



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

10-20-95
PM-14
429195-01
-03
215
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA Reg. No./File Symbol: 42697-1 / Safer Insecticidal Soap Concentrate

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

ADB 10/20/95

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)

Thomas C. Ellwanger / GMS for 6-6-94

Applicant: Safer, Inc.
9959 Valley View Road
Eden Prairie, MN 55344

FORMULATION FROM LABEL:

Active Ingredient(s)::
Potassium Salts of Fatty Acids
Inert Ingredient(s):

Total:

% by wt.
49.0
51.0
100.0%

079021



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BACKGROUND: Safer, Incorporated, has submitted three primary skin irritation studies in support of "Safer Insecticidal Concentrate" (EPA reg. no. 42697-1). The studies were submitted in response to the Ammonium and Potassium Salts of Fatty Acids (Soap Salts) RED. These three studies were forwarded to PRS prior to the submission of the other studies in the acute toxicity/ irritation series because the data is considered to be 6(a)2 data under FIFRA. Two of the primary skin irritation studies were conducted by Stillmeadow, Inc., the other was conducted by Product Safety Labs. The MRID numbers are 429105-01 and 429105-03.

Two of these studies were conducted using Safer Insecticidal Soap Concentrate, EPA reg. no. 42697-1. The other skin irritation study was conducted using "M-Pede", EPA reg. no. 53219-6, and was submitted because this product was placed in the same Soap Salts RED batch (3) as the registration product.

Primary skin irritation study MRID number 429105-01 was initially going to be classified supplementary data due to the report failing to state that the exposure site was wiped with water after the end of the exposure period. However, a memo dated 10/8/93 was sent to the PM requesting that the lab clarify this facet of their testing procedure. On 10/19/93, PRS received an amendment (MRID no. 429665-00) to the final report stating that the test sites were wiped with water and a clean towel at patch removal.

RECOMMENDATIONS:

1. Primary skin irritation study MRID number 429105-01 is graded core-guideline data and is acceptable to support the reregistration of reg. no. 42697-1.
2. Primary skin irritation study MRID number 429105-03 is classified core-guideline data and is acceptable to support the registration of the product.
3. Primary skin irritation study MRID number 429364-01 (conducted on 53219-6) is classified guideline data and is acceptable to support the reregistration of reg. no. 42697-1.

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. 42697-1 is currently:

PRIMARY SKIN IRRITATION I Guideline

LABELING:

1. PRS will defer the recommendation of precautionary statements and statements of practical treatment until the review of the other five studies in the acute toxicity studies series.
2. 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.
3. This product hits the trigger for Child Resistant Packaging due to skin irritation. The PM Team should decide what course of action would best offset the hazards posed by this product.
4. 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."

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

Product Manager:
MRID No.: 429105-01

Reviewer: Ian Blackwell
Study Completion Date: 8/30/93
Lab Project ID: T-2304

Testing Laboratory: Product Safety Labs
Author: Ralph Shapiro, Ph.D.

Quality Assurance (40 CFR §160.12): Included

Test Material: Safer Insecticidal Soap Concentrate; lot #C1243 (EPA reg. no. 42697-1).
Dosage: 0.5 ml

Species: New Zealand Albino rabbits
Age: not specified
Sex: 3 males + 3 females
Source: Davidson's Mill Farm
Weight: not specified

Summary:

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

Procedure (Deviations From §81-5):

Results: One hour after unwrapping, 4/6 test animals displayed severe erythema, 1/6 moderate-to-severe erythema, 1/6 well-defined erythema, 5/6 severe edema, 1/6 moderate edema and 4/6 displayed brown discoloration of the exposure site. Twenty-four hours after exposure, 4/6 test animals displayed severe erythema, 2/6 moderate-to-severe erythema, 5/6 severe edema, 1/6 moderate edema and 4/6 displayed eschar. Forty-eight hours after exposure, 4/6 test animals displayed severe erythema, 2/6 moderate-to-severe erythema, 6/6 severe edema and 3/6 displayed eschar. Seventy-two hours after exposure, 4/6 test animals displayed severe erythema, 2/6 moderate-to-severe erythema, 6/6 severe edema and 3/6 displayed eschar. Seven days after exposure, 4/6 test animals displayed severe erythema with severe edema and eschar, 2/6 displayed very slight erythema, 4/6 severe edema with eschar, 1/6 moderate edema and 1/6 displayed slight edema. On day 14, 2/6 test animals displayed severe erythema, 2/6 well-defined erythema, 1/6 very slight erythema, 1/6 severe edema, 4/6 slight edema, 2/6 eschar and 2/6 brown discoloration.

PII =	31	÷	4 = 7.75	Number of observations = 4
	27	÷	4 = 6.75	Number animals tested = 6
	28	÷	4 = 7	
	31	÷	4 = 7.75	
	32	÷	4 = 8	
	32	÷	4 = 8	
			45.25 ÷ 6 = 7.54 = PII	CORROSIVE

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

Product Manager: 14
MRID No.: 429105-03

Reviewer: Ian Blackwell
Study Completion Date: 7/29/93
Study No.: 0264-93

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

Quality Assurance (40 CFR §160.12): Included.

Test Material: Safer Insecticidal Soap Concentrate, pale yellow liquid
Dosage: 0.5 ml

Species: New Zealand White rabbit
Age: young adult (3 to 6 months)
Sex: 3 males + 3 females
Source: Ray Nichols Rabbitry

Weight: not specified

Summary:

1. Toxicity Category: III
2. Classification: core-guideline

Procedure (Deviations From §81-5):

Results:

Three-quarter hours after unwrapping, 3/6 test animals displayed moderate-to-severe erythema, 3/6 displayed well-defined erythema, 1/6 displayed moderate edema, 4/6 displayed slight edema and 1/6 displayed very slight edema. Twenty-four hours after unwrapping, 4/6 displayed moderate-to-severe erythema, 2/6 well-defined erythema, 1/6 displayed moderate edema, 4/6 displayed slight edema and 1/6 displayed very slight edema. Forty-eight hours after unwrapping, 4/6 displayed moderate-to-severe erythema, 2/6 well-defined erythema, 1/6 displayed moderate edema, 4/6 displayed slight edema and 1/6 displayed very slight edema. Seventy-two hours after unwrapping, 3/6 displayed moderate-to-severe erythema, 2/6 displayed well-defined erythema, 1/6 displayed very slight erythema, 1/6 displayed moderate edema, 3/6 slight edema and 2/6 very slight edema. Seven days after exposure, 1/6 displayed moderate to severe erythema, 3/6 well-defined erythema, 2/6 very slight erythema, 1/6 displayed moderate edema, 2/6 slight edema and 3/6 very slight edema. Fourteen days after exposure, 2/6 displayed well-defined erythema, 2/6 displayed very slight erythema and 3/6 displayed very slight edema. Twenty-one days after exposure, no erythema or edema was observed.

Primary Irritation Index

24	÷	4	= 6.00
14	÷	4	= 3.50
18	÷	4	= 4.50
20	÷	4	= 5.00
20	÷	4	= 5.00
12	÷	4	= 3.00
27.00 ÷ 6 = 4.5 = PII ⇒ Moderate irritation			

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