DATE: June 17, 1981

701 AB

SUBJECT: Safer's De-Moss Cryptocidal Soap CO-9-10
EPA File Symbol 42697-U

FROM Sherell A. Sterling
FHB/TSS

6-23-81

001229

TO: Richard Mountfort
Product Manager (23)

Applicant: Safer Agro-Chem, Inc.
3233 Vista Diego Road
Jamul, CA 92035

Active Ingredients
Potassium salts of fatty acids 40.0%
Inerts Ingredients 60.0%

Background:

Acute Oral, Acute Dermal, Eye and Skin Irritation studies were submitted for this product. The studies were conducted by Applied Biological Sciences Laboratory of Glendale, California. The method of support is "cite-all."

Recommendations:

1. The Acute Oral study is considered Core Supplementary Data and, as such, is not adequate for conditional registration purposes. Since mortalities produced at 5 g/kg, at least 3 dosage levels must be tested.
2. The Acute Dermal study is considered adequate and acceptable for conditional registration purposes.
3. An Acute Inhalation study was not submitted for this product. Data on this or a substantially similar formulation must be submitted.
4. The Eye Irritation and Skin Irritation studies are considered adequate and acceptable for conditional registration purposes.
5. A Dermal Sensitization study is necessary for this formulation.
6. Based on the Skin Irritation study, child resistant packaging is required for this product.

EPA FORM 1320-6 (REV 3-76)

Labeling Recommendations:

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1. Based on the Skin Irritation study, the appropriate signal word for this formulation is DANGER.

2. Under the "Directions for Use," remove the word "CAUTION" (preceding "Do not apply to foliage..."). This will help to avoid confusion with the "Hazard to Humans and Domestic Animals" signal words.

3. The statement "Keep out of reach of children" must precede the signal word DANGER.

4. The precautionary statements must be revised as follows. These statements must be preceded by the heading "Precautionary Statements."

"Hazards to Humans and Domestic Animals.

Danger. Corrosive. Causes burns. Causes substantial but temporary eye injury. Harmful if swallowed. Do not get on skin, in eyes, or on clothing. Wear protective clothing, rubber gloves and safety goggles. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Statement of Practical Treatment.

If in eyes: Flush with plenty of water. Get medical attehtion.

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

If swallowed: Drink promptly a large quantity of milk, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Get medical attention.

Environmental Hazards.

Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

Chemical or Physical Hazards.

Do not use or store near heat or open flame."

5. Delete the following statement from its current position on the labeling:

DIRECTIONS FOR USE. It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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Place the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling" directly beneath the heading "DIRECTIONS FOR USE," but preceding the word "MIX."

6. The "Storage and Disposal" statement must appear directly following the "Directions for Use" section. Revise this section according to the enclosed "Storage and Disposal" information sheets.

7. The precautionary statements must appear in a larger type-size for easier reading.

8. The product name on the label must be identical to the product name on the application forms.

Review:

1. Acute Oral Toxicity; Applied Bio. Science Report No. 16836; December 18, 1980; Acc. No. 244966.

   Procedure: A group of 5M and 5F Sprague-Dawley rats (200-300 g) each received 5 g/kg of "Fatty Acids Salts, Code CO-9-10." Animals were observed for 14 days post-dosing. All rats were necropsied.

   Results: Mortalities were 1/5 M and 2/5 F. Symptoms observed included: "hunched over," ruffled fur, rales, lethargy. Necropsies revealed: sanguineous nasal discharge; hemorrhagic lungs; transparent, distended stomach and intestines; dark kidneys.

   Study Classification: Core Supplementary Data. Mortality produced at 5 g/kg; therefore, at least 3 dosage levels must be tested.

2. Acute Dermal Toxicity Study; Applied Bio. Sciences Report No. 16836; December 18, 1980; Acc. No. 244966.

   Procedure: 5M, 5F New Zealand white rabbits each received 2 g/kg of "Fatty Acid Salts, Code CO-9-10" at abraded sites. Exposure was for 24 hours under occlusive wrap. All animals were subjected to necropsies.

   Results: No mortalities. LD_{50} is greater than 2 g/kg. Observations included: blackened skin; cracking and fissuring; eschar formation; flaking of epichelial layer; moderate erythema; black, hardened areas peeling with raw areas underneath. Necropsies revealed: diarrhea; adhesions in middle lobe of liver; liver discolored, grainy texture; enlarged heart (1/10).

   Study Classification: Core Guideline Data.

   Toxicity Category: III - CAUTION.

3. Eye Irritation Test; Applied Bio. Sciences Report No. 16836; December 18, 1980; Acc. No. 244966.

Procedure: 9 New Zealand white rabbits each received 0.1 ml of "Fatty Acid Salts, Code CO-9-01." Three eyes were subsequently washed for one minute with lukewarm water, 20-30 seconds post-instillation. Eyes were scored at 24, 48, 72 hours; 4, 7, 10, 13 days.

Results: At 24 hours, redness in 1/6 = 1, 5/6 = 2; chemosis in 2/6 = 2, 4/6 = 3; discharge in 2/6 = 2, 4/6 = 3. AT 7 days, corneal opacity in 1/6 = 20; iris irritation in 1/6 = 5; redness in 5/6 = 1, 1/6 = 2; chemosis in 2/6 = 1; discharge in 1/6 = 1, 1/6 = 3.. By day 13, all scores were zero.

The washed eyes at 24 hours exhibited redness in 3/3 = 2; chemosis in 1/3 = 1, 2/3 = 3; discharge in 3/3 = 3. By day 7, redness in 2/3 = 1. All scores were zero at day 10.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

4. EPA Skin Irritation Test; Applied Bio. Sciences Report No. 16836; December 18, 1980; Acc. No. 244966.

Procedure: 6 new Zealand white rabbits each received 0.5 ml of "Fatty Acids Salts, Code CO-9-10" at each of 4 sites. Two of the sites were intact, 2 abraded. Exposure was for 24 hours under occlusive wrap. Readings at 24, 72 hours.

Results: At 24 hours, intact and abraded sites exhibited erythema at 5/12 = 2, 7/12 = 4; edema at 4/12 = 1, 8/12 = 1. Both intact and abraded sites all exhibited severe erythema and no edema at 72 hours. Observations at 72 hours included cracking and fissuring of epithelial layers; blackened areas of skin. The Primary Irritation Index was 4.4.

Study Classification: Core Guidelines Data.

Toxicity Category: I - DANGER.