3-1-90

780

009101

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

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

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

APPLICANT: Transbas, Inc.
1525 Lockwood Rd.
Billings, MT 59103

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium methyldithiocarbamate	42.0
Inert Ingredient(s):	58.0
Total	100.0%

1/12

BACKGROUND

Transbes, 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 Transbes, Inc. are acceptable to RSB/PRS.
2) No additional acute toxicity studies are required.

LABELING

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)

009101

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

Conclusion:

1. LD_{50} (mg/kg): Males = 780.6 mg/kg (644.8-944.9) Females = 844.8 mg/kg (1.092-1.215); Combined = 811.8 mg/kg (711.4-926.5)
2. The estimated LD_{50} is 811.8 mg/kg.
3. Tox. Category: III. Classification: Guidelines

Procedure ~~(Deviations From §81-1)~~: 4 groups of 5M&5F each were separately 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 (4 days: Body weights - 0, 7 & 14 days - Gross necropsies on all animals.

Results:

Reported Mortality

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

Symptomology & Gross Necropsy Findings:

Clinical: In life symptoms included: activity decrease, body tremors, constricted pupils, convulsions, dyspnea, straining, lacrimation, nasal discharge, oral discharge, piloerection.

Necropsy: Probably compound related findings: Incontinence, discoloration of G-I tract contents, intestinal tract empty, polyuria, salivation -

009101

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

Product Manager: (21)
MRID No.: 412770-03
Testing Laboratory: Stillmeadow, inc.
Author(s): J. O. Kuhn
Species: Rabbit, NZ white
Sex: 5M & 5F
Test Material: Metam Sodium Technical - 42-0%, liquid
Quality Assurance (40 CFR §160.12): adequate

Reviewer: ~~M. Waller~~ Woodrow
Report Date: 2-22-90
Report No. 6112-89
Wt.: M 3.475-3.800, F 3.25-3.725 Kg.

Summary:

1. LD_{50} (mg/kg): Males = ______; Females = ______; Combined = ______;
2. The estimated LD_{50} is > 2020 mg/kg.
3. Tox. Category: III. Classification: Guidelines

Procedure (Deviations From §81-2): 2020 mg/kg (1.6 ml/kg) undiluted test material spread to approx 10x10 cm² clipped backs of 5M & 5F rabbits. 10x10 cm gauze/tape secured test material. Many-fold(?) trunks wrapped c̄ semi-permeable dressing/each animal. 24 hour contact. Wrappings removed, sites washed, animals observed for toxic signs/mortality 3x day of dosing, 1x daily to 14 days. Body wts. 0, 7 & 14 days.

Results:

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 necropsies.
Clinical signs: Decreased defecation, small feces.
Necropsy: No gross abnormalities.

BEST AVAILABLE COPY

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3)

Product Manager: (21)
MRID No.: 412770-04
Testing Laboratory: Stillmeadow
Author(s): M.J. Hulbert
Species: Rat, HSD SD
Sex: 15M & 15F
Source: Harlan Sprague Dawley, Houston
Test Material: Metam-Sodium Technical 42.7% liquid
Quality Assurance (40 CFR §160.12): adequate

Reviewer: W. Woodrow
Report Date: 2-22-90
Report No. 6116-89

Weight: M 261-302, F 181-218g

Summary:

1. LC_{50} (mg/kg): Males = 2.360 mg/L (2.146-2.595); Females = 2.238 mg/L (2.101-2.385); Combined = 2.275 mg/L (2.167-2.388)
2. The estimated LC_{50} is 2.275 mg/L
3. Mean Concentration:
4. Tox. Category: III. Classification: Guidelines

Procedure (~~Deviations from §81-2~~): 5M/5F per each of three exposure levels, were treated for 4 hrs to test material aerosol (undiluted). Treated animals observed for toxic signs and mortality day of exposure & 1X daily to 14 Days (or 17 day). Gross necropsies performed on all animals. The exposure chamber was 200L

Results:

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

~~Symptomology & Gross Necropsy findings~~

The aerosol was generated by using a pressure operated air nozzle, conc. aerosol then diluted & mixed, filtered air, and directed into chamber through orificed orifice (control flow). Aerosol concentration determined analytically using B&L 2000 Spectrophotometer 1X/hr & atomic feed apparatus - Nominal

5

concentration: weight test material supplied ÷ L air through chamber during exposure. Particle size determinations made using an Andersen Cascade Impactor. (Gravimetric means not used due to product volatility).

Results:

Cloud Concentration: AV. of 4 samples, each (B+L Spect 2000 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	2.206μ	2.042
	5	1.1–2.1	16.99	2.206μ	2.042
2.21 mg/L	4	2.1–3.3	48.29	2.108μ	2.023
	5	1.1–2.1	18.00	2.108μ	2.023
3.04 mg/L	4	2.1–3.3	37.32	2.545μ	2.072
	5	1.1–2.1	12.94	2.545μ	2.072

Animal Clinical symptoms included: activity decrease, ataxia, body tremors, dilated pupils, gasping, nasal discharge, salivation, polypnea, respiratory gurgle.

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

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4) 00[illegible]01

Product Manager: (21) Reviewer: (reviewer) ~~M. Heller~~
MRID No.: 412770-05 Report Date: 2-23-90
Testing Laboratory: Stillmeadow, Inc. Report No. 6113-89
Author(s): J. O. Kuhn
Species: Rabbit, N. Z. White
Sex: 3M x 6F Weight: not stated
Source: Ray Nichols Rabbitry, TX.
Dosage: 0.1 ml
Test Material: Morgan Septium Technical, Liquid
Quality Assurance (40 CFR §160.12): adequate

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 / 3M x 6F rabbits. Lids held together 1 second. 3 of 9 treated eyes washed w/ 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.

Results:

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: Eye wash did not seem to diminish irritation, so all nine eyes pooled for scoring.
Conjunctival irritation absent by Day 7. (No comment on iris involvement).

7

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

Product Manager: (21)
MRID No.: 411770-06
Testing Laboratory: Stillmeadow, inc.
Author(s): J. Q. Kubus
Species: Rabbit, NZ white
Age: young adult
Sex: 3M & 3F
Weight: not stated
Dosage: 0.5ml
Test Material: Metam Sodium Technical - 42.0%, liquid
Quality Assurance (40 CFR §160.12): adequate

Reviewer: Goodrow
Report Date: 2-23-90
Report No.: 6114-87

000910

Summary:

The Primary Irritation Index = 0.93

Toxicity Category: IV

Classification: Guidelines

Procedure (~~Deviations from §81-5~~): 0.5ml undiluted test material is introduced under 2.5 cm^2 gauze on clipped backs of 3M & 3F rabbits; patches secured & taped. Entire trunk wrapped with semi-permeable rubber/latex tape. 4 hour exposure; wrappings removed, test sites washed, animals observed for erythema/eschar, edema formation (scored) according to the Draize system @ 1, 24, 48, 72 hrs, and on day 7 and 10.

Results:

Time	Average Irritation Scores
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

009101

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

Product Manager: (21) Reviewer: ~~M. Walter~~ Woodrow
MRID No.: 412770-07 Report Date: 2-23-90
Testing Laboratory: Stillmeadow, Inc. Report No. 615-89
Author(s): J. O. Kuhn
Species: Guinea Pig, Hartley
Sex: 20 males Weight: 430-515 g.
Source: Harlan Sprague Dawley, Houston
Test Material: Metam 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: Guideline

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 test mat. in ethanol was selected. Induction: Group I animals (10M) treated w 0.06% W/V ~~Receive~~: sol of DNCB in ethanol, as positive control. After 1st treatment, dose volume reduced from 10% to 1.0% V/V for each succeeding dose and challenge treatments. Body wts recorded days 0 & 35 - 4 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 adhesive. Patches placed laterally on left front quadrant. Entire trunks wrapped w/ semi polyethylene + tape occlusive. On second day, dose reduced (1.0%), doses 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.

Results: Treatment	Study day	Group	Original test site	Virgin test site
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 primary skin reactions for the virgin site after the 36 day challenge — above those observed after the initial (+ control), or 2nd (test mat.) would be indicative of a contact sensitizing reaction.

All animals gained weight.

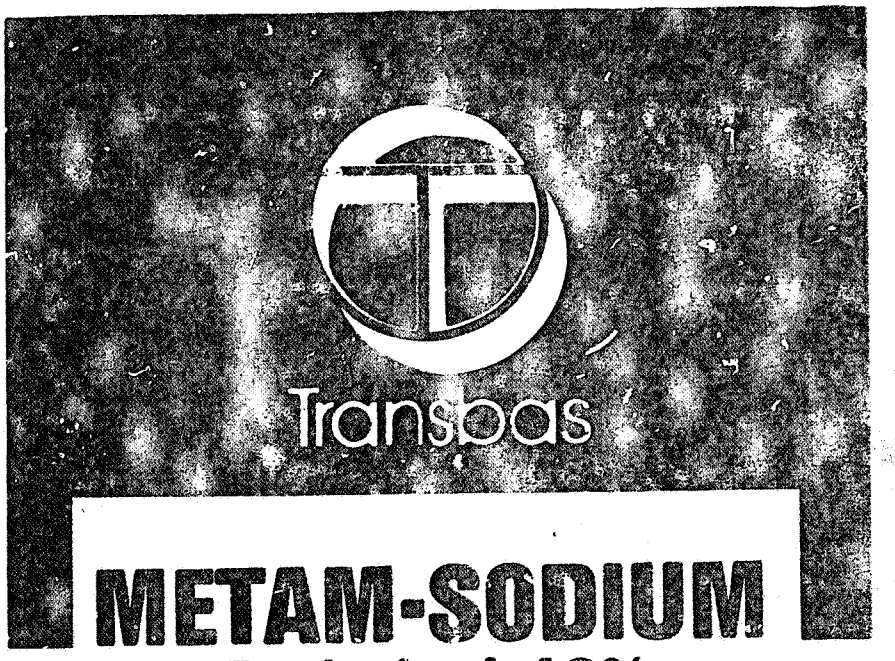
Conclusion: From above definition of + skin reaction:

a. DNCB did induce a contact sensitizing reaction.

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

10

009101



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-microbial agents

ACTIVE INGREDIENT:	
Sodium methyldithiocarbamate	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

11

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 ornamental, 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.

USA 9076

12