

US EPA ARCHIVE DOCUMENT

4-29-91

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

~~100-20-100~~

SUBJECT: EPA Reg. No./File Symbol 34704-647

Metam Soil Fumigant

FROM: Mary L. Waller Mary L. Waller E 4/29/91
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

TO: Susan Lewis (PM 21)
Herbicide-Fungicide Branch
Registration Division (H75-05C)

APPLICANT: Platte Chemical Company
150 South Main Street
Fremont, NE 68025

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>g by wt.</u>
<u>Sodium methyldithiocarbamate</u>	<u>31.7%</u>
_____	_____
_____	_____
<u>Inert Ingredient(s):</u>	<u>67.3%</u>
_____	_____
_____	_____
Total	100.0%

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BACKGROUND: The registrant has submitted an acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation and dermal sensitization studies. The studies were conducted by Cosmopolitan Safety Evaluation, Inc. The MRID numbers are 417240-01 through -06.

RECOMMENDATION: RSB/PRB findings are as follows:

1. The data is acceptable and all studies except the dermal sensitization study are classified as core guideline data.
2. The dermal sensitization study is classified as core minimum data. The study should have included a naive control group for comparison to the test group at challenge since the concentration used for challenge differed from the first induction concentration. In addition, historical data on a positive control group conducted within the last six months should have been submitted along with the data on the test group.
3. The signal word is "DANGER" based on the primary skin irritation study.

LABELLING:

1. Revise the first seven sentences of the precautionary statements as follows:
"Corrosive. Causes burns. May be fatal if absorbed through skin. Harmful or fatal if swallowed. Do not get in eyes, on skin, or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear protective clothing and rubber gloves. Avoid breathing vapors. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse.
2. Delete the following two last sentences under the precautionary statements:
"Do not store near food or feed. Keep children and pets out of treated areas until dry."
3. Since the signal word is "DANGER" based on the primary skin irritation study and the label permits chemigation, the label for this product must include the chemigation posting statements as specified in PR Notice 87-1, Part V.
4. This product meets the criteria for consideration as restricted-use based on the severity of the primary skin irritation data.

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The PM should decide if alternative labeling language as specified in 40 CFR 152.170(e) is sufficient to offset the hazard and not require restricted-use classification.

However, even if the PM feels that the product labeling is sufficient to mitigate the hazard of dermal exposure, PRS recommends that this product be classified as restricted-use since the registrant has included labeling requiring the use of a NIOSH-approved full face pesticide canister respirator or a full-face positive-pressure air-supplied respirator in certain situations. This type of specialized protective equipment requires special training for proper use and is not something that the general public would be expected to possess. Therefore, this label (in PRS's opinion) cannot meet the requirement for alternative labeling language. In addition, the label bears instructions for the treatment of small areas such as seed beds, plant beds, lawns, and other limited areas and based on these directions for use, this product could be used by a homeowner.

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

Product Manager: (JL) Reviewer: M. Waller
 MRID No.: 417340-01 Report Date: 9-19-90
 Testing Facility: Cosmochemical Safety Eval. Inc. Report No. 43023
 Author(s): Geoffrey Robbins
 Species: Albino Rats
 Age: Young Adult Observation Days (Post Exposure): (14); other ()
 Weight: ♂: 262-284 ♀: 212-221 g
 Source: Laboratory colony
 Test Material: Melan. Sol. Fum. Cont.
 Quality Assurance (40 CFR §160.12): Attached

Conclusion:

- LD₅₀ (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LD₅₀ is > 500 g and < 2000 mg/kg
- Tox. Category: III. Classification: Guideline Data

Procedure (Deviations From §81-1): dose level selection in accordance with Revised Policy on Acute Toxicity Testing (9-22-88)

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
500 g	0/5	0/5	0/10
1000 g	1/5	/	1/5
2000 g	3/5	/	3/5

Symptomology & Gross Necropsy Findings: **BEST AVAILABLE COPY**

Animals exhibited decreased/depressed activity, perineal staining, redness on skin on head.

Study survivors exhibited no abnormalities at necropsy. Study mortalities exhibited the following at necropsy: pulmonary congestion, hepatic mottling and intestinal congestion.

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

Product Manager: (31) Reviewer: M. Waller
 MRID No.: 417240 02 Report Date: 4-10-90
 Testing Laboratory: ~~Cosmogenics Safety Eval, Inc.~~ Report No. B-3042
 Author(s): Geoffrey Robbins
 Species: White Rabbits
 Sex: ♂ & ♀ Wt.: 2.50 - 2.95 Kg
 Test Material: Melan Soil Fumigant
 Quality Assurance (40 CFR §160.12): Attached

Summary:

- LD50 (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LD50 is > 1000 mg/kg and < 2000 mg/kg
- Tox. Category: II. Classification: Considerable Data

Procedure (Deviations From §81-2): ~~at~~ dose levels selection in accordance with Revised Policy on Acute Toxicity Testing (9-23-88)

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
500 mg/kg	/	0/5	0/5
1000 mg/kg	0/5	1/5	1/10
2000 mg/kg	3/5	1/5	4/10

Symptomology & Gross Necropsy Findings:

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Animals exhibited decreased locomotor activity at 1000 & 2000 mg/kg dose level. One male dosed at 1000 mg/kg had no feces in collection pan during first 3 days after dosing. At test site animals exhibited erythema and edema with superficial desquamation and exchar.

No abnormalities were observed in study survivors at necropsy. At necropsy, study mortalities exhibited congested lungs, mottled livers, red nasal discharge, irregular shaped whitish area on heart, mottled/pale kidneys, scattered.

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

Product Manager: (21)
 MRID No.: 412240-04
 Testing Laboratory: Metropolitan Safety Eval., Inc.
 Author(s): Geoffrey Robbins
 Species: alpine rabbits
 Sex: 3 males, 3 females
 Source: laboratory colony
 Dosage: 0.1 ml
 Test Material: Melan Sol. Fluorescent
 Quality Assurance (40 CFR §160.12): met

Reviewer: M. Waller
 Report Date: 7-19-80
 Report No. 23072

Summary:

Tox. Category: IV Classification: Guideline Data
 Procedure (Deviation From §81-4): _____

Results:

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

Comments: _____

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

Product Manager: (21) Reviewer: M. Waller
MRID No.: 417240-05 Report Date: 10-10-90
Testing Laboratory: Carmichael Safety Eval. Inc. Report No. E3042
Author(s): Geoffrey Robbins
Species: Albino rabbit
Age: Young adult
Sex: 3 ♂ + 3 ♀
Weight: 2.0 ± - 3.1 kg
Dosage: 0.5 ml
Test Material: Melan Soil Fumigant
Quality Assurance (40 CFR §160.12): attached

Summary:

The Primary Irritation Index = _____

Toxicity Category: I

Classification: Guideline Data

Procedure (Deviations From §81-5): _____

Results:

At 72 hours $\frac{1}{6}$ animals exhibited well-defined erythema, $\frac{3}{6}$ exhibited slight edema and $\frac{2}{6}$ exhibited moderate edema. From day 5 through day 19, $\frac{6}{6}$ exhibited severe erythema with eschar formation. From day 9 through day 20, animals exhibited sloughing and cicatrix-like appearance around periphery ~~of the~~ sloughed area. Day 19 through 21 slough separated revealing eschar (appearing superficial) with periphery having cicatrix-like appearance.

Special Comments:

Testing laboratory described test material as corrosive.

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DATA REVIEW FOR SKIN SENSITIZATION TESTING (81-6)

Product Manager: (31)
 MRID No.: 417240-06
 Testing Laboratory: Cosmopolitan Int'l. Lab. Inc.
 Author(s): Geoffrey Robbins
 Species: Guinea Pig
 Sex: male Weight: 267.961 g
 Source: Corn Research Lab. U.S. Army, NJ
 Test Material: Metam Sol. Emulsion
 Positive Control Material: 1% 2,4-DNP in saline
 Quality Assurance (40 CFR §160.12): attached

Reviewer: M. Waller
 Report Date: 4-13-90
 Report No. F1090

Method: Buehler

Summary:

1. This product is is not a dermal sensitizer.
2. Classification: CASE I/II/III/IV

Procedure (Deviation From 81-6): challenge - 1% w/v solution

- Study should include data on positive control conducted within last six months.
- Study should have included a naive control group for comparison

to the test group since a 1% w/v concentration was selected for challenge.

Results: Test animals exhibited very slight erythema and edema after the 1st and 2nd induction treatment. After the 3rd induction treatment, test animals exhibited very slight to well-defined erythema and moderate to severe edema. At challenge, 1/10 test animals exhibited very slight erythema. At re-challenge, test animals exhibited very slight to well-defined erythema and very slight to moderate edema.

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