Memorandum

Tox # 701AB

Date: July 21, 1980

Subject: EPA Reg. No. 42697-1 SAFER'S INSECTICIDAL SOAP
Caswell #741

From: B.T. Backus
IRB/TSS

To: Mr. William Miller
Product Manager 16

Registrant: Safer Agro-Chem
3233 Vista Diego Rd.
Jamul, CA 92035

Active Ingredients:
Potassium salts of fatty acids.....50.5%
Inert Ingredients:.....49.5%

Background:

IRB/TSS previously reviewed the registration application for this product from the standpoint of potential hazard January 23, 1980. No recommendations as to appropriate precautionary labeling could then be made since no data were submitted. The registrant has now submitted (received 6-3-80) dermal LD50, dermal and eye irritation studies on this formulation.

Comments and Recommendations:

1. The acute dermal LD50, eye and skin irritation studies are adequate and acceptable.

2. In the eye irritation study, 5/6 unwashed rabbit eyes exhibited corneal opacity at 24 and 48 hours which had cleared by 72 hours.

3. The appropriate precautionary labeling for this product is indicated below.

Labeling:

1. Since this product can cause reversible corneal opacity, the appropriate signal word is WARNING.

2. The appropriate statement under the heading HAZARDS TO HUMANS AND DOMESTIC ANIMALS would be something like the following:

WARNING: Causes eye irritation. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists. Harmful if swallowed. Avoid contamination of feed and foodstuffs.

Review:

The following studies were conducted at BioMed Research Laboratories, Inc. 1115 East Pike St. Seattle, Washington 98122 using the formulated product. Studies were received at EPA 6-3-80.

1. Acute Dermal Toxicity - Rabbit

Procedure: 12M, 12F NZ albino rabbits, half with abraded, half with intact skin, were dermally exposed for 24 hours to an occluded dose of 5 gm/kg with 14-day observation. An additional 2M, 2F rabbits served as controls an additional 2M, 2F rabbits served as controls and were sham-treated with water.

Results: No mortalities. All animals gained weight. No pathological lesions observed at 14 days. Skin in all intact areas was completely healed with no scarring; abraded skin had healed but showed granulation.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

2. Primary Dermal Irritation - Rabbit

Procedure: 6 NZ white rabbits, each with 2 intact, 2 abraded skin sites, received 0.5 ml of test material at each site, with 24-hr occluded exposure.

Results: Considerable erythema (scores 2-3) and edema (scores 2-3) at the abraded sites at 24 hrs; some erythema (scores 1-2) but no edema (all 0) at intact sites at 24 hrs. At 72 hrs all scores zero at intact skin sites, some erythema (scores 1-2) but no edema at the abraded sites. Primary dermal irritation index = 2.1.

Study Classification: Core Guideline Data

Product Classification: Tox. Cat. III

3. Eye Irritation - Rabbit

Procedure: 0.1 ml was instilled in each of 9 rabbit eyes. Three eyes were washed with lukewarm water 20-30 seconds after instillation; the remaining 6 eyes were unwashed.

Results: 5/6 unwashed eyes had corneal opacity at 24 and 48 hours. No corneal opacity at 24 and 48 hrs. No corneal opacity noted in any eye at 72 hrs; all eyes clear by 96 hrs. No corneal opacity in any of the washed eyes.

Study Classification: Core Guideline Data

Product Classification: Tox. Cat. II:WARNING

Byron T. Backus 7/21/80

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