



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

PM-14
Robert Forrest
Room 719 11-28-94
43277701

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA Reg. No./File Symbol: 53219-6 / M-PEDE Insecticide

From: Ian Blackwell, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

UDB 11/28/94

To: Rob Forrest, PM 14
Insecticide-Rodenticide Branch
Registration Division (7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

Applicant: Mycogen Corporation
4980 Carrol Canyon Road
San Diego, CA 92121

FORMULATION FROM LABEL:

<u>Active Ingredient(s)::</u>	<u>% by wt.</u>
Potassium Salts of Fatty Acids	49
<u>Inert Ingredient(s):</u>	<u>51</u>
Total:	100%

079021



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

BACKGROUND: Mycogen Corporation has submitted a primary skin irritation study to support "M-Pede Insecticide". The study, conducted by Hazleton Washington, was given the the MRID number 432777-01.

This product initially shared some reregistration data with reg. no. 42697-1. Both reg. nos. 53219-6 and 42697-1 were placed into Soap Salts RED batch #3. The registrant previously submitted a complete series of acute toxicity studies to support M-Pede. The results of the 6/3/94 PRS review of reg. no. 53219-6 were:

acute oral toxicity	IV	guideline
acute dermal toxicity	III	guideline
acute inhalation toxicity	III	minimum
primary eye irritation	I	guideline
primary skin irritation	I	guideline
dermal sensitization	nonsensitizer	guideline

The registrant did not feel that the results of the primary skin irritation study (MRID number 429364-01) were accurate. Because the registrant questioned the validity of that study, they had another conducted.

RECOMMENDATIONS:

The primary skin irritation study (MRID number 432777-01) is classified core-guideline data. Although the most recent primary skin irritation study submitted for 53219-6 is classified toxicity category IV, a previous skin irritation study for this product was placed into toxicity category I. PRS cannot overlook the results of the previous skin irritation study (MRID 432777-01, lab project no. HWA 2711-105). After considering the two studies, along with studies conducted on reg. no. 42697-1 (also of batch #3), PRS has decided to place the primary dermal irritation for reg. no. 53219-6 into toxicity category II. Protective gloves will be required for the user.

The acute toxicity profile for reg. no. 53219-6 is currently:

acute oral toxicity	IV	guideline
acute dermal toxicity	III	guideline
acute inhalation toxicity	III	minimum
primary eye irritation	I	guideline
primary skin irritation	II	guideline
dermal sensitization	nonsensitizer	guideline

LABELING:

1. The signal word is "DANGER", based on the primary eye irritation study.

2

2. The precautionary statements should state:

"Corrosive. Causes irreversible eye damage and skin irritation. Harmful if inhaled or absorbed through skin. Due to irritating nature, may be harmful if swallowed. Do not get on skin, in eyes, or on clothing. Avoid breathing vapor or spray mist. Wear gloves and goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse."

3. The statements of practical treatment should state:

"If in eyes: Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Call a physician."

"If on Skin: Wash with plenty of soap and water. Get medical attention."

"If swallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol. Get medical attention. Do not induce vomiting. Do not give anything by mouth to an unconscious person."

"If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

4. This product hits the trigger for restricted use due to eye and skin irritation. The PM Team should decide if alternative labeling is sufficient to offset the need for restricted use classification and the hazards posed by this product.
5. This product hits the trigger for Child Resistant Packaging due to eye and skin irritation. The PM Team should decide what course of action would best offset the hazards posed by this product.
6. This product is classified as an acute hazardous waste based on eye and skin irritation. The following statement must appear on the label:

"Pesticide wastes are acutely hazardous. 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."

3

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

Product Manager: 14
MRID No.: 432777-01

Reviewer: Ian Blackwell
Study Completion Date: 6/10/94
Lab Project No.: HWA 2711-105

Testing Laboratory: Hazleton Washington, Inc.
Author: Marie E. McKeon, M.Phil.

Quality Assurance (40 CFR §160.12): Included

Test Material: M-Pede, ID no. 290624544; "yellow liquid"

Dosage: 0.5 ml

Species: rabbit, Hra: (NZW)SPF/HRP

Age: young adult

Sex: 3 males + 3 females

Weight: males = 2.05-2.10; females 1.84-2.32

Source: HRP, Inc.; Denver, PA

Summary:

1. **Toxicity Category:** IV
2. **Classification:** core-guideline

Procedure (Deviations From §81-5):

Results: Very slight erythema was observed in 2/6 at 1, 24 and 48 hours. No erythema was noted at 72 hours. No edema was noted during the study.

ACUTE TOX ONE-LINER

1. PC CODE: 079021
2. CURRENT DATE: November 23, 1994
3. TEST MATERIAL: Potassium Salts of Fatty Acids ... 49%
EPA reg. no. 53219-6

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
primary skin irritation / rabbit / Hazleton Washington, Inc. / HWA 2711-105 / 6-10-94	432777-01	Very slight erythema in 2/6 at 1, 24 and 48 hours.	IV	G

Core Grade Key:

- G = Guideline
- M = Minimum
- S = Supplementary

5