

US EPA ARCHIVE DOCUMENT



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

12-20-93  
429105-02

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM:

Subject: EPA Reg. No./File Symbol: 53219-4 / **DeMoss**

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

*IB 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 2/20/93*

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	40.0
<u>Inert Ingredient(s):</u>	60.0
Total:	100.0%

079021

**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, but 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 Product Safety Labs using *Safer Moss and Algae Killer Concentrate* (reg. no. 42697-7). Both EPA reg. no. 42697-7 and EPA reg. no. 53219-4 were placed into Soap Salts batch 5 during the development of the Soap Salts RED. A letter included in the submission states that reg. nos. 42697-7 and 53219-4 are identical. The MRID number is 429105-02.

**RECOMMENDATIONS:**

1. The primary skin irritation study is classified core minimum data and is acceptable to support the registration of reg. no. 53219-4. The study deficiencies are as follows:
  - a. The lab wiped the exposure area after unwrapping but failed to wipe the exposure area using water or another appropriate diluent as per Subdivision F Guidelines, §81-5(f)(4)(i).
  - b. The lab failed to specify the ages or weights of the test animals as per Subdivision F Guidelines. Please refer to Subdivision F, §80-4 (b)(2)(iv)(F).

PRS is not able to compile a complete acute toxicity profile for reg. no. 53219-4 at this time. Because of this the acute toxicity profile for 53219-4 is currently:

primary skin irritation                      I                      minimum

**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.

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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 in the series.

**ACUTE TOX ONE-LINER**

1. PC CODE: 79021  
2. CURRENT DATE: 10/4/93  
3. TEST MATERIAL: Potassium salts of fatty acids ..... 40.0%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
primary skin irritation / rabbit / Product Safety Labs / T-2404 / 8-30-93	429105-02	Seventy-two hours after challenge, 6/6 test material treated animals displayed severe erythema with severe edema, 1/6 displayed brown discoloration with fissuring and 5/6 displayed eschar. PII = 5.3	I	M

**Core Grade Key:**

- G = Guideline  
M = Minimum  
S = Supplementary

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