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**RHÔNE-POULENC INC.**

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October 23, 1992

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Attn: Section 8(e) Coordinator (CAP Agreement)  
Office of Toxic Substances  
Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance  
Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0212

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Chemical Identity: Monocalcium phosphate anhydrous  
CAS Registry No: 7758-23-8  
CAS Registry Name: Phosphoric acid, calcium salt (2:1)

mm  
3/1/95

2

The title of the enclosed report is:

Acute Toxicity Test Battery For Monocalcium Phosphate Anhydrous

The following is a summary of the adverse effects observed in this report.

The test material was corrosive to the eyes of rabbits. Signs of ocular damage consisting of corneal opacity, conjunctivitis, and corneal epithelial erosion were still present in unwashed eyes 24 days after instillation of test material. Washing the eye reduced the severity and persistence of the irritation. The pH of the product is reported to be 4.2.

RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,



Charles E. Moyer, Jr., Ph.D.  
Director, Product Safety  
(609)860-3589

CEMjr/mm  
Enclosures

CC: RTL, T-files copy 1  
ENC Central Files, (originals)

L. M. Crawford, copy 2  
M. J. Pellegrini, copy 3  
J. J. Wise, copy 4  
A. C. Casey, copy 5  
H. B. Reisman, copy 6  
R. I. Freudenthal, copy 7\*  
H. L. Northrop, copy 8\*  
J. W. Eickenhorst, copy 9\*  
S. E. Hastings, copy 10\*  
J. R. Solga, copy 11\*

R. F. Potrepka, copy 12\*  
D. R. Saunders, copy 13\*  
J. T. Elfstrum, copy 14\*  
M. W. Sauerhoff, copy 15\*  
J. A. Kieft, copy 16\*

Date May 10, 1985

SUMMARY OF RICHMOND TOXICOLOGY LABORATORY REPORT -- T-12163

Acute Toxicity Test Battery For Monocalcium Phosphate Anhydrous (Lot # 525)

Project Number: 180004

I. PURPOSE This study was conducted to evaluate the acute toxicity of Monocalcium Phosphate Anhydrous.

II. MATERIALS

Test Material: The sample was a white powder, received on 8-1-84 at the request of J. V. Feminella. The sample was identified as Monocalcium Phosphate Anhydrous (Lot # 525), a food ingredient.

Animals: The Sprague-Dawley albino rats were purchased from Charles River Laboratories, Portage, MI and the Stauffland albino rabbits were purchased from Phillips Rabbitry, Soquel, CA.

III. EXPERIMENTAL DESIGN

The study was conducted according to the following protocols: RTL-A-11, RTL-A-12, RTL-A-13 and RTL-A-19. These protocols are consistent with or exceed EPA and OECD Guidelines.

IV. SUMMARY OF RESULTS

Acute oral LD<sub>50</sub>, male rats: >5000 mg/kg

Acute oral LD<sub>50</sub>, female rats: 3986 mg/kg (95% confidence limits = 3341-4757)

Acute dermal LD<sub>50</sub>, rabbits: >2000 mg/kg

Skin irritation classification: Non-irritant  
(4-hour exposure)

Eye irritation classification: Corrosive

Written by: Sally S. Sorenson  
S. S. Sorenson

Study Director: Ronald L. Morgan  
R. L. Morgan, Ph.D.

Reviewed by: Thomas L. Foster  
T. L. Foster

Approved by: Thomas R. Castles  
T. R. Castles, Ph.D.

\*receive summary only

Monocalcium Phosphate Anhydrous

The purpose of this study was to determine the acute toxicity of Monocalcium Phosphate Anhydrous. The study included acute oral and dermal toxicity, and skin and eye irritation. It was initiated on 8-20-84 and completed on 11-7-84.

Materials

Monocalcium Phosphate Anhydrous (Lot # 525) was used throughout this study. The sample was supplied at the request of J. V. Feminella. It was a white powder which was described as a food ingredient.

Animals used for this study were purchased from Charles River Laboratories, Portage, Michigan (Sprague-Dawley albino rats) and from Phillips Rabbitry, Soquel, California (Stauffland albino rabbits).

Methods

Test methods used for the evaluation of Monocalcium Phosphate Anhydrous are given in the following protocols: RTL-A-11, RTL-A-12, RTL-A-13 and RTL-A-19. In all tests, the animals were observed closely prior to testing to ascertain their physical well-being. In addition, all animals in the oral and dermal tests were observed a minimum of twice daily during the testing periods with the exception of weekends and holidays when a single daily observation was made. Necropsies were performed on all animals in the oral and dermal LD<sub>50</sub> tests that died during the study (with the exception of cannibalized animals) and on all survivors observed for at least 14 days.

Results and Discussion

Results of these tests are given in the following paragraphs.

Oral Toxicity. The acute oral LD<sub>50</sub> for Monocalcium Phosphate Anhydrous given to male albino rats was >5000 mg/kg. Mortality at this dose level was 3/10. Commonly observed adverse clinical signs included mild to moderate depression and piloerection. Frequently observed signs at necropsy included a clear fluid issuing from the nostrils, pale livers, and darkened spleens.

Monocalcium Phosphate Anhydrous

The acute oral LD<sub>50</sub> for Monocalcium Phosphate Anhydrous given to female albino rats was 3986 mg/kg. Commonly observed adverse clinical signs included depression, piloerection, and ptosis. Frequently observed signs at necropsy included mottled, pale or reddened lungs; mottled or pale livers; darkened spleens; and pale kidneys.

Dermal Toxicity. The acute dermal LD<sub>50</sub> for Monocalcium Phosphate Anhydrous given to a mixed population of albino rabbits was >2000 mg/kg. There were no mortalities at this dose level. All rabbits appeared normal throughout the 14 day test. Local dermal effects included darkened dose sites, severe erythema, mild edema, and the skin at the abrasion marks was separated and filled with reddish fluid and pus-like material. All rabbits appeared normal at necropsy.

Dermal Irritation. Monocalcium Phosphate Anhydrous was a non-irritant to intact and abraded skin of albino rabbits after a 4 hour exposure. This formulation was classified as a non-irritant to the intact and abraded skin of 6 rabbits.

Ocular Irritation. Monocalcium Phosphate Anhydrous was a corrosive in the eyes of albino rabbits. In the 6 rabbits whose eyes were left unwashed, this formulation produced mild to severe corneal opacity (6 rabbits); moderate to severe iritis (6 rabbits); mild to severe conjunctival irritation (6 rabbits); mild to severe corneal epithelial erosion (6 rabbits); contraction of the palpebral conjunctivae (6 rabbits); contraction of the bulbar conjunctivae (6 rabbits); neovascularization (6 rabbits); pannus (6 rabbits); white deposits in the sub-epithelial layer of the cornea (1 rabbit); and a corneal ulcer (1 rabbit). One rabbit phonated when the test material was administered. On day 24, irritation included mild to severe corneal opacity (5 rabbits); mild to severe conjunctival irritation (6 rabbits); mild to severe corneal epithelial erosion (3 rabbits);

Monocalcium Phosphate Anhydrous

Ocular Irritation (continued)

contraction of the palpebral conjunctivae (5 rabbits); contraction of the bulbar conjunctivae (5 rabbits); neovascularization (6 rabbits); and pannus (5 rabbits).

In the 3 rabbits whose eyes were washed 20-30 seconds after treatment, this formulation produced mild to severe conjunctival irritation (3 rabbits); and a thickened and rough sclera (1 rabbit). On day 21, the only irritation was mild conjunctival irritation (1 rabbit) which cleared by day 24.

Data Summaries. Individual observations, symptoms, and pertinent information pertaining to each section described above are given in Appendix I, Sections A through E. Raw data, the final report and any protocol deviations are stored at the Richmond Toxicology Laboratory, Stauffer Chemical Company, Richmond, California.

APPENDIX I

Supportive Data

<u>Section</u>		<u>Page</u>
A	Acute Oral Toxicity - Rats	A-1
B	Acute Dermal Toxicity - Rabbits	B-1
C	Primary Dermal Irritation - Rabbits	C-1
D	Primary Eye Irritation - Rabbits	D-1
E	Bibliography	E-1

## Section A

## Monocalcium Phosphate Anhydrous

MALE RAT ACUTE ORAL TOXICITYLD<sub>50</sub>, mg/kg: >5000

This test is consistent with the protocol outlined in the Environmental Protection Agency's Guidelines for Registering Pesticides in the U.S.; Hazard Evaluation: Humans and Domestic Animals, Fed. Reg. 43:163, 37336-37402 (1978). This test also is consistent with OECD Guidelines (1981).

Sprague-Dawley albino rats were used for test purposes. The test material was either dissolved or suspended in a suitable vehicle. In the case of an insoluble or granular solid, the test material was ground to a fine powder, passed through a #300 mesh screen and suspended in corn oil. The test material was administered in single doses by means of the gavage tube. A minimum of ten animals were used for each dose level. The animals were fasted for 16-18 hours prior to treatment. The animals were observed for at least 14 days after treatment for mortality and signs of toxicity.

Necropsies were performed on all animals that died during the study (with the exception of cannibalized animals) and on all survivors.

Weight Range, grams: 202-250

Dose Volume to Body Weight Ratio, ml/kg: 10

Vehicle: Water

<u>Dose Level, mg/kg</u>	5000
<u>Mortality</u>	3/10

Clinical Signs:

A single dose of 5000 mg/kg killed 3 rats within 24 hours (1 rat died prior to the first observation). Adverse clinical signs for the observed rats included mild to moderate depression (9 rats); diarrhea (1 rat); and piloerection (8 rats). The survivors appeared normal within 24 hours.

Necropsy Results:

Ten rats were necropsied. Observations for the rats that died during the test included evidence of salivation (1 rat); clear discharge from the nostrils (2 rats); pale lungs (1 rat); reddened lungs (1 rat); a purple-spotted thymus (1 rat); a pale liver (1 rat); darkened spleens (2 rats); test material-like fluid in the gastrointestinal tract (1 rat); a distended stomach filled with clear fluid (1 rat); reddened stomach mucosa (1 rat); pale intestines (1 rat); pale kidneys (1 rat); and gelatinous appearing intestines (1 rat). The survivors were necropsied following termination on day 14. Observations for one rat included pale lungs, a pale liver, a darkened spleen, test material-like fluid in the stomach, and dark gelatinous-like material lining the stomach.

## Monocalcium Phosphate Anhydrous

MALE RAT ACUTE ORAL TOXICITY (continued)

<u>Dose Level, mg/kg</u>	0
<u>Mortality</u>	0/10

Clinical Signs:

A total of ten rats were dosed with water and served as vehicle controls. All rats appeared normal throughout the 14 day test.

Necropsy Results:

Ten rats were necropsied following termination on day 14 and appeared normal.

Work Performed by P. K. Doane and S. S. Sorenson

## Monocalcium Phosphate Anhydrous

FEMALE RAT ACUTE ORAL TOXICITY

LD<sub>50</sub>, mg/kg: 3986 (95% confidence limits = 3341-4757)

This test is consistent with the protocol outlined in the Environmental Protection Agency's Guidelines for Registering Pesticides in the U.S.; Hazard Evaluation: Humans and Domestic Animals, Fed. Reg. 43:163, 37336-37402 (1978).

Sprague-Dawley albino rats were used for test purposes. The test material was either dissolved or suspended in a suitable vehicle. In the case of an insoluble or granular solid, the test material was ground to a fine powder, passed through a #300 mesh screen and suspended in corn oil. The test material was administered in single doses by means of the gavage tube. A minimum of ten animals were used for each dose level. The animals were fasted for 16-18 hours prior to treatment. The animals were observed for at least 14 days after treatment for mortality and signs of toxicity.

Necropsies were performed on all animals that died during the study (with the exception of cannibalized animals) and on all survivors. LD<sub>50</sub> determinations, slopes of the curves, and the 95% confidence limits were determined according to the procedures described by Litchfield and Wilcoxon (1949).

Weight Range, grams: 153-226

Dose Volume to Body Weight Ratio, ml/kg: 10

Vehicle: Water

<u>Dose Level, mg/kg</u>	5000
<u>Mortality</u>	7/10

Clinical Signs:

A single dose of 5000 mg/kg killed 7 rats within 24 hours. Adverse clinical signs for all rats included mild to severe depression, piloerection, ptosis, and diarrhea. Other signs included prostration (1 rat); and ataxia (1 rat). The survivors appeared normal on day 2, however, there was evidence of alopecia (1 rat) from day 13 through day 14.

Necropsy Results:

Ten rats were necropsied. Observations for the rats that died during the test included evidence of lachrimation (3 rats); reddish stains at the nostrils (1 rat); mottled lungs (4 rats); clear fluid in the thoracic cavities (2 rats); greenish lungs (2 rats); purple-spotted thymuses (2 rats); pale livers (6 rats); darkened or dark-tipped spleens (7 rats); test material-like fluid in the gastrointestinal tract (1 rat); distended stomachs filled with clear fluid (4 rats); pale kidneys (5 rats); pale intestines (3 rats); and pale uterine horns (6 rats). The survivors were necropsied following termination on day 14 and appeared normal.

## Monocalcium Phosphate Anhydrous

FEMALE RAT ACUTE ORAL TOXICITY (continued)

<u>Dose Level, mg/kg</u>	<u>4467</u>
Mortality	7/10

Clinical Signs:

A single dose of 4467 mg/kg killed 7 rats within 24 hours. Adverse clinical signs for all rats included mild to severe depression, ptosis, piloerection, and diarrhea. Other signs included lacrimation (1 rat) and dyspnea (1 rat). The survivors appeared normal within 24 hours.

Necropsy Results:

Nine rats were necropsied (1 rat was cannibalized and therefore not necropsied). Observations for the remaining rats that died during the test included yellowish anogenital stains (2 rats); evidence of lacrimation (1 rat); pale lungs (1 rat); discolored lungs (1 rat); mottled livers (5 rats); pale kidneys (2 rats); a darkened spleen (1 rat); reddened intestines (1 rat); and gelatinous appearing intestines (1 rat). The survivors were necropsied following termination on day 14 and appeared normal.

<u>Dose Level, mg/kg</u>	<u>3981</u>
Mortality	4/10

Clinical Signs:

A single dose of 3981 mg/kg killed 4 rats within 24 hours. Adverse clinical signs for all rats included mild depression, piloerection, a hunched posture, and ptosis. The only other observation was lacrimation (1 rat). The survivors appeared normal within 24 hours.

Necropsy Results:

Ten rats were necropsied. Observations for the rats that died during the test included cannibalized facial areas (2 rats); pale lungs (3 rats); pale kidneys (4 rats); reddish-yellow, gelatinous fluid in the intestines (4 rats); darkened spleens (2 rats); and a pale spleen (1 rat). The survivors were necropsied following termination on day 14 and appeared normal.

<u>Dose Level, mg/kg</u>	<u>3162</u>
Mortality	3/10

Clinical Signs:

A single dose of 3162 mg/kg killed 3 rats within 24 hours. Adverse clinical signs for all rats included mild depression and piloerection. The survivors appeared normal within 24 hours.

## Monocalcium Phosphate Anhydrous

FEMALE RAT ACUTE ORAL TOXICITY (continued)Necropsy Results:

Ten rats were necropsied. Observations for the rats that died during the test included a purple-spotted thymus (1 rat); reddened lungs (3 rats); pale, dark-edged livers (3 rats); darkened spleens (2 rats); and pale kidneys (2 rats). The survivors were necropsied following termination on day 14 and appeared normal.

<u>Dose Level, mg/kg</u>	0
<u>Mortality</u>	0/40

Clinical Signs:

A total of forty rats were dosed with water and served as vehicle controls. All rats appeared normal throughout the 14 day test.

Necropsy Results:

Forty rats were necropsied following termination on day 14 and appeared normal.

Work Performed by P. K. Doane

## Monocalcium Phosphate Anhydrous

DETERMINATION OF THE LD<sub>50</sub> ACCORDING TO  
THE METHOD OF LITCHFIELD AND WILCOXON

T-12163

ROUTE: ORAL

SPECIES: RAT

SEX: FEMALE

DOSE (MG/KG)	MORTALITY	OBSERVED % EFFECT	EXPECTED % EFFECT	OBSERVED - EXPECTED	CONTRIBUTION TO CHI-SQUARE
5000	7/10	70.00	71.75	-1.75	0.0015
4467	7/10	70.00	61.50	8.50	0.0305
3981	4/10	40.00	49.86	-9.86	0.0389
3162	3/10	30.00	27.83	2.17	0.0023

TOTAL ANIMALS = 40  
NUMBER OF DOSES = 4 (K)  
ANIMALS/DOSE = 10  
R = 5000/3162 = 1.58  
N' = 40

TOTAL = .0732

$(CHI)^2 = (ANIMALS/DOSE) (TOTAL) = (10) (.0732) = .732$   
DEGREES OF FREEDOM, N = K-2 = 2  
 $(CHI)^2$  FROM TABLE 2 FOR N OF 2 = 5.99

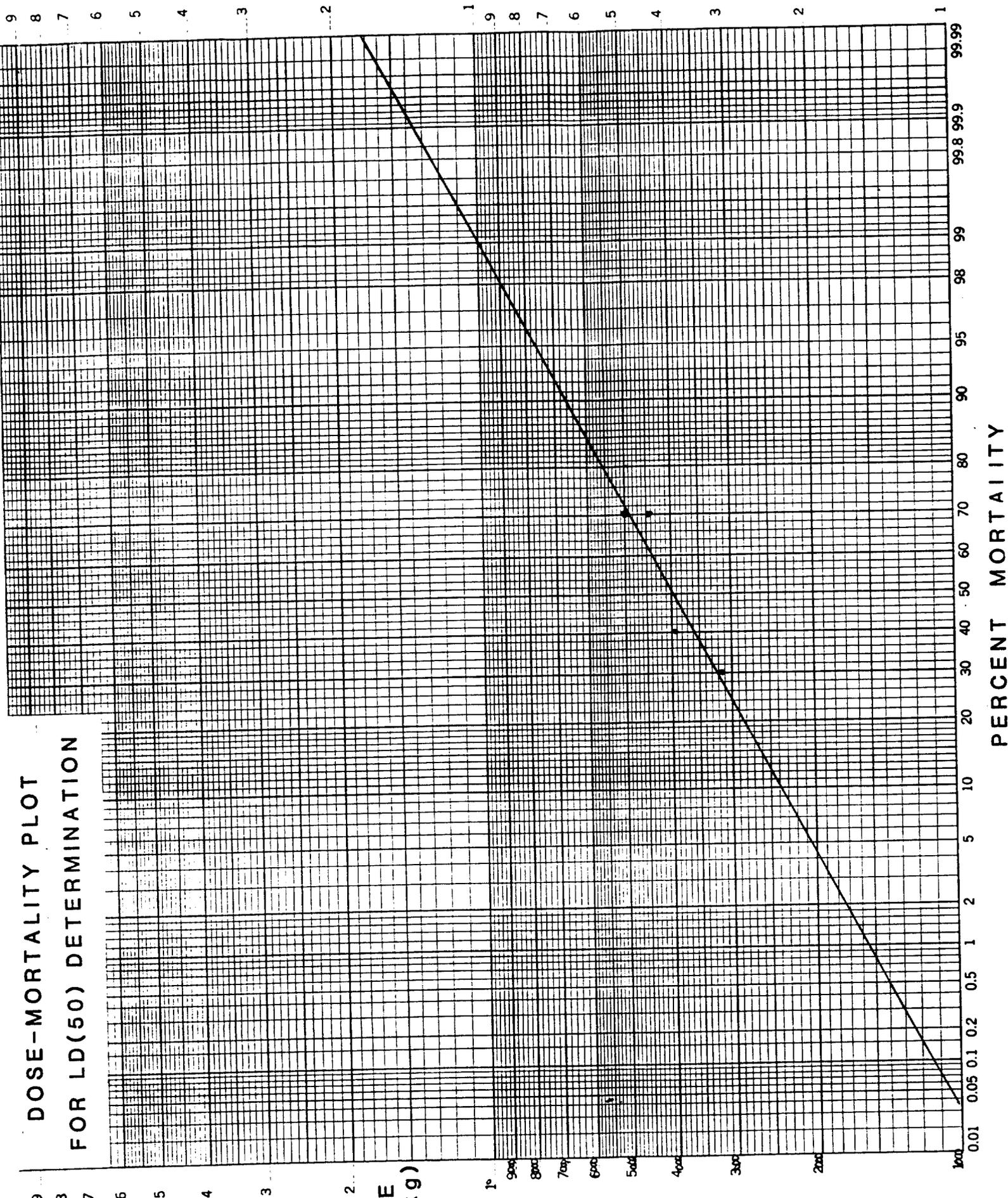
FED<sub>50</sub> = 1.19  
LD<sub>94</sub> = 5968  
LD<sub>50</sub> = 3986  
LD<sub>16</sub> = 2663

S = 1.5  
FS = 1.59  
A = 1.48

CONFIDENCE LIMITS FOR S = .94-2.38 (95%)  
CONFIDENCE LIMITS FOR LD<sub>50</sub> = 3341-4757 (95%)

T-12163  
♀  
not  
oral  
SSS

# DOSE-MORTALITY PLOT FOR LD(50) DETERMINATION



**Section B**

## Monocalcium Phosphate Anhydrous

RABBIT ACUTE DERMAL TOXICITYLD<sub>50</sub>, mg/kg: >2000

This test is consistent with the protocol outlined in the Environmental Protection Agency's Guidelines for Registering Pesticides in the U.S.; Hazard Evaluation: Humans and Domestic Animals, Fed. Reg. 43:163, 37336-37402 (1978). The test exceeds the protocol recommended in the OECD Guidelines (1981).

Stauffland albino rabbits were used in this study. A minimum of four male and four female rabbits had the test material applied to the closely clipped abdominal skin beneath a protective binder. The skin was abraded on half of the animals and left intact on the others. After a 24-hour period, the binder material and test material were removed, the abdominal skin was inspected for irritation and rewrapped in a gauze binder. Three days later, this gauze binder was removed. The test animals were observed for at least 14 days following the initial treatment.

Necropsies were performed on all animals that died during the study and on all survivors.

Weight Range, kg: 1.642-2.146

<u>Dose Level, mg/kg</u>	2000
<u>Mortality</u>	0/10

Clinical Signs:

A single dermal dose of 2000 mg/kg produced no mortalities in a mixed group of albino rabbits (5 male and 5 female). All rabbits appeared normal throughout the 14 day test.

Local Effects:

Local dermal effects included darkened dose sites, severe erythema, mild edema, and the skin at the abrasion marks was separated and filled with reddish fluid and pus-like material.

Necropsy Results:

Ten rabbits were necropsied following termination on day 14 and appeared normal.

<u>Dose Level, mg/kg</u>	0
<u>Mortality</u>	0/4

Clinical Signs:

Two male and two female rabbits were sham-treated and served as controls. These rabbits appeared normal throughout the 14 day test.

Local Effects:

There were no apparent local dermal effects following a 24 hour sham-treatment.

Necropsy Results:

Four rabbits were necropsied following termination on day 14 and appeared normal.

Work Performed by T. L. Foster and B. J. Jones

## Section C

## Monocalcium Phosphate Anhydrous

PRIMARY SKIN IRRITATION

Skin Irritation Classification: Non-irritant

This test is consistent with the protocol outlined in the Environmental Protection Agency's Guidelines for registering Pesticides in the U.S.; Hazard Evaluation: Humans and Domestic Animals, Fed. Reg. 43:163, 37336-37402 (1978). This test exceeds OECD Guidelines (1981).

The primary irritation of the skin was measured by a patch-test technique on the abraded and intact skin of six Stauffland albino rabbits. Half a milliliter (in case of liquids) or 0.5 grams (in case of solids and semi-solids) of the test substance was introduced under a one-inch square gauze patch. The patches were secured in place by adhesive tape and wrapped with rubberized damming for a 4-hour period. After 4-hours of exposure, the patches and test material were removed, and the resulting reactions were given a score. Readings were also made after 24- and 72-hours, and the final score represents an average of all readings. The scoring and evaluation criteria are those described by Draize (1965).

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	72 hr.	4 hr.	24 hr.	72 hr.		
84-M-1084	Intact	0	0	0	0	0	0	0	0
	Abraded	0	0	0	0	0	0		
84-M-1085	Intact	0	0	0	0	0	0	0	0
	Abraded	0	0	0	0	0	0		
84-M-1086	Intact	0	0	0	0	0	0	0	0
	Abraded	0	0	0	0	0	0		
84-M-1087	Intact	0	0	0	0	0	0	0	0
	Abraded	0	0	0	0	0	0		
84-M-1088	Intact	0	0	0	0	0	0	0	0
	Abraded	0	0	0	0	0	0		
84-M-1089	Intact	0	0	0	0	0	0	0	0
	Abraded	0	0	0	0	0	0		
Primary Irritant Score -----								0	

\*Score = Sum of individual values for each rabbit divided by six.

Comments: Monocalcium Phosphate Anhydrous was classified as a non-irritant to the intact and abraded skin of 6 albino rabbits.

Work Performed By: T. L. Foster and B. J. Jones

**Section D**

## Monocalcium Phosphate Anhydrous

OCULAR IRRITATION

Eye Irritation Classification: Corrosive

This test is consistent with the Environmental Protection Agency's Proposed Guidelines (May 24, 1982, FR22405), OECD Guidelines (1981), and PR Notice 81-3 (EPA Office of Pesticides and Toxic Substances, September, 1981).

Staufferland albino rabbits were used for this eye irritation toxicity study. The eyes of the rabbits were examined at least 24 hours before application of the test substance for ocular and periocular abnormalities. Further examination with fluorescein dye to detect corneal epithelial abnormalities was also performed. One or two drops of fluorescein, diluted with physiological saline, were deposited on the corneas of each rabbit. After waiting 15 seconds, excess fluorescein was flushed from the eye with saline and the corneas were examined in a semi-darkened room with the aid of an ultraviolet light source. Rabbits with preexisting ocular or periocular lesions or abnormalities were excluded from further ocular testing.

In the case of a solid material, the fines, which passed through a #300 mesh screen, were used. If insufficient fines were available, the test material was ground to a fine powder and passed through a #300 mesh screen. One tenth of a milliliter (in the case of a liquid) or 100 mg (in the case of a solid) of the test material was placed in the conjunctival sac of the left eye of each of nine rabbits. The treated eye was washed with water 20-30 seconds after exposure in 3 rabbits and the eyes were left unwashed in the remaining 6 rabbits. The untreated eye of each animal served as a negative control. The cornea, the iris, and the bulbar and palpebral conjunctivae were observed at 1, 24, 48, and 72 hours, and at 4 and 7 days after treatment. Observations with fluorescein staining were made at 24 hours after the application of the test substance and until there was no staining for 3 consecutive observations. If irritation was present after 7 days, an additional observation was made every 3-4 days until the injury subsided or was found to be irreversible. The guidelines described by Draize (1965) were used to assign numerical scores to the observed effects and to develop a weighted total score for each animal for each day of observations. Fluorescein staining was graded using a modified procedure outlined by the National Research Council (1977).

## Monocalcium Phosphate Anhydrous

OCULAR IRRITATION (continued)

## Total Draize Scores for Rabbits Whose Eyes Were Unwashed:

Animal Number	Pre-Dose	1 Hour	Day 1	Day 2	Day 3	Day 4	Day 7	Day 10	Day 15	Day 17	Day 21	Day 24
84-F-1087	0	32	47	64	64	64	64	62	61	56	56	56
84-F-1088	0	14	59	59	59	84	a	a	74	76	52	54
84-F-1089	0	54	84	56	54	57	79	57	46	53	40	30
84-F-1090	0	31	39	51	49	57	37	22	16	12	12	10
84-F-1091	0	16	64	54	54	37	69	39	26	24	22	20
84-F-1092	0	16	64	86	86	86	a	49	81	72	a	a
Average	0	27.17	59.50	61.67	61.00	64.17	n=4 62.25	n=5 45.80	50.67	48.83	n=5 36.40	n=5 34.00

## Total Draize Scores for Rabbits Whose Eyes Were Washed:

Animal Number	Pre-Dose	1 Hour	Day 1	Day 2	Day 3	Day 4	Day 7	Day 10	Day 15	Day 17	Day 21	Day 24
84-F-1093	0	14	10	6	0	0	0	0	-	-	-	-
84-F-1094	0	12	2	0	0	0	0	0	-	-	-	-
84-F-1095	0	12	10	4	4	4	4	4	6	6	6	0
Average	0	12.67	7.33	3.33	1.33	1.33	1.33	n=1 6.00	n=1 6.00	n=1 6.00	n=1 6.00	n=1 0

- = Sacrificed

a = Opacity obscured the iris

## Monocalcium Phosphate Anhydrous

OCULAR IRRITATION (continued)

Total Corneal Epithelial Erosion Scores for Rabbits Whose Eyes Were Unwashed (Fluorescein Staining):

Animal Number	Pre-Dose	Day 1	Day 2	Day 3	Day 4	Day 7	Day 10	Day 15	Day 17	Day 21	Day 24
84-F-1087	0	2	4	4	4	4	3	2	2	3	2
84-F-1088	0	3	2	8	6	6	6	2	0	0	0
84-F-1089	0	6	4	6	4	6	3	2	2	2	2
84-F-1090	0	4	4	4	4	2	0	2	0	0	0
84-F-1091	0	6	4	4	6	4	2	2	2	2	0
84-F-1092	0	2	2	6	6	4	3	2	2	2	3
Average	0	3.83	3.33	5.33	5.00	4.33	2.83	2.00	1.33	1.50	1.17

Total Corneal Epithelial Erosion Scores for Rabbits Whose Eyes Were Washed (Fluorescein Staining):

Animal Number	Pre-Dose	Day 1	Day 2	Day 3
84-F-1093	0	0	0	0
84-F-1094	0	0	0	0
84-F-1095	0	0	0	0
Average	0	0	0	0

Monocalcium Phosphate Anhydrous

OCULAR IRRITATION (continued)

Individual Draize Scores For Rabbits Whose Eyes Were Unwashed:

Animal Number	Irritation	Pre-Dose	1 Hour	Day 1	Day 2	Day 3	Day 4	Day 7	Day 10	Day 15	Day 17	Day 21	Day 24
84-F-1087	Cornea: Opacity Area	0 0	3 1	3 2	4 2	4 2	4 2	4 2	2 4	3 3	2 4	2 4	2 4
	Iris	0	1	1	2	2	2	2	2	0	0	0	0
	Conjunctiva: Redness Chemosis Discharge	0 0 0	2 1 3	2 1 3	3 1 3	3 1 3	3 1 3	3 1 3	2 1 3	3 2 3	3 2 3	3 2 3	3 2 3
84-F-1088	Cornea: Opacity Area	0 0	0 0	2 4	2 4	2 4	3 4	4 4	4 4	3 4	3 4	2 4	2 4
	Iris	0	0	1	1	1	2	a	a	0	0	0	0
	Conjunctiva: Redness Chemosis Discharge	0 0 0	2 2 3	2 2 3	3 1 3	3 1 3	3 1 3	3 2 3	3 1 3	2 2 3	3 2 3	2 1 3	2 2 3
84-F-1089	Cornea: Opacity Area	0 0	4 2	4 3	3 2	3 2	4 2	4 3	4 2	3 2	3 3	2 3	2 2
	Iris	0	0	2	2	2	1	1	1	0	0	0	0
	Conjunctiva: Redness Chemosis Discharge	0 0 0	2 2 3	2 2 3	3 2 3	3 1 3	2 1 3	3 1 3	2 1 3	3 2 3	1 1 2	2 1 2	1 1 3
84-F-1090	Cornea: Opacity Area	0 0	3 1	2 2	3 2	3 2	4 2	4 1	2 1	0 0	0 0	0 0	0 0
	Iris	0	0	1	1	1	1	1	0	0	0	0	0
	Conjunctiva: Redness Chemosis Discharge	0 0 0	2 3 3	2 2 3	3 2 3	3 1 3	2 1 3	3 1 2	3 1 2	3 2 3	2 1 3	2 1 3	1 1 3
84-F-1091	Cornea: Opacity Area	0 0	0 0	2 4	2 3	3 2	2 2	3 3	3 1	2 1	2 1	2 1	2 1
	Iris	0	0	2	2	2	1	2	2	0	0	0	0
	Conjunctiva: Redness Chemosis Discharge	0 0 0	2 3 3	2 2 3	3 1 3	3 1 3	3 1 2	3 1 3	3 2 2	3 2 3	3 2 2	3 2 1	3 1 1
84-F-1092	Cornea: Opacity Area	0 0	0 0	2 4	3 4	3 4	3 4	4 4	3 2	3 4	3 4	4 4	4 4
	Iris	0	0	2	2	2	2	a	1	1	0	a	a
	Conjunctiva: Redness Chemosis Discharge	0 0 0	2 3 3	2 2 3	3 2 3	3 2 3	3 2 3	3 2 3	3 1 3	3 2 3	2 1 3	2 1 3	2 2 3

a = Opacity obscured the iris

Monocalcium Phosphate Anhydrous

OCULAR IRRITATION (continued)

Individual Draize Scores For Rabbits Whose Eyes Were Washed:

Animal Number	Irritation	Pre-Dose	1 Hour	Day 1	Day 2	Day 3	Day 4	Day 7	Day 10	Day 15	Day 17	Day 21	Day 24
84-F-1093	Cornea:	0	0	0	0	0	0	0	0	-	-	-	-
	Opacity	0	0	0	0	0	0	0	0	-	-	-	-
	Area	0	0	0	0	0	0	0	0	-	-	-	-
84-F-1094	Iris	0	0	0	0	0	0	0	0	-	-	-	-
	Conjunctiva:	0	2	2	1	0	0	0	0	-	-	-	-
	Redness	0	3	1	1	0	0	0	0	-	-	-	-
84-F-1095	Chemosis	0	2	2	1	0	0	0	0	-	-	-	-
	Discharge	0	2	2	1	0	0	0	0	-	-	-	-
	Cornea:	0	0	0	0	0	0	0	0	-	-	-	-
84-F-1095	Opacity	0	0	0	0	0	0	0	0	-	-	-	-
	Area	0	0	0	0	0	0	0	0	-	-	-	-
	Iris	0	0	0	0	0	0	0	0	-	-	-	-
84-F-1095	Conjunctiva:	0	2	2	0	0	0	0	0	-	-	-	-
	Redness	0	2	0	0	0	0	0	0	-	-	-	-
	Chemosis	0	2	0	0	0	0	0	0	-	-	-	-
84-F-1095	Discharge	0	2	0	0	0	0	0	0	-	-	-	-
	Cornea:	0	0	0	0	0	0	0	0	-	-	-	-
	Opacity	0	0	0	0	0	0	0	0	-	-	-	-
84-F-1095	Area	0	0	0	0	0	0	0	0	-	-	-	-
	Iris	0	0	0	0	0	0	0	0	-	-	-	-
	Conjunctiva:	0	2	2	0	0	2	2	2	-	-	-	-
84-F-1095	Redness	0	2	1	0	0	0	0	0	-	-	-	-
	Chemosis	0	2	1	1	0	0	0	0	-	-	-	-
	Discharge	0	2	2	1	0	0	0	0	-	-	-	-

- = Sacrificed

## Monocalcium Phosphate Anhydrous

OCULAR IRRITATION (continued)

Individual Corneal Epithelial Erosion Scores For Rabbits Whose Eyes Were Unwashed (Fluorescein Staining):

Animal Number	Observation	Pre-Dose	Day 1	Day 2	Day 3	Day 4	Day 7	Day 10	Day 15	Day 17	Day 21	Day 24
84-F-1087	Intensity	0	2	2	2	2	2	3	2	2	3	2
	Area	0	1	2	2	2	2	1	1	1	1	1
84-F-1088	Intensity	0	3	2	2	2	3	3	2	0	0	0
	Area	0	1	1	4	3	2	2	1	0	0	0
84-F-1089	Intensity	0	3	2	3	2	3	3	2	2	2	2
	Area	0	2	2	2	2	2	1	1	1	1	1
84-F-1090	Intensity	0	2	2	2	2	2	0	2	0	0	0
	Area	0	2	2	2	2	1	0	1	0	0	0
84-F-1091	Intensity	0	2	2	2	3	2	2	2	2	2	0
	Area	0	3	2	2	2	2	1	1	1	1	0
84-F-1092	Intensity	0	2	2	2	2	2	3	2	2	2	3
	Area	0	1	1	3	3	2	1	1	1	1	1

## Monocalcium Phosphate Anhydrous

OCULAR IRRITATION (continued)

Individual Corneal Epithelial Erosion Scores For Rabbits  
Whose Eyes Were Washed (Fluorescein Staining):

Animal Number	Observation	Pre-Dose	Day 1	Day 2	Day 3
84-F-1093	Intensity	0	0	0	0
	Area	0	0	0	0
84-F-1094	Intensity	0	0	0	0
	Area	0	0	0	0
84-F-1095	Intensity	0	0	0	0
	Area	0	0	0	0

## Monocalcium Phosphate Anhydrous

OCULAR IRRITATION (continued)

Comments: In the 6 rabbits whose eyes were left unwashed, Monocalcium Phosphate Anhydrous produced mild to severe corneal opacity (6 rabbits); moderate to severe iritis (6 rabbits); mild to severe conjunctival irritation (6 rabbits); mild to severe corneal epithelial erosion (6 rabbits); contraction of the palpebral conjunctivae (6 rabbits); contraction of the bulbar conjunctivae (6 rabbits); neovascularization (6 rabbits); pannus (6 rabbits); white deposits in the subepithelial layer of the cornea (1 rabbit); and a corneal ulcer (1 rabbit). One rabbit phonedated when the test material was administered. On day 24, irritation included mild to severe corneal opacity (5 rabbits); mild to severe conjunctival irritation (6 rabbits); mild to severe corneal epithelial erosion (3 rabbits); contraction of the palpebral conjunctivae (5 rabbits); contraction of the bulbar conjunctivae (5 rabbits); neovascularization (6 rabbits); and pannus (5 rabbits).

In the 3 rabbits whose eyes were washed 20-30 seconds after treatment, this formulation produced mild to severe conjunctival irritation (3 rabbits) and a thickened and rough sclera (1 rabbit). On day 21, the only irritation was mild conjunctival irritation (1 rabbit) which cleared by day 24.

Work Performed By: S. S. Sorenson

Section E

## Monocalcium Phosphate Anhydrous

BIBLIOGRAPHY

Draize, J. H. (1965). Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics - Dermal Toxicity, Assoc. of Food and Drug Officials of the U.S. Topeka, Kansas, pp. 49-52.

Litchfield, J. T. Jr., and Wilcoxon, F. (1949). A Simplified Method of Evaluating Dose-Effect Experiments. J. Pharmacol-Exp. Therap. 95:95-113.

The National Research Council (1977). Principles and Procedures for Evaluating the Toxicity of Household Substances. pp. 50-51. National Academy of Sciences, Washington, D.C.

## QUALITY ASSURANCE STATEMENT

T-No: 12163Test Material: Monocalcium Phosphate, Anhydrous (lot # 525)Type of Study: Acute toxicity test battery

A Quality Assurance review of this report was conducted on 5-10-85 and it is confirmed that the reported results accurately reflect the data collected for the study.

In-life inspections of T-12163 were conducted on the days listed below. All findings were reported to the Study Director and to management.

Dates of Inspections:

8-21-84  
8-22-84  
8-23-84  
9-5-84  
9-5-84  
10-24-84  
10-31-84

Dates inspections reported to the Study Director and Management:

8-22-84  
8-22-84  
8-23-84  
9-6-84  
9-5-84  
10-25-84  
11-1-84

Lance Sandvik  
Quality Assurance Inspector

REVIEWED FOR THE SECTION 8(e) COMPLIANCE

AUDIT PROGRAM, ON 9-30-81 BY

JCZ . CAD ID NO. B-CB-JLT - 0064



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

Charles E. Moyer, Jr., Ph.D.  
Director, Product Safety  
Rhône-Poulenc Inc.  
CN 7500  
Cranberry, New Jersey 08512-7500

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MAY 08 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

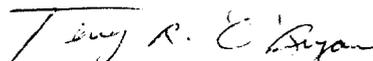
All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

  
Terry R. O'Bryan  
Risk Analysis Branch

Enclosure

12620A



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**Triage of 8(e) Submissions**

Date sent to triage: 12/14/95

NON-CAP

CAP

Submission number: 1262DA

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

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entire document: 0 1 2

pages 1,2

pages

1,2

Notes:

Contractor reviewer: ROL

Date:

4/18/95

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # SEHO. 1092-12620 SEQ. A  
 TYPE INT SUPP FLWP  
 SUBMITTER NAME: Rhone-Poulenc Inc.

INFORMATION REQUESTED: FLWP DATE:  
 0501 NO INFO REQUESTED  
 0502 INFO REQUESTED (TECH)  
 0503 INFO REQUESTED (VOL. ACTIONS)  
 0504 INFO REQUESTED (REPORTING RATIONAL/R)  
 DISPOSITION:  
 0505 REFER TO CHEMICAL SCREENING  
 0506 CAP NOTICE

VOLUNTARY ACTIONS:  
 0400 ACTION REPORT ID  
 0401 STUDY'S PLANNED DRAINAGE  
 0402 MUTATION IN WORKING  
 0403 LABELS (TIANHIS)  
 0404 PROFESSIONAL IN, (TIANHIS)  
 0405 APP USE DISCONTINUED  
 0406 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

SUB. DATE: 10/23/92 OTS DATE: 10/23/92 CSRAD DATE: 03/01/95

CHEMICAL NAME: CASE  
7758-23-8

INFORMATION TYPE	P.F.C.	INFORMATION TYPE	P.F.C.	INFORMATION TYPE	P.F.C.
0201 ONCO (HUMAN)	01 02 04	EPICLIN	01 02 04	0241 BAMBINO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 BAMBINO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEMOPHY PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	ECOAQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	ENV. OCCURENCE/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAMAGE/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	RESPONSE REQUEST DELAY	01 02 04	0248 PRODUCE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	PRODUCOMP/CHEM ID	01 02 04	0251 ASSES	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	REPORTING RATIONALE	01 02 04	0259 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METAPHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	METAPHARMACO (HUMAN)	01 02 04		

IRIS/BLINDNESS YES NON-CELL INVENTORY YES (DROP/REFER) NO (CONTINUE) REF-R  
 CAS SR NO IN IT ANIM  
 SPECIES RAT TOXICOLOGICAL CONCERN LOW Dermal Irritation, Acute Oral Toxicity, Acute Dermal Toxicity  
MED Dermal Irritation (acute dermal tox)  
HIGH Ocular Irritation  
 USE: PRODUCTION:

12620A

Ocular Irritation - High

Dermal Irritation - Medium (Acute Dermal Toxicity), Low

Acute Oral Toxicity - Low

Acute Dermal Toxicity - Low

Ocular irritation is high based on corrosion with damage to the cornea and conjunctivae in rabbits (pH=4.2). Dermal irritation is medium based on severe erythema and mild edema in rabbits exposed to 2000 mg/kg (acute dermal tox test). Acute oral toxicity is low based on a calculated LD<sub>50</sub> of 3986 mg/kg in female rats. Mortality and corresponding doses (mg/kg) were 7/10 (4467, 5000), 4/10 (3981) and 3/10 (3162) in females, and 3/10 (5000) in male rats. Clinical signs included depression (both sexes) and ataxia (females, 5000). Necropsy revealed abnormalities of the lungs, kidneys, liver, spleen, GI tract (males, females ≥3981), uterus (females, 5000) and thymus (5000). Acute dermal toxicity is low based on no mortality (0/10) in rabbits exposed to 2000 mg/kg. Dermal irritation is low based on no irritation in rabbits.