

**HAZLETON**

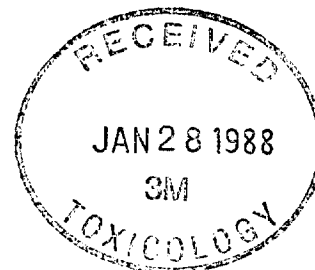
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AR226-0229

Chemical & BioMedical Sciences Division

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FINAL REPORT



ROGER G. PERKINS
MINNESOTA MINING & MANUFACTURING COMPANY
TOXICOLOGY SERVICES
ST. PAUL, MN 55101

SAMPLE NUMBER: 7090576

SAMPLE ENTERED: 09/25/8

REPORT PRINTED: 01/25/8

SAMPLE: T-4102

PURCHASE ORDER NUMBER: T837389-410 754

ENCLOSED: ACUTE ORAL TOXICITY STUDY IN RATS (OECD GUIDELINES)

- o Key Personnel
- o Method
- o Summary
- o Individual Pathology Comments
- o References
- o Pathology Report
- o Raw Data Appendix

SIGNED:

Steven M. Glaza
STEVEN M. GLAZA
STUDY DIRECTOR
ACUTE TOXICOLOGY

.....1-25-88
DATE

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KEY PERSONNEL

Acute ToxicologySteven M. Glaza
Study DirectorCalvin L. Horton
Group Leader
Support ServicesSharen L. Howery
Report CoordinatorQuality AssuranceDebra Curley Arndt
ManagerAnatomical PathologyThomas E. Palmer, PhD
Anatomical PathologistRobert Salava
Senior Section SupervisorDennis Hoffman
Group Leader
NecropsyAnne Mosher
Group Leader
Pathology DataLaboratory Animal VeterinarianCindy J. Cary, DVM
Diplomate, ACLAM

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SAMPLE: T-4102

OECD ORAL SCREEN

Objective: To determine the acute oral toxicity produced when a test material is administered by the oral route (gavage) to rats according to the Organisation for Economic Cooperation and Development's Guidelines for Testing of Chemicals.

Test Material: T-4102

Physical Description: Dark amber liquid

Purity and Stability: Sponsor assumes responsibility for purity and stability determinations.

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

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

Test Animal: Young adult albino rats of the Sprague-Dawley strain were procured, separated by sex, maintained in group cages in temperature- and humidity-controlled quarters, provided continuous access to Purina Rodent Chow 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". 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. 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: The rat is the animal classically used due to its small size, ready availability, and large amount of background data.

Method: Five male and five female rats weighing from 200 to 284 g were used for each dose level. The study consisted of two dose levels (0.50 and 5.0 g/kg).

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

The dose volume of the test material varied per dose level based upon an average bulk density of 1.06 g/ml.

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OECD ORAL SCREEN

(CONTINUED)

Reason for Route of Administration: This is the method for administering a known quantity of test substance and has been the route of choice historically.

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 a day for mortality.

All animals were weighed just before test material administration, at 7 days and at study termination (or at death).

Pathology: At study termination surviving animals were euthanatized. Animals which died on study or euthanatized at study termination were subjected to a gross necropsy examination and abnormalities recorded. Following necropsy, animals were discarded and no tissues were saved.

Statistical Methods: Other than average body weights, no other statistical method 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-4102

OECD ORAL SCREEN

(CONTINUED)

SUMMARY

Test Animal: Albino Rats - Sprague-Dawley strain
Source: Charles River Laboratories, Inc., Portage MI
Date Animals Received: 09/08, 10/12, and 10/26/87

Method of Administration: Oral Gavage

Date Test Started: 10/26/87

Date Test Completed: 11/20/87

Estimated Oral LD50: Male - Between 0.50 and 5.0 g/kg of body weight
Female - Between 0.50 and 5.0 g/kg of body weight

	Dose Level (g/kg)	Average Body Weights (g)			Mortality (Number Dead/Number Dosed)
		Initial	Day 7	Terminal	
Male	0.50	272	273	339	2/5
	5.00	255	---	---	5/5
Female	0.50	210	198	238	0/5
	5.00	216	---	---	5/5

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SAMPLE: T-4102

DECD DRAL SCREEN

(CONTINUED)

CLINICAL SIGNS
(No. of Animals Affected)

	Hours			Days													
	1.0	2.5	4.0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
DOSE LEVEL: 0.50 g/kg of body weight																	
Males																	
Appeared normal	5	5	5	5	5	5	4	0	0	3	3	3	3	3	3	3	3
Aggressive behavior	0	0	0	0	0	0	3A	1	1	0	0	0	0	0	0	0	0
Hypersensitivity to touch	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0
Hypoactivity	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0
Intermittent clonic convulsions	0	0	0	0	0	0	0	0	1A	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	2B	0	0	0	0	0	0	0	0	0	0
Females																	
Appeared normal	5	5	5	5	5	5	0	0	0	3	3	3	4	4	4	4	4
Aggressive behavior	0	0	0	0	0	0	5	4	0	0	0	0	0	0	0	0	0
Hypoactivity	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
Hypersensitivity to touch	0	0	0	0	0	0	0	2	4	1	1	1	0	0	0	0	0
Ataxia	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
Intermittent clonic convulsions	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
Alopecia - back region	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1

A - Sign noted after a.m. observation.

B - One animal found dead after a.m. observation.

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SAMPLE: T-4102

OECD ORAL SCREEN

(CONTINUED)

CLINICAL SIGNS (Continued)
(No. of Animals Affected)

	Hours			Days													
	1.0	2.5	4.0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
DOSE LEVEL: 5.0 g/kg of body weight																	
Males																	
Hypoactivity	5	5	5	5	2	0	0	-	-	-	-	-	-	-	-	-	-
Miosis	4	0	0	0	0	0	0	-	-	-	-	-	-	-	-	-	-
Ataxia	2	1	0	0	0	1	0	-	-	-	-	-	-	-	-	-	-
Red-stained face	0	0	0	3	1	0	0	-	-	-	-	-	-	-	-	-	-
Lacrimation	0	0	0	2	0	0	0	-	-	-	-	-	-	-	-	-	-
Yellow-stained genital region	0	0	0	0	1	0	0	-	-	-	-	-	-	-	-	-	-
Pain reflex absent	0	0	0	0	1	0	0	-	-	-	-	-	-	-	-	-	-
Diarrhea	0	0	0	0	0	1	0	-	-	-	-	-	-	-	-	-	-
Tonic convulsions	0	0	0	0	0	1	0	-	-	-	-	-	-	-	-	-	-
Excessive salivation	0	0	0	0	0	1	0	-	-	-	-	-	-	-	-	-	-
Death	0	0	0	1A	2	1	1	-	-	-	-	-	-	-	-	-	-
Females																	
Appeared normal	0	0	0	2	0	0	0	0	0	-	-	-	-	-	-	-	-
Hypoactivity	5	5	5	1	0	1	0	0	0	-	-	-	-	-	-	-	-
Miosis	5	0	0	0	0	0	0	0	0	-	-	-	-	-	-	-	-
Ataxia	1	2	1	1	0	1	0	0	0	-	-	-	-	-	-	-	-
Yellow-stained genital region	0	0	0	2	1	2	2	2	0	-	-	-	-	-	-	-	-
Gasping	0	0	0	1	0	0	0	0	0	-	-	-	-	-	-	-	-
Red-stained face	0	0	0	1	1	1	0	0	0	-	-	-	-	-	-	-	-
Respiratory congestion	0	0	0	1	0	0	0	0	0	-	-	-	-	-	-	-	-
Diarrhea	0	0	0	0	1	0	0	0	0	-	-	-	-	-	-	-	-
Tonic convulsions	0	0	0	0	0	1	0	2	0	-	-	-	-	-	-	-	-
Death	0	0	0	1A	1	0	1	1A	1	-	-	-	-	-	-	-	-

A - Found dead at p.m. mortality check.

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OECD ORAL SCREEN

(CONTINUED)

PATHOLOGY

DOSE LEVEL: 0.50 g/kg of body weight

Animal Number	Sex	Test Day		Necropsy Comments
		Died	Sacrificed	
C03081	M	4	-	No visible lesions.
C03080	M	4	-	Ventral cervical region and both mandibles cannibalized.
C03082	M	-	14	No visible lesions.
C03079	M	-	14	No visible lesions.
C03088	M	-	14	No visible lesions.
C03249	F	-	14	No visible lesions.
C03247	F	-	14	No visible lesions.
C03250	F	-	14	No visible lesions.
C03248	F	-	14	No visible lesions.
C03326	F	-	14	No visible lesions.

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OECD ORAL SCREEN

(CONTINUED)

PATHOLOGY (continued)

DOSE LEVEL: 5.0 g/kg of body weight

Animal Number	Sex	Test Day Died Sacrificed	Necropsy Comments
C00499	M	4 -	Perineum stains - tan; stomach - glandular portion has dark brown focal areas (1 mm in diameter).
C00504	M	3 -	Perineum/perianal stains - yellow; nasal discharge - dark red and crusted.
C00503	M	2 -	Nasal and mouth areas - stained brown; stomach - glandular portion has dark brown areas (up to 5 x 1 mm).
C00501	M	1 -	Stomach - glandular portion has multiple, dark brown, pinpoint foci.
C00562	M	2 -	Stomach - glandular portion has dark brown areas (up to 2 x 1 mm).
C03035	F	2 -	No visible lesions.
C03034	F	4 -	Stomach - glandular portion has dark brown areas (up to 3 x 1 mm).
C03032	F	6 -	Stomach - glandular mucosa has dark brown areas (up to 4 x 1 mm).
C03029	F	1 -	No visible lesions.
C03038	F	5 -	Perineum stains - brown; paranasal discharge - red.

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OECD ORAL SCREEN

(CONTINUED)

References:

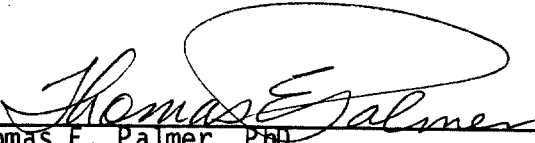
1. Organisation for Economic Cooperation and Development's Guidelines for Testing of Chemicals, Section 401, Acute Oral Toxicity, adopted May 12, 1981.
2. OECD's Principles of Good Laboratory Practice, Annex 2, C(81)30 (Final).
3. NIH Publication No. 86-23 (revised 1985).

600538

HLA LAB NO. 70905761
PATHOLOGY REPORT
Acute Oral Toxicity

Ten rats (five males, five females) from each of two dose levels (0.5 and 5.0 g/kg) were necropsied. The animals that died on test 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 pages 8 and 9 of this report.

The most frequently recorded observations were in those animals that died on test. The mucosa of the stomach (glandular portion) of several animals had dark brown areas of variable size which were possibly treatment related. All other observations were considered related to postmortem change or incidental findings which were not related to treatment.



Thomas E. Palmer, PhD
Pathologist

Date 1-25-88

(1734mcs)

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HLA No. 70905761

**Personnel Signature Sheet
Acute Toxicology**

<u>Name</u>	<u>Job Title</u>	<u>Signature</u>	<u>Initials</u>
Becky Beckwith	Sr. Lab. Animal Asst.	<u>Becky Beckwith</u>	<u>BB</u>
Steve Beloungy	Lab. Animal Asst.	<u>Steve Beloungy</u>	<u>SB</u>
Ken Bridges	Sr. Lab. Animal Asst.	<u>Ken Bridges</u>	<u>KB</u>
Pat Crary	Sr. Lab. Animal Asst.	<u>Pat Crary</u>	<u>PC</u>
Shane Eith	Lab Animal Asst.	<u>Shane Eith</u>	<u>SE</u>
Shawn Frazier	Lab Animal Asst.	<u>Shawn Frazier</u>	<u>SF</u>
Steven M. Glaza	Group Leader	<u>Steven M. Glaza</u>	<u>SG</u>
Molly Hahn	Admin. Clerk	<u>Molly Hahn</u>	<u>MH</u>
Kevin Hamilton	Lab. Animal Asst.	<u>Kevin Hamilton</u>	<u>KH</u>
Jeff Hicks	Sr. Lab. Animal Asst.	<u>Jeff Hicks</u>	<u>JH</u>
Calvin Horton	Group Leader	<u>Calvin Horton</u>	<u>CH</u>
Sharen L. Howery	Administrative Asst.	<u>Sharen L. Howery</u>	<u>SH</u>
Gregory Johnson	Lab. Animal Tech.	<u>Gregory Johnson</u>	<u>GJ</u>
Paul Krebs	Lab. Animal Asst.	<u>Paul Krebs</u>	<u>P.K.</u>
Wayne Madison	Section Supervisor	<u>Wayne A. Madison</u>	<u>WAM</u>
Scott McConnell	Lab. Animal Tech.	<u>Scott McConnell</u>	<u>SM</u>
Shelley McConnell	Lab. Animal Tech.	<u>Shelley McConnell</u>	<u>SMC</u>
Dawn Conant	Sr. Lab. Animal Asst.	<u>Dawn Conant</u>	<u>DC</u>
Don Navis	Lab. Animal Asst.	<u>Don Navis</u>	<u>DN</u>
Robin Olson	Lab. Animal Asst.	<u>Robin Olson</u>	<u>RO</u>
Patricia Padgham	Team Leader	<u>Patricia Padgham</u>	<u>TP</u>
Joseph J. Daun	Lab. Animal Asst.	<u>Joseph J. Daun</u>	<u>JD</u>
Michael Patzka	Lab. Animal Asst.	<u>Michael Patzka</u>	<u>MP</u>
John Paulson	Sr. Lab. Animal Asst.	<u>John Paulson</u>	<u>JP</u>
Jane Polnow	Lab. Animal Tech.	<u>Jane Polnow</u>	<u>JP</u>
Dennis B. Steiner	Lab. Animal Tech.	<u>Dennis B. Steiner</u>	<u>D.S.</u>
Michael Thesing	Lab. Animal Asst.	<u>Michael Thesing</u>	<u>MT</u>
Paula G. Vangen	Administrative Asst.	<u>Paula G. Vangen</u>	<u>P.G.V.</u>
Albert Olson	Manpower	<u>Albert Olson</u>	<u>AO</u>
Jim Jirschele	LTE	<u>Jim Jirschele</u>	<u>JJ</u>
Ben Haley	Sr. Lab Animal Asst.	<u>Ben Haley</u>	<u>BH</u>

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DOSE ADMINISTRATION/BODY WEIGHT/MORTALITY RECORD

Study Title: Acute Oral Toxicity

Test Material: T-4102

Vehicle: NA

Bulk Density: 1.06 (g/mL) Species/Strain: Albino Rat/Sprague-Dawley Source: Charles River Date Received: 10/26/87 ^{10/28/87} ♀

Dose Level: 0.50 (g/kg) Fasted Date/Time/Technician 11/5/87/3:30 p.m./BHA Room No. 5

Route of Administration: Oral Gavage

Dose Volume	Sex: <u>Male</u> Female					Dose Time: <u>11:25AM</u>	Technician	1987 Date	Scale Used <u>1/2TBW</u>
Animal No. <u>CO</u>	<u>3081</u>	<u>3082</u>	<u>3080</u>	<u>3079</u>	<u>3088</u>	/	<u>BH</u>	<u>11/6</u>	<u>NA</u>
Prefasted Body Weight (g)	<u>NA</u>								
Fasted Body Weight (g)	<u>248</u>	<u>263</u>	<u>284</u>	<u>280</u>	<u>283</u>		<u>BH</u>	<u>11/6</u>	<u>5228</u>
Actual Dose (mL)	<u>0.12</u>	<u>0.12</u>	<u>0.13</u>	<u>0.13</u>	<u>0.13</u>		<u>BH</u>	<u>11/6</u>	Verified by: <u>M</u> <u>11/6/87</u>
Day 7 Body Weight (g)	<u>Found Dead</u> <u>11/11/87</u>	<u>263</u>	<u>Found Dead</u> <u>11/10/87</u>	<u>289</u>	<u>266</u>		<u>BH</u>	<u>11/13</u>	<u>15019</u>
Day 14 Body Weight (g)	<u>BH</u>	<u>328</u>	<u>BH</u>	<u>349</u>	<u>340</u>		<u>BH</u>	<u>11/20</u>	<u>5228</u>
Dead Body Weight (g)	<u>235</u>		<u>247</u>						

Dose Volume	Sex: Male/Female					Dose Time:	Technician	Date	Scale Used
0.47 (ml/kg)						11:30am		1987	KTRON
Animal No.	CO 3249	3247	3250	3248	3326	/	BH	11/6	NA
Prefasted Body Weight (g)	NA					/			
Fasted Body Weight (g)	214	212	222	200	201	/	BH	11/6	5228
Actual Dose (ml.)	0.10	0.10	0.10	0.09	0.09	/	BH	11/6	Verified by: m 11/6/87
Day 7 Body Weight (g)	195 ^H	205 ^H	218 ^H	197 ^H	180 ^H	/	BH	11/13	15019
Day 14 Body Weight (g)	218	248	254	239	229	/	BH	11/20	5228
Dead Body Weight (g)						/			

Dose level (g/kg)		Sex	Hours 0-4	MORTALITY (NO. DIED/NO. DOSED)																												Total	
				Study Day																													
				1		2		3		4		5		6		7		8		9		10		11		12		13		14			
				AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		
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	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	NA	2/5	
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	0/5	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	NA	0/5
Tech.		3/4	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	0/1	3/4
Date 1987		11/6	11/7	11/7	11/8	11/8	11/9	11/9	11/10	11/10	11/11	11/11	11/12	11/12	11/13	11/13	11/14	11/14	11/15	11/15	11/16	11/16	11/17	11/17	11/18	11/18	11/19	11/19	11/20	11/20	11/20	11/20	11/20

NA - Not Applicable

* - Dosage calculated, but not administered
unused animal returned to stock

Reviewed By QPS Date 12-16-87

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HLA: 70905761

OBSERVATIONS (Individual)

Dose level: 0.5 g./kg.Test material: T-4102Male/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
CO 3081	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Dead	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3082	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypersensitive to touch	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3080	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Dead	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3079	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hyporeactive	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3088	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hyporeactive	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypersensitive to touch	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3088	intermittent clonic convulsions	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Deaths		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Collected by		NA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA	BA
Date 1987		11/16	11/16	11/16	11/16	11/17	11/17	11/17	11/17	11/17	11/17	11/17	11/17	11/17	11/17	11/17	11/17	11/17	11/17

- Surviving animals submitted for terminal necropsy.

Technician BADate 11/20/87

- Surviving animals designated for sacrifice and discard.

Technician NADate NA

✓ Indicates condition exists

SI Slight.

- Condition not evident.

* Found dead, P.M. check.

N/A NOT APPLICABLE 12-16-87

Reviewed by: BADate: 12-16-87

BEST COPY AVAILABLE

600542

D Found dead 11am 11/10/87 BA

HLA: 70905761

OBSERVATIONS (Individual)

Dose level: 0.5 g./kg. Test material: T-4102

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
CO 3249	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypersensitive to touch	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3247	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypoaactive	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	ataxic	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3250	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypersensitive to touch	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3248	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	intermittent clonic convulsions	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypersensitive to touch	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO 3326	Appeared Normal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	aggressive behavior	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	alopecia back region	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypersensitive to touch	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Deaths																			
Collected by																			
Date 1987																			

② Entry errors 11-11-87 5m

- Surviving animals submitted for terminal necropsy.

Technician BKDate 11/20/87

- Surviving animals designated for sacrifice and discard.

Technician NADate NA

✓ Indicates condition exists

S1 Slight.

- Condition not evident.

* Found dead, P.M. check

NA - NOT APPLICABLE 12-16-87

Reviewed by: JSDate: 12-16-87

① Incorrect entry 11/10/87 BK

BEST COPY AVAILABLE

000543

HLA: 70905761

DOSE ADMINISTRATION/BODY WEIGHT/MORTALITY RECORD

Study Title: Acute Oral ToxicityTest Material: T-4102Vehicle: NABulk Density: 1.06 (g/mL) Species/Strain: Albino Rat/Sprague-Dawley Source: Charles River Date Received: 9/5/87 ♂
10/12/87 ♀Dose Level: 5.0 (g/kg) Fasted Date/Time/Technician 10/25/87 2:30 p.m./ BB Room No. 5
10/25/87Route of Administration: Oral Gavage

Dose Volume ^{4.72} <u>0.94</u> (mL/kg)	Sex: <u>Male/Female</u>	Dose Time: <u>11:15 AM</u>	Technician	Date	Scale Used
Animal No. <u>CO</u>	<u>0499</u> <u>0504</u> <u>0503</u> <u>0501</u> <u>0562</u>		<u>BHA</u>	<u>10/26</u>	<u>NA</u>
Prefasted Body Weight (g)	<u>NA</u>				
Fasted Body Weight (g)	<u>274</u> <u>262</u> <u>260</u> <u>227</u> <u>251</u>		<u>BHA</u>	<u>10/26</u>	<u>15019</u>
Actual Dose (mL)	<u>1.3</u> <u>1.2</u> <u>1.2</u> <u>1.1</u> <u>1.2</u>		<u>BB</u>	<u>10/26</u>	Verified by: <u>TH 10-26-87</u>
Day 7 Body Weight (g)	<u>Dead</u> <u>Dead</u> <u>Dead</u> <u>Dead</u> <u>Dead</u>				
Day 14 Body Weight (g)	<u>10/30/87</u> <u>10/29/87</u> <u>10/25/87</u> <u>10/27/87</u> <u>10/28/87</u>				
Dead Body Weight (g)	<u>234</u> <u>240</u> <u>232</u> <u>213</u> <u>232</u>				

Dose Volume ^{4.72} <u>0.94</u> (mL/kg)	Sex: <u>Male/Female</u>	Dose Time: <u>11:10 AM</u>	Technician	Date	Scale Used
Animal No. <u>CO</u>	<u>3035</u> <u>3034</u> <u>3032</u> <u>3029</u> <u>3038</u>		<u>BHA</u>	<u>10/26</u>	<u>NA</u>
Prefasted Body Weight (g)	<u>NA</u>				
Fasted Body Weight (g)	<u>213</u> <u>220</u> <u>221</u> <u>214</u> <u>211</u>		<u>BHA</u>	<u>10/26</u>	<u>15019</u>
Actual Dose (mL)	<u>1.0</u> <u>1.0</u> <u>1.0</u> <u>1.0</u> <u>0.9, 1.0</u>		<u>BB</u>	<u>10/26</u>	Verified by: <u>TH 10-26-87</u>
Day 7 Body Weight (g)	<u>Dead</u> <u>Dead</u> <u>Dead</u> <u>Dead</u> <u>Dead</u>				
Day 14 Body Weight (g)	<u>10/28/87</u> <u>10/30/87</u> <u>10/28/87</u> <u>10/27/87</u> <u>10-31-87</u>				
Dead Body Weight (g)	<u>189</u> <u>195</u> <u>178</u> <u>202</u> <u>167</u>				

Dose Level (g/kg)	Sex	Hours	Study Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
5.0	♂	0/5	0/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	5/5
5.0	♀	0/5	0/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	1/5	5/5
tech.		<u>BB</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>	<u>CH</u>
Date 1987		<u>10/25</u>	<u>10/27</u>	<u>10/27</u>	<u>10/28</u>	<u>10/28</u>	<u>10/29</u>	<u>10/29</u>	<u>10/30</u>	<u>10/30</u>	<u>10/31</u>	<u>10/31</u>	<u>10/31</u>	<u>10/31</u>	<u>10/31</u>	<u>10/31</u>	<u>10/31</u>	<u>11/13</u>

NA - Not Applicable

* - Dosage calculated, but not administered
unused animal returned to stockReviewed By Jim Date 10-16-87

BEST COPY AVAILABLE

① Entry Errors BB 10/26/87

② Entry Error Corrected late.

BB 10/27/87

③ entry errors all
animals dead on
10/30 AM.
10-11-87

000544

HLA: 70905761

OBSERVATIONS (Individual)

Dose level: 5.0g/Kg

Test material: T-4102

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
CO- 0499	Appeared Normal	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypoaactive	—	✓	✓	✓	✓	✓	—	—	—	—	—	—	—	—	—	—	—	—
	diarrhea	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	convulsions (tonic)	—	—	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—
	ataxic	—	—	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—
	excessive salivation	—	—	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—
CO- 0504	Dead	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Appeared Normal	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypoaactive	—	✓	✓	✓	✓	✓	—	—	—	—	—	—	—	—	—	—	—	—
	Miosis	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	red stained face	—	—	—	—	✓	✓	—	—	—	—	—	—	—	—	—	—	—	—
	yellow stained genital region	—	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—	—
CO- 0503	Dead	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Appeared Normal	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypoaactive	—	✓	✓	✓	✓	—	—	—	—	—	—	—	—	—	—	—	—	—
	Miosis	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	red stained face	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—
	Dead	—	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—	—
CO- 0501	Dead	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Appeared Normal	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypoaactive	—	✓	✓	✓	✓	—	—	—	—	—	—	—	—	—	—	—	—	—
	Ataxic	—	✓	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Miosis	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	lacrimation	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—
CO- 0562	red stained face	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—
	Dead	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Appeared Normal	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Ataxic	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	hypoaactive	—	✓	✓	✓	✓	—	—	—	—	—	—	—	—	—	—	—	—	—
	Miosis	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
CO- 0562	lacrimation	—	—	—	—	✓	—	—	—	—	—	—	—	—	—	—	—	—	—
	Dead	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
	Deaths	0	0	0	0	1	2	1	1	—	—	—	—	—	—	—	—	—	—
	Collected by	BP	BP	BP	BP	BP	BP	BP	BP	—	—	—	—	—	—	—	—	—	—
	Date	1987	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26

BEST COPY AVAILABLE

- Surviving animals submitted for terminal necropsy.

Technician NADate NA

- Surviving animals designated for sacrifice and discard.

Technician NADate NA

✓ Indicates condition exists

S1 Slight.

- Condition not evident.

* Found dead, P.M. check.

NA - NOT APPLICABLE 12-16-87

Reviewed by: BPDate: 12-16-87

000545

HLA: 70905761

OBSERVATIONS (Individual)

Dose level: 5.0g/Kg

Test material: T-4102

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
C0- 3035	Appeared Normal	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	hypoaactive	-	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	miosis	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	yellow stained genitals	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	Dead	-	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-
C0- 3033 3034	Appeared Normal	✓	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	hypoaactive	-	✓	✓	✓	-	-	✓	-	-	-	-	-	-	-	-	-	-	-
	miosis	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	red stained face	-	-	-	-	-	✓	✓	-	-	-	-	-	-	-	-	-	-	-
	convulsions (tonic)	-	-	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-
	ataxic	-	-	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-
C0- 3032	Appeared Normal	✓	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	hypoaactive	-	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	miosis	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	diarrhea	-	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-
	yellow stained genital region	-	-	-	-	-	-	✓	✓	✓	-	-	-	-	-	-	-	-	-
	tonic convulsions	-	-	-	-	-	-	-	-	✓	-	-	-	-	-	-	-	-	-
C0- 3029	Appeared Normal	✓	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	hypoaactive	-	✓	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	miosis	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Ataxic	-	-	✓	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	gasping	-	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-
	yellow stained genitals	-	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-
C0- 3038	Appeared Normal	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Ataxic	-	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	hypoaactive	-	✓	✓	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	miosis	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	respiratory congestion	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	-	-	-	-
	yellow stained genital region	-	-	-	-	-	✓	✓	✓	✓	-	-	-	-	-	-	-	-	-
Deaths		0	0	0	0	1	1	0	1	0	1								
Collected by		BB	BB	BB	BB	BB	BB	BB	BB	BB	BB								
Date		10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26	10/26								

- Surviving animals submitted for terminal necropsy.

Technician NADate NA

- Surviving animals designated for sacrifice and discard.

Technician NADate NA

✓ Indicates condition exists

S1 Slight.

- Condition not evident.

* Found dead, P.M. check.

NA - NOT APPLICABLE 12-16 B7D

Reviewed by: JPDate: 12-16-87

BEST COPY AVAILABLE

000546

(D) Entry Error BB 10/26/87