4-29-91

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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

~~MAR 28 1991~~

EMORANDUM

UBJECT: EPA Reg. No./File Symbol 34704-647
Metam Soil Fumigant

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

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

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

ORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Sodium methyldithiocarbamate	32.7%
Inert Ingredient(s):	67.3%
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/PRS 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.

LABELING:

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 precautionry 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.

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: (31) Reviewer: M. Waller
MRID No.: 417240-01 Report Date: 9-19-90
Testing Facility: Cosmopolitan Safety Eval. Inc. Report No. 13028
Author(s): Geoffrey Robbins
Species: albino rats
Age: young adult Observation Days (Post
Weight: ♂: 262-284 ♀: 212-221 g Exposure): (14); other ( )
Source: laboratory colony
Test Material: Melam Sc. 1 Fungicide
Quality Assurance (40 CFR §160.12): Attached

Conclusion:

1. LD_{50} (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LD_{50} is > 500 g and < 2000 mg/kg
3. 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, perioral staining, dichromorhinorrhea.

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)
MRID No.: 41724 02
Testing Laboratory: Cosmopolitan Safety Eval., Inc.
Author(s): Geoffrey Robbins
Species: Albino rabbits
Sex: ♂ + ♀ Wt.: 2.50 - 2.95 Kg
Test Material: Melam Soil Fumigant
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
Report Date: 9-10-90
Report No. B3092

Summary:

1. LD_{50} (mg/kg): Males = _____; Females = _____; Combined = _____;
2. The estimated LD_{50} is > 1000 mg/Kg and < 2000 mg/Kg
3. Tox. Category: II. Classification: Guideline Data

Procedure (Deviations From §81-2): ~~Guideline~~ dose levels selection in accordance with Revised Policy on Acute Toxicity Testing (7-22-58)

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: 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 eschar.

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 INHALATION TOXICITY TESTING (§81-3)

Product Manager: (21)
MRID No.: 417240-03
Testing Laboratory: Cosmopolitan Safety Eval. Inc
Author(s): Geoffrey Robbins
Species: Albino rats
Sex: ♂ + ♀
Source: laboratory colony
Test Material: Metam Soil Fumigant
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
Report Date: 10-10-90
Report No. C3032
Weight: ♂: 258-285 g; ♀: 201-204 g

Summary:

1. LC_{50} (mg/kg): Males = ; Females = ; Combined =
2. The estimated LC_{50} is >1.37 mg/L and <2.4 mg/L
3. Mean Concentration:
4. Tox. Category: III. Classification: Guideline Data

Procedure (Deviations From §81-2): ———

Results:

Reported Mortality

Exposure Concentration (mg/L) gravimetric	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
1.37 mg/L mean MMAD: 1.1 µ	1/5	0/5	1/10
2.4 mg/L mean MMAD = 0.6 µ	5/5	5/5	10/10

Symptomology & Gross Necropsy Findings

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Animals exhibited decreased activity, dyspnea, abdominal distention, rales, gasping, yellow oral discharge & perineal staining. At higher dose, 4/5 males died prior to end of exposure and remainder of rats died before morning of day 1.

Gross necropsy revealed scattered white foci and small red areas on the pleural surface of the lobes of the lungs, mottled liver, edematous lungs, pale kidneys, G.I. tract distended with gas, and yellow viscous material in respiratory passage.

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

Product Manager: (21)
MRID No.: 417340-04
Testing Laboratory: Consolidation Safety Eval. Inc.
Author(s): Geoffrey Robbins
Species: albino rabbits
Sex: 2 males + 2 females
Source: laboratory colony
Dosage: 0.1 ml
Test Material: Melon 30.1 Fungicant
Quality Assurance (40 CFR §160.12): attached

Reviewer: M. Waller
Report Date: 7-19-90
Report No. 53012

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)
MRID No.: 417290-05
Testing Laboratory: Cannon Laboratories Inc.
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: Mean Soil Fumigant
Quality Assurance (40 CFR §160.12): attached

Reviewer: M. Waller
Report Date: 10-10-90
Report No. E3042

Summary:

The Primary Irritation Index = _____

Toxicity Category: I

Classification: Guideline Data

Procedure (Deviations From §81-5): —

Results:

At 72 hours 6/6 animals exhibited well-defined erythema, 3/6 exhibited slight edema and 3/6 exhibited moderate edema. From day 5 through day 19 6/6 exhibited severe erythema with eschar formation. From day 9 through day 30, animals exhibited sloughing and cratrix-like appearance around peripheries of the sloughed area. Day 19 through 21 sloughed 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)
Reviewer: M. Waller
MRID No.: 417240-06
Report Date: 9-13-90
Testing Laboratory: Cosmopolitan Safety Eval. Inc.
Report No. F3092
Author(s): Geoffrey Robbins
Species: Guinea Pig
Sex: male
Weight: 269-901 g
Source: Camm Research Lab Animals Wayne, NJ
Test Material: Metam Soil Fumigant 10% w/v in saline
Positive Control Material:
Quality Assurance (40 CFR §160.12): attached

Method: Buehler

Summary:
1. This product is / is not a dermal sensitizer.
2. Classification: Case Minimum

Procedure ~~(Deviation From §81-6)~~: challenge - 1% w/v solution
Rechallenge - 50% 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, 9/10 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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