



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

PM-14
Robert Forrest
Room 219

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM:

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

From: Ian Blackwell, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

ILB 10/4/93

To: Rob Forrest, PM 14
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505W)

E 12/17/93

Applicant: Mycogen Corporation
4980 Carroll 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>	51
Total:	100%

BACKGROUND: Mycogen Corporation has submitted a primary skin irritation study under section 6(a)2 of FIFRA. The study was conducted in response to the Ammonium and Potassium Salts of Fatty Acids (Soap Salts) RED. The study was forwarded prior to the submission of the complete series of acute toxicity studies as it meets the criteria for 6(a)2 data. The study was conducted by Stillmeadow, Inc. The MRID number is 429364-01. This product was placed in Soap Salts batch #3.

RECOMMENDATIONS:

The primary dermal irritation study is classified core-guideline data and is acceptable to support the reregistration of EPA reg. no. 53219-6.

PRS will not compile an acute toxicity profile at this time as only one of the six required studies has been submitted. However, the primary skin irritation profile of EPA reg. no. 53219-6 is currently:

PRIMARY SKIN IRRITATION I Guideline

LABELING:

1. The signal word is "DANGER" based on the primary skin irritation study.
2. The precautionary statements should contain the following:

"Corrosive. Causes burns. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash contaminated clothing before reuse."
3. The following statements of practical treatment should be added to the label of the registration product:

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

"If swallowed: Call a physician. Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

Note to Physician: Probable mucosal damage may contraindicate use of gastric lavage.
4. This product hits the trigger for restricted use due to 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 skin irritation.
6. This product is classified as an acute hazardous waste based on 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."
7. Additional labeling may be recommended upon the review of the other acute toxicity studies.

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

Product Manager: 14
MRID No.: 429364-01

Reviewer: Ian Blackwell
Study Completion Date: 8/2/93
Lab Study No.: 0266-93

Testing Laboratory: Stillmeadow, Inc.
Author: Janice O. Kuhn, Ph.D.

Quality Assurance (40 CFR §160.12): Included.

Test Material: M-Pede, "pale yellow liquid"

Dosage: 0.5 ml

Species: New Zealand White rabbit

Age: young adult (3 to 6 months)

Sex: 3 males + 3 females

Weight: Not specified

Source: Ray Nichols Rabbitry

Summary:

1. Toxicity Category: I
2. Primary Irritation Index = 5.04
3. Classification: core-guideline

Procedure (Deviations From §81-5): None

Results: Three quarter hours after unwrapping, 3/6 test animals displayed moderate-to-severe erythema, 2/6 displayed well-defined erythema, 1/6 displayed very slight erythema, 2/6 moderate edema, 3/6 slight edema and 1/6 displayed very slight edema. Twenty-four hours after exposure, 1/6 test animals displayed severe erythema, 5/6 displayed moderate-to-severe erythema, 2/6 moderate edema, 3/6 slight edema, 1/6 very slight edema and 1/6 displayed eschar. Forty-eight and seventy-two hours after exposure, 1/6 test animals displayed severe erythema, 4/6 displayed moderate-to-severe erythema, 1/6 well-defined erythema, 1/6 moderate edema, 5/6 slight edema, and 1/6 displayed eschar. Seven days after exposure, 1/6 test animals displayed severe erythema, 2/6 moderate-to-severe erythema, 2/6 well-defined erythema, 1/6 very slight erythema, 1/6 moderate edema, 4/6 slight edema, 1/6 very slight edema, 1/6 eschar and 5/6 desquamation. Fourteen days after exposure, 1/6 test animals displayed moderate-to-severe erythema, 1/6 well defined erythema, 4/6 very slight erythema, 1/6 slight edema, 1/6 very slight edema and 5/6 desquamation. Twenty-one days after exposure, 2/6 test animals displayed very slight erythema.

Special Comments: Although the Primary Irritation Index places the product in toxicity category II, the presence of eschar from 24 hours through day 10 demonstrates corrosivity and causes this product to be placed into toxicity category I.

ACUTE TOX ONE-LINER

1. PC CODE: 079021
2. CURRENT DATE: 10/4/93
3. TEST MATERIAL: Potassium Salts of Fatty Acids 49%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Primary skin irritation / rabbit / Sunmeadow, Inc. / 0266-93 / 8-2-93	429364-01	Forty-eight and seventy-two hours after exposure, 1/6 test animals displayed severe erythema, 4/6 displayed moderate-to-severe erythema, 1/6 well-defined erythema, 1/6 moderate edema, 5/6 slight edema, and 1/6 displayed eschar.	I	G

Core Grade Key:

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

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

Safer Inc
 c/o Delta Analytical Corp.
 7910 Woodmont Ave. Suite 1000
 Bethesda, MD 20814

429665-00

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

FIFRA 6(a) 2

DATE RECEIVED BY EPA

10/14/93

LIST OF SUBMITTED STUDIES:

Harrison, E. (1993) Letter sent to B. Madden dated Oct 12, 1993: Response of study director to Ian Blackwell's inquiry on dermal irritation study: Safer Insecticidal Soap Concentrate. Prepared by Delta Analytical for Safer, Inc. 4 p. 2 Product Safety Labs
 42966501

FOR ISB USE

Date to ISB: 10/14/93 Company No.: 042697 Reg. No.(s): 42697-1
 Date to Index: 10/15/93 Guideline:
 Date frm Indx: Page Count: 4
 Addressee: B Madden Groundwater? State(s):
 Notify: V. Dutch Chem. Name(s) & Code(s): 079021
 Category: (1) 6a2 2) adv. flag

Rel to 42910501
 42926208