

3-1-90

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 37507-LMETAM-SODIUM Technical

FROM: William S. Woodrow WSW 2-23-90
Precautionary Review Section
Registration Support Branch E 3/1/90
Registration Division (H7505C)

TO: Lewis / Stone (PM 21)
Fungicides - Herbicides Branch
Registration Division (H7505C)

APPLICANT: Transbas, Inc.
1525 Lockwood Rd.
Billings, MT 58103

FORMULATION FROM LABEL:

Active Ingredient(s):	\$ by wt.
<u>Sodium methyl dithiocarbamate</u>	<u>42.0</u>
Inert Ingredient(s):	<u>58.0</u>
Total	100.0%

1712

BACKGROUND

Transbas, Inc. submitted acute oral, dermal, inhalation, primary eye, and skin irritation and dermal sensitization studies to support registration of Metam-Sodium Technical. MRID NOS. used were 412770-02 through 412071-07.

RECOMMENDATION

- 1) The acute toxicity studies submitted by Transbas, Inc. are acceptable to RSB/PRS.
- 2) No additional acute toxicity studies are required.

LABELLING

- 1) The CAUTION signal word is appropriate.
- 2) Under Precautionary Statements, add
"Wash thoroughly after handling - Remove contaminated clothing and wash before reuse."
- 3) The Statement of Practical Treatment is appropriate.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

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Product Manager: (21) Reviewer: W. Waller
 MRID No.: 412770-02 Report Date: 2-22-90
 Testing Facility: Stillmeadow, Inc. Report No. 6111-39
 Author(s): L.O. Kulyn
 Species: Rat, FSD (SD)
 Age: Young adult Observation Days (Post
 Weight: 1M 183-318 F 170-227g Exposure): (14); other ()
 Source: Kallen Sprague Dawley, Houston
 Test Material: Metam Sodium, Technical, 42.0%, liquid
 Quality Assurance (40 CFR §160.12): adequate

Conclusion:

- LD₅₀ (mg/kg): Males = 780.6 mg/kg (644.8-944.9) Females = 844.8 mg/kg (1072-1215); Combined = 811.8 mg/kg (711.4-926.5)
- The estimated LD₅₀ is 811.8 mg/kg.
- Tox. Category: III. Classification: Guidelines

Procedure (Deviations From §81-1): 4 groups of 5M & 5F each in separate
treated by gavage with different dose levels of test material. Animals
were observed for toxic signs and mortality 3x day of treatment,
1x daily to 14 days. Body weights 0, 7 & 14 days. Gross necropsies
 Results: on all animals.

Reported Mortality

DOSAGE (Mg./kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
<u>500 mg/kg</u>	<u>0/5</u>	<u>0/5</u>	<u>0/10</u>
<u>750 mg/kg</u>	<u>2/5</u>	<u>1/5</u>	<u>3/10</u>
<u>1250 mg/kg</u>	<u>5/5</u>	<u>5/5</u>	<u>10/10</u>
<u>2000 mg/kg</u>	<u>5/5</u>	<u>5/5</u>	<u>10/10</u>

Symptomology & Gross Necropsy Findings:

Clinical: In life symptoms included: activity decrease, body
 tremors, contracted pupils, convulsions, diarrhea, shaking,
 lacrimation, nasal discharge, oral discharge, piloerection.
Necropsy: Pathology confirmed related findings: lacrimation,
 discharge of GI tract contents, intestinal tract empty,
 pleuritis, salivator.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

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Product Manager: (21)
 MRID No.: 412770-03
 Testing Laboratory: Stillmeadow, Inc.
 Author(s): J. O. Kuhn
 Species: Rabbit, NZ White
 Sex: SM & SF Wt.: M 3.475-3.800, F 3.25-3.725 Kg.
 Test Material: Matron Sodium Technical - 42-9%, liquid
 Quality Assurance (40 CFR §160.12): adequate

Reviewer: Woodrow
 Report Date: 2-22-90
 Report No.: 6112-29

Summary:

- LD₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LD₅₀ is 2020 mg/kg
- Tox. Category: III Classification: Guidelines

Procedure (Deviations From §81-2): 2020 mg/kg (1.6 ml/kg) undiluted test material applied to approx 10x10cm² clipped backs of SM & SF rabbits. 10x10cm gauze / tape secured test material. Dressing paint on trunk. Wrapped E semi-permeable dressing / each animal. 24 hour contact. Woundings removed, site washed, animals observed for toxic signs / mortality 3x day of dosing, 1x daily to 4 days. Body wts. 0, 1 & 4 days.
 Reported Mortality

DOSAGE (mg/kg)	(NUMBER KILLED / NUMBER TESTED)		
	Males	Females	Combined
2020 mg/kg	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

All animals subjected to gross necropsy.
 Clinical signs: Decreased defecation, small feces.
 Necropsy: No gross abnormalities.

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DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (581-3)

Product Manager: (21)
 MRID No.: 412770-04
 Testing Laboratory: Stillmeadow
 Author(s): M. S. Hulbert
 Species: Rat, HSP SD
 Sex: 15M & 15F
 Source: Harlan Sprague Dawley, Johnston
 Test Material: Metam Sodium Thioacetate 47.9% liquid
 Quality Assurance (40 CFR 160.12): adequate
 Reviewer: W. Woodrow
 Report Date: 2-22-90
 Report No. 6116-89

Summary:

1. LC₅₀ (mg/kg): Males = 2.360 mg/L (2.146-2.595); Females = 2.237 mg/L (2.101-2.385); combined = 2.275 mg/L (2.167-2.388)
2. The estimated LC₅₀ is 2.275 mg/L
3. Mean Concentration:
4. Tox. Category: III. Classification: Guidelines

Procedure (Deviation from 581-2): 51M & 51F per each of three exposure levels, were treated for 4 hrs to test material aerosol (undiluted). Total animals observed for toxic signs and mortality - day of exposure + 1x daily to 14 days (or 17 days). Gross necropsies performed on all animals.
 Results: The exposure chamber was 200L

Reported Mortality

Exposure Concentration (mg/L)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
1.90 mg/L	0/5	0/5	0/10
2.21 mg/L	1/5	2/5	3/10
3.04 mg/L	5/5	5/5	10/10

Symptomatology & Gross Necropsy

The aerosol was generated by using a pressure operated air nozzle, conc. aerosol. Then directed to bird, followed air, and directed into chamber through coiled wire (control flow). Aerosol concentration determined analytically using BTL 2000 Spectrophotometer 1x/hr & at end of each exposure. Normal.

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concentration: weight test material suspended in 1 liter through chamber during exposure. Particle size determination made using an Andersen Cascade Impactor. (Gravimetric means not used due to product volatility).

Results:

Cloud Concentration: A.V. of 4 samples, each (BAL spect. 1000 analysis).

low dose = 1.9

middle dose = 2.21

high dose = 3.04

Particle size distribution

Dose	Stage (C. Impactor)	Size Range	Cum. % than range	MMAD	GSD
1.9 mg/l	4	2.1-3.3	44.79	2.206/μ	2.042
	5	1.1-2.1	16.99	2.206/μ	2.042
2.21 mg/l	4	2.1-3.3	48.29	2.108/μ	2.023
	5	1.1-2.1	18.00	2.108/μ	2.023
3.04 mg/l	4	2.1-3.3	37.32	2.545/μ	2.072
	5	1.1-2.1	12.94	2.545/μ	2.072

Animal Clinical symptoms included: activity decrease, ataxia, body tremors, dilated pupils, gasping, nasal discharge, piloerection, polyuria, respiratory grunts.

Necropsy findings: nasal discharge, salivation, discoloration of G.I. tract contents, distended esophagus, discoloration of lungs.

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (21)
 MRID No.: 412770-05
 Testing Laboratory: Stillmeadow, Inc.
 Author(s): J. O. Kuhn
 Species: Rabbit, Al Z. White
 Sex: 3111 x 6 F Weight: not stated
 Source: Ray Nichols Rabbitry, TX.
 Dosage: 0.1 ml
 Test Material: Mergam Sulfonam Technical, liquid
 Quality Assurance (40 CFR §160.12): adequate

Reviewer: M. Hatter
 Report Date: 2-23-90
 Report No. 6117-89

Summary:

Tox. Category: III Classification: Guidelines

Procedure (~~Deviation from §81-4~~): 0.1 ml undiluted test material placed into the conjunctival sac of 1 eye / 3111 x 6 F rabbits. Lids held together 1 second. 3 of 9 treated eyes washed & water 1 minute beginning 30 sec. after treatment. All eyes examined & scored for ocular response, according to the Draize system, @ 1, 24, 48, 72 hours, and at 4 & 7 days.

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Cornea								
Opacity	0/9	0/9	0/9	0/9	0/9	0/9		
Iris	0/9	0/9	0/9	0/9	0/9	0/9		
Conjunctivae								
Redness	6/6	6/6	6/6	4/9	3/9	0/9		
Chemosis	9/9	8/9	0/9	0/9	0/9	0/9		
Discharge	6/9	4/9	1/9	0/9	0/9	0/9		

1.0 scores

1.0 scores

1/2, or 3.0 scores

Comments: Eyes wash did not seem to diminish irritation, so all nine eyes pooled for scoring.
 Conjunctival irritation about by day 7. (No corneal or iris involvement).

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: (2-1)
 MRID No.: 442770-06
 Testing Laboratory: Stillmeadow, inc.
 Author(s): J. O. Kuhn
 Species: rabbit, N 2 white
 Age: young adult
 Sex: 3M & 2F
 Weight: not stated
 Dosage: 0.5ml
 Test Material: Mercon Sodium Technical - 42.0%, liquid
 Quality Assurance (40 CFR 9160-12): adequate

Reviewer: H. H. H. H.
 Report Date: 2-23-70
 Report No.: 6114-87

Woudrow 00910

Summary:

The Primary Irritation Index = 0.93

Toxicity Category: IV

Classification: Guidelines

Procedure (Deviations from §81-5): 0.5ml undiluted test material introduced under 2.5cm² gauze on clipped back of 3M & 3F rabbits; patches secured w/ tape. Entire trunk wrapped with semi-permeable dressing/tape. 4 hour exposure; dressing removed, test sites washed, animals observed for erythema/eschar.
 Results: edema formation (scored) according to the Army system A 1, 24, 48, 72 hrs, and on day 7 and 10.

Average Irritation

time	Score
1 hr	1.7
24 hr	1.3
48 hr	1.0
72 hr	0.5
day 7	0.2
day 10	0.0

Special Comments:

Max. irritation score = 1.7, P.I. index = 0.93

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DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: (21)

MRID No.: 412770-07

Testing Laboratory: Stillmeade, Inc.

Author(s): J. O. Kuhn

Species: Guinea Pig, Hartley

Sex: 2 males

Source: Harlan Sprague Dawley, Houston

Test Material: Metem Sodium Technical - 42% liquid

Positive Control Material: 2,4-dinitrochlorobenzene (DNCB)

Quality Assurance (40 CFR §160.12): adequate

Method: Open epicutaneous Test

Summary:

1. This product is / (is not a dermal sensitizer.)
2. Classification: Exempt

Procedure (~~Deviation from §81-6~~): A pre-test screening was performed to determine the highest non-irritating dose level of test material; 10.0% v/v sol. of t. mat. in ether was selected.

Induction: Group I animals (10m) treated c. 0.06% w/v sol. of DNCB in ether, as positive control. After 1st treatment, dose level reduced from 10% to 1.0% v/v for each succeeding dose and challenge. Treatment. Body wts. recorded days 0 & 35. Animals (+ control and test animals) treated on Days 1, 3, 6, 8, 10, 13, 15, 17, 20, 22, and 36. 10m test animals, and 10m + control animals.

0.5ml of appropriate material introduced beneath 3.8x5cm gauze pad secured to 3.8x5cm piece of adhesion. Patches placed laterally on left front quadrant. Entire trunk wrapped c. 4 mil polyethylene - 6 hr exposure. On second day, dose reduced (1.0%), dose changed to left rear quadrant (used for remaining doses and challenge). After ^{each} exposure, animals returned to cages. On day 36, animals challenged, with addition of a second challenge site on right rear quadrant.

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<u>Results:</u>	<u>study</u>	<u>Group</u>	<u>Original</u>	<u>lesion</u>
<u>Treatment</u>	<u>day</u>		<u>test site</u>	<u>test site</u>
initial	1	+ control	0.1	NA
challenge	36	+ control	4.6	0.9
2nd treat	1	test mat.	0.0	NA
challenge	36	test mat.	4.5	0.0

A marked increase in positive skin reactions for the lesion site after the 36 day challenge - above those observed after the initial (+ control), or 1st (test mat.) would be indicative of a contact sensitizing reaction.

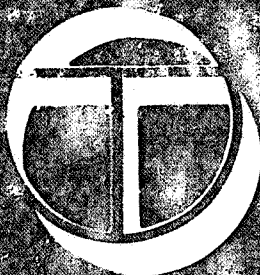
All animals gained weight.

Conclusion: From above definition of + skin reaction:

a. DNCB did induce a contact sensitizing reaction.

b. Test material did not induce a contact sensitizing reaction in guinea pigs.

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Transbas

METAM-SODIUM

Technical 42%

For the Formulation of End-Use Products

- for uses as fumigant solutions for the control of weeds, fungi and nematodes in soil of ornamental, food and fiber crops.
- For use as fumigant solutions for the control of decay and insects in wood.
- for use as anti-microbia: agents

ACTIVE INGREDIENT:

Sodium methylthiocarbamate 42%

INERT INGREDIENTS: 58%

TOTAL 100%

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA REG. NO. 37507- EPA EST. NO. _____

NET CONTENTS _____ GALLONS

Manufactured For
Transbas, Inc.
P.O. Box 957 Billings, MT 59103

EXP-1

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**PRECAUTIONARY
STATEMENTS
HAZARDS TO HUMANS
AND DOMESTIC ANIMALS
CAUTION**

Harmful if swallowed, inhaled, or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes, or clothing. Causes skin and eye irritation. Wear impervious boots or shoe covering when handling. Wear chemical resistant apron and gloves. Keep children and pets off treated areas until material is watered into soil and treated area is completely dried.

**STATEMENT OF
PRACTICAL TREATMENT**

FIRST AID: Immediately start the procedures given below and contact a Poison Center, a physician, or the nearest hospital. Report the type and extent of exposure, describe the victim's symptoms, and follow the advice given.

IF ON SKIN: Remove contaminated clothing immediately. Wash with plenty of soap and water. Get medical attention immediately.

IF IN EYES: Immediately flush eyes with plenty of running water. Hold eyelids apart to ensure rinsing of the entire surface of the eye and lids with water. Get medical attention immediately.

IF INHALED: Remove to fresh air. If not breathing, clear the victim's airway and start mouth-to-mouth artificial respiration. If breathing is difficult, give oxygen, preferably with a physician's advice. Get medical attention immediately.

IF SWALLOWED: Immediately give several glasses of water but do not induce vomiting. If vomiting does occur, give fluids again. Have a physician determine if condition of patient will permit induction of vomiting or evacuation of stomach. Do not give anything by mouth to an unconscious or convulsing person.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Do not apply where runoff is likely to occur. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Dilute this concentrate with water or a miscible solvent system to the concentration of active ingredient specified on the label of currently registered end-use products containing metal sodium, such as the following types of products:

- Fumigant solutions for the control of weeds, fungi and nematodes in soil of ornamentals, food and fiber crops.
- Fumigant solutions for controlling decay and insects in wood.
- Anti-microbial agents.

Each formulator is responsible for obtaining and maintaining EPA registration for his formulated product(s).

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. Do not store under conditions which might adversely affect the container or its ability to function properly.

STORAGE: Do Not Store Below 0°F. Product crystallizes at lower temperatures. Warm or store at higher temperatures and mix to redissolve crystals and assure uniformity before use. Store in a safe manner. Store in original container only. Keep container tightly closed when not in use. Reduce stacking height where local conditions, such as humidity or pallet overhang, can affect package strength. Personnel should use clothing and equipment consistent with good pesticide handling.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Metal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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