



MOSES LAKE INDUSTRIES, INC.

8248 Randolph Rd. NE
Moses Lake, WA 98837

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OPPT 8/16
2005 JUL 28 11:18 AM
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July 21, 2005

8EHQ-0705-16103

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Contain NO CBI

2005 JUL 25 AM 9:27

RECEIVED
OPPT 8/16

RE: TSCA 8(e) Substantial Risk Notice on Tetramethylammonium Hydroxide

Moses Lake Industries has received final reports for acute dermal and oral toxicity in rats conducted with Tetramethylammonium Hydroxide (CAS No. 75-59-2) (TMAH) indicating both dermal and oral toxicity.

Dermal

The study was conducted for Acute Dermal Toxicity/LD₅₀ according to OECD Guidelines for Testing Chemicals, Number 402 adopted February 24, 1987. The conclusion of the study is that a 25% solution of TMAH in water exhibits an Acute Dermal LD₅₀ in rats (skin-rat LD₅₀) greater than 50 mg/kg but less than 200 mg/kg.

Oral

Single dose Oral Toxicity/LD₅₀ tests were conducted on 25% and 2.38% solutions of TMAH in water according to test protocol designed to comply with 49 CFR 173.132 (b)(1).

The 2.38% solution (under our product designation AD-200) was found to exhibit an Acute Oral LD₅₀ (orl-rat LD₅₀) greater than 500 mg/kg. The 25% solution was found to exhibit an Acute Oral LD₅₀ (orl-rat LD₅₀) greater than 50 mg/kg but less than 500 mg/kg.

In order to more accurately determine the oral-rat LD₅₀ for 25% tetramethylammonium hydroxide, further testing was conducted based on the Acute Oral Toxicity-Up and Down Procedure (UDP) according to standards set forth in EPA Health Effects Test Guidelines, OPPTS 870.1100 December 2002 and OECD Guidelines for Testing of Chemicals, Guideline 425 adopted December 17, 2001. The conclusion of this study was that the orl-rat LD₅₀ for a 25% aqueous solution of tetramethylammonium hydroxide is 175 mg/kg. A copy of the final report is attached.

Sincerely,

Mike Harvey
Executive Vice President/ General Counsel



Enclosure

MR287945

MB Research Laboratories

1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968
phone (215) 536-4110
fax (215) 536-1816

VOLUME I

Study Title : Single Dose Oral Toxicity/LD₅₀ in Rats

Test Article : 25% TMAH, Lot/batch #10410158

Author : Daniel R. Cerven, M.S., Study Director

Study Completed On : June 14, 2005

Performing Laboratory : MB Research Laboratories
1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968

MB Research Project # : MB 05-13180.01

MB Research Protocol # : 4000

Sponsor : Moses Lake Industries, Inc.
10198 Dean Drive
Manassas, VA 20110

Citation : Daniel R. Cerven, M.S. (2005)
Unpublished Report by MB Research
Laboratories

MB Research Laboratories

Amended Page: Page amended on 06/21/05.
The page was inadvertently not signed and
dated at time of final report processing.

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

 2/2/05
Daniel R. Cerven Date
Study Director

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study was conducted in accordance with the Good Laboratory Practices of the EPA, 40 CFR 160 and 792, FDA 21 CFR 58, and as specified in Testing of Chemicals, published by the Organization for Economic Cooperation & Development (OECD), 1997.

STUDY DIRECTOR :

 2/2/05
Daniel R. Cerven, M.S. Date
MB RESEARCH LABORATORIES

MB Research Laboratories

PROJECT NUMBER : MB 05-13180.01
TEST ARTICLE : 25% TMAH, Lot/batch #10410158
SPONSOR : MOSES LAKE INDUSTRIES, INC.
TITLE : Single Dose Oral Toxicity/LD₅₀ in Rats
PROTOCOL # : 4000

A B S T R A C T

Objective: To determine by oral exposure if a substance is a "poisonous material", and, if so, to assign the substance to the applicable packing group category, (49 CFR 173.132(a), as published in the Federal Register, Vol. 55, No. 246, 12/21/90). This study was designed to comply with the testing methods described in 49 CFR 173.132(b)(1).

Method Synopsis: Five healthy male and five healthy female Wistar albino rats were dosed orally with 25% TMAH, Lot/batch #10410158 at 500 mg/kg of body weight. Based on the results of the initial dose, an additional group of five males and five females were dosed at 50 mg/kg of body weight. Mortality and systemic observations were recorded 3-4 hours postdose and once daily thereafter for 14 days. Body weights were recorded pretest and at termination in the survivors. All animals were examined for gross pathology.

Summary:

50 mg/kg: All animals survived the 50 mg/kg oral dose in good health. Body weight changes and necropsy results were normal.

500 mg/kg: One female animal survived the 500 mg/kg oral dose. One instance of chromorrhinorrhea was the only abnormal physical sign noted in the surviving animal. Body weight changes and necropsy results of the surviving animal were normal.

Five males and four females died within four hours of the 500 mg/kg oral dose. Necropsy revealed abnormalities of the liver and stomach.

Conclusion: The oral LD₅₀ of 25% TMAH, Lot/batch #10410158 is greater than 50 mg/kg but less than 500 mg/kg of body weight.

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

OBJECTIVE

To determine by oral exposure if a substance is a "poisonous material", and, if so, to assign the substance to the applicable packing group category, (49 CFR 173.132(a), as published in the Federal Register, Vol. 55, No. 246, 12/21/90). This study was designed to comply with the testing methods described in 49 CFR 173.132(b)(1).

TEST ARTICLE

Identity : 25% TMAH, Lot/batch #10410158
Supplied By : Moses Lake Industries, Inc.
Test Article
Characterization : See Appendix A for Test Article Characterization
Date Received : 02/23/05
Storage : Room temperature and humidity
Specific Gravity : 1.02
Description : Clear liquid
Sample Preparation : Used as received

TEST DATES

Study Initiation (date protocol signed) : 02/24/05
Experimental Start Date (1st exposure to test substance) : 03/03/05
Experimental Term Date (last date data collected) : 03/23/05
Draft Report Signed (if applicable) : 04/07/05
Final Report Signed (study completion) : 06/14/05

EXPERIMENTAL DESIGN

Test Animals

Animals were received from Ace Animals, Boyertown, PA on 02/24/05. Following an equilibration period of at least one week, ten healthy male and ten healthy female Wistar albino rats were selected for this test from a larger group without conscious bias.

The animals were born the weeks of 12/30/04 and 01/06/05. The pretest body weight range was 198 - 251 grams for males and 172 - 224 grams for females. Body weights of some animals were less than the required 200 grams. This did not affect the outcome of the study as the animals were dosed by weight. Animals were identified by cage notation and indelible body marks. The animals were housed 1/cage in suspended wire mesh cages. Bedding was placed beneath the cages and changed at least three times/week. Fresh PMI Rat Chow (Diet #5012) was freely available except for 16-20 hours prior to dosing. Water was freely available at all times. The animal room, reserved exclusively for rats on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

EXPERIMENTAL DESIGN (continued)

Dosing

The test article was used as received and the dose was based on the sample weight as calculated from the specific gravity. The doses were administered orally by syringe and dosing needle at dose levels of 50 mg/kg and 500 mg/kg.

Type and Frequency of Observations

In Vivo - Animals were observed 3-4 hours postdose and once daily thereafter for 14 days for mortality, toxicity and pharmacological effects. Body weights were recorded pretest and at termination in the survivors.

Post Mortem: All animals were humanely sacrificed using CO₂ and examined for gross pathology.

Analysis of Data

An estimate of the LD₅₀ was made based on the mortality results.

Interpretation of Data

Determination of Poisonous Materials:

Liquids - A liquid with an LD₅₀ for acute oral toxicity of not more than 500 mg/kg is considered for the purposes of the applicable sub-chapter, i.e. 49 CFR 173.132(a)(1)(i), to be a "poisonous material".

Solids - A solid with an LD₅₀ for acute oral toxicity of not more than 200 mg/kg is considered for the purposes of the applicable sub-chapter, i.e. 49 CFR 173.132(a)(1)(i), to be a "poisonous material".

Assignment of Packing Group: If the substance is determined to be a poison, it will be assigned to a packing group based on the following table which was published in the Federal Register, Vol. 55, No. 246, 12/21/90, (49 CFR 173.133(a)(1)):

<u>Packing Group Assignment</u>	<u>Oral Toxicity LD₅₀ (mg/kg)</u>
I	< 5
II	> 5, ≤ 50
III	> 50, ≤200 (Solids) > 50, ≤500 (Liquids)

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

EXPERIMENTAL DESIGN (continued)

Retention of Data

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be discarded following submission of the report.

Amendment to the Protocol

Subsequent to the submission of the draft report, the sponsor requested that the test article be discarded.

Deviation to the Protocol

Animal #12 was inadvertently dosed at 0.011 ml rather than 0.012 ml. This less than 10% difference did not affect the outcome of the study since the animal responded similarly to others that were dosed at that volume.

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

RESULTS & DISCUSSION

1. LD₅₀

The oral LD₅₀ is greater than 50 mg/kg but less than 500 mg/kg of body weight. Therefore, the Packing Group Assignment is III.

4. Systemic Observations

50 mg/kg: All animals survived the 50 mg/kg oral dose in good health. Body weight changes and necropsy results were normal.

500 mg/kg: One female animal survived the 500 mg/kg oral dose. One instance of chromorhinorrhea was the only abnormal physical sign noted in the surviving animal. Body weight changes and necropsy results of the surviving animal were normal.

Five males and four females died within four hours of the 500 mg/kg oral dose. Necropsy revealed abnormalities of the liver and stomach.

MB Research Laboratories

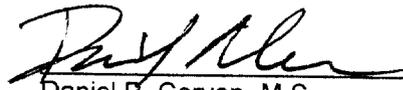
Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

CONCLUSION

The oral LD₅₀ of 25% TMAH, Lot/batch #10410158 is greater than 50 mg/kg but less than 500 mg/kg of body weight. Therefore, the Packing Group Assignment is III.

FINAL REPORT

Approved by:


Daniel R. Cerven, M.S.
Study Director

14205
Date

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

Table 1: Body Weights in grams and Dose Volume – 50 mg/kg

An. #	Sex	Dose Volume		
		in ml	Day 0	Day 14
11	M	0.012	251	371
12	M	0.011	241	345
13	M	0.012	247	364
14	M	0.012	237	343
15	M	0.011	234	334
	MEAN		242	351
	S.D.		7.0	15.5
	#		5	5
16	F	0.010	209	270
17	F	0.010	200	241
18	F	0.011	224	283
19	F	0.010	204	253
20	F	0.010	202	270
	MEAN		208	263
	S.D.		9.7	16.4
	#		5	5

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

Table 1: Body Weights in grams and Dose Volume – 500 mg/kg

An. #	Sex	Dose Volume		
		in ml	Day 0	Day 14
1	M	0.10	202	
2	M	0.10	208	
3	M	0.10	204	
4	M	0.10	198	
5	M	0.10	199	
MEAN			202	
S.D.			4.0	
#			5	
6	F	0.09	180	
7	F	0.08	172	
8	F	0.09	179	241
9	F	0.09	176	
10	F	0.08	173	
MEAN			176	
S.D.			3.5	
#			5	

No entry indicates animal died before observation period.

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Study Title : Oral Toxicity in Rats
 Project # : MB 05-13180.01
 Test Article : 25% TMAH, Lot/batch #10410158
 Protocol : 4000

Table 2: Systemic Observations

TIME PERIODS	Dose Level: 50 mg/kg						
	11/M	12/M	13/M	14/M	15/M	16/F	17/F
Hour 3-4							
Day 1							
Day 2							
Day 3							
Day 4							
Day 5							
Day 6							
Day 7							
Day 8							
Day 9							
Day 10							
Day 11							
Day 12							
Day 13							
Day 14							

No entry indicates animal appeared normal at that observation period.

MB Research Laboratories

Study Title : Oral Toxicity in Rats
 Project # : MB 05-13180.01
 Test Article : 25% TMAH, Lot/batch #10410158
 Protocol : 4000

Table 2: Systemic Observations (cont'd)

TIME PERIODS	Dose Level: 500 mg/kg									
	1/M	2/M	3/M	4/M	5/M	6/F	7/F	8/F	9/F	10/F
Hour 3-4	Z	Z	Z	Z	Z	Z	Z	S	Z	Z
Day 1										
Day 2										
Day 3										
Day 4										
Day 5										
Day 6										
Day 7										
Day 8										
Day 9										
Day 10										
Day 11										
Day 12										
Day 13										
Day 14										

No entry indicates animal appeared normal at that observation period. S = chromorrhinorrhea Z = dead

MB Research Laboratories

Study Title : Oral Toxicity in Rats
 Project # : MB 05-13180.01
 Test Article : 25% TMAH, Lot/batch #10410158
 Protocol : 4000

Table 3: Necropsy Observations

Dose Level: 50 mg/kg

OBSERVATION	11	M	12	M	13	M	14	M	15	M	16	F	17	F	18	F	19	F	20	F
Death/Sacrifice	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S
Normal	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

CODES: S = sacrifice
 X = observed

MB Research Laboratories

Study Title : Oral Toxicity in Rats
 Project # : MB 05-13180.01
 Test Article : 25% TMAH, Lot/batch #10410158
 Protocol : 4000

Table 3: Necropsy Observations (cont'd)

Dose Level: 500 mg/kg

OBSERVATION	1		2		3		M		4		5		6		7		8		9		10	
	D	S	D	S	D	S	D	S	D	S	D	S	D	S	D	S	D	S	D	S	D	S
Normal																						
Liver: protruded through diaphragm									1													
Stomach: red	3		3		3		3		3		3		3		3		3		3		3	

CODES:

D = death
 S = sacrifice
 X = observed

1 = slight or scattered
 3 = pronounced or many

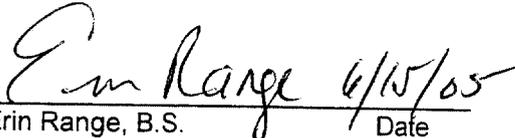
MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13180.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 4000

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit has inspected an in-life phase of this study, audited the raw data and the report and determined that the methods and results contained herein accurately reflect the raw data. No deviations from the approved protocol or Standard Operating Procedures were made without proper authorization and documentation. A summary of the compliance inspections is presented below.

Date of Inspection	Phase	Performed By	Date Findings Reported to	
			Mgmt.	Sty. Dir.
03/03/05	Necropsy	Erin Range	06/13/05	06/14/05
03/25/05	Raw data audit	Erin Range	06/13/05	06/14/05
04/06/05	Draft report audit	Erin Range	06/13/05	06/14/05
06/13/05	Final report audit	Erin Range	06/13/05	06/14/05


Erin Range, B.S. Date
Quality Assurance Unit

MB Research Laboratories

1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968
phone (215) 536-4110
fax (215) 536-1816

TEST ARTICLE CHARACTERIZATION INFORMATION

Characterization of the test article is required in support of data submissions and should include identity, concentration, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and included in the final report. (EPA 40 CFR 160.105 and 792.105; FDA 21 CFR 58.105, OECD 6.2). Accordingly, please supply the following information for each test article submitted:

- Test Article Identity : Tetramethylammonium hydroxide
- Concentration : 25%
- Purity : Semiconductor grade - ultra pure
- Composition : TMAH in water
- Stability : stable
- Uniformity : homogeneous aqueous solution

BY: Jim Bland 2/21/05
(signature) (date)

FOR: Moses Lake Industries, Inc.
(company) (date)

MB Research Laboratories

1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968
phone (215) 536-4110
fax (215) 536-1816

VOLUME I

Study Title : Single Dose Oral Toxicity/LD₅₀ in Rats

Test Article : AD-200, Lot/batch #U04J10

Author : Daniel R. Cerven, M.S., Study Director

Study Completed On : June 14, 2005

Performing Laboratory : MB Research Laboratories
1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968

MB Research Project # : MB 05-13179.01

MB Research Protocol # : 4000

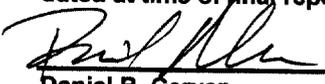
Sponsor : Moses Lake Industries, Inc.
10198 Dean Drive
Manassas, VA 20110

Citation : Daniel R. Cerven, M.S. (2005)
Unpublished Report by MB Research
Laboratories

MB Research Laboratories

Amended Page: Page amended on 06/21/05.
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Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
Test Article : AD-200, Lot/batch #U04J10
Protocol : 4000

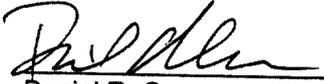

Daniel R. Cerven
Study Director

21 Jun 05
Date

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study was conducted in accordance with the Good Laboratory Practices of the EPA, 40 CFR 160 and 792, FDA 21 CFR 58, and as specified in Testing of Chemicals, published by the Organization for Economic Cooperation & Development (OECD), 1997.

STUDY DIRECTOR :


Daniel R. Cerven, M.S. 21 Jun 05
Date
MB RESEARCH LABORATORIES

MB Research Laboratories

PROJECT NUMBER : MB 05-13179.01
TEST ARTICLE : AD-200, Lot/batch #U04J10
SPONSOR : MOSES LAKE INDUSTRIES, INC.
TITLE : Single Dose Oral Toxicity/LD₅₀ in Rats
PROTOCOL # : 4000

A B S T R A C T

Objective: To determine by oral exposure if a substance is a "poisonous material", and, if so, to assign the substance to the applicable packing group category, (49 CFR 173.132(a), as published in the Federal Register, Vol. 55, No. 246, 12/21/90). This study was designed to comply with the testing methods described in 49 CFR 173.132(b)(1).

Method Synopsis: Five healthy male and five healthy female Wistar albino rats were dosed orally with AD-200, Lot/batch #U04J10 at 500 mg/kg of body weight. Mortality and systemic observations were recorded 3-4 hours postdose and once daily thereafter for 14 days. Body weights were recorded pretest and at termination. All animals were examined for gross pathology.

Summary: All animals survived the 500 mg/kg oral dose.

Instances of diarrhea, noted in two animals, were the only abnormal physical signs noted during the observation period.

Body weight changes were normal.

Necropsy results were normal.

Conclusion: The oral LD₅₀ of AD-200, Lot/batch #U04J10 is greater than 500 mg/kg of body weight. Therefore, no Packing Group Assignment is required.

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
Test Article : AD-200, Lot/batch #U04J10
Protocol : 4000

OBJECTIVE

To determine by oral exposure if a substance is a "poisonous material", and, if so, to assign the substance to the applicable packing group category, (49 CFR 173.132(a), as published in the Federal Register, Vol. 55, No. 246, 12/21/90). This study was designed to comply with the testing methods described in 49 CFR 173.132(b)(1).

TEST ARTICLE

Identity : AD-200, Lot/batch #U04J10
Supplied By : Moses Lake Industries, Inc.
Test Article
Characterization : See Appendix A for Test Article Characterization.
Date Received : 02/23/05
Storage : Room temperature and humidity
Specific Gravity : 0.98
Description : Clear liquid
Sample Preparation : Used as received

TEST DATES

Study Initiation (date protocol signed) : 02/24/05
Experimental Start Date (1st exposure to test substance) : 03/03/05
Experimental Term Date (last date data collected) : 03/17/05
Draft Report Signed (if applicable) : 04/07/05
Final Report Signed (study completion) : 06/14/05

EXPERIMENTAL DESIGN

Test Animals

Animals were received from Ace Animals, Boyertown, PA on 02/24/05. Following an equilibration period of at least one week, five healthy male and five healthy female Wistar albino rats were selected for this test from a larger group without conscious bias.

The animals were born the weeks of 12/30/04 and 01/06/05. The pretest body weight range was 200 - 208 grams for males and 166 - 192 grams for females. The female rats weighed less than the required 200 grams. This did not affect the outcome of the study as the animals were dosed by weight. Animals were identified by cage notation and indelible body marks. The animals were housed 1/cage in suspended wire mesh cages. Bedding was placed beneath the cages and changed at least three times/week. Fresh PMI Rat Chow (Diet #5012) was freely available except for 16-20 hours prior to dosing. Water was freely available at all times. The animal room, reserved exclusively for rats on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
Test Article : AD-200, Lot/batch #U04J10
Protocol : 4000

EXPERIMENTAL DESIGN (continued)

Dosing

The test article was used as received and the dose was based on the sample weight as calculated from the specific gravity. A single dose was administered orally by syringe and dosing needle at a dose level of 500 mg/kg. All rats received the same concentration of dosing solution.

Type and Frequency of Observations

In Vivo - Animals were observed 3-4 hours postdose and once daily thereafter for 14 days for mortality, toxicity and pharmacological effects. Body weights were recorded pretest and at termination.

Post Mortem: All animals were humanely sacrificed using CO₂ and examined for gross pathology.

Analysis of Data

An estimate of the LD₅₀ was made based on the mortality results.

Interpretation of Data

Determination of Poisonous Materials:

Liquids - A liquid with an LD₅₀ for acute oral toxicity of not more than 500 mg/kg is considered for the purposes of the applicable sub-chapter, i.e. 49 CFR 173.132(a)(1)(i), to be a "poisonous material".

Solids - A solid with an LD₅₀ for acute oral toxicity of not more than 200 mg/kg is considered for the purposes of the applicable sub-chapter, i.e. 49 CFR 173.132(a)(1)(i), to be a "poisonous material".

Assignment of Packing Group: If the substance is determined to be a poison, it will be assigned to a packing group based on the following table which was published in the Federal Register, Vol. 55, No. 246, 12/21/90, (49 CFR 173.133(a)(1)):

<u>Packing Group Assignment</u>	<u>Oral Toxicity LD₅₀ (mg/kg)</u>
I	< 5
II	> 5, ≤ 50
III	> 50, ≤200 (Solids) > 50, ≤500 (Liquids)

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
Test Article : AD-200, Lot/batch #U04J10
Protocol : 4000

EXPERIMENTAL DESIGN (continued)

Retention of Data

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be returned to the sponsor following submission of the report.

Amendment to the Protocol

Subsequent to the submission of the draft report, the sponsor requested that the test article be discarded.

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
Test Article : AD-200, Lot/batch #U04J10
Protocol : 4000

RESULTS & DISCUSSION

1. LD₅₀

The oral LD₅₀ is greater than 500 mg/kg of body weight.

2. Mortality

All animals survived the 500 mg/kg oral dose.

3. Body Weights and Dose Volume (Table 1)

Body weight changes were normal.

4. Systemic Observations (Table 2)

Instances of diarrhea, noted in two animals, were the only abnormal physical signs noted during the observation period.

5. Necropsy Findings (Table 3)

Necropsy results were normal.

MB Research Laboratories

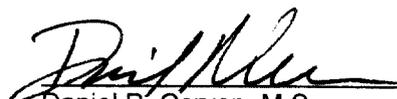
Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
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Protocol : 4000

CONCLUSION

The oral LD₅₀ of AD-200, Lot/batch #U04J10 is greater than 500 mg/kg of body weight. Therefore, no Packing Group Assignment is required.

FINAL REPORT

Approved by:

 14 Feb 05
Daniel R. Cerven, M.S. Date
Study Director

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
Test Article : AD-200, Lot/batch #U04J10
Protocol : 4000

Table 1: Body Weights in grams and Dose Volume

An. #	Sex	Dose Volume		
		in ml	Day 0	Day 14
1	M	0.10	200	335
2	M	0.10	204	350
3	M	0.11	208	357
4	M	0.11	207	341
5	M	0.10	202	326
MEAN			204	342
S.D.			3.3	12.2
#			5	5
6	F	0.10	192	229
7	F	0.10	192	259
8	F	0.09	178	247
9	F	0.09	171	248
10	F	0.08	166	224
MEAN			180	241
S.D.			11.9	14.5
#			5	5

MB Research Laboratories

Study Title : Oral Toxicity in Rats
Project # : MB 05-13179.01
Test Article : AD-200, Lot/batch #U04J10
Protocol : 4000

Table 2: Systemic Observations

TIME PERIODS	Dose Level: 500 mg/kg									
	1/M	2/M	3/M	4/M	5/M	6/F	7/F	8/F	9/F	10/F
Hour 3-4										
Day 1		D								
Day 2										
Day 3										
Day 4										
Day 5										
Day 6										
Day 7										
Day 8										
Day 9										
Day 10										
Day 11										
Day 12										
Day 13										
Day 14										

No entry indicates animal appeared normal at that observation period. D = diarrhea

MB Research Laboratories

Study Title : Oral Toxicity in Rats
 Project # : MB 05-13179.01
 Test Article : AD-200, Lot/batch #U04J10
 Protocol : 4000

Table 3: Necropsy Observations

Dose Level: 500 mg/kg

	1	M	2	M	3	M	4	M	5	M	6	F	7	F	8	F	9	F	10	F	
OBSERVATION																					
Death/Sacrifice	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S
Normal	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

CODES: S = sacrifice
 X = observed

MB Research Laboratories

1765 Wentz Road
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TEST ARTICLE CHARACTERIZATION INFORMATION

Characterization of the test article is required in support of data submissions and should include identity, concentration, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and included in the final report. (EPA 40 CFR 160.105 and 792.105; FDA 21 CFR 58.105, OECD 6.2). Accordingly, please supply the following information for each test article submitted:

- Test Article Identity : AD200
- Concentration : 2.38% TMAH
- Purity : semiconductor grade
- Composition : TMAH in water w/surfactant
- Stability : stable
- Uniformity : homogeneous aqueous solution

BY: Jim Bland 2/21/05 FOR: Moses Lake Industries, Inc.
(signature) (date) (company) (date)

MB Research Laboratories

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P.O. Box 178
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VOLUME I

Study Title : Acute Oral Toxicity - Up and Down Procedure
(UDP)

Test Article : 25% TMAH, Lot/batch #10410158

Data Requirements : EPA 40 CFR 158.340, Guideline Reference
OPPTS 870.1100

Author : Daniel R. Cerven, M.S., Study Director

Study Completed On : June 14, 2005

Performing Laboratory : MB Research Laboratories
1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968

MB Research Project # : MB 05-13345.01

MB Research Protocol # : 1010-01

Sponsor : Moses Lake Industries, Inc.
10198 Dean Drive
Manassas, VA 20110

Citation : Daniel R. Cerven, M.S. (2005)
Unpublished Report by MB Research
Laboratories

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in the above study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B) or (C).

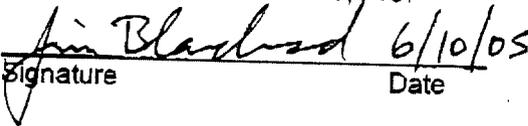
COMPANY : MOSES LAKE INDUSTRIES, INC.
COMPANY AGENT : Jim Blanchard
TITLE : R&D Manager
SIGNATURE : Jim Blanchard
DATE : 6/10/05

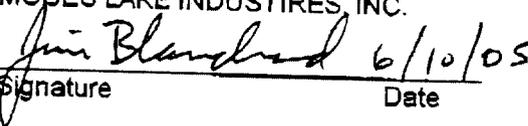
MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study was conducted in accordance with the Good Laboratory Practices Regulations of the EPA 40 CFR 160 and 792, FDA 21 CFR 58, and as specified in The Testing of Chemicals, published by the Organization for Economic Cooperation & Development (OECD), 1997.

SUBMITTER : MOSES LAKE INDUSTRIES, INC.

Signature Date 6/10/05

SPONSOR : MOSES LAKE INDUSTRIES, INC.

Signature Date 6/10/05

STUDY DIRECTOR : 
Daniel R. Cerven, M.S. Date 14 June 05
MB RESEARCH LABORATORIES

MB Research Labs

PROJECT NUMBER : MB 05-13345.01
TEST ARTICLE : 25% TMAH, Lot/batch #10410158
SPONSOR : MOSES LAKE INDUSTRIES, INC.
TITLE : Acute Oral Toxicity - Up and Down Procedure (UDP)
PROTOCOL # : 1010-01

A B S T R A C T

Objective: To determine the potential for toxicity of the test article when administered orally. This study is designed to comply with the standards set forth in EPA Health Effects Test Guidelines, OPPTS 870.1100 December 2002, and in OECD Guidelines for the Testing of Chemicals, Guideline 425 adopted December 17, 2001.

Method Synopsis: Initially, a single female Wistar rat was dosed orally with 25% TMAH, Lot/batch #10410158 at a dose level of 175 mg/kg. Since the animal died, additional animals were dosed, one at a time, by a single ordered dose progression as indicated in the chart below. The rats were observed 1/2, 1, 2 and 4 hours postdose and once daily for 14 days for toxicity and pharmacological effects. All animals were observed twice daily for mortality. Body weights were recorded immediately pretest, weekly, at death and at termination in the survivors. All animals were examined for gross pathology. Abnormal tissues were preserved in 10% neutral buffered formalin for possible future histological examination. The potential for toxicity was based on the mortality response noted. The LD₅₀ and 95% Confidence Limits were calculated using AOT425 Stat Pgm provided by the EPA.

Summary:

Mortality responses to the oral dosing was:

Animal #	Dose mg/kg	Response (O=alive, X=dead)
1/F	175	X
2/F	55	0
3/F	175	0
4/F	550	X
5/F	175	X
6/F	55	0
7/F	175	X
8/F	55	0

The deaths occurred within 4 hours of dosing and were preceded by physical signs of lethargy, sagging eyelids, dyspnea, coma, ataxia, decreased body temperature and wetness of the nose/mouth area. Necropsy revealed abnormalities of the stomach.

There were no abnormal physical signs noted in the survivors. Body weight changes and necropsy results of the survivors were normal.

Conclusion: The estimated LD₅₀ and 95% Confidence Limits are 175 (62-275) mg/kg.

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

OBJECTIVE

To determine the potential for toxicity of the test article when administered orally. This study is designed to comply with the standards set forth in EPA Health Effects Test Guidelines, OPPTS 870.1100 December 2002, and in OECD Guidelines for the Testing of Chemicals, Guideline 425 adopted December 17, 2001.

TEST ARTICLE

Identity : 25% TMAH, Lot/batch #10410158
Test Article
Characterization : See Appendix A for Test Article Characterization
Supplied by : Moses Lake Industires, Inc.
Date Received : 02/23/05
Storage : Room temperature and humidity.
Description : Clear liquid
Specific Gravity : 1.01
Sample Preparation : Used as received.

TEST DATES

Study Initiation (date protocol signed) : 04/01/05
Experimental Start Date (1st exposure to test substance) : 04/05/05
Experimental Term Date (last date data collected) : 05/10/05
Draft Report Signed (if applicable) : 05/25/05
Final Report Signed (study completion) : 06/14/05

EXPERIMENTAL DESIGN

Test Animals

Animals were received from Ace Animals, Boyertown, PA on 03/29/05, 04/05/05 and 04/12/05. Following an equilibration period of at least five days, eight healthy, non-pregnant and nulliparous female Wistar albino rats were assigned to treatment groups without conscious bias.

The animals were born the weeks of 02/08/05, 02/15/05 and 02/22/05. The pretest body weight range was 175 - 190 grams. The weight variation of each animal used did not exceed $\pm 20\%$ of the mean initial weight of all previously dosed animals.

The animals were identified by cage notation and indelible body marks, and housed in suspended wire mesh cages; 1/cage. Bedding was placed beneath the cages and changed at least three times/week. Fresh PMI Rat Chow (Diet #5012) was freely available except for 16-20 hours prior to dosing. Water was freely available at all times. The animal room, reserved exclusively for rats on acute tests, was temperature controlled, had a 12 hour light/dark cycle, and was kept clean and vermin free.

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

EXPERIMENTAL DESIGN (continued)

Dosing

The test article was used as received and the dose was based on the sample weight as calculated from the specific gravity. Initially, a single female Wistar rat was dosed orally by syringe and dosing needle at a dose level of 175 mg/kg. Since the animal died, additional animals were dosed, one at a time, by a single ordered dose progression.

Type and Frequency of Observations

In Vivo - Animals were observed 1/2, 1, 2 and 4 hours postdose and once daily for 14 days for toxicity and pharmacological effects. All animals were observed twice daily for mortality. Body weights were recorded immediately pretest, weekly, at death and at termination in the survivors.

Post Mortem - All survivors were humanely sacrificed using CO₂ following study termination and examined for gross pathology. Abnormal tissues were preserved in 10% neutral buffered formalin for possible future histological examination.

Analysis of Data

The LD₅₀ and 95% Confidence Limits were calculated using AOT425 Stat Pgm provided by the EPA.

Retention of Data

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number. The preserved tissues are stored at MB Research by sponsor name and MB project number. The sponsor will be contacted for final disposition of the tissues upon submission of the report.

The test article will be discarded following submission of the report.

Amendment to the Protocol

Subsequent to the submission of the draft report, the sponsor requested that the test article be discarded.

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

RESULTS & DISCUSSION

1. Mortality, Body Weights, Systemic Observations & Necropsy Findings (Tables 1 - 3)

Mortality responses to the oral dosing was:

Animal #	Dose mg/kg	Response (O=alive, X=dead)
1/F	175	X
2/F	55	0
3/F	175	0
4/F	550	X
5/F	175	X
6/F	55	0
7/F	175	X
8/F	55	0

The deaths occurred within 4 hours of dosing and were preceded by physical signs of lethargy, sagging eyelids, dyspnea, coma, ataxia, decreased body temperature and wetness of the nose/mouth area. Necropsy revealed abnormalities of the stomach.

There were no abnormal physical signs noted in the survivors. Body weight changes and necropsy results of the survivors were normal.

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

CONCLUSION

The estimated LD₅₀ and 95% Confidence Limits are 175 (62-275) mg/kg.

FINAL REPORT

Approved by:


Daniel R. Cerven, M.S. 14 Feb 05
Study Director Date

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

Table 1: Dose Volume and Body Weights in grams

An. #	Sex	Dose mg/kg	Dose Volume in cc	Body weights in grams		
				Day 0	Day 7	Day 14
1	F	175	0.032	183		
2	F	55	0.010	190	249	251
3	F	175	0.032	185	232	249
4	F	550	0.10	187		
5	F	175	0.030	175		
6	F	55	0.010	176	227	239
7	F	175	0.030	178		
8	F	55	0.010	187	249	263

No entry indicates animal died before observation period.

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

Table 3: Necropsy Observations

DOSE – mg/kg	175	55	175	550	175	55	175	55
Animal number/Sex	1/F	2/F	3/F	4/F	5/F	6/F	7/F	8/F
Observations	D	S	S	D	D	S	D	S
Normal		X	X			X		X
Stomach: red areas on mucosal lining	3			3	2		2	

CODES:
D = death
S = sacrifice
X = observed
2 = moderate or few
3 = pronounced or many

MB Research Labs

Study Title : Oral Toxicity in Rats (UDP)
Project # : MB 05-13345.01
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 1010-01

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit has inspected an in-life phase of this study, audited the raw data and the report and determined that the methods and results contained herein accurately reflect the raw data. No deviations from the approved protocol or Standard Operating Procedures were made without proper authorization and documentation. A summary of the compliance inspections is presented below.

Date of Inspection	Phase	Performed By	Date Findings Reported to	
			Mgmt.	Sty. Dir.
04/05/05	Necropsy	Erin Range	06/13/05	06/14/05
05/13/05	Raw data audit	Erin Range	06/13/05	06/14/05
05/25/05	Draft report audit	Erin Range	06/13/05	06/14/05
06/13/05	Final report audit	Erin Range	06/13/05	06/14/05


Erin Range 6/15/05
Quality Assurance Unit Date

MB Research Laboratories

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phone (215) 536-4110
fax (215) 536-1816

TEST ARTICLE CHARACTERIZATION INFORMATION

Characterization of the test article is required in support of data submissions and should include identity, concentration, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and included in the final report. (EPA 40 CFR 160.105 and 792.105; FDA 21 CFR 58.105, OECD 6.2). Accordingly, please supply the following information for each test article submitted:

- Test Article Identity : Tetramethylammonium hydroxide
- Concentration : 25%
- Purity : semiconductor grade - ultra pure
- Composition : TMAH in water
- Stability : stable
- Uniformity : homogeneous aqueous solution

BY:

Jim Blandford
(signature)

2/21/05
(date)

FOR:

Moses Lake Industries, Inc.
(company)

(date)

MB Research Laboratories

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VOLUME II

Study Title : Acute Dermal Toxicity/LD₅₀ in Rats

Test Article : 25% TMAH, Lot/batch #10410158

Author : Albert C. Gilotti, Ph.D., Study Director

Study Completed On : June 14, 2005

Performing Laboratory : MB Research Laboratories
1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968

MB Research Project # : MB 05-13180.02

MB Research Protocol # : 2100A-01

Sponsor : Moses Lake Industries, Inc.
10198 Dean Drive
Manassas, VA 20110

Citation : Albert C. Gilotti, Ph.D. (2005)
Unpublished Report by MB Research
Laboratories

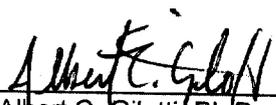
MB Research Laboratories

Study Title : Dermal Toxicity in Rats
Project # : MB 05-13180.02
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 2100A-01

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study meets the Good Laboratory Practices of the EPA, 40 CFR 160 and 792, FDA 21 CFR 58 and as specified in The Testing of Chemicals, published by the Organization for Economic Cooperation & Development (OECD), 1997.

STUDY DIRECTOR :

 June 14 '05
Albert C. Gilotti Ph.D. Date
MB RESEARCH LABORATORIES

MB Research Laboratories

PROJECT NUMBER : MB 05-13180.02
TEST ARTICLE : 25% TMAH, Lot/batch #10410158
SPONSOR : MOSES LAKE INDUSTRIES, INC.
TITLE : Acute Dermal Toxicity/LD 50 in Rats
PROTOCOL # : 2100A-01

A B S T R A C T

Objective: To determine the potential for toxicity of the test article when applied dermally. This study was designed to comply with the standards set forth in OECD Guidelines for Testing Chemicals, Number 402, adopted February 24, 1987.

Method Synopsis: At the request of the sponsor, three healthy female Wistar Albino rats were dosed dermally with 25% TMAH, Lot/batch #10410158 at 2000 mg/kg of body weight. In addition, three females were dosed at 1000 mg/kg, and five males and five females were dosed at 200 mg/kg. Since compound related mortality occurred at all three levels, an additional five males and five females were dosed at 50 mg/kg. The test article was kept in contact with the skin for 24 hours. Dermal responses were recorded at 24 hours postdose and on days 7 and 14. Animals were observed for toxicity and pharmacological effects at 1, 2 and 4 hours postdose and once daily for 14 days. All animals were observed twice a day for mortality. Body weights were recorded pretest, weekly and at termination in the survivors. All animals were examined for gross pathology. Abnormal tissues were preserved in 10% buffered formalin for possible future microscopic examination.

Summary:

50 mg/kg – Five males and five females were dosed dermally at 50 mg/kg. All animals survived the dermal application in generally good health. All animals appeared normal throughout the study. Body weight changes were normal. Dermal effects were well-defined to severe on day 1 and absent to severe on days 7 and 14. Necropsy results revealed abnormalities to the treated skin and the kidneys.

200 mg/kg - Five males and five females were dosed dermally at 200 mg/kg. Three of the males and all of the females did not survive beyond day 1. Predeath observations included sagging eyelids, closed eyes, lethargy, flaccid muscle tone, ataxia, tremors and coma. Necropsy of the animals that died revealed abnormalities of the treated skin and liver in all animals, with one instance of a white discharge was noted in the nose/mouth area.

Two males survived the 200 mg/kg dermal application. One instance of chromorhinorrhea was noted at 4 hours postdose. All other observations appeared normal. Body weight changes were normal. Dermal effects were well defined on day 1, very slight to severe on day 7 and absent to severe on day 14. Necropsy results revealed abnormalities to the treated skin and kidneys.

MB Research Laboratories

Study Title : Dermal Toxicity in Rats
Project # : MB 05-13180.02
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 2100A-01

Summary (continued):

1000 mg/kg - Three females were dosed dermally at 1000 mg/kg. All animals appeared comatose at one and two hours postdose and did not survive beyond the four hour postdose observation. Necropsy results revealed abnormalities of the treated skin and the liver of all three animals.

2000 mg/kg - Three females were dosed dermally at 2000 mg/kg. All animals appeared comatose at one and two hours postdose and did not survive beyond the 4 hour postdose observation. Necropsy results revealed abnormalities of the treated skin and the liver of all three animals. One instance of a white discharge was noted in the nose/mouth area.

Conclusion: The dermal LD₅₀ of 25% TMAH, Lot/batch #10410158 is greater than 50 mg/kg but less than 200 mg/kg of body weight.

MB Research Laboratories

Study Title : Dermal Toxicity in Rats
Project # : MB 05-13180.02
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 2100A-01

OBJECTIVE

To determine the potential for toxicity of the test article when applied dermally. This study was designed to comply with the standards set forth in OECD Guidelines for Testing Chemicals, Number 402, adopted February 24, 1987.

TEST ARTICLE

Identity : 25% TMAH, Lot/batch #10410158
Test Article
Characterization : See Appendix A for Test Article Characterization.
Supplied By : Moses Lake Industries, Inc.
Date Received : 02/23/05
Storage : Room temperature and humidity
Description : Clear liquid
Specific Gravity : 1.02
Sample Preparation : The test article was used as received.

TEST DATES

Study Initiation (date protocol signed) : 02/28/05
Experimental Start Date (1st exposure to test substance) : 03/02/05
Experimental Term Date (last date data collected) : 03/23/05
Draft Report Signed (if applicable) : 04/07/05
Final Report Signed (study completion) : 06/14/05

EXPERIMENTAL DESIGN

Test Animals

Animals were received from Ace Animals, Boyertown, PA on 01/25/05, 02/08/05 and 02/24/05. Ten healthy males and sixteen healthy, non-pregnant and nulliparous female Wistar Albino rats were randomly assigned to the treatment group using standard methods of randomization.

The animals were born the weeks of 11/30/04, 12/21/04, 12/30/04 and 01/06/05. The pretest body weight range was 226-270 g for males and 202-293 g for females. The weight variation of the animals used did not exceed $\pm 20\%$ of the mean weight for each sex.

The animals were identified by an indelible body mark and housed 1/cage in suspended wire cages. Bedding was placed beneath the cages and changed at least three times/week. Fresh PMI Rat Chow (Diet #5012) was provided daily. Water was freely available at all times. The animal room, reserved exclusively for rats on acute tests, was temperature controlled, had a 12 hour light/dark cycle, and was kept clean and vermin free.

MB Research Laboratories

Study Title : Dermal Toxicity in Rats
Project # : MB 05-13180.02
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 2100A-01

EXPERIMENTAL DESIGN (continued)

Site Preparation

The day prior to application of the test article, the dorsal area of the trunk of each animal was clipped free of hair. The prepared site was approximately 10% of the body surface and remained intact.

Dosing

The test article was applied to the prepared site, under a 4 ply porous gauze dressing measuring 10 x 15 cm at a dose levels of 50, 200, 1000 and 2000 mg/kg. The dose was based on the sample weight as calculated from the specific gravity. Gentle pressure was applied to the gauze to aid in the distribution of the test substance over the prepared site. The torso was wrapped with plastic in a semi-occlusive manner and was secured with non-irritating tape. The test article remained in contact with the skin for 24 hours at which time the wrappings were removed. Residual test article was removed in the surviving animals by gently washing with distilled water.

Type and Frequency of Observations

In vivo - The test sites in the survivors were scored for dermal irritation at 24 hours postdose and on days 7 and 14 postdose using the numerical Draize scoring code below. The skin was also evaluated for ulceration and necrosis or any evidence of tissue destruction. Additional signs were described.

Erythema & Eschar	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Edema	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm, extending beyond the area of exposure)	4

MB Research Laboratories

Study Title : Dermal Toxicity in Rats
Project # : MB 05-13180.02
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 2100A-01

EXPERIMENTAL DESIGN (continued)

Type and Frequency of Observations (continued)

The animals were observed 1, 2 and 4 hours postdose and once daily for 14 days for toxicity and pharmacological effects. The animals were observed twice daily for 14 days for mortality.

Body weights were recorded pretest, weekly and at termination in the survivors.

Post Mortem – All surviving animals were humanely sacrificed using CO₂ following study termination and were examined for gross pathology. Abnormal tissues were preserved in 10% buffered formalin for possible future microscopic examination.

Analysis of Data

An estimate of the LD₅₀ was made based on the survival during the study.

Retention of Data

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number. The preserved tissues are stored at MB Research by sponsor name and MB project number. The sponsor will be contacted for final disposition of the tissues upon submission of the report.

The test article will be discarded following submission of the report.

Amendment to the Protocol

Subsequent to the submission of the draft report, the sponsor requested that the test article be discarded.

Deviations to the Protocol

Thirteen animals were equilibrated for only 6 days, instead of one week as indicated in the protocol. This had no impact on the outcome of the study since the OECD guidelines for acute dermal toxicity #402 requires an equilibration period of at least 5 days prior to experimental start of the study.

Two animals were inadvertently not observed on day 12. This deviation had no impact on the study as the animals were in generally good health before and after this observation period.

No morning mortality checks were performed on two animals on day 9. This oversight had no impact on the study since the animals were alive in the afternoon.

MB Research Laboratories

Study Title : Dermal Toxicity in Rats
Project # : MB 05-13180.02
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 2100A-01

RESULTS & DISCUSSION

50 mg/kg – Five males and five females were dosed dermally at 50 mg/kg. All animals survived the dermal application in generally good health. All animals appeared normal throughout the study. Body weight changes were normal. Dermal effects were well-defined to severe on day 1 and absent to severe on days 7 and 14. Necropsy results revealed abnormalities to the treated skin and the kidneys.

200 mg/kg - Five males and five females were dosed dermally at 200 mg/kg. Three of the males and all of the females did not survive beyond day 1. Predeath observations included sagging eyelids, closed eyes, lethargy, flaccid muscle tone, ataxia, tremors and coma. Necropsy of the animals that died revealed abnormalities of the treated skin and liver in all animals, with one instance of a white discharge was noted in the nose/mouth area.

Two males survived the 200 mg/kg dermal application. One instance of chromorhinorrhea was noted at 4 hours postdose. All other observations appeared normal. Body weight changes were normal. Dermal effects were well defined on day 1, very slight to severe on day y and absent to severe on day 14. Necropsy results revealed abnormalities to the treated skin and kidneys.

1000 mg/kg - Three females were dosed dermally at 1000 mg/kg. All animals appeared comatose at one and two hours postdose and did not survive beyond the four hour postdose observation. Necropsy results revealed abnormalities of the treated skin and the liver of all three animals.

2000 mg/kg - Three females were dosed dermally at 2000 mg/kg. All animals appeared comatose at one and two hours postdose and did not survive beyond the 4 hour postdose observation. Necropsy results revealed abnormalities of the treated skin and the liver of all three animals. One instance of a white discharge was noted in the nose/mouth area.

MB Research Laboratories

Study Title : Dermal Toxicity in Rats
Project # : MB 05-13180.02
Test Article : 25% TMAH, Lot/batch #10410158
Protocol : 2100A-01

CONCLUSION

The dermal LD₅₀ of 25% TMAH, Lot/batch #10410158 is greater than 50 mg/kg but less than 200 mg/kg of body weight.

FINAL REPORT

Approved by:

 June 14 '05
Albert C. Gilotti, Ph.D. Date
Study Director

MB Research Laboratories

Study Title : Dermal Toxicity in Rats
 Project # : MB 05-13180.02
 Test Article : 25% TMAH, Lot/batch #10410158
 Protocol : 2100A-01

Table 1: Body Weights, Dose Volume in cc and Dermal Observations

An. #	Sex	Dose Volume in cc	Body Weight in (g)				Dose Level: 50 mg/kg				% Remaining at 24 hours	
			Day 0	Day 7	Day 14	24 Hours	Day 7	Day 14	24 hours			
17	M	0.013	264	311	353	Erythema >4m ^p	Edema 2	Erythema >4m	Edema 0	Erythema 0 ^{ab}	Edema 0	10%
18	M	0.013	270	318	359	Erythema >4m ^p	Edema 2	Erythema >4ms	Edema 1	Erythema >4m ^b	Edema 0	10%
19	M	0.013	265	320	365	Erythema 2 ^f	Edema 0	Erythema 0	Edema 0	Erythema 0 ^{p*}	Edema 0	10%
20	M	0.013	256	310	352	Erythema 2 ^f	Edema 0	Erythema 1 ^p	Edema 1	Erythema 0 [*]	Edema 0	10%
21	M	0.013	266	303	333	Erythema >4m ^p	Edema 2	Erythema >4ms ^p	Edema 1	Erythema >4m ^{ab}	Edema 0	10%
MEAN			264	312	352							
S.D.			5.1	6.8	12.0							
#			5	5	5							
22	F	0.011	233	237	264	Erythema >4m ^p	Edema 2	Erythema 3	Edema 1	Erythema 0 [*]	Edema 0	10%
23	F	0.011	220	225	247	Erythema >4m ^p	Edema 1	Erythema >4ms	Edema 1	Erythema 4 ^{bc}	Edema 0	10%
24	F	0.011	220	237	263	Erythema >4m ^p	Edema 1	Erythema >4ms	Edema 1	Erythema 0 ^{bc}	Edema 0	10%
25	F	0.011	219	247	280	Erythema >4m	Edema 2	Erythema >4s	Edema 2	Erythema >4m ^b	Edema 0	10%
26	F	0.011	228	251	262	Erythema >4m ^p	Edema 1	Erythema >4ms	Edema 1	Erythema 0 ^{bc*}	Edema 0	10%
MEAN			224	239	263							
S.D.			6.2	10.1	11.7							
#			5	5	5							

% Remaining = a visual estimate of the amount of material remaining on the skin, gauze and binding at 24 hours, after the binding was removed

* = reclippped a = area of white tissue b = area of poor hair regrowth c = shiny areas >4m = moderate eschar >4ms = moderate to severe eschar

>4s = severe eschar f = flaking skin p = pale areas

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Table 1: Body Weights, Dose Volume in cc and Dermal Observations (continued)

An. #	Sex	Dose Volume in cc	Body Weight in (g)				Dose Level: 200 mg/kg				% Remaining at 24 hours
			Day 0	Day 7	Day 14	24 Hours		Day 7		Day 14	
			Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	
1	M	0.044									Dead Day 0
2	M	0.044									Dead Day 0
3	M	0.046		275	322	2	1	1*	0	0	0
4	M	0.044									Dead Day 0
5	M	0.044		278	336	2 ^p	1	>4m	1	>4m	0
MEAN				277	329						
S.D.				3.1	2.1						
#				5	2						
6	F	0.043		219							Dead Day 0
7	F	0.045		232							Dead Day 0
8	F	0.040		204							Dead Day 0
9	F	0.040		205							Dead Day 0
10	F	0.042		212							Dead Day 0
MEAN				214							
S.D.				11.5							
#				5							

% Remaining = a visual estimate of the amount of material remaining on the skin, gauze and binding at 24 hours, after the binding was removed.

* = reclipped p = pale areas >4m = moderate eschar

MB Research Laboratories

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Table 1: Body Weights, Dose Volume in cc and Dermal Observations (continued)

An. #	Sex	Dose Volume in cc	Body Weight in (g)				% Remaining at 24 hours				
			Day 0	Day 7	Day 14	Day 21	Erythema	Edema	Erythema	Edema	
11	F	0.22	223								
12	F	0.21	210								
13	F	0.20	202								
MEAN			212								
S.D.			10.6								
#			3								

No entry indicates animal died before that time period

An. #	Sex	Dose Volume in cc	Body Weight in (g)				% Remaining at 24 hours				
			Day 0	Day 7	Day 14	Day 21	Erythema	Edema	Erythema	Edema	
14	F	0.43	217								
15	F	0.57	293								
16	F	0.41	208								
MEAN			239								
S.D.			46.7								
#			3								

No entry indicates animal died before that time period

% Remaining = a visual estimate of the amount of material remaining on the skin, gauze and binding at 24 hours, after the binding was removed.

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Table 2: Systemic Observations

TIME PERIODS	Dose Level: 50 mg/kg					
	17 M	18 M	19 M	20 M	21 M	22 F
Hour 1						
Hour 2						
Hour 4						
Day 1						
Day 2						
Day 3						
Day 4						
Day 5						
Day 6						
Day 7						
Day 8						
Day 9						
Day 10						
Day 11						
Day 12						
Day 13						
Day 14						

No entry indicates animal appeared normal at that observation period.

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Table 2: Systemic Observations (continued)

TIME PERIODS	Dose Level: 200 mg/kg									
	1	2	3	4	5	6	7	8	9	10
	M	M	M	M	M	F	F	F	F	F
	Q	1	S	Q	Q	Q	1	Q	Q	1
	1,B,C,E	1		Q			H	1,B,C	1,B,C,E	1,B
	H,Z	1,B,C,Z	S	1,B,O,Z	H,Z	H,Z	Z	H,Z	Z	1,B,E
Hour 1										
Hour 2										
Hour 4										
Day 1										
Day 2										
Day 3										
Day 4										
Day 5										
Day 6										
Day 7										
Day 8										
Day 9										
Day 10										
Day 11										
Day 12			*							
Day 13										
Day 14										

1 = eyes closed B = lethargy C = flaccid muscle tone E = ataxia H = coma O = tremors Q = sagging eyelids S = chromothinorrhea Z = dead
 No entry indicates animal appeared normal at that observation period. * = animal was inadvertently not observed

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Table 2: Systemic Observations (continued)

Dose Level: 1000 mg/kg

TIME PERIODS	A N I M A L #	&	S E X
Hour 1	11 F	12 F	13 F
Hour 2	H	H	H
Hour 4	H	H	H
	Z	Z	Z

H = coma Z = dead

Dose Level: 2000 mg/kg

TIME PERIODS	A N I M A L #	&	S E X
Hour 1	14 F	15 F	16 F
Hour 2	H	H	H
Hour 4	H	H	H
	Z	Z	Z

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Table 3: Necropsy Observations

		Dose Level: 50 mg/kg									
		17	18	19	20	21	22	23	24	25	26
Animal number	Sex	M	M	M	M	M	F	F	F	F	F
Death/Sacrifice		S	S	S	S	S	S	S	S	S	S
OBSERVATION											
Normal					X						
Treated skin abnormalities		X	X	X		X	X	X	X	X	X
Kidneys: mottled						2	3				

		Dose Level: 200 mg/kg									
		1	2	3	4	5	6	7	8	9	10
Animal number	Sex	M	M	M	M	M	F	F	F	F	F
Death/Sacrifice		D	D	S	D	S	D	D	D	D	D
OBSERVATION											
Treated skin abnormalities		3	3		3	3	3	3	3	3	3
Nose/mouth area: white discharge											
Liver: mottled		2	1		2		2	2	1	1	
Liver: pale margins		2	1		2		1	2	1	2	1
Liver: pale areas					1		1				1
Kidneys: mottled				2							1

CODES: D = death
 S = sacrifice
 X = observed
 1 = slight or scattered
 2 = moderate or few
 3 = pronounced or many

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Table 3: Necropsy Observations (continued)

OBSERVATION	Dose Levels: 1000 mg/kg			Dose Levels: 2000 mg/kg		
	Animal number	11	12	13	14	15
Sex	F	F	F	F	F	F
Death/Sacrifice	D	D	D	D	D	D
Treated skin abnormalities	3	3	2	3	2	3
Nose/mouth area: white discharge				2		
Liver: mottled	2	1		2	2	2
Liver: pale margins	2	2	2	2	2	2

CODES: D = death
 1= slight or scattered
 2= moderate or few
 3= pronounced or many

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QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit has inspected an in-life phase of this study, audited the raw data and the report and determined that the methods and results contained herein accurately reflect the raw data. No deviations from the approved protocol or Standard Operating Procedures were made without proper authorization and documentation. A summary of the compliance inspections is presented below.

Date of Inspection	Phase	Performed By	Date Findings Reported to	
			Mgmt.	Sty. Dir.
03/02/05	Dosing administration	Erin Range	06/13/05	06/14/05
03/30/05	Raw data audit	Erin Range	06/13/05	06/14/05
04/06/05	Draft report audit	Betty Salyer	06/13/05	06/14/05
06/13/05	Final report audit	Betty Salyer	06/13/05	06/14/05

Betty Salyer 6/14/05
Betty Salyer Date
Quality Assurance Unit

MB Research Laboratories

1765 Wentz Road
P.O. Box 178
Spinnerstown, PA 18968
phone (215) 536-4110
fax (215) 536-1816

TEST ARTICLE CHARACTERIZATION INFORMATION

Characterization of the test article is required in support of data submissions and should include identity, concentration, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and included in the final report. (EPA 40 CFR 160.105 and 792.105; FDA 21 CFR 58.105, OECD 6.2). Accordingly, please supply the following information for each test article submitted:

- Test Article Identity : Tetramethylammonium hydroxide
- Concentration : 25%
- Purity : semiconductor grade - ultra pure
- Composition : TMAH in water
- Stability : stable
- Uniformity : homogeneous aqueous solution

BY:

Jim Blauder 2/21/05
(signature) (date)

FOR:

Moses Lake Industries, Inc.
(company) (date)