



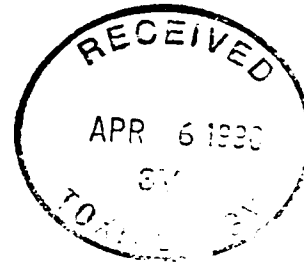
HAZLETON
LABORATORIES AMERICA, INC.
3301 KINSMAN BLVD., P.O. BOX 7545
MADISON, WI 53707 USA

FINAL REPORT

Karen Armstrong
3M
Toxicology Services
Building 220-2E-02
St. Paul, MN 55144-1000

HLA Number: 91201739

Sample: T-4416



Enclosed: Acute Oral Toxicity Study in Rats (OECD Guidelines)

- o Key Personnel
- o Methodology
- o Summary of Results
- o Individual Pathology Comments
- o References
- o Pathology Report
- o Raw Data/Appendix

Signed: _____

Steven M. Glaza
Study Director
Acute Toxicology

Date

4-2-90



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KEY PERSONNEL

Acute Toxicology

Steven M. Glaza
Study Director
Section Supervisor

Steven R. Sorenson
Study Coordinator

Patricia Padgham
Group Leader

Sharen L. Howery
Report Coordinator

Quality Assurance

Deborah L. Keller
Manager

Laboratory Animal Veterinarian

Cindy J. Cary, DVM
Diplomate, ACLAM

Anatomical Pathology

Thomas E. Palmer, PhD
Anatomical Pathologist

Dennis Hoffman
Group Leader
Necropsy

Anne Mosher
Group Leader
Pathology Data



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Sample: T-4416

METHODOLOGY

Objective: To assess the acute oral toxicity produced when a test material is administered by oral gavage to rats.¹

Test Material: T-4416

Physical Description: Clear colorless liquid

Purity and Stability: Sponsor assumes responsibility for purity and stability determinations (including under test conditions).

Storage and Retention: The test material was stored at room temperature. Any unused material will be returned to the Sponsor according to HLA Standard Operating Procedure.

Safety Precautions: Normal handling procedures were used according to HLA Standard Operating Procedure.

Test Animal: Adult albino rats, CrI:CD®BR, were procured, separated by sex, maintained in group cages in temperature- and humidity-controlled quarters, provided continuous access to Rodent Chow® 5001, Purina Mills, Inc., and water, and held for an acclimation period of at least 7 days. Animal husbandry and housing at HLA comply with standards outlined in the "Guide for the Care and Use of Laboratory Animals".² If variations from the prescribed environmental conditions existed, they were documented and considered to have no effect on the study outcome. No contaminants were expected to have been present in the feed or water which would have interfered with or affected the results of the study.

Acclimated animals were chosen at random for the study. Five male and five female rats, weighing from 204 to 299 g, were used for each dose level. The study consisted of three dose levels (0.2, 1.0 and 5.0 g/kg of body weight). Test animals were housed by sex in groups of five and identified by animal number and corresponding ear tag. Food and water were available *ad libitum* throughout the study, except for an overnight period just before test material administration when food, but not water, was withheld.

Reason for Species Selection: Historically, rats have been used as a representative of a rodent species and are preferred by various regulatory agencies.

Preparation and Administration of Test Material: The test material was administered as received. An individual dose of the undiluted material was calculated for each animal based upon its fasted body weight and administered by gavage.

The dose volume of the test material varied for each dose level based upon the bulk density of the material of 1.28 g/mL.



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Reason for Route of Administration: Historically, the oral route has been the route of choice for administering a known amount of test material.

Observations: The animals were observed for clinical signs and mortality at 1, 2.5 and 4 hours after test material administration. The animals were observed daily thereafter for 14 days for clinical signs and twice daily for mortality.

Animals were weighed just before test material administration. Surviving animals were weighed again at Day 7 and at termination of the experimental phase or at death (when survival exceeded 1 day).

Pathology: All animals whether dying on test or euthanatized at termination of the experimental phase were subjected to a gross necropsy examination and all abnormalities were recorded. After necropsy, the animals were discarded and no tissues were saved.

Statistical Methods: The LD₅₀ value for males, females and the combined sexes was calculated based upon the observed mortality using a computer program utilizing a modified Behrens-Reed-Muench Cumulant Method.³ No other statistical analysis was performed.

Location of Raw Data and Final Report: The raw data and a copy of the final report will be retained in the archives of HLA.



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Sample: T-4416

SUMMARY OF RESULTS

Test Animal: Albino Rats - Cr1:CD®BR
Source: Charles River Laboratories, Inc., Portage MI
Date Animals Received: 12/04/89, 12/18/89 and 01/08/90

Method of Administration: Oral Gavage

Start Date (In-life): 12/28/89

End Date (In-life): 02/16/90

Estimated Oral LD₅₀ : Male - 1.8 g/kg of Body Weight
95% Confidence Limits - 0.7 to 4.9 g/kg

Female - 0.6 g/kg of Body Weight
95% Confidence Limits - 0.2 to 1.5 g/kg

Sexes Combined - 1.0 g/kg of Body Weight
95% Confidence Limits - 0.4 to 2.4 g/kg

Sex	Dose Level (g/kg)	Average Body Weights (g)			Mortality (Number Dead/Number Dosed)
		Initial	Day 7	Terminal	
Male	0.2	290	332	362	0/5
	1.0	272	264	315	1/5
	5.0	274	---	---	5/5
Female	0.2	211	247	254	0/5
	1.0	233	257	268	4/5
	5.0	230	---	---	5/5



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Clinical Signs
(Number of Animals Affected)

<u>Observation</u>	<u>Hour</u>			<u>Day</u>													
	<u>1.0</u>	<u>2.5</u>	<u>4.0</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>	<u>12</u>	<u>13</u>	<u>14</u>
<u>Males (0.2 g/kg)</u>																	
Appeared normal	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
<u>Females (0.2 g/kg)</u>																	
Appeared normal	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
<u>Males (1.0 g/kg)</u>																	
Appeared normal	5	5	5	5	2	1	1	1	2	3	3	3	3	3	3	4	4
Hypoactivity	0	0	0	0	3	2	2	2	2	1	1	1	0	0	0	0	0
Red-stained face	0	0	0	0	1	2	2	2	1	1	1	1	1	1	0	0	0
Yellow-stained urogenital area	0	0	0	0	1	3	3	3	1	1	1	1	1	1	1	0	0
Ataxia	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0
Thin appearance	0	0	0	0	0	0	0	0	1	1	1	1	1	0	0	0	0
Diarrhea	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0
Death	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
<u>Females (1.0 g/kg)</u>																	
Appeared normal	5	5	5	5	1	1	1	1	1	1	1	1	1	1	1	1	1
Hypoactivity	0	0	0	0	2	2	1	0	0	0	0	0	0	0	0	0	0
Red-stained face	0	0	0	0	2	2	1	0	0	0	0	0	0	0	0	0	0
Ataxia	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Prostration	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	1	2	1	0	0	0	0	0	0	0	0	0	0



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Clinical Signs (Continued)
(Number of Animals Affected)

<u>Observation</u>	<u>Hour</u>			<u>Day</u>													
	<u>1.0</u>	<u>2.5</u>	<u>4.0</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>	<u>12</u>	<u>13</u>	<u>14</u>
<u>Males (5.0 g/kg)</u>																	
Appeared normal	1	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Diarrhea	4	4	4	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Hypoactivity	0	4	4	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Red-stained face	0	2	4	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Lacrimation	0	0	1	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Ataxia	0	0	0	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Death	0	0	1	4*	-	-	-	-	-	-	-	-	-	-	-	-	-

* - One animal found dead after the morning observation.

<u>Females (5.0 g/kg)</u>																	
Appeared normal	2	0	0	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Diarrhea	3	3	2	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Hypoactivity	1	3	2	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Lacrimation	0	2	2	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Ataxia	0	1	1	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Red-stained face	0	1	1	0	-	-	-	-	-	-	-	-	-	-	-	-	-
Death	0	2	1	2	-	-	-	-	-	-	-	-	-	-	-	-	-



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INDIVIDUAL PATHOLOGY COMMENTS

Dose Level: 0.2 g/kg of Body Weight

<u>Animal Number</u>	<u>Sex</u>	<u>Test Day</u>		<u>Necropsy Observation</u>
		<u>Died</u>	<u>Sacrificed</u>	
C50366	M	-	14	No visible lesions
C50367	M	-	14	No visible lesions
C50363	M	-	14	No visible lesions
C50369	M	-	14	No visible lesions
C50370	M	-	14	No visible lesions
C50501	F	-	14	No visible lesions
C50502	F	-	14	No visible lesions
C50503	F	-	14	No visible lesions
C50504	F	-	14	No visible lesions
C50500	F	-	14	No visible lesions



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INDIVIDUAL PATHOLOGY COMMENTS (continued)

Dose Level: 1.0 g/kg of Body Weight

<u>Animal Number</u>	<u>Sex</u>	<u>Test Day</u>		<u>Necropsy Observation</u>
		<u>Died</u>	<u>Sacrificed</u>	
C49861	M	-	14	No visible lesions
C49862	M	-	14	No visible lesions
C49863	M	-	14	No visible lesions
C49864	M	2	-	Stomach, Glandular Mucosa: diffusely red
C49860	M	-	14	No visible lesions
C49921	F	3	-	Stomach, Glandular Mucosa: diffusely red
C49917	F	2	-	No visible lesions
C49918	F	4	-	Perinasal Discharge: red Stomach, Glandular Mucosa: multiple dark areas, up to 2 x 4 mm
C49919	F	3	-	Stomach, Glandular Mucosa: diffusely red
C49920	F	-	14	No visible lesions



Sample: T-4416

INDIVIDUAL PATHOLOGY COMMENTS (continued)

Dose Level: 5.0 g/kg of Body Weight

<u>Animal Number</u>	<u>Sex</u>	<u>Test Day</u>		<u>Necropsy Observation</u>
		<u>Died</u>	<u>Sacrificed</u>	
C49191	M	1	-	No visible lesions
C49192	M	1	-	No visible lesions
C49193	M	1	-	Stomach, Glandular Mucosa; multiple brown areas, up to 3 x 1 mm
C49194	M	0	-	Stomach, Glandular Mucosa: diffusely dark red
C49490	M	1	-	No visible lesions
C49131	F	0	-	Stomach contents: clear white fluid
C49132	F	1	-	Stomach, Glandular Mucosa: multiple brown areas, up to 4 x 2 mm
C49128	F	0	-	Stomach Contents: clear white fluid
C49129	F	0	-	Stomach Contents: clear white fluid
C49130	F	1	-	No visible lesions



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REFERENCES

1. "Acute Oral Toxicity," *Organisation for Economic Cooperation and Development's Guidelines for Testing of Chemicals*, Section 401 (adopted May 12, 1981).
2. NIH Publication No. 86-23 (revised 1985).
3. Thakur, A. K. and Fezio, W. L., "A Computer Program for Estimating LD₅₀ and its Confidence Limits Using a Modified Behrens-Reed-Muench Cumulant Method," *Drug and Chemical Toxicology*, 4(3):297-305 (1981).



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PATHOLOGY REPORT

There were 10 rats (5 males, 5 females) from each of 3 dose levels (0.2, 1.0, and 5.0 g/kg) necropsied. The animals that died on test (DOT) were refrigerated and necropsied within 24 hours, usually the same day. All surviving animals were euthanatized and necropsied at the termination of the study. The dose level, day of death, and gross observations recorded for each animal are on page 8 through 10 of this report.

All animals in the 5.0 g/kg dose group died on test. At necropsy, the only changes observed were in the animals that died on test. The most frequently recorded observations pertained to the content and coloration changes in the mucosa of the stomach. These findings possibly represent test material mixed with ingesta, postmortem change, or both. All remaining observations in the DOTs were considered postmortem change, incidental, and unrelated to the test material. There were no visible lesions in the sacrificed animals.


Thomas E. Palmer, PhD
Pathologist

4-3-90
Date

(91201739.cjr)

HLA: 9/20/739PERSONNEL SIGNATURE SHEET
ACUTE TOXICOLOGY

<u>Name</u>	<u>Job Title</u>	<u>Signature</u>	<u>Initials</u>
Becky Beckwith	Lab Animal Technician	<u>Becky Beckwith</u>	<u>B/B</u>
Ann Bursaw	Sr. Clerk	<u>Ann Bursaw</u>	<u>AnnB</u>
Anthony Cass	Lab Animal Assistant	<u>Anthony Cass</u>	<u>AC</u>
Cindy J. Cary, DVM	Lab Animal Veterinarian	<u>Cindy J. Cary</u>	<u>CK</u>
Kari Gassen	Sr. Lab Animal Assistant	<u>Kari Gassen</u>	<u>KG</u>
Steven M. Glaza	Section Supervisor	<u>Steven M. Glaza</u>	<u>SG</u>
Ben Haley	Sr. Lab Animal Assistant	<u>Ben Haley</u>	<u>BH</u>
Jeff Hicks	Lab Animal Technician	<u>Jeff Hicks</u>	<u>JH</u>
Sharen L. Howery	Research Assistant	<u>Sharen L. Howery</u>	<u>SLH</u>
Jim Jirschele	Lab Animal Assistant	<u>Jim Jirschele</u>	<u>JJ</u>
Wayne Madison	Senior Section Supervisor	<u>Wayne A. Madison</u>	<u>WAM</u>
Bud McDonald	Sr. Lab Animal Assistant	<u>Bud McDonald</u>	<u>BMC</u>
Eileen McConnell	Administrative Clerk	<u>Eileen McConnell</u>	<u>EMC</u>
Henry Mikula	Lab Animal Assistant	<u>Henry Mikula</u>	<u>HM</u>
Albert Oleson	Sr. Lab Animal Assistant	<u>Albert Oleson</u>	<u>AO</u>
Patricia Padgham	Group Leader	<u>Patricia Padgham</u>	<u>TP</u>
Jane Polnow	Lab Animal Technician	<u>Jane Polnow</u>	<u>JP</u>
Steven R. Sorenson	Study Coordinator	<u>Steven R. Sorenson</u>	<u>SRS</u>
Dawn Thieding	Clerk	<u>Dawn Thieding</u>	<u>DT</u>
Annette R. Turner	Sr. Clerk	<u>Annette R. Turner</u>	<u>AT</u>
<u>GEN BRIDGES</u>	<u>SR. LAB ANIMAL ASST.</u>	<u>Gen Bridges</u>	<u>GB</u>

(09/11/89)

HLA: 91201739

DOSE ADMINISTRATION/BODY WEIGHT/MORTALITY

SECOND

Study Title: Acute Oral Toxicity

Test Material: T-4416

Vehicle: NA

Bulk Density: 1.28 (g/mL) Species/Strain: Albino Rat/Sprague-Dawley Source: Charles River Date Received: 1-8-90

Dose Level: 0.2 (g/kg) Fasted Date/Time/Technician: 2-1-90/3:05 p.m./ QA Room No. 102

Route of Administration: Oral Gavage

Route of Administration: ORAL GAVAGE

1990

Dose Volume <u>0.16</u> (ml/kg)	Sex: (Male/Female)	Dose Time: <u>9:50 AM</u>	Technician	Date	Scale Used <u>KTRON</u>
Animal No. <u>CS-0366</u>	<u>0367 0363</u>	<u>0370</u>	<u>QA</u>	<u>2/2</u>	<u>NA</u>
Prefasted Body Weight (g)	<u>NA</u>				
Fasted Body Weight (g)	<u>284</u>	<u>299</u>	<u>QA</u>	<u>2/2</u>	<u>5228</u>
Actual Dose (ml)	<u>0.05</u>	<u>0.05</u>	<u>QA</u>	<u>2/2</u>	<u>Verified by: 2-2-90</u>
Day 7 Body Weight (g)	<u>329</u>	<u>351</u>	<u>QA</u>	<u>2/4</u>	<u>5228</u>
Day 14 Body Weight (g)	<u>356</u>	<u>386</u>	<u>QA</u>	<u>2/16</u>	<u>5228</u>
Dead Body Weight (g)					

1990

Dose Volume <u>0.16</u> (ml/kg)	Sex: (Male/Female)	Dose Time: <u>9:52 AM</u>	Technician	Date	Scale Used <u>KTRON</u>
Animal No. <u>CS-0501</u>	<u>0502 0503</u>	<u>0500</u>	<u>QA</u>	<u>2/2</u>	<u>NA</u>
Prefasted Body Weight (g)	<u>NA</u>				
Fasted Body Weight (g)	<u>218</u>	<u>209</u>	<u>QA</u>	<u>2/2</u>	<u>5228</u>
Actual Dose (ml)	<u>0.03</u>	<u>0.03</u>	<u>QA</u>	<u>2/2</u>	<u>Verified by: 2-2-90</u>
Day 7 Body Weight (g)	<u>258</u>	<u>243</u>	<u>QA</u>	<u>2/9</u>	<u>5228</u>
Day 14 Body Weight (g)	<u>270</u>	<u>246</u>	<u>QA</u>	<u>2/16</u>	<u>5228</u>
Dead Body Weight (g)					

MORTALITY (NO. DIED/NO. DOSED)

Dose Level (g/kg)	Sex	Hours 0-4	Study Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
0.2	♂	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
0.2	♀	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5
Techn.		QA	QA	QA	QA	QA	QA	QA	QA	QA	QA	QA	QA	QA	QA	QA	QA	QA
Time		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Date 1990		2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2

NA - Not Applicable

Reviewed By: JH Date: 2-22-90

HLA: 91201739

OBSERVATIONS (Individual)

Dose level: 0.2 g/kg Test material: T-441C

Female		Observations	Pre-dose	Hours				Study Day													
				1	2	5	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14
CS-0366	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CS-0367	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CS-0363	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CS-0369	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
CS-0370	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Deaths		NA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Collected by		SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ	SSJ
Date 1990		2/2	4/2	2/2	4/2	2/2	4/2	2/2	4/2	2/2	4/2	2/2	4/2	2/2	4/2	2/2	4/2	2/2	4/2	2/2	4/2

- Surviving animals submitted for terminal necropsy. Technician AW
Date 2-16-90

- Surviving animals designated for sacrifice and discard. Technician NA
Date NA

✓ Indicates condition exists
S1 Slight.
- Condition not evident.
* Found dead, P.M. check.
NA Not applicable
Reviewed by: SSJ
Date: 2-22-90

HLA: 91201739

OBSERVATIONS (Individual)

Dose level: 0.2 g/kg

Test material: T-4416

Male/Female

Animal Number	Observations	Pre-dose	Hours				Study Day													
			1	2	3	4	5	6	7	8	9	10	11	12	13	14				
CS-0501	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
CS-0502	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
CS-0503	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
CS-0504	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
CS-0500	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				
Deaths		NA	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
Collected by		641	741	741	741	741	741	741	741	741	741	741	741	741	741	741				
Date 1990		2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2	2/2				

- Surviving animals submitted for terminal necropsy.
Technician BH
Date 2-16-90

- Surviving animals designated for sacrifice and discard.
Technician NA
Date NA

✓ Indicates condition exists
SI Slight.
- Condition not evident.
* Found dead, P.M. check.
NA Not applicable
Reviewed by: JH
Date: 2-22-90

DOSE ADMINISTRATION/BODY HEIGHT/MONIA. / RECORD

Test Material: T-4416

Vehicle: NA

Dose Level: 1.0 (g/kg) Fasted Date/Time/Technician 1-8-90/3:30 p.m./P.H.

Route of Administration: Oral Gavage

Head Body Weight (g)	Dose Volume 0.78 (ml/kg)	Sex: Male/Female	Dose Time: 9:28 AM	220	1990	
	C4-	9921	9917	9918	9919	9920
		NA				
Prefasted Body Weight (g)		235	268	220	215	229
Fasted Body Weight (g)		0.18	0.21	0.17	0.17	0.18
Actual Dose (ml)		Dead	Dead	Dead	Dead	257
Day 7 Body Weight (g)		1-12-90 235	1-11-90	1-10-90	1-9-90	268
Day 14 Body Weight (g)		203	224	190	183	
Dead Body Weight (g)						

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Dead Body Weight (g)						

Head Body Weight (g)	Dose Volume 0.78 (ml/kg)	Sex: Male/Female	Dose Time: 9:2
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Hose level (g/kg)			Sex	MORTALITY (NO. DIED/NO. DOSED)																											
1.0		1.0		Study Day																											
1.0			♀	Study Day																											
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HA - Hot Applicable

Reviewed By JH Date 2-22-90

HLA: 91201739

OBSERVATIONS (Individual)

Dose level: 1.0 g/kg Test material: T-4416

Male/Female

Animal Number	Observations	Pre-dose	Hours					Study Day											
			1	2	3	4	5	6	7	8	9	10	11	12	13	14			
C4-9861	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
C4-9862	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
	Yellow stained ventral area																		
C4-9863	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
	Hypocative																		
C4-9864	Red stained face																		
	Yellow stained ventral area																		
C4-9865	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
	Hypocative																		
C4-9866	Red stained face																		
	Dead																		
C4-9867	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
	Hypocative																		
C4-9868	Yellow stained ventral area																		
	Red stained face																		
C4-9869	Diarrhea																		
	Diarrhea																		
C4-9870	Deaths	NA	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
	Collected by	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH			
C4-9871	Date 1990	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9			

- Surviving animals submitted for terminal necropsy. Technician JH

Date 1-23-90

- Surviving animals designated for sacrifice and discard. Technician NA

Date NA

✓ Indicates condition exists
S1 Slight.

- Condition not evident.
* Found dead, P.M. check.

NA Not applicable

Reviewed by: JH

Date: 2-22-90

HLA: 91201739

OBSERVATIONS (Individual)

Dose level: 1.0 g/kg Test material: T-4416

Animal Number	Observations	Pre-dose	Hours				Study Day													
			1	2	5	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14
C4-9921	Observed Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypertensive																			
	Red stained face																			
	Dead																			
C4-9917	Observed Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypertensive																			
	Red stained face																			
	Prostrate																			
C4-9918	Observed Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypertensive																			
	Red stained face																			
	Prostrate																			
C4-9919	Observed Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypertensive																			
	Red stained face																			
	Dead																			
C4-9920	Observed Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypertensive																			
	Red stained face																			
	Dead																			
Deaths		NA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Collected by		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Date 1990		1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9	1/9

- Surviving animals submitted for terminal necropsy. Technician DL
Date 1-23-90

- Surviving animals designated for sacrifice and discard. Technician NA
Date NA

✓ Indicates condition exists
SI Slight.
- Condition not evident.
* Found dead, P.M. check.
NA Not applicable
Reviewed by: JA
Date: 2-22-80

HLA: 91201739

DOSE ADMINISTRATION/BODY WEIGHT/MORTALITY RECORD

Study Title: Acute Oral Toxicity

Test Material: T-4416

Bulk Density: 1.28 (g/mL) Species/Strain: Albino Rat/Sprague-Dawley

Dose Level: 5.0 (g/kg) Fasted Date/Time/Technician: 12-27-89/2:45 p.m./BH

Route of Administration: Oral Gavage

Vehicle: NA

Date Received: 12-4-89

Room No. 102

1989/90
 Entry error
 QA 12-28-89
 ② C49194 was found dead at P.M. check
 QA 12-28-89
 ③ Last animal found dead at 10 AM.
 QA 12-29-89

Dose Volume	3.91	(ml/kg)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			</
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HLA: 91201739

OBSERVATIONS (Individual)

Dose level: S.Og/kg Test material: T-4416

Animal Number	Observations	Pre-dose	Hours				Study Day													
			1	2	5	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14
C4-9191	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypertensive																			
	Diarrhea																			
	Red stained face																			
C4-9192	Ataxia																			
	Dead																			
	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Diarrhea																			
C4-9193	Red stained face																			
	Dead																			
	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Diarrhea																			
C4-9194	Hypertensive																			
	Red stained face																			
	Diarrhea																			
	Dead																			
C4-9190	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Diarrhea																			
	Hypertensive																			
	Red stained face																			
Deaths	Collected by	NA	C	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O	O
	Date	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88
	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	
	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	12/18/88	

Found dead at 10 am.
 12 29-89

Surviving animals
 submitted for terminal
 necropsy.
 Technician NA

Date NA

Surviving animals
 designated for sacrifice
 and discard.
 Technician NA

Date NA

Indicates condition
 exists
 S1 Slight.

Condition not evident.
 Found dead, P.M. check.

NA Not applicable

Reviewed by: JH

Date: 2-22-90

HLA: 91201739

OBSERVATIONS (Individual)

Dose level: 5.0 g/kg

Test material: T-4416

Male/Female

Animal Number	Observations	Pre-dose	Hours				Study Day													
			1	2	5	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14
C4-9131	Appeared Normal	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Diarrhea	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypactive		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Dead				✓															
C4-9132	Appeared Normal	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Diarrhea	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypactive		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Lactation		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C4-9128	Appeared Normal	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Diarrhea	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypactive		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Dead				✓															
C4-9129	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Diarrhea	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypactive		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Dead				✓															
C4-9130	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Diarrhea	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hypactive		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Lactation		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C4-9130	Red stained face				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Dead																			
	Deaths	NA	2	2	1	2														
	Collected by	NA	DH	AM	AM	AM														
Date 1989/90		14/28	17/28	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29	17/29

- Surviving animals
submitted for terminal
necropsy.
Technician NA

Date NA

- Surviving animals
designated for sacrifice
and discard.
Technician NA

Date NA

✓ Indicates condition
exists
SI Slight.

- Condition not evident.
* Found dead, P.M. check.

NA Not applicable

Reviewed by: JH

Date: 2-22-90