G2 (50)	10	19957	9110	51	0.55	10847	42	0.38	93	0.46	1:1.2
G3 (500)	10	22181	10016	63	0.62	12161	28	0.23	91	0.41	1:1.2
G4 (5000)	10	23576	10416	101	0.96 c	13160	62	0.47	163	0.69	1:1.3
G5 @ (100)	10	23820	8200	194	2.36 +	15620	218	1.39 +	412	1.72 +	1:1.9

MN : Micronuclei ; RBC : Red Blood Corpuscles; @: Positive control
Significantly higher (+) than control group by contingency test
c : 't' test for dose-response relationship significant ($P \leq 0.10$)

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APPENDIX 1

MUTAGENICTY-MICRONUCLEUS TEST 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.	M 491	M	32	32	32	NAD	NAD
	2.	M 492	M	32	32	32	NAD	NAD
	3.	M 493	M	30	30	32	NAD	NAD
	4.	M 494	M	36	36	36	NAD	NAD
	5.	M 495	M	30	30	32	NAD	NAD
	6.	M 601	M	30	32	32	NAD	NAD
	7.	M 602	M	26	32	32	NAD	NAD
	8.	M 603	M	26	26	30	NAD	NAD
	9.	M 604	M	30	30	32	NAD	NAD
	10.	M 605	M	26	30	32	NAD	NAD
	11.	M 496	F	32	32	34	NAD	NAD
	12.	M 497	F	32	32	32	NAD	NAD
	13.	M 498	F	32	32	34	NAD	NAD
	14.	M 499	F	34	34	36	NAD	NAD
	15.	M 500	F	34	34	36	NAD	NAD
	16.	M 606	F	26	26	26	NAD	NAD
	17.	M 607	F	28	28	26	NAD	NAD
	18.	M 608	F	26	26	26	NAD	NAD
	19.	M 609	F	28	28	26	NAD	NAD
	20.	M 610	F	28	28	26	NAD	NAD
G2 (50)	1.	M 501	M	32	32	34	NAD	NAD
	2.	M 502	M	30	32	32	NAD	NAD
	3.	M 503	M	32	32	32	NAD	NAD
	4.	M 504	M	30	30	30	NAD	NAD
	5.	M 505	M	36	36	36	NAD	NAD
	6.	M 506	F	30	30	32	NAD	NAD
	7.	M 507	F	32	32	34	NAD	NAD
	8.	M 508	F	30	30	32	NAD	NAD
	9.	M 509	F	28	30	30	NAD	NAD
	10.	M 510	F	30	32	32	NAD	NAD

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

Contd.

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APPENDIX 1 Contd...

MUTAGENICTY-MICRONUCLEUS TEST 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
G3 (500)	1.	M 511	M	32	32	32	NAD	NAD
	2.	M 512	M	30	32	32	NAD	NAD
	3.	M 513	M	34	34	32	NAD	NAD
	4.	M 514	M	30	32	30	NAD	NAD
	5.	M 515	M	30	32	32	NAD	NAD
	6.	M 516	F	30	30	30	NAD	NAD
	7.	M 517	F	32	30	30	NAD	NAD
	8.	M 518	F	30	30	30	NAD	NAD
	9.	M 519	F	32	30	30	NAD	NAD
	10.	M 520	F	30	28	30	NAD	NAD
G4 (5000)	1.	M 521	M	32	30	28	Loose stool	NAD
	2.	M 522	M	32	30	30	NAD	NAD
	3.	M 523	M	32	30	32	NAD	NAD
	4.	M 524	M	30	30	30	NAD	NAD
	5.	M 525	M	36	34	34	NAD	NAD
	6.	M 526	F	32	32	30	NAD	NAD
	7.	M 527	F	30	28	28	NAD	NAD
	8.	M 528	F	28	26	26	NAD	NAD
	9.	M 529	F	30	28	28	NAD	NAD
	10.	M 530	F	28	28	26	NAD	NAD
G5 @ (100)	1.	M 531	M	36	34	34	NAD	NAD
	2.	M 532	M	36	34	34	NAD	NAD
	3.	M 533	M	32	28	28	NAD	NAD
	4.	M 534	M	36	34	34	NAD	NAD
	5.	M 535	M	34	32	32	NAD	NAD

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

Contd

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APPENDIX 1 Contd...

MUTAGENICTY-MICRONUCLEUS TEST 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
G5 @ (100)	6.	M 536	F	28	24	26	NAD	NAD
	7.	M 537	F	28	22	22	NAD	NAD
	8.	M 538	F	28	26	26	NAD	NAD
	9.	M 539	F	28	26	26	NAD	NAD
	10.	M 540	F	28	26	26	NAD	NAD

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

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APPENDIX 2

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA - MICRONUCLEAR INCIDENCE and PCE:NCE RATIO

Group / Dose (mg/kg)	Interval Before Harvesting (hrs)	Animal No.	Sex	Total RBCs scored	Erythrocytes Differentiated: Polychromatic (PCE) No.	PCE No. with MN	PCE %	Normochromatic (NCE) No.	NCE No. with MN	NCE %	Total RBCs No.	Total RBCs No. with MN	Total RBCs %	Ratio PCE:NCE
G1 (0)	24	M 491	M	2082	961	15	1.60	1121	16	1.40	31		1.49	1:1.2
		M 492	M	2186	1063	15	1.40	1123	15	1.30	30		1.37	1:1.1
		M 493	M	1857	920	10	1.10	937	8	0.90	18		0.97	1:1.0
		M 494	M	2038	947	9	1.00	1091	9	0.80	18		0.88	1:1.2
		M 495	M	1880	907	6	0.70	973	9	0.90	15		0.80	1:1.1
		M 601	M	2046	938	1	0.10	1108	1	0.10	2		0.09	1:1.2
		M 602	M	1662	754	1	0.10	908	1	0.10	2		0.12	1:1.2
		M 603	M	2053	956	1	0.10	1097	1	0.10	2		0.09	1:1.1
		M 604	M	2142	983	5	0.50	1159	3	0.30	8		0.37	1:1.2
		M 605	M	2028	908	2	0.20	1120	3	0.30	5		0.25	1:1.2
		M 496	F	2564	1189	12	1.00	1375	6	0.40	18		0.70	1:1.2
		M 497	F	2231	1087	5	0.50	1144	2	0.20	7		0.31	1:1.1
		M 498	F	2331	1058	8	0.80	1273	6	0.50	14		0.60	1:1.2
		M 499	F	2393	1097	7	0.60	1296	9	0.70	16		0.67	1:1.2
		M 500	F	2176	1025	7	0.70	1151	5	0.40	12		0.55	1:1.1
		M 606	F	2032	925	3	0.30	1107	4	0.40	7		0.34	1:1.2
		M 607	F	2084	929	2	0.20	1155	5	0.40	7		0.34	1:1.2
		M 608	F	2081	932	2	0.20	1149	3	0.30	5		0.24	1:1.2
		M 609	F	2019	900	3	0.30	1119	5	0.40	8		0.40	1:1.2
		M 610	F	1888	829	2	0.20	1059	2	0.20	4		0.22	1:1.3

M : Male; F : Female; RBC : Red Blood Corpuscles; MN : Micronuclei

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APPENDIX 3

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA - MICRONUCLEAR INCIDENCE and PCE:NCE RATIO

Group Dose (mg/kg)	Interval Before Harvesting (hrs)	Animal No.	Sex	Total RBCs scored	Erythrocytes Differentiated: Polychromatic (PCE) No.	Polychromatic (PCE) No. with MN	Polychromatic (PCE) %	Normochromatic (NCE) No.	Normochromatic (NCE) No. with MN	Normochromatic (NCE) %	Total RBCs No. with MN	Total RBCs %	Ratio PCE:NCE
G2 (50)	24	M 501	M	2062	989	13	1.30	1073	11	1.00	24	1.16	1:1.1
		M 502	M	1790	869	12	1.40	921	8	0.90	20	1.11	1:1.1
		M 503	M	1849	859	2	0.20	990	2	0.20	4	0.22	1:1.2
		M 504	M	1975	918	5	0.50	1057	6	0.60	11	0.56	1:1.2
		M 505	M	1930	878	6	0.70	1052	6	0.60	12	0.62	1:1.2
		M 506	F	1915	864	4	0.50	1051	2	0.20	6	0.31	1:1.2
		M 507	F	2027	914	2	0.20	1113	3	0.30	5	0.25	1:1.2
		M 508	F	2197	985	4	0.40	1212	2	0.20	6	0.27	1:1.2
		M 509	F	2127	920	0	0.00	1207	1	0.10	1	0.05	1:1.3
		M 510	F	2085	914	3	0.30	1171	1	0.10	4	0.19	1:1.3

M : Male; F : Female; RBC : Red Blood Corpuscles; MN : Micronuclei

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APPENDIX 4

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA - MICRONUCLEAR INCIDENCE and PCE:NCE RATIO

Group Dose (mg/kg)	Interval Before Harvesting (hrs)	Animal No.	Sex	Erythrocytes Differentiated: Polychromatic (PCE) Total RBCs scored	PCE No.	PCE No. with MN	PCE %	Normochromatic (NCE) No.	NCE No. with MN	NCE %	Total RBCs No. with MN	Total RBCs %	Ratio PCE:NCE
G3 (500)	24	M 511	M	1833	828	13	1.60	1005	7	0.70	20	1.09	1:1.2
		M 512	M	2395	1063	9	0.80	1332	0	0.00	9	0.37	1:1.3
		M 513	M	2192	969	4	0.40	1223	1	0.10	5	0.23	1:1.3
		M 514	M	2230	988	4	0.40	1242	2	0.20	6	0.27	1:1.3
		M 515	M	2366	1056	6	0.60	1310	4	0.30	10	0.42	1:1.2
		M 516	F	2333	1053	2	0.20	1276	3	0.20	5	0.21	1:1.2
		M 517	F	2239	1074	5	0.50	1165	2	0.20	7	0.31	1:1.1
		M 518	F	2270	1046	2	0.20	1224	3	0.20	5	0.22	1:1.2
		M 519	F	2115	961	5	0.50	1154	1	0.10	6	0.29	1:1.2
		M 520	F	2208	978	13	1.30	1230	5	0.40	18	0.81	1:1.3

M : Male; F : Female; RBC : Red Blood Corpuscles; MN : Micronuclei

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APPENDIX 5

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA - MICRONUCLEAR INCIDENCE and PCE:NCE RATIO

Group Dose (mg/kg)	Interval Before Harvesting (hrs)	Animal No.	Sex	Total RBCs scored	Erythrocytes Differentiated: Polychromatic (PCE) No.	PCE No. with MN	PCE %	Normochromatic (NCE) No.	NCE No. with MN	NCE %	Total RBCs No. with MN	Total RBCs %	Ratio PCE:NCE
G4 (5000)	24	M 521	M	2373	1084	9	0.80	1289	7	0.50	16	0.67	1:1.2
		M 522	M	2530	1137	13	1.10	1393	4	0.30	17	0.67	1:1.2
		M 523	M	2338	1060	8	0.80	1278	8	0.60	16	0.68	1:1.2
		M 524	M	2683	1112	11	1.00	1571	8	0.50	19	0.71	1:1.4
		M 525	M	2228	995	7	0.70	1233	5	0.40	12	0.53	1:1.2
		M 526	F	2267	998	14	1.40	1269	5	0.40	19	0.83	1:1.3
		M 527	F	2289	1027	8	0.80	1262	8	0.60	16	0.69	1:1.2
		M 528	F	2331	1027	10	1.00	1304	3	0.20	13	0.56	1:1.3
		M 529	F	2317	1031	17	1.60	1286	7	0.50	24	1.03	1:1.2
		M 530	F	2220	945	4	0.40	1275	7	0.50	11	0.50	1:1.3

M : Male; F : Female; RBC : Red Blood Corpuscles; MN : Micronuclei

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APPENDIX 6

MUTAGENICITY-MICRONUCLEUS TEST IN SWISS ALBINO MICE WITH GLYPHOSATE TECHNICAL

INDIVIDUAL ANIMAL DATA - MICRONUCLEAR INCIDENCE and PCE:NCE RATIO

Group Dose (mg/kg)	Interval Before Harvesting (hrs)	Animal No.	Sex	Total RBCs scored	Erythrocytes Differentiated: Polychromatic (PCE) No.	PCE No. with MN	PCE %	Normochromatic (NCE) No.	NCE No. with MN	NCE %	Total RBCs No. with MN	Total RBCs %	Ratio PCE:NCE
G5 (100) @	24	M 531	M	2775	905	14	1.50	1870	29	1.60	43	1.54	1:2.1
		M 532	M	2614	882	28	3.20	1732	17	1.00	45	1.72	1:2.0
		M 533	M	2481	895	28	3.10	1586	18	1.10	46	1.85	1:1.8
		M 534	M	2692	933	18	1.90	1759	23	1.30	41	1.52	1:1.9
		M 535	M	2524	917	18	2.00	1607	14	0.90	32	1.27	1:1.8
		M 536	F	2419	859	12	1.40	1560	24	1.50	36	1.49	1:1.8
		M 537	F	2049	703	11	1.60	1346	19	1.40	30	1.46	1:1.9
		M 538	F	2048	722	23	3.20	1326	26	2.00	49	2.39	1:1.8
		M 539	F	2093	698	19	2.70	1395	23	1.60	42	2.01	1:2.0
		M 540	F	2125	686	23	3.40	1439	25	1.70	48	2.25	1:2.1

M : Male; F : Female; RBC : Red Blood Corpuscles; MN : Micronuclei; @ : Positive control

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APPENDIX 7

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 (%)	55.0
	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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APPENDIX 8

RALLIS AGROCHEMICAL RESEARCH STATION
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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/49a

Date: 30/11/1991

Sample Details: Name : Mice Feed   Sampling Date: 10/1

Batch No. : LP No. 25212

Supplier : M/s Kamadhenu Agencies Bangalore-42

Manufacturer: M/s Lipton India Ltd., Bangalore-52

ANALYSIS RESULTS
(Analysis on "as is basis")

No.	PARAMETER	(%)
1.	Moisture	13.7
2.	Crude protein (Nx6.25)	21.1
3.	Crude fat (Ether extract)	3.2
4.	Crude fibre	10.2
5.	Total ash	8.9
6.	Acid insoluble ash	1.8
7.	Nitrogen free extract	42.9
8.	Calcium (Ca)	----
9.	Phosphorus (P)	----

sd\-
Soil Chemist
for RALLIS INDIA LIMITED

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APPENDIX 9

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/13

Date: 28/11/1991

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

Date of Collection : 10/10/1991

ANALYSIS RESULTS

Sl. No.	PARAMETER	CONTENT	Sl. No.	PARAMETER	CONTENT (ppm)
1.	Colour	Colour-less	11.	Chemical Oxygen Demand	6.5
2.	Odour	Odour-less	12.	Total hardness as $CaCO_3$	176
3.	Turbidity	Clear	13.	Calcium as $CaCO_3$	99
4.	pH	8.4	14.	Magnesium as $CaCO_3$	77
5.	Electrical Conductivity mmho/cm	1.04	15.	Chlorides as Cl^-	133
6.	Total Solids, (ppm)	510	16.	Sulphate as SO^{-2}_4	5.2
7.	Suspended Solids, (ppm)	30	17.	Carbonates as CO^{-2}_3	37.8
8.	Dissolved Solids (ppm)	480	18.	Bicarbonates as HCO^-_3	422
9.	Dissolved Oxygen, (ppm)	5.8	19.	Sulphides as S^{-2}	--
10.	Biochemical Oxygen Demand 5 days at 20° C, (ppm)	1.1	20.	Fluorides as F^-	0.1

Soil Chemist
for RALLIS INDIA LIMITED

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Dr. Ehrenstorfer GmbH

D-8900 Augsburg
RALLIS AGROCHEMICAL RESEARCH STATION
Peenya, II Phase, Bangalore-560 058

APPENDIX 10

CERTIFICATE OF ANALYSIS

Product Identification

Common name: Glyphosate, free acid
Other names:

Code No.:C 140500
Charge:00516
Expiry(at +4°C):5/94

Systematic name: N-(phosphonomethyl)glycine (IUPAC; CA)

Formula: $C_3H_8NO_5P$

Molecular weight: 169.08

CAS No.: 1071-83-6

Use: Herbicide

Purity of the sample was determined by :
O GC O HPLC O TLC X others:potentiometric Titra.

	C %	H %	N %	O %	P %
Elemental analysis calc.:					
found:					

Documented value of purity: 99%

Physical Data

Melting point:215-217°C Boiling point: Vapor pressure: --

Solubility: 1% in water at 25°C, sparingly soluble in common organic solvents

Product is X stable at 4°C
O hygroscopic
O flammable
O instable
O light sensitive
O air sensitive

Toxicological Data

LD_{50}: acute oral dosis for rats 4320 mg/kg

Product is O caustic
O carcinogen
O teratogen
X skin irritant
O mutagen
X harmful
O toxic

Special Remarks

avoid contact with skin and eyes, otherwise rinse thoroughly with water
Potentiometric Titration with 0,1N NaOH (graphical representation of the points of inflection)

The information herein is believed to be correct, but is provided without warranty of any kind

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Bundesgesundheitsamt

- GLP-Bundesstelle -

bga

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 ~~Auftra~~

[redacted]

Leiter GLP-Bundesstelle
GLP Federal Office

BUNDESGESUNDHEITSAMT

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