ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
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COMMENTS:

DOES NOT CONTAIN CBI

DOW CORNING

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February 8, 2010

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Document Control Office (7407)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20004

8EHQ-10-17823

Re: TSCA Section 8(e) Notification of Substantial Risk:

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances and Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, Dow Corning is submitting information from an acute oral toxicity study in the rat for 1,2-bis(triethoxysilyl)-ethane.

1,2-bis(triethoxysilyl)ethane is the subject of Reconsile REACH Consortium's effort to register the material within Phase 2 (substances supplied at greater than or equal to 1000 tonnes per year) of the REACH program. This effort led us to re-examine the acute oral study report for this material. As specified in TSCA 8(e) guidance, a decision to submit acute toxicity data under TSCA 8(e) for chemicals classified as "moderately toxic" includes a consideration of exposure. The inclusion of 1,2-bis(triethoxysilyl)ethane in Phase 2 of the REACH program suggests that the volume of this chemical in commerce is significantly higher than previously realized by Dow Corning and, as such, the potential for exposure may also be more significant. Recognizing that there may be a greater potential for exposure a decision was made to submit this study report at this time under TSCA 8(e).

Dow Corning has not made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings.

Chemical Substances

16068-37-4 1,2-bis(triethoxysilyl)ethane

88100000152

Study Title

1,2-bis(triethoxysilyl)ethane. Acute Oral Toxicity Study in Rats.

Dow Corning Corporation
Midland, Michigan 48686-0994
Phone: (989) 496-4000
www.dowcorning.com

CONTAINS NO CBI

324667

Study Design

The study design meets the requirements of the OECD 401.

Animals were fasted overnight. The test article and corn oil (control) were administered in a single neat oral dose to test animals. Five animals per sex per group received 0, 175, 225 or 250 mg/kg test article based on the fasting body weights. Feed was returned to the animals approximately 4 hours after dosing. The animals were observed at approximately 1, 2, and 4 hours after dosing and daily thereafter for 14 days. Body weights were taken on day 1 (prior to dosing), 8, and 15. Any animals which did not survive for 14 days were weighed at the time of death or at the time they were found dead. A necropsy was performed on all animals which died or were found dead during the study. At termination of the observation period (Day 15), all surviving animals were euthanized via exsanguination following carbon dioxide inhalation.

A necropsy was performed which included macroscopic post mortem examinations of external surface and all orifices, the organs and tissues of the cranial, thoracic, abdominal and pelvic cavities and neck and the remainder of the carcass. All abnormalities were recorded and tissues with lesions were saved in 10% neutral buffered formalin.

Results

Corn oil control animals were free of clinical signs throughout the study. All treated animals were free of clinical signs on the day of dosing and most were free of clinical signs on the day after dosing. By day 3 most 250 mg/kg animals exhibited decreased food consumption and fecal volume; by day 5 most animals from treated groups exhibited decreased food consumption and fecal volume. These signs continued for most survivors during the next several days. During the same time period, some animals from all groups were pale and exhibited lethargy and/or decreased activity. In addition, some 250 mg/kg and 225 mg/kg animals exhibited hypothermia, emaciation and prostration. Most survivors were free of clinical signs by day 13. Three males and two females in the 225 mg/kg dose group died between day 7 and 11. Four males and three females in the 250 mg/kg dose group died between day 6 and 10.

All corn oil control animals gained weight at days 8 and 15. Most animals that survived treatment lost weight by day 8, but gained weight by day 15. All animals found dead had weight losses of 7 to 108 grams.

Corn oil control animals were free of macroscopic postmortem abnormalities. Macroscopic postmortem examinations of animals treated with test material revealed tan discoloration of the liver in most animals. Other liver abnormalities such as enlargement, firmness, surface irregularity and adhesions were also observed in some of these animals. In addition, red, thin fluid was observed in presumably the abdominal cavity of two of the 225 mg/kg and two of the 250 mg/kg animals. These findings appear to be related to treatment with test article.

Enlarged spleens were observed in a few animals treated with the test material. However, based on macroscopic postmortem examinations only, the toxicologic significance of this finding remains equivocal. Other abnormalities occurred sporadically and were considered incidental and not related to treatment with the test article.

The oral LD50 of 1,2-bis(triethoxysilyl)ethane in rats, under the conditions of this study, are 218, 237, 227 mg/kg of body weight for males, females and combined male and female, respectively.

Dow Coming has not made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings. The final report for the subject study is attached to this letter.

Sincerely,

Kathleen P. Plotzke

Kathleen P. Plotzke, Ph.D.
Director, Health and Environmental Sciences
(989) 496-8046

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98 FEB 16 AM 10: 11

HEALTH & ENVIRONMENTAL SCIENCES
TECHNICAL REPORT

Report No: 1997-I0000-43718

Title: 1,2-*bis*(Triethoxysilyl)ethane.
ACUTE ORAL TOXICITY STUDY IN RATS

Dow Corning
Study No:

Test Material: 1,2-*bis*(Triethoxysilyl)ethane
(also known as Dow Corning® RMS 820
P Intermediate)

Study Director:

Author:

Sponsor:

Sponsor
Representative:

Test Facility:

Study Completion Date: 3 December 1997

324667

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

ABSTRACT

This study was conducted for in order to determine the oral LD_{50} of 1,2-*bis*(triethoxysilyl)ethane in rats. Data from this study may serve as a basis for classification and labelling of the test material. The study was performed at

Dosing was initiated on 7 January 1997 and observations were completed on 14 February 1997.

A range-finding study (at 100, 500, 1000, 2500 and 5000 mg/kg) was conducted in order to select an initial dose level. Base on the results of the range-finding study, an initial level for the LD_{50} study was 250 mg/kg. 1,2-*bis*(Triethoxysilyl)ethane was administered as received, by oral intubation, to 10 (5/sex) fasted Sprague-Dawley rats. Based on mortality seen, additional dose levels of 175 and 225 mg/kg were administered to 20 (5/sex/group) rats. A separate group of control animals (5/sex) received corn oil at the same dose volume as administered to the high dose animals.

Observations of mortality, pharmacologic and toxicologic signs and food consumption were made daily; body weights were measured pretest and weekly throughout the study. At termination of the study (Day 15), a necropsy was performed and all survivors were examined macroscopically. In addition, any animal which died during the study was examined macroscopically.

Dose levels, mortality and the estimated LD_{50} with 95% confidence limits were as follows:

Dose Level (mg/kg)	Mortality		
	Males	Females	Combined Sexes
Corn Oil	0/5	0/5	0/10
175	0/5	0/5	0/10
225	3/5	2/5	5/10
250	4/5	3/5	7/10

All animals were free of clinical signs on the day of dosing and most were free of clinical signs on day after dosing. Corn oil control animals were free of clinical signs throughout the study. By Day 5, most

ABSTRACT (cont.)

animals from all treated groups exhibited decreased food consumption and fecal volume. These signs continued for most survivors during the next several days. During the same time period, some animals from all treated groups were pale and exhibited lethargy and/or decreased activity. In addition, some 250 mg/kg and 225 mg/kg animals exhibited hypothermia, emaciation and prostration.

All corn oil control animals gained weight at Days 8 and 15. After treatment with the test material, most survivors lost weight by Day 8, but gained weight by Day 15. All animals found dead had body weight losses of 7 to 108 grams.

Corn oil control animals were free of macroscopic postmortem abnormalities. Macroscopic postmortem examinations of animals treated with test material revealed tan discoloration of the liver in most animals. Other liver abnormalities such as enlargement, firmness, surface irregularity and adhesions were also observed in some of these animals. In addition, red, thin fluid was observed presumably in the abdominal cavity of two of the 225 mg/kg and two of the 250 mg/kg animals. These findings appear to be related to treatment with the test material. Enlarged spleens were observed in a few animals treated with the test material. However, based on macroscopic postmortem examinations only, the toxicologic significance of this finding remains equivocal. Other abnormalities occurred sporadically and were considered incidental and not related to treatment with the test material.

In conclusion, the oral LD_{50} of 1,2-*bis*(triethoxysilyl)ethane in rats, under the conditions of this study, is 218 milligrams per kilogram of body weight in male rats, 237 milligrams per kilogram of body weight in female rats and 227 milligrams per kilogram of body weight in male and female rats combined.

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

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Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

GLP COMPLIANCE STATEMENT

This study was conducted in compliance with the United States Environmental Protection Agency (TSCA) Good Laboratory Practice Standards (40 CFR Part 792) and the Organization for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practices [C(81)30 (Final) Annex 2] with the following exceptions:

1. The identity, strength, purity and composition, or other characteristics to define the test or control material were not determined by the Testing Facility.

2. Analyses to determine the uniformity, concentration, or stability of the test or control mixtures were not performed by the Testing Facility.

3. The stability of the test or control material under the test conditions was not determined by the Testing Facility.

Confirmatory analyses of the test material were done by the Sponsor using the best available practices. The records for these analyses are located at the address indicated for the Sponsor.

03Dec97

D.V.M., D.A.B.T. Date

Study Director

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

QUALITY ASSURANCE STATEMENT

Listed below are dates that this study was inspected by the Quality Assurance Unit of
and the dates that findings were reported to the Study Director and Management.

Type of Inspection	Date(s) of Inspection	Reported to Study Director and Management
GLP Protocol Review	21Nov96	21Nov96, 9Dec96 and 3Jan97
Group I Necropsy Data	21Jan97	21Jan97, 4Apr97 and 27May97
Terminal Sacrifice Group II	31Jan97	4Feb97, 10Mar97 and 21Mar97
Report	13May97 and 14May97	14May97

Ann Nelson — 20Nov97

Senior Auditor — Date

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

APPROVAL SIGNATURES

This report consists of pages 1 through 47 including Figure 1, Tables I through IV and Appendix A.

_____ Ph.D., D.A.B.T. 24 November 1997 Date
Study Monitor

_____ B.A., D.A.B.T. 3 December 1997 Date
Senior Director, Toxicology

_____ D.V.M., D.A.B.T. 03 Dec 97 Date
Study Director

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

STUDY INFORMATION

	Range-Finding Study	LD_{50} Determination
Study Initiation: (Date Study Director signed the protocol)	18 December 1996	18 December 1996
Experimental Start Date: (Dosing)	20 December 1996	-
175 mg/kg		17 January 1997
225 mg/kg		31 January 1997
250 mg/kg (initial)		7 January 1997
Experimental Termination Date (Last Observation):	27 December 1996	-
175 mg/kg		31 January 1997
225 mg/kg		14 February 1997
250 mg/kg (initial)		21 January 1997
Study Completion Date: (Date Study Director signed the Final Report)	3 December 1997	3 December 1997
Study Personnel:		
Study Director/ Pathologist:		D.V.M., D.A.B.T.
Study Supervisor: (coordinates in-life phase of study)		
Study Monitor:		
Quality Assurance Director:		
Staff Veterinarian:		
Sponsor:		
Sponsor Representative:		

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

I. OBJECTIVE

This study was conducted for in order to determine the oral LD_{50} or to establish a non-lethal dose-level of 2000 mg/kg of 1,2-*bis*(triethoxysilyl)ethane in rats. Data from this study may serve as a basis for classification and labelling of the test material. The study was performed at

The procedures used followed the methods described in:

OECD (Organization for Economic Cooperation and Development): Guidelines for Testing of Chemicals, February 24, 1987, (No. 401).

This report has been reviewed by the Quality Assurance Unit of the Testing Facility to assure its conformance with the protocol and raw data.

II. TEST/CONTROL MATERIAL INFORMATION

A. Test Material:	1,2-*bis*(Triethoxysilyl)ethane (also known as Dow Corning® RMS 820 P Intermediate)
Lot/Batch No.:	
CAS No.:	
Description:	Colorless liquid
Date of Receipt:	3 December 1996
Expiration Date:	31 March 1997
Received from:	
Storage:	Ambient temperature under N_2 cap.
Sampling:	An archival sample of approximately 10 mL is stored in the archives of the Testing Facility.
Purity and Analysis:	The identity, stability, and method of synthesis, fabrication and/or derivation of the test material remain the responsibility of the Sponsor.

II. TEST/CONTROL MATERIAL INFORMATION (cont.)

A. Test Material (cont.):

Purity and Analysis (cont.):	Prior to the initiation of this study, the Sponsor characterized the test material by gas chromatography with a thermal conductivity detector and a mass selective detector. Five replicate samples were tested. The purity (average ± standard deviation) was 99.5717% ± 0.0054%. Following completion of the in-life phases of this study, test material was transferred from the external testing facility to the Sponsor, and five additional replicate samples were analyzed. The purity was 98.6658% ± 0.0175%.

B. Control Material: Corn Oil

Lot/Batch No.:	
Description:	Viscous yellow liquid
Date of Receipt:	14 January 1997
Expiration Date:	14 January 1998
Received from:	
Storage:	Room temperature.
Sampling:	An archival sample of approximately 10 g is stored in the archives of the Testing Facility.

III. ROUTE OF EXPOSURE

A. Route of Administration:

The test material was administered orally, via intubation.

B. Justification for Route of Administration:

The study was intended to provide information on the health hazards likely to arise from a short-term accidental exposure to the test material by the oral route.

III. ROUTE OF EXPOSURE (cont.)

C. Duration of Study:

A single dose was administered to each animal, followed by 14 days of observations. Animals used for range-finding screens were sacrificed 7 days after being dosed.

IV. TEST SYSTEM

A. Test Animals: Albino Rats (Outbred)

1. Breed: Sprague-Dawley - derived (CD®) [Crl: CD® BR]

B. Supplier:

C. Justification for Test System Selection:

The rat is a rodent model commonly used in oral toxicity studies as recommended in the referenced guidelines. In addition, a historical data base is available for comparative evaluation. Number of animals is based on test guidelines.

D. Animal Requirements/Specifications:

1. Number: Range-finding: 10 (one/sex/dose level)
   LD_{50} Determination: 30 (five/sex/dose level)

2. Age: Young adult (approximately 9-12 weeks old at study initiation). Females were nulliparous and non-pregnant.

3. Weight (Day 0):

   Males: 290 - 322 grams
   Females: 215 - 273 grams

4. Acclimation Period: 8 or 10 days

   All animals were checked for viability twice daily. Prior to assignment to study all animals received a physical examination performed by a veterinarian.

IV. TEST SYSTEM (cont.)

E. Husbandry:

Currently acceptable practices of good animal husbandry were followed, e.g., Guide for the Care and Use of Laboratory Animals; National Research Council, 1996. is fully accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC).

1. Housing: Group-housed (six/cage) during acclimation. Individually housed during study. Cages were suspended, stainless steel cages (approximately 28 x 18 x 18 cm in size) with wire mesh bottoms.

2. Food: Certified Rodent Diet, No. 5002; (Meal) *ad libitum*.

3. Feed Analysis: Analysis of each feed lot used during this study was performed by Results are maintained on file at the Testing Facility and have been reviewed by the Study Director.

4. Water: Automatic watering system. *ad libitum*. Municipal water supply

5. Water Analysis: Monthly analysis of water supplied to the Testing Facility was provided by

   Results are maintained on file at the Testing Facility and have been reviewed by the Study Director.

   Biannual chemical and microbiological analysis of water samples collected from representative rooms in the Testing Facility were conducted to assure that water met standards specified under the EPA National Primary Drinking Water Regulations (40 CFR Part 141). Results are maintained on file at the Testing Facility and have been reviewed by the Study Director.

6. Contaminants: There were no known contaminants reasonably expected to be found in the feed or water which would interfere with the results of this study.

IV. TEST SYSTEM (cont.)

E. Husbandry (cont.):

7. Environmental Conditions:

   a. Light/Dark Cycle: 12 hours light/dark cycle controlled by an automatic timer.

   b. Temperature: 64-79°F (18-26°C) is considered an acceptable temperature range for rats; room temperature was monitored and recorded twice daily and maintained within this range to the extent possible. [Note: Actual range was 64-75°F (18-24°C).]

   c. Humidity: 30-70% is considered an acceptable humidity range for rats; room humidity was monitored and recorded daily and maintained within this range to the maximum extent possible. (Note: Actual range was 14-58%.)

   d. Air Changes: 20.7 or 21.8 per hour

8. Veterinary Care: Animals were monitored by the technical staff for any conditions requiring possible veterinary care.

9. Identification: Each animal was identified with a Monel ear tag, bearing a unique number prior to testing. Each cage was provided with a cage card which contained the study number, animal number, sex and dose-group information.

V. EXPERIMENTAL DESIGN

A. Range-finding Study:

Number of Animals		Dose (mg/kg)	Density (mg/mL)	Dose Volume (mL/kg)
Male	Female			
1	1	100	960	0.1
1	1	500	960	0.52
1	1	1000	960	1.0
1	1	2500	960	2.6
1	1	5000	960	5.2

V. EXPERIMENTAL DESIGN (cont.)

B. LD_{50} Determination:

Number of Animals		Dose (mg/kg)	Density (mg/mL)	Dose Volume (mL/kg)
Male	Female			
5	5	Corn Oil	n/a	0.26
5	5	175	960	0.182
5	5	225	960	0.234
5	5	250	960	0.26

C. Selection for Study:

More animals than required for the study were purchased and acclimated. Animals were arbitrarily placed in cages upon receipt, and were placed on study as available at the time of study initiation. Any animals considered unsuitable on the basis of pretest physical examinations or outlying body weights were excluded from selection. Individual weights of animals placed on test did not exceed ± 20% of the mean weight for each sex. Disposition of all animals not used in the study is maintained on file at the Testing Facility.

D. Preparation of Animals:

Animals were fasted overnight (for approximately 18 hours) prior to treatment.

E. Preparation of Test and Control Materials:

The test and control materials were administered as received; no preparation was necessary.

F. Administration of Test and Control Materials:

The test and control materials were administered by oral intubation, using a ball-tipped intubation needle fitted onto a syringe of appropriate size. Doses were calculated using post-fasted body weights.

Animals were given food approximately four hours after test material administration.

V. EXPERIMENTAL DESIGN (cont.)

G. Frequency of Administration:

A single administration was given to each animal.

H. Observations:

Animals used for range-finding screens were observed for viability twice daily for seven days and deaths were recorded. The following observations were made on animals which were dosed for LD_{50} determination.

1. Viability Check (in-cage):

   Observations for mortality were made twice daily.

2. Observations of Pharmacologic and Toxicologic Signs:

   Each animal was removed from its cage and examined approximately 1, 2 and 4 hours after dosing and daily thereafter for fourteen days.

   Examinations included observations for general condition, skin and fur, eyes, nose, oral cavity, abdomen and external genitalia as well as evaluations of respiration and palpation for tissue masses. All abnormalities were recorded.

I. Body Weights:

Day 0 (at time prior to initiation of fasting)

Day 1 (just prior to dosing; weights used for calculation of doses)

Days 8 and 15

Terminal: Any animals which did not survive for 14 days were weighed at the time of death or at the time they were found dead.

J. Food Consumption:

Each animal's quantity of feed was visually inspected daily and any decrease in food consumption, relative to other on-test animals and technician experience, was recorded as such.

V. EXPERIMENTAL DESIGN (cont.)

K. Postmortem:

A necropsy was performed on all animals which died or were found dead during the study. At termination of the observation period (Day 15), all surviving animals were sacrificed by exsanguination following carbon dioxide inhalation.

A necropsy was performed which included macroscopic postmortem examination of the external surface and all orifices, the organs and tissues of the cranial, thoracic, abdominal and pelvic cavities and neck and the remainder of the carcass. All abnormalities were recorded and tissues were saved in 10% neutral buffered formalin. Samples of tissues with lesions were saved in 10% neutral buffered formalin.

L. Statistical Treatment of Data:

A calculation of an estimate of the median lethal concentration, with 95% confidence limits was performed for males, females and combined sexes using the following method:

Litchfield, J.T. and Wilcoxon, F., A Simplified Method of Evaluating Dose - Effect Experiments, J. Pharma. Exp. Ther., Vol. 96, pp 99-113 (1949).

M. Protocol Deviations:

The following protocol deviations occurred during the study but were not considered to have compromised the validity or integrity of the study:

1. The actual relative humidity range of 14-58% deviated occasionally from the protocol specified range of 30-70%.

2. Actual air changes were 20.7 or 21.8 per hour, not 12-15 per hour as stated in the protocol.

3. Due to technician error, tissues for Animal No. 2047 were not saved.

VI. RESULTS AND DISCUSSION

A. Mortality:

1. Range-Finding Study

Dose levels and mortality for the preliminary range-finding studies were as follows:

Dose Level (mg/kg)	Total Mortality
100	0
500	2
1000	2
2500	2
5000	2

2. LD_{50} Determination (Figure 1):

Dose levels, mortality and the estimated LD_{50} with 95% confidence limits were as follows:

Dose Level (mg/kg)	Mortality			Time of Death
	Males	Females	Combined Sexes	
Corn Oil[a]	0/5	0/5	0/10	
175	0/5	0/5	0/10	
225	3/5	2/5	5/10	Days 7, 8, 9 and 11
250	4/5	3/5	7/10	Days 6, 7, 8 and 9
LD_{50} (mg/kg)	218	237	227	
95% Confidence Limits (mg/kg)	197-242	207-272	211-244	

[a]Not included in LD_{50} calculation.

VI. RESULTS AND DISCUSSION (cont.)

B. Pharmacologic and Toxicologic Signs (Tables I and II):

Corn oil control animals were free of clinical signs throughout the study.

All treated animals were free of clinical signs on the day of dosing and most were free of clinical signs on day after dosing. By Day 3, however, most 250 mg/kg animals exhibited decreased food consumption and fecal volume; by Day 5 most animals from treated groups exhibited decreased food consumption and fecal volume. These signs continued for most survivors during the next several days. During the same time period, some animals from all groups were pale and exhibited lethargy and/or decreased activity. In addition, some 250 mg/kg and 225 mg/kg animals exhibited hypothermia, emaciation and prostration. Additional signs seen in individual animals are detailed in Table II. Most survivors were free of clinical signs by Day 13.

C. Body Weights (Table III):

All corn oil control animals gained weight at Days 8 and 15.

After treatment with test material, most survivors lost weight by Day 8, but gained weight by Day 15. All animals found dead had body weight losses of 7 to 108 grams.

VI. RESULTS AND DISCUSSION (cont.)

D. Macroscopic Postmortem Observations (Tables IV):

Corn oil control animals were free of macroscopic postmortem abnormalities.

Macroscopic postmortem examinations of animals treated with test material revealed tan discoloration of the liver in most animals. Other liver abnormalities such as enlargement, firmness, surface irregularity and adhesions were also observed in some of these animals. In addition, red, thin fluid was observed in presumably the abdominal cavity of two of the 225 mg/kg and two of the 250 mg/kg animals. These findings appear to be related to treatment with the test material.

Enlarged spleens were observed in a few animals treated with the test material. However, based on macroscopic postmortem examinations only, the toxicologic significance of this finding remains equivocal.

Other abnormalities occurred sporadically and were considered incidental and not related to treatment with the test material.

VII. CONCLUSION

The oral LD_{50} of 1,2-*bis*(triethoxysilyl)ethane in rats, under the conditions of this study, is 218 milligrams per kilogram of body weight in male rats, 237 milligrams per kilogram of body weight in female rats and 227 milligrams per kilogram of body weight in male and female rats combined.

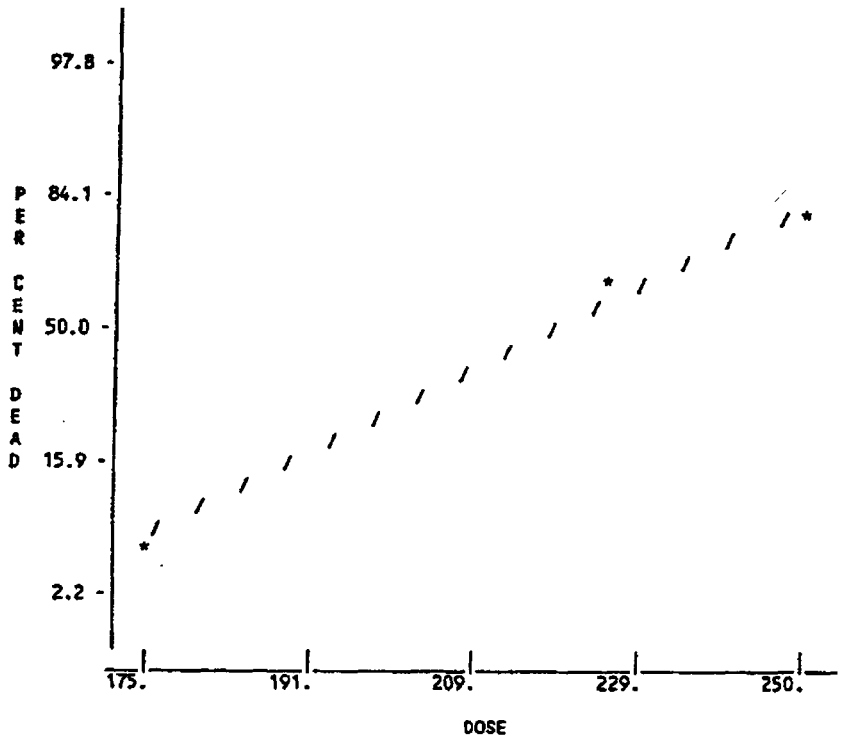
VIII. ARCHIVE

All raw data, the original study protocol, a sample of the test material, and the final report will be retained on file in the archives of the Testing Facility for a period of five years after submission of the signed final report. The location of the Testing Facility archive is

Figure 1

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

LD_{50} Determination
Males



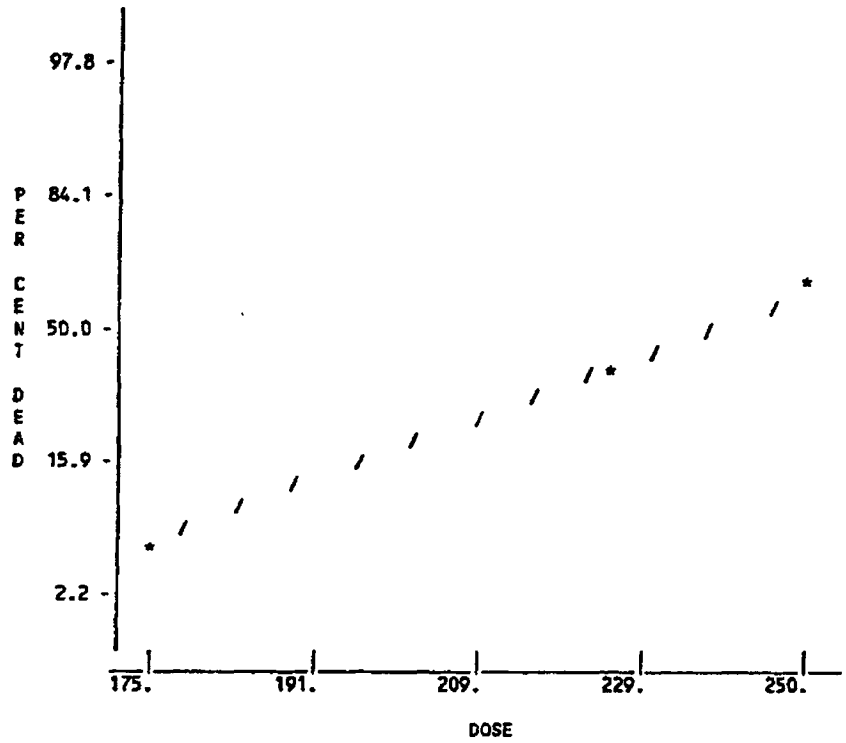
THE SLOPE AND ASSOCIATED CONFIDENCE INTERVAL 1.156, (1.107, 1.207)

THE LD 50 IS 218.312,
WITH 95% CONFIDENCE LIMITS
OF 196.828 TO 242.141

Figure 1 (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

LD_{50} Determination
Females



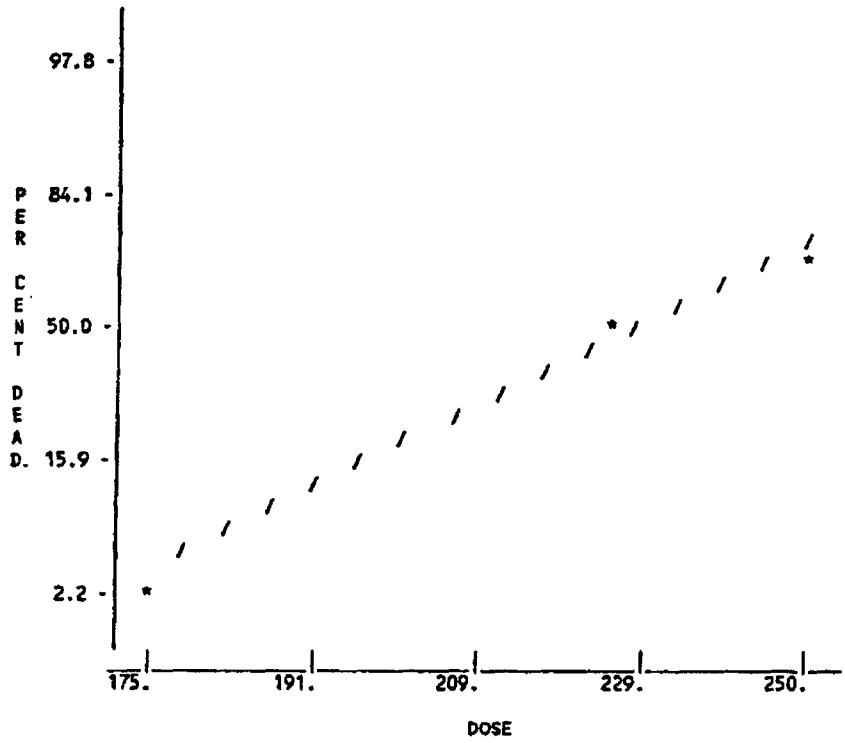
THE SLOPE AND ASSOCIATED CONFIDENCE INTERVAL 1.212, (1.123, 1.309)

THE LD 50 IS 237.333,
WITH 95% CONFIDENCE LIMITS
OF 206.786 TO 272.392

Figure 1 (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

LD_{50} Determination
Combined Sexes



THE SLOPE AND ASSOCIATED CONFIDENCE INTERVAL 1.157, (1.121, 1.193)

THE LD 50 IS 227.110,
WITH 95% CONFIDENCE LIMITS
OF 210.987 TO 244.465

Table I

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Summary of Pharmacologic and Toxicologic Signs[a]

	Interval																
Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
Hour	1	2	4														
Observations	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F
Corn Oil																	
Within Normal Limits	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5	5/5
175 mg/kg																	
Within Normal Limits	4/5	5/5	5/5	5/5	5/5	2/-	2/-	3/1	2/1	2/1	3/2	4/2	4/1	4/3	5/4	5/4	5/4
Pale	-	-	-	-	-	-	-	-/1	-/1	-/1	-/1	-/1	-/1	-/1	-/1	-/1	-/1
Excessive Salivation	1/-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Decreased Activity	-	-	-	-	-	-	-	-	-	-/1	-/1	-/1	-	-	-/1	-/1	-/1
Lethargy	-	-	-	-	-	-	-/2	-/2	-	-	-	-	-	-	-	-	-
Decreased Food Consumption	-	-	-	-	-	2/5	2/5	1/4	2/4	2/4	1/3	1/2	1/2	1/2	-/1	-	-
Decreased Fecal Volume	-	-	-	-	-	3/5	3/5	2/3	3/4	3/4	2/3	1/3	1/4	1/2	-/1	-/1	-/1
225 mg/kg																	
Within Normal Limits	5/5	5/5	5/5	5/5	5/5	5/3	1/-	1/-	1/-	1/-	1/-	1/-	1/-	1/1	2/2	2/3	2/3
Animal Dead[b]	-	-	-	-	-	-	-	-	1/-	-/1	1/1	-	1/-	-	-	-	-

[a]Numbers represent number of males and females (M/F), out of 5 per sex or of those surviving, which exhibited signs one or more times during the interval.
[b]Animals dead - Numbers represent number of animals found dead at the indicated interval; cumulative mortality is not presented; death of animals which died after clinical observations are indicated at the next interval.

Table I (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Summary of Pharmacologic and Toxicologic Signs (cont.)[a]

Observations	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
		M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F
225 mg/kg (cont.)																		
Emaciation		-	-	-	-	-	-	-	-	-/1	-	-	-	-	-	-	-	-
Pale		-	-	-	-	-	-	-/2	2/2	1/3	1/2	2/1	2/1	1/1	-/1	-	-	-
Hypothermia		-	-	-	-	-	-	-	-	-/1	1/1	-	-	-	-	-	-	-
Yellow Ano-genital Staining																		
Moderate		-	-	-	-	-	-	-	-	-	1/-	-	-	-	-	-	-	-
Lethargy		-	-	-	-	-	-	-/1	1/1	1/-	-/1	-	-	-	-	-	-	-
Prostrate		-	-	-	-	-	-	-	-	-/1	1/-	-	-	-	-	-	-	-
Labored Breathing		-	-	-	-	-	-	-	-	-	-	-	1/	-	-	-	-	-
Decreased Activity		-	-	-	-	-	-	-	-	-	-	-	-/1	-/1	-/1	-	-	-
Decreased Food Consumption		-	-	-	-	-	-/2	4/5	4/5	3/5	3/4	2/3	2/3	1/3	1/2	-	-	-
Decreased Fecal Volume		-	-	-	-	-	-/2	4/5	4/5	3/5	3/4	2/3	2/3	1/3	-/1	-/1	-	-
Poor Condition		-	-	-	-	-	-	-	-	-	1/-	-	-	-	-	-	-	-

[a]Numbers represent number of males and females (M/F), out of 5 per sex or of those surviving, which exhibited signs one or more times during the interval.
[b]Animals dead - Numbers represent number of animals found dead at the indicated interval; cumulative mortality is not presented; death of animals which died after clinical observations are indicated at the next interval.

Table I (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Summary of Pharmacologic and Toxicologic Signs (cont.)[a]

	Interval																	
Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
Hour	1	2	4														
Observations	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F	M/F
250 mg/kg																	
Within Normal Limits	5/5	5/5	5/5	5/5	2/1	-	-	-	-/1	-/1	-/2	-/2	-/2	-/2	1/2	1/2	1/2
Animal Dead[b]	-	-	-	-	-	-	-	-/1	1/-	1/1	2/-	-/1	-	-	-	-	-
Emaciation	-	-	-	-	-	-	-	-	-	1/-	-/1	-	-	-	-	-	-
Pale	-	-	-	-	-	-	-	-/1	1/1	2/1	-/1	-	-	-	-	-	-
Hypothermia	-	-	-	-	-	-	-	-	-/1	1/-	-/1	-	-	-	-	-	-
Lethargy	-	-	-	-	-	-	-/1	-/1	2/-	1/-	-/1	-	-	-	-	-	-
Prostrate	-	-	-	-	-	-	-	-	-/1	-	-	-	-	-	-	-	-
Irregular Gait	-	-	-	-	-	-	-/1	-	-	-	-	-	-	-	-	-	-
Decreased Food Consumption	-	-	-	-	3/4	5/4	5/4	5/3	4/3	3/2	1/1	1/-	1/-	1/-	-	-	-
Decreased Fecal Volume	-	-	-	-	3/4	4/5	4/4	5/4	4/3	3/2	1/1	1/-	1/-	-	-	-	-
No Stool	-	-	-	-	-	1/-	1/1	-	-	-	-	-	-	-	-	-	-

[a]Numbers represent number of males and females (M/F), out of 5 per sex or of those surviving, which exhibited signs one or more times during the interval.
[b]Animals dead - Numbers represent number of animals found dead at the indicated interval; cumulative mortality is not presented; death of animals which died after clinical observations are indicated at the next interval.

Table II

Acute Oral Toxicity Study in Rats with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs

An. No. & Sex	Observations	Interval																
		Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
		Hour	1	2	4														
Corn Oil																			
1998 M	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2003 M	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2011 M	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2015 M	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2017 M	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2026 F	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2031 F	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2038 F	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2043 F	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2044 F	Within Normal Limits		P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
175 mg/kg																			
1945 M	Within Normal Limits		P	P	P	P	P	-	-	-	-	-	P	P	P	P	P	P	P
	Decreased Food Consumption		-	-	-	-	-	P	P	P	P	P	-	-	-	-	-	-	-
	Decreased Fecal Volume		-	-	-	-	-	P	P	P	P	P	-	-	-	-	-	-	-

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
175 mg/kg (cont.)																		
1948 M	Within Normal Limits	P	P	P	P	P	-	-	-	-	-	-	P	P	P	P	P	P
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	P	P	-	-	-	-	-	-
1953 M	Within Normal Limits	P	P	P	P	P	P	P	P	-	-	-	-	-	-	P	P	P
	Decreased Food Consumption	-	-	-	-	-	-	-	-	P	P	P	P	P	P	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	-	-	-	P	P	P	P	P	P	-	-	-
1961 M	Within Normal Limits	P	P	P	P	P	-	-	P	P	P	P	P	P	P	P	P	P
	Decreased Food Consumption	-	-	-	-	-	P	P	-	-	-	-	-	-	-	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	P	P	-	-	-	-	-	-	-	-	-	-
1967 M	Within Normal Limits	-	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
	Excessive Salivation	P	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1972 F	Within Normal Limits	P	P	P	P	P	-	-	-	-	-	-	-	-	P	P	P	P
	Pale	-	-	-	-	-	-	-	P	P	-	-	-	-	-	-	-	-
	Lethargy	-	-	-	-	-	-	P	P	-	-	-	-	-	-	-	-	-
	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	P	P	-	-	-	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	P	P	P	P	-	-	-	-

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
175 mg/kg (cont.)																		
1978 F	Within Normal Limits	P	P	P	P	P	-	-	-	-	-	-	-	-	-	-	-	-
	Pale	-	-	-	-	-	-	-	-	-	P	P	P	P	P	P	P	P
	Decreased Activity	-	-	-	-	-	-	-	-	-	P	P	P	-	-	P	P	P
	Lethargy	-	-	-	-	-	-	P	P	-	-	-	-	-	-	-	-	-
	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	P	P	P	P	P	P	-	-
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	P	P	P	P	P	P	P	P
1984 F	Within Normal Limits	P	P	P	P	P	-	-	-	-	-	-	-	-	P	P	P	P
	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	P	P	P	-	-	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	P	P	-	P	P	P	P	P	-	-	-	-
1985 F	Within Normal Limits	P	P	P	P	P	-	-	P	P	P	P	P	-	-	P	P	P
	Decreased Food Consumption	-	-	-	-	-	P	P	-	-	-	-	-	P	P	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	P	P	-	-	-	-	-	P	P	-	-	-
1994 F	Within Normal Limits	P	P	P	P	P	-	-	-	-	-	P	P	P	P	P	P	P
	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	P	-	-	-	-	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	P	-	-	-	-	-	-	-

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
		Day 1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
		Hour 1	2	4														
225 mg/kg																		
2000 M	Within Normal Limits	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
2004 M	Within Normal Limits	P	P	P	P	P	P	-	-	-								
	Animal Dead[a]	-	-	-	-	-	-	-	-	P								
	Pale	-	-	-	-	-	-	-	P	-								
	Lethargy	-	-	-	-	-	-	-	P	-								
	Decreased Food Consumption	-	-	-	-	-	-	P	P	-								
	Decreased Fecal Volume	-	-	-	-	-	-	P	P	-								
2009 M	Within Normal Limits	P	P	P	P	P	P	-	-	-	-	-						
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	-	P						
	Pale	-	-	-	-	-	-	-	P	P	P	-						
	Hypothermia	-	-	-	-	-	-	-	-	-	P	-						
	Yellow Ano-genital Staining	-	-	-	-	-	-	-	-	-	Mo	-						
	Lethargy	-	-	-	-	-	-	-	-	P	-	-						
	Prostrate	-	-	-	-	-	-	-	-	-	P	-						
	Decreased Food Consumption	-	-	-	-	-	-	P	P	P	P	-						

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
225 mg/kg (cont.)																		
2009 M	Decreased Fecal Volume	-	-	-	-	-	-	P	P	P	P	-						
(cont.)	Poor Condition	-	-	-	-	-	-	-	-	-	P	-						
2014 M	Within Normal Limits	P	P	P	P	P	P	-	-	-	-	-	-	-				
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	-	-	-	P				
	Pale	-	-	-	-	-	-	-	-	-	-	P	P	-				
	Labored Breathing	-	-	-	-	-	-	-	-	-	-	-	P	-				
	Decreased Food Consumption	-	-	-	-	-	-	P	P	P	P	P	P	-				
	Decreased Fecal Volume	-	-	-	-	-	-	P	P	P	P	P	P	-				
2020 M	Within Normal Limits	P	P	P	P	P	P	-	-	-	-	-	-	-	-	P	P	P
	Pale	-	-	-	-	-	-	-	-	-	-	P	P	P	-	-	-	-
	Decreased Food Consumption	-	-	-	-	-	-	P	P	P	P	P	P	P	P	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	-	P	P	P	P	P	P	P	-	-	-	-
2027 F	Within Normal Limits	P	P	P	P	P	P	-	-	-	-	-	-	-	-	P	P	P
	Decreased Food Consumption	-	-	-	-	-	-	P	P	P	P	P	P	P	P	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	-	P	P	P	P	P	P	P	-	-	-	-

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
225 mg/kg (cont.)																		
2032 F	Within Normal Limits	P	P	P	P	P	P	-	-	-	-	-	-	-	-	-	P	P
	Pale	-	-	-	-	-	-	-	-	P	P	P	P	P	P	-	-	-
	Decreased Activity	-	-	-	-	-	-	-	-	-	-	-	P	P	P	-	-	-
	Decreased Food Consumption	-	-	-	-	-	-	P	P	P	P	P	P	P	P	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	-	P	P	P	P	P	P	P	P	P	-	-
2036 F	Within Normal Limits	P	P	P	P	P	P	-	-	-	-	-	-	-	P	P	P	P
	Decreased Food Consumption	-	-	-	-	-	-	P	P	P	P	P	P	P	-	-	-	-
	Decreased Fecal Volume	-	-	-	-	-	-	P	P	P	P	P	P	P	-	-	-	-
2041 F	Within Normal Limits	P	P	P	P	P	-	-	-	-	-							
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	P							
	Emaciation	-	-	-	-	-	-	-	-	P	-							
	Pale	-	-	-	-	-	-	P	P	P	-							
	Hypothermia	-	-	-	-	-	-	-	-	P	-							
	Lethargy	-	-	-	-	-	-	P	P	-	-							
	Prostrate	-	-	-	-	-	-	-	-	P	-							

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
225 mg/kg (cont.)																		
2041 F	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	-							
(cont.)	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	-							
2047 F	Within Normal Limits	P	P	P	P	P	-	-	-	-	-	-						
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	-	P						
	Pale	-	-	-	-	-	-	P	P	P	P	-						
	Hypothermia	-	-	-	-	-	-	-	-	-	P	-						
	Lethargy	-	-	-	-	-	-	-	-	-	P	-						
	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	P	-						
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	P	-						
250 mg/kg																		
1893 M	Within Normal Limits	P	P	P	P	P	-	-	-	-	-							
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	P							
	Lethargy	-	-	-	-	-	-	-	-	P	-							
	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	-							
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	-							

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval: Day 1, Hour 1	Day 1, Hour 2	Day 1, Hour 4	Day 2	3	4	5	6	7	8	9	10	11	12	13	14	15
250 mg/kg (cont.)																		
1898 M	Within Normal Limits	P	P	P	P	-	-	-	-	-	-	-						
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	-	P						
	Emaciation	-	-	-	-	-	-	-	-	-	P	-						
	Pale	-	-	-	-	-	-	-	-	P	P	-						
	Hypothermia	-	-	-	-	-	-	-	-	-	P	-						
	Lethargy	-	-	-	-	-	-	-	-	P	P	-						
	Decreased Food Consumption	-	-	-	-	P	P	P	P	P	P	-						
	Decreased Fecal Volume	-	-	-	-	P	-	-	P	P	P	-						
	No Stool	-	-	-	-	-	P	P	-	-	-	-						
1900 M	Within Normal Limits	P	P	P	P	-	-	-	-	-	-	-	-	-	-	P	P	P
	Decreased Food Consumption	-	-	-	-	P	P	P	P	P	P	P	P	P	P	-	-	-
	Decreased Fecal Volume	-	-	-	-	P	P	P	P	P	P	P	P	P	-	-	-	-

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
250 mg/kg (cont.)																		
1906 M	Within Normal Limits	P	P	P	P	-	-	-	-	-								
	Animal Dead[a]	-	-	-	-	-	-	-	-	P								
	Decreased Food Consumption	-	-	-	-	P	P	P	P	-								
	Decreased Fecal Volume	-	-	-	-	P	P	P	P	-								
1909 M	Within Normal Limits	P	P	P	P	P	-	-	-	-	-	-						
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	-	P						
	Pale	-	-	-	-	-	-	-	-	-	P	-						
	Decreased Food Consumption	-	-	-	-	-	P	P	P	P	P	-						
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	P	P	-						
1916 F	Within Normal Limits	P	P	P	P	-	-	-	-	-	-							
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	P							
	Pale	-	-	-	-	-	-	-	P	P	-							
	Hypothermia	-	-	-	-	-	-	-	-	P	-							
	Lethargy	-	-	-	-	-	-	-	P	-	-							
	Prostrate	-	-	-	-	-	-	-	-	P	-							

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
250 mg/kg (cont.)																		
1916 F	Decreased Food Consumption	-	-	-	-	P	P	P	P	P	-							
(cont.)	Decreased Fecal Volume	-	-	-	-	P	P	P	P	P	-							
1922 F	Within Normal Limits	P	P	P	P	P	-	-	-	P	P	P	P	P	P	P	P	P
	Decreased Fecal Volume	-	-	-	-	-	P	P	P	-	-	-	-	-	-	-	-	-
1926 F	Within Normal Limits	P	P	P	P	-	-	-	-									
	Animal Dead[a]	-	-	-	-	-	-	-	P									
	Lethargy	-	-	-	-	-	-	P	-									
	Irregular Gait	-	-	-	-	-	-	P	-									
	Decreased Food Consumption	-	-	-	-	P	P	P	-									
	Decreased Fecal Volume	-	-	-	-	P	P	-	-									
	No Stool	-	-	-	-	-	-	P	-									
1932 F	Within Normal Limits	P	P	P	P	-	-	-	-	-	-	P	P	P	P	P	P	P
	Decreased Food Consumption	-	-	-	-	P	P	P	P	P	P	-	-	-	-	-	-	-
	Decreased Fecal Volume	-	-	-	-	P	P	P	P	P	P	-	-	-	-	-	-	-

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table II (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Individual Pharmacologic and Toxicologic Signs (cont.)

An. No. & Sex	Observations	Interval																
	Day	1			2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Hour	1	2	4														
250 mg/kg (cont.)																		
1936 F	Within Normal Limits	P	P	P	P	-	-	-	-	-	-	-	-					
	Animal Dead[a]	-	-	-	-	-	-	-	-	-	-	-	P					
	Emaciation	-	-	-	-	-	-	-	-	-	-	P	-					
	Pale	-	-	-	-	-	-	-	-	-	P	P	-					
	Hypothermia	-	-	-	-	-	-	-	-	-	-	P	-					
	Lethargy	-	-	-	-	-	-	-	-	-	-	P	-					
	Decreased Food Consumption	-	-	-	-	P	P	P	P	P	P	P	-					
	Decreased Fecal Volume	-	-	-	-	P	P	P	P	P	P	P	-					

[a]Death of animal which died after clinical observations is indicated at the next interval.

S=Slight; Mo=Moderate; E=Extreme; P=Present
M=Male, F=Female.

Table III

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Body Weights, Body Weight Changes (Grams), and Time Found Dead

Dose Level (mg/kg)	Animal No. & Sex	Day 0	Day 1	Interim Deaths: Terminal Weight	Interim Deaths: Chg[a]	Interim Deaths: Time Found Dead	Survivors: Day 8	Survivors: Chg[a]	Survivors: Day 15	Survivors: Chg[a]
Corn Oil	1998 M	305	279				364	59	398	93
	2003 M	300	278				354	54	392	92
	2011 M	291	266				342	51	383	92
	2015 M	309	282				357	48	404	95
	2017 M	310	286				368	58	409	99
	2026 F	216	200				243	27	257	41
	2031 F	218	200				248	30	249	31
	2038 F	227	206				259	32	272	45
	2043 F	218	203				255	37	232	14
	2044 F	220	203				252	32	264	44
175	1945 M	293	272				286	-7	336	43
	1948 M	294	270				263	-31	331	37
	1953 M	290	266				254	-36	326	36
	1961 M	322	295				324	2	400	78
	1967 M	320	292				344	24	396	76
	1972 F	215	198				208	-7	280	65
	1978 F	220	202				191	-29	196	-24
	1984 F	216	200				223	7	262	46
	1985 F	220	202				212	-8	246	26
	1994 F	218	200				219	1	268	50

[a]Change from Day 0 weight (grams).

M=Male; F=Female.

Table III (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Body Weights, Body Weight Changes (Grams), and Time Found Dead (cont.)

Dose Level (mg/kg)	Animal No. & Sex	Day 0	Day 1	Interim Deaths: Terminal Weight	Interim Deaths: Chg[a]	Interim Deaths: Time Found Dead	Survivors: Day 8	Survivors: Chg[a]	Survivors: Day 15	Survivors: Chg[a]
225	2000 M	348	320				424	76	490	142
	2004 M	302	276	250	-52	Day 7				
	2009 M	293	266	248	-45	Day 8	250	-43		
	2014 M	314	288	241	-73	Day 11	277	-37		
	2020 M	302	280				290	-12	305	3
	2027 F	209	194				229	20	248	39
	2032 F	216	199				200	-16	220	4
	2036 F	204	193				233	29	248	44
	2041 F	218	200	163	-55	Day 8				
	2047 F	222	205	173	-49	Day 9	182	-40		
250	1893 M	300	278	257	-43	Day 8				
	1898 M	299	282	191	-108	Day 9	193	-106		
	1900 M	296	272				251	-45	302	6
	1906 M	302	280	211	-91	Day 7				
	1909 M	310	285	303	-7	Day 9	322	12		
	1916 F	268	250	192	-76	Day 7				
	1922 F	266	248				278	12	300	34
	1926 F	251	234	186	-65	Day 6				
	1932 F	253	235				236	-17	302	49
	1936 F	273	252	194	-79	Day 9	213	-60		

[a]Change from Day 0 weight (grams).

M=Male; F=Female.

Table IV

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Macroscopic Postmortem Observations[a]

Corn Oil

Sex	Males					Females				
Type of Death	Terminal Sacrifice					Terminal Sacrifice				
Animal Number	1998	2003	2011	2015	2017	2026	2031	2038	2043	2044
No Observable Abnormalities	P	P	P	P	P	P	P	P	P	P

Observations: P=Present.

[a]For reporting purposes some findings have been generalized; i.e. size and location within an organ.

Table IV (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Macroscopic Postmortem Observations[a]

175 mg/kg

Sex	Males					Females				
Type of Death	Terminal Sacrifice					Terminal Sacrifice				
Animal Number	1945	1948	1953	1961	1967	1972	1978	1984	1985	1994
Liver										
Firm						E				S
Small										M
Discolored (tan)	P	P	P	P	P	E	M	P	P	
Enlarged	M			M		M				
Irregular Surface/rough	M	E	E			M	E			
Spleen										
Enlarged			S							
Discolored (white)				S						

Observations: P=Present, S=Slight, M=Moderate, E=Extreme.

[a]For reporting purposes some findings have been generalized; i.e. size and location within an organ.

Table IV (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Macroscopic Postmortem Observations[a]

225 mg/kg

Sex	Males					Females				
Type of Death	Terminal Sacrifice		Found Dead			Terminal Sacrifice			Found Dead	
Animal Number	2000	2020	2004	2009	2014	2027	2032	2036	2041	2047[b]
No Observable Abnormalities	P							P		
Kidney Distended Pelvis					S					
Liver Discolored (tan) Enlarged Firm		S	P S	P	S M	P	M		M	S
Lungs Discolored/foci							P			
Cavity (contents)[c] Abnormal (thin red/white fluid)				M						P

Observations: P=Present, S=Slight, M=Moderate, E=Extreme.

[a]For reporting purposes some findings have been generalized; i.e. size and location within an organ.
[b]Due to technician error, tissues were not saved.
[c]Due to technician error, cavity location not addressed.

Table IV (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Macroscopic Postmortem Observations[a]

225 mg/kg (cont.)

Sex	Males					Females				
Type of Death	Terminal Sacrifice		Found Dead			Terminal Sacrifice			Found Dead	
Animal Number	2000	2020	2004	2009	2014	2027	2032	2036	2041	2047[b]
Spleen Enlarged		M			M	S				
Thymic Region Discolored (orange)			E						M	
Urinary Bladder (contents) Red thin fluid				M	S					
General Comments Multiple organs and viscera discolored (yellow)				E						

Observations: P=Present, S=Slight, M=Moderate, E=Extreme.

[a]For reporting purposes some findings have been generalized; i.e. size and location within an organ.
[b]Due to technician error, tissues were not saved.

Table IV (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Macroscopic Postmortem Observations[a]

250 mg/kg

Sex	Males					Females				
Type of Death	Terminal Sacrifice	Found Dead				Terminal Sacrifice		Found Dead		
Animal Number	1900	1893	1898	1906	1909	1922	1932	1916	1926	1936
No Observable Abnormalities						P			P	
Kidney										
Distended pelvis				M						
Discolored (pale)				M	S					
Liver										
Discolored/area (tan)	P	P		P	P		P	P		
Irregular Surface (rough)					M					
Adhesions			S	S	S					M
Lungs										
Fluid filled										S
Trachea										
Fluid filled (white frothy)										S

Observations: P=Present, S=Slight, M=Moderate, E=Extreme.

[a]For reporting purposes some findings have been generalized; i.e. size and location within an organ.

Table IV (cont.)

Acute Oral Toxicity Study in Rats
with 1,2-*bis*(Triethoxysilyl)ethane

Macroscopic Postmortem Observations[a]

250 mg/kg (cont.)

Sex	Males					Females				
Type of Death	Terminal Sacrifice	Found Dead				Terminal Sacrifice		Found Dead		
Animal Number	1900	1893	1898	1906	1909	1922	1932	1916	1926	1936
Cavity (contents)[b] Abnormal (thin red)		P			E					
Spleen Enlarged					S					S
Stomach Mucosa discolored/foci (red)		P								
Mesenteric Lymph Node Discolored (red)								M		

Observations: P=Present, S=Slight, M=Moderate, E=Extreme.

[a]For reporting purposes some findings have been generalized; i.e. size and location within an organ.
[b]Due to technician error, cavity location not addressed.

Appendix A

Acute Oral Toxicity Study in Rats with 1,2-*bis*(Triethoxysilyl)ethane

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Report Amendments

There are no amendments for this report at this time.

UPS Internet Shipping: View/Print Label

1. **Print the label(s):** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.

2. **Fold the printed label at the solid line below.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. **GETTING YOUR SHIPMENT TO UPS**
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TRACKING #: 1Z 464 696 25 9523 7396

BILLING: P/P

Reference#1: Submitted 020810
Reference#2: 1,2-bis(triethoxysilyl)-ethane
US 12.0.23. WXPE60 99.0A 01/2010

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