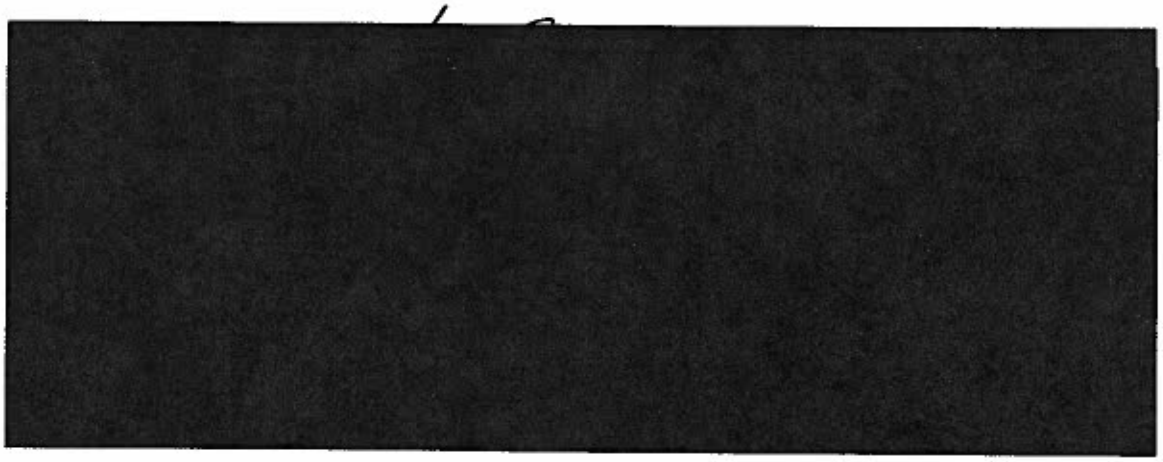
MONSANTO COMPANY
THE AGRICULTURAL GROUP
ENVIRONMENTAL HEALTH LABORATORY
645 S. NEWSTEAD
ST. LOUIS, MISSOURI 63110

Acute Oral Toxicity Study of CP4 EPSPS Protein in Albino Mice

Study Number: 92223
Project Number: ML-92-542

[]

SUMMARY

CP4 EPSPS protein (CP4) was administered as a single dose by gavage to groups of ten CD-1 mice/sex at dosages of 49, 154 and 572 mg/kg (target doses were 40, 100 and 400 mg/kg). A vehicle control group of 10 mice/sex was administered the vehicle, 50mM Na bicarbonate buffer solution, at a dosage of 33.33 ml/kg. Another control group (also termed vehicle control in the computer tables) of 10 mice/sex was administered bovine serum albumin (BSA) at a dosage of 363 mg/kg (also at 33.33 ml/kg; target dosage was 400 mg/kg). Clinical observations were performed, and body weights and food consumption were determined. All surviving animals were necropsied at study termination (Days 8-9). Numerous tissues were retained, but no tissues were examined microscopically.

There were no treatment-related effects on body weight, food consumption, survival, clinical observations or gross pathology.

There were no adverse effects by CP4 protein at dosages up to 572 mg/kg, administered by gavage to mice. Therefore, the highest dosage (572 mg/kg) of CP4 protein administered by gavage to mice was considered a No-Effect-Level (NOEL).

TABLE OF CONTENTS

TRADEMARKS

The following registered trademarks were used in this report:

ITEM	REGISTERED TRADEMARK OF:
RODENT CHOW	Purina Mills, Inc., St. Louis, MO
CD-1	Charles River Laboratories, Inc. Wilmington, MA

NOTES TO READER

TERMS

The following terms are used as column headings in some data tables:

GEN Generation (F0, F1, etc.) used in reproduction studies.

PERIOD (PER) A number corresponding to a specified interval within the study; used to facilitate data reporting.

WINDOW A series of days within a study when data could have been collected for the corresponding period. Actual data collection occurred on one or more of the days within the window.

ANIMAL IDENTIFICATION SYSTEM

The current EHL animal number format is YYXXXSGAANNN where YYXXX is the study number, Y is the study year, and X is the sequence number within the year. The S represents the animal's sex, G is the primary group code, A's may represent the subgroup code (in most cases these characters are blank), and N is the animal's sequence number within the group (or subgroup), e.g., 99999M2 001. The animal designation may be further reduced by exclusion of the study number and blank subgroup codes, e.g., M2001. These abbreviated animal identifications will include five to seven characters, depending on the number of characters in the subgroup code.

INTRODUCTION

Purpose: To determine the toxicity of CP4 protein when administered as a single dose by gavage to mice.
Date Protocol Signed by Study Director: December 21, 1992
Date of First Exposure (Day 1 of Study): December 21, 1992
Date Last Animal Sacrificed: December 29, 1992
Experimental Design: CP4 protein was administered by gavage to groups of ten CD-1 mice/sex at dosages of 49, 154 and 572 mg/kg (target doses were 40, 100 and 400 mg/kg). A vehicle control group of 10 mice/sex was administered the vehicle, 50mM Na bicarbonate buffer solution, at a dosage of 33.33 ml/kg. Another control group of 10 mice/sex was administered bovine serum albumin (BSA) at a dosage of 363 mg/kg (also at 33.33 ml/kg; target dosage was 400 mg/kg). Clinical observations were performed, and body weights and food consumption were determined. All animals were necropsied at study termination (Days 8-9). Numerous tissues were retained, but no tissues were examined microscopically.

MATERIALS AND METHODS

Test Material and Vehicle

Source (Test Material and Vehicle): The Agricultural Group, Monsanto Co., St. Louis, MO
Date Received: December 21, 1992

Identification: CP4 protein - >90% purity
3 solutions were prepared and provided by the sponsor; stated to be 1.2, 3.0 and 12.0 mg/ml in vehicle (Monsanto Report #MSL-12900)
EHL Substance Identification Codes: T920187, T920186 and T920185, respectively
Lot Number: nbp's 5192245 and 5212605

Identification: Vehicle - 50mM Na Carbonate buffer solution, pH 8.5
EHL Substance Identification Code: T920189
Lot Number: nbp's 5192245 and 5212605

Control Material

Identification: BSA - Crystallized and lyophilized, >98% purity
Source: Sigma Chemical Co., St. Louis, MO 63178
EHL Substance Identification Code: T920188
Lot Number: 50H9300

Test Material Formulation

Group Designations and Dosages:

Treatment Level	Group Designations (Male, Female)	Target Dosage	Nominal Conc.	Actual Dosage
Carb. buffer vehicle	MV1, FV1	33.33 ml/kg	N/A	33.33 ml/kg
BSA + vehicle	MV2, FV2	400 mg/kg	12 mg/ml	363 mg/kg*
T-1 (CP4 protein)	M1, F1	40 mg/kg	1.2 mg/ml	49 mg/kg*
T-2 (CP4 protein)	M2, F2	100 mg/kg	3 mg/ml	154 mg/kg*
T-3 (CP4 protein)	M3, F3	400 mg/kg	12 mg/ml	572 mg/kg*

*The 50mM carbonate buffer solution was used as the vehicle, and all groups were given a volume of 33.33 ml/kg. Both the BSA and CP4 protein were dissolved using the carbonate buffer vehicle. All of the dosing mixtures were true solutions. Actual dosages of CP4 groups were determined by ELISA analyses of the dosing solutions (Monsanto Report #MSL-12900).

Animals

Note: Animal housing and husbandry were in accordance with the provisions of the 'Guide to the Care and Use of Laboratory Animals', USPHS-NIH Publication No. 86-23.

Species: Albino mouse
Strain: CD-1
Source: Charles River Breeding Laboratory, Portage MI
Date of Arrival at EHL: December 8, 1992
Acclimation Period: 13 days
Number Used in Study: 100 (50 males, 50 females). Any unhealthy animals were excluded from assignment to the study.
Test Group Size: 10/sex
Method of Assignment: Computer randomization by weight
Method of Identification: Individual ear tag and bar-coded cage card
Age at Study Start: Males; approximately 5.5 weeks
Females; approximately 7 weeks (*Note* - The study protocol specified an age of 7-9 weeks on the first day of the study. The younger age of the males was not considered to have had an effect on the results of this study.)
Weight Range at Study Start: Males - 25.2 to 29.8 grams
Females - 22.7 to 27.2 grams
Type of Housing: Individual stainless steel cages
Water Availability: *ad libitum* (St. Louis public water supply, zeolite-conditioned upon entering the laboratory)
Food Availability: *ad libitum* (Purina Certified RODENT CHOW #5002)
Light Cycle: 12 hours daily (on at 6:30 A.M.)

Inlife Observations

Checks for Mortality and Moribundity: Twice daily (AM and PM)
Detailed Observations for Signs of Toxicity: Once (Day 7)
Body Weight: Prior to randomization, on Day 7 and at termination (after an overnight fast)
Food Consumption Measurement: Once (Days 1 to 7)

Gross Pathology

Animals Examined: All
Scheduled Sacrifice: Days 8-9
Extent of Examination: External and internal. Internal cavities were opened, and organs were examined *in situ* and then removed. Hollow organs were opened and examined.
Organs Weighed: None
Tissues Retained: Aorta, adrenals, brain, cecum, colon, duodenum, esophagus, eyes, femur with joint, gall bladder, gross lesions, heart, ileum, jejunum, kidneys, lungs (with mainstem bronchi), liver, lymph node (mesenteric and submaxillary), muscle (quadriceps femoris), ovaries, pancreas, pituitary, prostate, rectum, salivary gland (submaxillary), sciatic nerve, seminal vesicles, skin (with mammary tissue), spinal cord (cervical, thorax, lumbar), spleen, sternum with marrow, stomach, testes with epididymides, thymus, thyroid/parathyroid, trachea, uterus (corpus and cervix), urinary bladder
Fixatives: Eyes: 5% buffered neutral formalin/0.5% glutaraldehyde
Remaining tissues: 10% buffered neutral formalin

Statistics

The following procedures were used to detect statistically significant differences between treated animals and their respective controls:

Dunnett's Multiple Comparison Test (two-tailed) (1): Inlife body weights, cumulative weight gain and food consumption

Terminal body weights were evaluated by decision-tree statistical analysis procedures which, depending on the results of tests for normality (2) and homogeneity of variances (Bartlett's Test), utilized either parametric (Dunnett's Test and Linear Regression) or nonparametric (Kruskal-Wallis, Jonckheere's and/or Mann-Whitney Tests) routines to detect group differences and analyze for trend.

Other statistical routines used for some data were: Bartlett's Test (3) to evaluate homogeneity of variances, Analysis of Variance (4) to determine if the sample (group) means could be considered as an estimate of a common population.

RESULTS

Inlife

Mortality

Refer to Appendix 1, Table 4; Appendix 2, Table 4. All animals survived to the scheduled termination of the study.

Body Weight

Refer to Appendix 1, Tables 1 and 2; Appendix 2, Table 1. There were no statistically significant differences in group mean body weight or cumulative weight gain in any of the groups treated with either BSA or the CP4 protein, when compared to the carbonate buffer vehicle control group.

Food Consumption

Refer to Appendix 1, Table 3; Appendix 2, Table 2. There were no statistically significant differences in group mean food consumption by any of the groups treated with either BSA or the CP4 protein, when compared to the carbonate buffer vehicle control group.

Clinical Signs

Refer to Appendix 1, Table 4; Appendix 2, Table 3. There were no abnormal clinical signs.

Pathology

Gross Pathology

Refer to Appendix 1, Tables 5-6; Appendix 3, Table 1. There were no statistically significant differences in group mean terminal body weights, and there were no gross lesions considered related to treatment.

DISCUSSION

There were no adverse findings considered related to treatment in any of the groups. Therefore, the highest dosage (572 mg/kg) of CP4 protein administered by gavage to mice was considered a No-Observed-Effect-Level (NOEL).

REFERENCES

1. Dunnett, C.W. A multiple comparison procedure for comparing several treatments with a control. Jour. Am. Stat. Assoc. 50: 1096-1121 (1955).

2. BMDP Biomedical Computer Programs P Series Manual, Health Sciences Computing Facility, UCLA, University of California Press (1977).

3. Dixon, W.J. and Massey, F.J. Jr. Introduction to Statistical Analysis, 3rd Edition. McGraw-Hill Company, NY (1969).

4. Snedecor, G.W. and Cochran, W.G. Statistical Methods. Iowa State University Press, Ames, IA (1967).

ESH QUALITY ASSURANCE AUDIT STATEMENT

Study Number: 92223
ML-92-542

Protocol Amendments: None

Study Title: Acute Oral Toxicity Study of CP4 EPSPS Protein in Albino Mice

Dates of Inspections and Communication of Findings: December 28, 30, 1992
January 22, 28, 1993
March 16, 1993
June 10, 11, 16, 1993

Quality Assurance Review Conducted by: [redacted]

Results: The Quality Assurance review indicates the final report accurately presents the raw data as developed during the study. There appears to be no significant deviation from applicable GLP regulations that adversely affected study quality or integrity.

[redacted]

[redacted]

STATEMENT OF COMPLIANCE

The study EHL 92223 (ML-92-542) was conducted in general conformance with the EPA FIFRA (40 CFR Part 160), FDA (21 CFR Part 58), OECD and MAFF Good Laboratory Practice (GLP) Standards/Principles, with the following exception:

Test material characterization and stability were the responsibility of the Operating Unit and were not performed by the EHL.

[[redacted]]

[[redacted]]

SUPPLEMENTARY STUDY INFORMATION

Study Performed at: Environmental Health Laboratory (EHL), 645 S. Newstead, St. Louis, MO 63110

Location of Study Protocol, Original Data, Retained Tissues, Final Report and Facility Records: Environmental Health Laboratory Archives

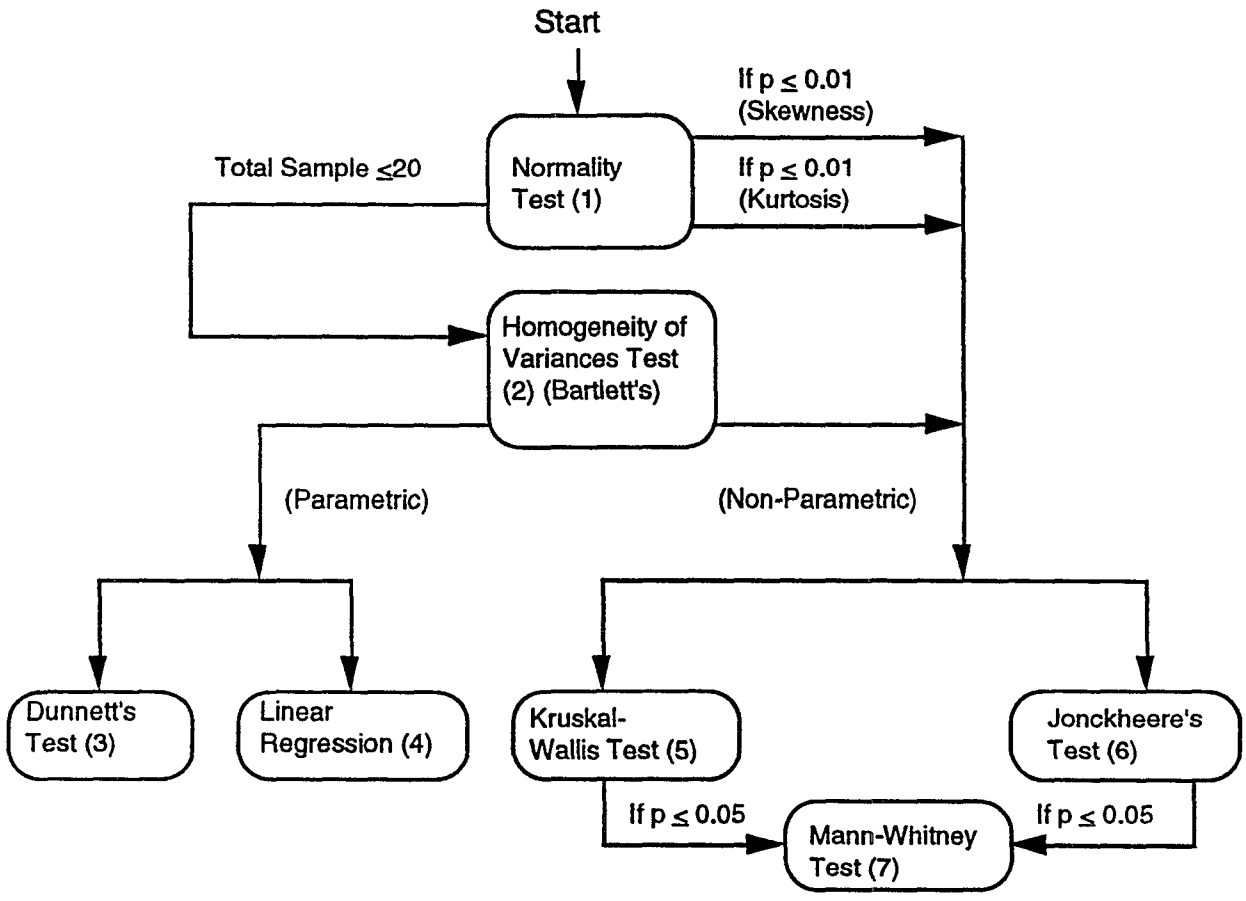
Supervisory Personnel:

[[redacted]]

[[redacted]]

[[redacted]]

EHL DECISION-TREE STATISTICAL ANALYSIS



Note 1: Categorical data were analyzed with an Uncorrected Chi-square Test (8)
Note 2: Dunnett's and Mann-Whitney tests to detect group differences were performed two-tailed.

EHL DECISION-TREE STATISTICAL ANALYSIS

REFERENCES

1. BMDP Biomedical Computer Programs P Series Manual, Health Sciences Computing Facility, UCLA, University of California Press (1977).

2. Dixon, W.J. and Massey, F.J. Jr., Introduction to Statistical Analysis, 3rd Edition, McGraw-Hill Company, NY (1969).

3. Dunnett, C.W. A multiple comparison procedure for comparing several treatments with a control. Jour. Am. Stat. Assoc. 50: 1096-1121 (1955).

4. Draper, N.R. and Smith, H. Applied Regression Analysis. Wiley, NY (1966).

5. Breslow, N. A generalized Kruskal-Wallis test for comparing K-Samples subject to unequal patterns of censorship. Biometrika. 57: 579-594 (1970).

6. Hollander, M. and Wolfe, D.A. Nonparametric Statistical Methods. Wiley, NY (1973).

7. Mann, H.B. and Whitney, D.R. On a test of whether one of two random variables is stochastically larger than the other. Ann. Math. Stat. 18: 50-60 (1947).

8. Snedecor, G.W. and Cochran, W.G. Statistical Methods. Iowa State University Press, Ames, IA (1967).

APPENDIX 1

SUMMARY TABLES

STUDY NUMBER: 92223 SUMMARY OF BODY WEIGHT DATA (GM)
DMEH NUMBER: ML92542
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE STRAIN/BREED: CD-1 STUDY START DATE: 21-DEC-92

SEX: MALE

GROUP	TARGET DOSE	DATE (1992): DAY OF STUDY:	PRE-TEST	27-DEC 7
MV1	33.33 ML/KG	MEAN	28.0	29.3
VEHICLE CONTROL		STD. DEV.	1.52	1.79
Na CARBONATE BUFFER		SAMPLE SIZE	10	10
MV2	33.33 ML/KG	MEAN	28.1	29.9
VEHICLE CONTROL		STD. DEV.	1.35	1.21
PROTEIN (BSA) CONTROL		SAMPLE SIZE	10	10
M1	49.00 MG/KG	MEAN	28.0	30.2
TEST GROUP		STD. DEV.	1.33	1.09
CP4 EPSPS PROTEIN		SAMPLE SIZE	10	10
M2	154.0 MG/KG	MEAN	28.0	29.5
TEST GROUP		STD. DEV.	1.32	1.67
CP4 EPSPS PROTEIN		SAMPLE SIZE	10	10
M3	572.0 MG/KG	MEAN	28.1	29.5
TEST GROUP		STD. DEV.	1.30	1.27
CP4 EPSPS PROTEIN		SAMPLE SIZE	10	10

- - - L E G E N D - - -

* -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .05$)
** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 92223
DMEH NUMBER: ML92542
RTE OF ADMIN: ORAL (GAVAGE)

SUMMARY OF BODY WEIGHT DATA (GM)

SPECIES: MOUSE STRAIN/BREED: CD-1 STUDY START DATE: 21-DEC-92

SEX: FEMALE

GROUP	TARGET DOSE	DATE (1992): DAY OF STUDY:	PRE-TEST	27-DEC 7
FV1	33.33 ML/KG	MEAN	24.8	25.2
VEHICLE CONTROL		STD. DEV.	1.20	1.65
Na CARBONATE BUFFER		SAMPLE SIZE	10	10
FV2	33.33 ML/KG	MEAN	24.8	25.0
VEHICLE CONTROL		STD. DEV.	1.19	0.87
PROTEIN (BSA) CONTROL		SAMPLE SIZE	10	10
F1	49.00 MG/KG	MEAN	24.6	24.8
TEST GROUP		STD. DEV.	1.24	1.51
CP4 EPSPS PROTEIN		SAMPLE SIZE	10	10
F2	154.0 MG/KG	MEAN	24.6	25.0
TEST GROUP		STD. DEV.	1.12	1.04
CP4 EPSPS PROTEIN		SAMPLE SIZE	10	10
F3	572.0 MG/KG	MEAN	24.6	24.7
TEST GROUP		STD. DEV.	1.27	1.46
CP4 EPSPS PROTEIN		SAMPLE SIZE	10	10

- - - L E G E N D - - -

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** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 92223 SUMMARY OF FOOD CONSUMPTION DATA
DMEH NUMBER: ML92542
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE STRAIN/BREED: CD-1 STUDY START DATE: 21-DEC-92

SEX: MALE

FROM DATE : 21-DEC-92
TO DATE : 27-DEC-92
DAY OF STUDY (FROM-TO) : 1-7

MV1	VEHICLE CONTROL	MEAN GM/DAY	5.4
33.33 ML/KG		STD. DEV.	0.50
Na CARBONATE BUFFER		SAMPLE SIZE	10
MV2	VEHICLE CONTROL	MEAN GM/DAY	5.4
33.33 ML/KG		STD. DEV.	0.43
PROTEIN (BSA) CONTROL		SAMPLE SIZE	10
M1	TEST GROUP	MEAN GM/DAY	5.5
49.00 MG/KG		STD. DEV.	0.27
CP4 EPSPS PROTEIN		SAMPLE SIZE	10
M2	TEST GROUP	MEAN GM/DAY	5.5
154.0 MG/KG		STD. DEV.	0.37
CP4 EPSPS PROTEIN		SAMPLE SIZE	10
M3	TEST GROUP	MEAN GM/DAY	5.5
572.0 MG/KG		STD. DEV.	0.38
CP4 EPSPS PROTEIN		SAMPLE SIZE	10

- - - L E G E N D - - -

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** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 92223 SUMMARY OF FOOD CONSUMPTION DATA
DMEH NUMBER: ML92542
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE STRAIN/BREED: CD-1 STUDY START DATE: 21-DEC-92

SEX: FEMALE

FROM DATE : 21-DEC-92
TO DATE : 27-DEC-92
DAY OF STUDY (FROM-TO) : 1-7

FV1 VEHICLE CONTROL	MEAN GM/DAY	5.5
33.33 ML/KG	STD. DEV.	0.89
Na CARBONATE BUFFER	SAMPLE SIZE	10
FV2 VEHICLE CONTROL	MEAN GM/DAY	5.1
33.33 ML/KG	STD. DEV.	0.65
PROTEIN (BSA) CONTROL	SAMPLE SIZE	10
F1 TEST GROUP	MEAN GM/DAY	5.3
49.00 MG/KG	STD. DEV.	0.85
CP4 EPSPS PROTEIN	SAMPLE SIZE	10
F2 TEST GROUP	MEAN GM/DAY	5.3
154.0 MG/KG	STD. DEV.	0.50
CP4 EPSPS PROTEIN	SAMPLE SIZE	10
F3 TEST GROUP	MEAN GM/DAY	5.1
572.0 MG/KG	STD. DEV.	0.37
CP4 EPSPS PROTEIN	SAMPLE SIZE	9

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** -- DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE ($P \leq .01$)
BT -- BARTLETT'S TEST INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE AMONG VARIANCES OF THE DIFFERENT GROUPS ($P \leq .01$)
NA -- DUNNETT'S TEST NOT APPROPRIATE FOR THIS GROUP/SEX/DATE

STUDY NUMBER: 92223 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES (GM) REPORT PRINT DATE: 12-AUG-93
DMEH NUMBER: ML92542
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE STRAIN/BREED: CD-1 STUDY START DATE: 21-DEC-92

SEX: MALE

		FROM DATE: 21-DEC-92 TO DATE : 27-DEC-92 DAY OF STUDY (FROM-TO): 1- 7
MV1 VEHICLE CONTROL 33 ML/KG Na CARBONATE BUFFER	MEAN GM STD. DEV. SAMPLE SIZE	1.26 0.917 10
MV2 VEHICLE CONTROL 33 ML/KG PROTEIN (BSA) CONTROL	MEAN GM STD. DEV. SAMPLE SIZE	1.88 0.853 10
M1 TEST GROUP 49 MG/KG CP4 EPSPS PROTEIN	MEAN GM STD. DEV. SAMPLE SIZE	2.20 0.892 10
M2 TEST GROUP 154 MG/KG CP4 EPSPS PROTEIN	MEAN GM STD. DEV. SAMPLE SIZE	1.54 1.171 10
M3 TEST GROUP 572 MG/KG CP4 EPSPS PROTEIN	MEAN GM STD. DEV. SAMPLE SIZE	1.46 0.675 10

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* - DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE (P < 0.05)
** - DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE (P < 0.01)
NA - DUNNETT'S TEST NOT APPROPRIATE FOR THIS PERIOD

STUDY NUMBER: 92223 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES (GM) REPORT PRINT DATE: 12-AUG-93
DMEH NUMBER: ML92542
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE STRAIN/BREED: CD-1 STUDY START DATE: 21-DEC-92

SEX: FEMALE

		FROM DATE: 21-DEC-92 TO DATE : 27-DEC-92 DAY OF STUDY (FROM-TO): 1- 7
FV1 VEHICLE CONTROL 33 ML/KG Na CARBONATE BUFFER	MEAN GM STD. DEV. SAMPLE SIZE	0.47 0.753 10
FV2 VEHICLE CONTROL 33 ML/KG PROTEIN (BSA) CONTROL	MEAN GM STD. DEV. SAMPLE SIZE	0.26 0.450 10
F1 TEST GROUP 49 MG/KG CP4 EPSPS PROTEIN	MEAN GM STD. DEV. SAMPLE SIZE	0.11 0.995 10
F2 TEST GROUP 154 MG/KG CP4 EPSPS PROTEIN	MEAN GM STD. DEV. SAMPLE SIZE	0.35 0.688 10
F3 TEST GROUP 572 MG/KG CP4 EPSPS PROTEIN	MEAN GM STD. DEV. SAMPLE SIZE	0.12 0.760 10

- - - L E G E N D - - -

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** - DUNNETT'S TEST (TWO-TAILED) INDICATES STATISTICALLY SIGNIFICANT DIFFERENCE (P < 0.01)
NA - DUNNETT'S TEST NOT APPROPRIATE FOR THIS PERIOD

STUDY NUMBER: 92223 SUMMARY OF CLINICAL SIGNS REPORT PRINT DATE: 12-AUG-1993
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE
STUDY START DATE: 21-DEC-1992 STRAIN/BREED: CD-1

CATEGORY	OBSERVATION	GEN.	SEX	WINDOW	GROUP	NO. ANIMALS AFFECTED	NO. OF OCCURRENCES
DEATH	SCHEDULED SACRIFICE		M	D7-9	MV1	10	10
					MV2	10	10
					M1	10	10
					M2	10	10
					M3	10	10
			F	D7-9	FV1	10	10
					FV2	10	10
					F1	10	10
					F2	10	10
					F3	10	10

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STUDY NUMBER: 92223 SUMMARY OF TERMINAL BODY AND ORGAN WEIGHT DATA (GM) REPORT PRINT DATE: 10-JUN-1993
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE
STUDY START DATE: 21-DEC-1992 STRAIN/BREED: CD-1

ITEM OF INTEREST	GEN.	SEX	PERIOD	WINDOW	GROUP	MEAN	%CONTROL	STD.DEV.	N	STAT FLAGS
TERM. BODY WGT.		M	1	D8-9	MV1	24.1800		1.4297	10	(PA)
					MV2	24.4900	(101)	1.2252	10	
					M1	24.7000	(102)	1.0750	10	
					M2	24.0700	(100)	1.6573	10	
					M3	24.3100	(101)	1.1080	10	
		F	1	D8-9	FV1	21.9500		1.5006	10	(PA)
					FV2	21.1300	(96)	1.0166	10	
					F1	21.3200	(97)	1.1961	10	
					F2	21.3300	(97)	0.9417	10	
					F3	21.1300	(96)	1.4376	10	

STUDY NUMBER: 92223 SUMMARY OF TERMINAL BODY AND ORGAN WEIGHT DATA (GM) REPORT PRINT DATE: 10-JUN-1993
RTE OF ADMIN: ORAL (GAVAGE) SPECIES: MOUSE
STUDY START DATE: 21-DEC-1992 STRAIN/BREED: CD-1

EXPLANATION OF STATISTICAL FLAGS

GENERAL

Flag	Statistical Statement
NA	Statistics not done, insufficient or inappropriate data

NONCATEGORICAL DATA

Flag	Statistical Statement
Parametric (PA)	
L-	The response is linearly related to dose (p<=0.05) with a negative slope
L--	The response is linearly related to dose (p<=0.01) with a negative slope
L+	The response is linearly related to dose (p<=0.05) with a positive slope
L++	The response is linearly related to dose (p<=0.01) with a positive slope
*	Significantly different from control (p<=0.05; Dunnett's)
**	Significantly different from control (p<=0.01; Dunnett's)
Nonparametric (NP)	
L-	The response is linearly related to dose (p<=0.05) with a negative slope
L--	The response is linearly related to dose (p<=0.01) with a negative slope
L+	The response is linearly related to dose (p<=0.05) with a positive slope
L++	The response is linearly related to dose (p<=0.01) with a positive slope
*	Significantly different from control (p<=0.05; Mann-Whitney)
**	Significantly different from control (p<=0.01; Mann-Whitney)

CATEGORICAL DATA

Flag	Statistical Statement
C+	Significantly different from control (p<=0.05; uncorrected Chi square)
C++	Significantly different from control (p<=0.01; uncorrected Chi square)

STUDY NO: 92223 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: MOUSE SUBSTANCE: CP4 EPSPS PROTEIN PRINTED: 30-APR-93

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	MALE				
NO. IN GROUP AT RISK:	MV1 10	MV2 10	M1 10	M2 10	M3 10
EYE(S)					
-CORNEAL OPACITY	0	0	0	0	0
KIDNEY(S)					
-CYST	0	0	0	0	0
PITUITARY					
-FOCUS, RED/PURPLE/BLACK	0	0	0	0	0
UTERUS					
-HYDROMETRA	0	0	0	0	0

STUDY NO: 92223 ***** MONSANTO ENVIRONMENTAL HEALTH LAB ***** PAGE: 1
P A T H O L O G Y S E C T I O N
STUDY TYPE: SC SPECIES: MOUSE SUBSTANCE: CP4 EPSPS PROTEIN PRINTED: 30-APR-93

** SUMMARY INCIDENCE OF INDIVIDUAL GROSS NECROPSY ALTERATIONS **
SELECTION CRITERIA: ALL DEATHS REPORTED

	---- F E M A L E ----				
	FV1	FV2	F1	F2	F3
NO. IN GROUP AT RISK:	10	10	10	10	10
EYE(S)					
-CORNEAL OPACITY	0	0	0	1	0
KIDNEY(S)					
-CYST	0	0	1	0	0
PITUITARY					
-FOCUS, RED/PURPLE/BLACK	1	0	0	0	0
UTERUS					
-HYDROMETRA	2	1	1	1	2

Pages 30 to 171 contain Confidential Business Information and were placed in the Confidential Appendix of this report.