



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

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

*PM-23  
Joanne Miller  
Room 237*

MEMORANDUM:

Subject: EPA Reg. No.: 802-509 / Lilly/Miller Moss-Out

From: Ian Blackwell, Biologist  
Precautionary Review Section  
Registration Support Branch  
Registration Division (7505W)

*ADB 5/1/95*

To: JoAnne Miller, PM 23  
Fungicide-Herbicide Branch  
Registration Division (7505C)

Applicant: The Chas. H. LILLY Co.  
7737 N.E. Killingsworth  
Portland, OR 97218

FORMULATION FROM LABEL:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Ferric Sulfate, anhydrous	35
<u>Inert Ingredient(s)</u>	<u>65</u>
Total:	100%

BACKGROUND: The Chas. H. Lilly company has submitted information in supplement to the a 12/5/94 PRS review of "Lilly/Miller Moss-Out". In that review, the dermal sensitization study was graded core-supplementary data because the report did not include a positive control study. In this submission, the registrant has submitted a positive control study conducted by the laboratory one month before the finish of the dermal sensitization study. The MRID number of this positive control study is 435816-01.

RECOMMENDATIONS:

The positive control study is classified as acceptable data and is sufficient to support the reregistration of the product.

The acute toxicity profile for reg. no. 802-509 is currently:

acute oral toxicity	III	acceptable
acute dermal toxicity	III	acceptable
acute inhalation toxicity	III	acceptable
primary eye irritation	I	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	non-sensitizer	acceptable

LABELING:

1. The signal word is "DANGER", based on the results of the primary eye irritation study.
2. The precautionary statements must state:

"Corrosive. Causes irreversible eye damage. Harmful if swallowed, inhaled or absorbed through skin. Do not get in eyes, on skin on clothing. Avoid breathing dust or spray mist. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse."

3. The statements of practical treatment must state:

"*If in eyes:* Hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Get medical attention."

"*If swallowed:* Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol. Do not induce vomiting. Get medical attention. Do not give anything by mouth to an unconscious person."

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

*"If inhaled:* Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

**"Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage."

4. This product hits the trigger for Restricted Use due to eye irritation. The PM Team should decide if alternate 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 eye irritation. The PM Team should decide what course of action would best offset the hazards posed by this product.
6. This product is classified as an acute hazardous waste based on eye 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."

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## DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6)

**Product Manager:** 23  
**MRID No.:** 407587-03

**Reviewer:** I. Blackwell  
**Study Completion Date:** 1/3/91  
**Study No.:** F3082

**Testing Laboratory:** Cosmopolitan Safety Evaluation, Inc.  
**Author:** Geoffrey Robbins

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Ferri-floc; "beige granules"

**Positive Control Material:** p-phenylenediamine (MRID number 435816-01)

**Species:** albino guinea pig

**Weight:** 366-392

**Age:** young adult

**Source:** Camm Research Lab Animals

**Method:** Modified Buehler Method

**Summary:**

1. **This Product is not a dermal sensitizer.**
2. **Classification:** Acceptable

**Procedure (Deviation From §81-6):**

**Procedure:** An amount of 0.5 g of powdered test material was moistened 0.25 ml normal saline was applied to the exposure site under a non-allergenic pad, and wrapped with elastic bandage for 6 hours. This was the dosage for both induction and challenge. There was one induction per week over a period of three weeks for a total of nine induction treatments.

**Results:** Twenty-four hours after induction treatment #1, 2/10 test material-treated animals displayed very slight erythema. Twenty-four hours after induction #2, 3/10 test material-treated animals displayed very slight erythema. Twenty-four hours after induction treatment #3, 7/10 test material-treated animals displayed very slight erythema. Twenty four hours after challenge with the test material, 3/10 test material-treated animals displayed very slight erythema on virgin sites.

Twenty-four hours after induction treatment #1, no irritation was observed in positive control animals. Twenty four hours after induction treatment #3, 3/5 positive control animals displayed well-defined erythema, 2/5 very slight erythema, 4/5 slight edema and 1/5 very slight edema. Twenty-four hours after challenge with the positive control, 1/5 displayed moderate-to-severe erythema, 2/5 well-defined erythema, 2/5 very slight erythema, 1/5 moderate edema, 3/5 slight edema, and 1/5 very slight edema.

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ACUTE TOX ONE-LINER

1. PC CODE: 034902
2. CURRENT DATE: May 1, 1995
3. TEST MATERIAL: Ferric Sulfate, anhydrous ... 35%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
dermal sensitization / guinea pig / Cosmopolitan Safety Evaluation / F3082 / 1-3-91	407587-03 (435816-01)	Not a dermal sensitizer.	---	A

Core Grade Key:

- A = Acceptable
- U = Unacceptable
- S = Supplementary (upgradeable)