Memorandum

Date: February 13, 1980

Subject: EPA File Symbol: 42697-R SAFER'S INSECTICIDAL SOAP
Caswell #741

From: B.T. Backus
IRB/TSS

70, AB

To: Mr. William Miller
Product Manager 16

Applicant: Safer Agro-Chem
3233 Vista Diego Road
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Active Ingredient:
Potassium salts of fatty acids.....50%
Inert Ingredients:.....50%

Background:

This application was previously reviewed January 23, 1980. At that time it was indicated that the applicant had stated that dermal LD50, dermal and eye irritation studies would be forthcoming shortly. These have now been submitted.

Recommendations:

1. The dermal LD50, dermal and eye irritation studies received 1-24-80 are not adequate or acceptable to support the conditional registration of this proposed product.

2. The major problem with these studies is that they were not conducted with the product as proposed for registration, but on a 1:40 dilution in deionized water.

3. With respect to the acute dermal toxicity testing, if data based on a study with at least 5 animals of each sex with abraded skin are submitted showing that the LD50 is greater than 5 g/kg with a 24 hr contact period, no further testing at other dose levels would be necessary. Refer also to FR43, #163, Aug. 22, 1978, pp. 37356-37357.

4. With respect to the primary dermal irritation study, a dose of 0.5 ml of liquid should be applied at each of 2 intact and 2 abraded skin sites on each of 6 young albino rabbits. Animals should be exposed for 24 hrs to this occluded dosage; erythema and edema should be graded (and results reported for each individual subject) according to the criteria of Draize at 24 and 72 hrs. Refer also to FR43, #163, Aug. 22, 1978, pp. 37360-37361.

5. With respect to the eye irritation study, 0.1 ml of liquid should be placed in the everted lid of one eye of each of 6 rabbits, with the upper and lower lid of this eye then gently held together for 1 second. Eyes should be examined and scored (Draize) at 24, 48, 72 hrs, 4, 7 and possibly 14 and 21 days if irritation has not subsided. Refer also to FR43, #163, Aug. 22, 1978, pp. 37359-37360.

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Review:

The following studies were conducted at Bio Med Research Laboratories, 1115 E. Pike St., Seattle, Washington, 98122, on material identified as a 1:40 dilution of "Safer's Insecticidal Soap" in deionized water. The submission is dated January 7, 1980, and was received at EPA 1-24-80.

1. Acute Dermal Toxicity - Rabbit.

   Procedure: 6 rabbits (2.1-2.9 kg) received a dermal dosage of 5.0 ml/kg of the diluted soap with 24-hr occluded exposure and 15-day observation.

   Results: No mortalities reported. Slight erythema in 3/6 rabbits, with no edema. Erythema was gone at 48 hrs.

   Study Classification: Core Supplementary Data. Material tested was not the product as proposed for registration, but a dilution thereof. Also, no information was provided as to individual subject sexes, terminal body weights, or even whether necropsies were conducted.

2. Dermal Irritation - Rabbit.

   Procedure: 2.0 mls of the diluted soap was applied to the back of each of 6 rabbits, with 24-hr occluded exposure.

   Results: Stated that one subject out of 6 showed slight erythema at the end of 24 hrs, with no evidence of edema or necrosis.

   Study Classification: Core Supplementary Data. Material tested was not the product as proposed for registration, but a dilution thereof. Material tested was applied at apparently only one intact site per subject (no abraded sites). No Draize scores reported.

3. Primary Eye Irritation - Rabbit.

   Procedure: 0.5 mls of the diluted material was put directly into the eye of each of 6 rabbits, and the eyelid lifted "to insure the material was uniformly covering the eye."

   Results: All animals reported as having conjunctival redness, disappearing within 24 hrs following application.

   Study Classification: Core Supplementary Data. Material tested was not the product as proposed for registration, but a dilution thereof. No Draize scoring; 0.5 ml applied to each eye instead of 0.1 ml as specified in FR43, #163, Aug. 22, 1978; the material was placed directly in the eye, rather than the everted lower lid of one eye as specified in these Guidelines.

Byron T Backus 02/13/80

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