10-6-92

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009114

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 5481-350 Metam-Sodium

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

MJP 7-17-92

To: Susan Lewis, PM 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

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Applicant: Amvac Chemical Corp.
4100 East Washington Blvd.
Los Angeles, CA 9023

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): Sodium Methyldithiocarbamate	32.7
Inert Ingredient(s):	67.3
Total:	100%

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BACKGROUND

Amvac Chemical submitted a dermal irritation study to support a downgrade of the signal word from "warning" to "caution." The product is Metam Sodium, a soil fumigant solution, and the active ingredient is sodium methyldithiocarbamate (32.7%). Stillmeadow, Inc. performed the dermal irritation study under MRID number 422831-01.

RECOMMENDATION

1. The dermal irritation study is acceptable as core guideline data.

2. Since PRS has been unable to find additional acute study data supporting product registration, the appropriate precautionary labeling (including the signal word) cannot be determined. The Registrant must submit or cite acceptable acute oral, acute dermal, acute inhalation, eye irritation and dermal sensitization studies. Following the receipt and review of these studies, the requested label amendments will be considered.

LABELING

1. The appropriate precautionary labeling will be determined following the submission of requested acute study data.

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

Product Manager:21
MRID No.:422831-01
Testing Laboratory: Stillmeadow
Author(s):J. Kuhn
Species: Rabbit
Age: Young adult
Sex:3 male, 3 female
Weight:--
Dosage:0.5 ml
Test Material: Metam Sodium 32.7%
Quality Assurance (40 CFR §160.12): Present

Reviewer:M. Perry
Report Date:12/23/91
Report No.:8567-91

Summary:

1. **The Primary Irritation Index = --**
2. **Toxicity Category:**III
3. **Classification:**Guideline

Procedure: A dose of 0.5 ml of test material was applied to the clipped exposure sites and occluded for a period of four hours. Dermal evaluations were performed at 1/2, 24, 48, and 72 hours, and on Days 7, 10, 14 and 17.

Results: Grade one erythema (n=4) and grade one (n=1) and two edema (n=1) were present at the 72 hour evaluation period. Grade two edema persisted in one animal until Day 10 of the study. All signs of irritation cleared by Day 17.

Special Comments:

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