



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

Memorandum

July 18, 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
Technical Review Branch

Subject: Name of the Product: Lilly/Miller Moss Out
EPA Reg. No. /File Symbol: 802-509
DP Barcode: 388612
Decision No.: 447071
Action Code: R340
PC Codes 034902

From: Masih Hashim, Toxicologist/Team Leader
Technical Review Branch
Registration Division (7505P)

MH
Byron T. Bailey
July 18 2011

To: Bethany Benbow/ RM Team 23
Herbicide Branch
Registration Division (7505P)

Registrant: Lilly Miller Brands
Salem, VA 24153

FORMULATION:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Ferric sulfate	35.0
<u>Other Ingredient(s):</u>	<u>65.0</u>
TOTAL	100.0

ACTION REQUESTED: The Risk Manager requests:

A review of the acute eye study for the revision of the current labelling.

BACKGROUND:

This product currently has the Signal Word Danger due to an eye study submitted earlier. A new study has been submitted to make changes in the tox category for eye.

RECOMMENDATIONS:

The new eye study MRID 48432201 has been reviewed and is in compliance with EPA guidelines. The Signal Word is Warning. The revised tox profile for the Product #802-509 is as follows:

Acute oral toxicity	III	cited	MRID 42171701
Acute dermal toxicity	III	cited	MRID 42171702
Acute inhalation toxicity	III	cited	MRID 42171703
Primary eye irritation	II	acceptable	MRID 48432201
Primary dermal irritation	IV	cited	MRID 41758702
Dermal sensitization (g.pig)	neg	acceptable	MRID 48391304

PRODUCT ID #: 000802-00509

PRODUCT NAME: LILLY/MILLER MOSS OUT

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

SPANISH SIGNAL WORD:

AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

Hazards to Humans and Domestic Animals:

Causes substantial but temporary eye injury. Harmful if absorbed through skin. Harmful if inhaled. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and gloves. Avoid breathing spray mist. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin:

- Take off contaminated clothing.

- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Reviewer: M. Hashim

Date: July 18 2011

Risk Manager (EPA): 23

STUDY TYPE: Primary Eye Irritation- Rabbits OPPTS 870.2400; OECD 405

TEST MATERIAL: Product #802-509, (Ferric sulfulfate, 35%-anhydrous, reddish brown solution, Lilly Miller Moss out, EPSL No. 101206-8H. pH (1% solution) 4.8

CITATION: Lowe, C. (2011). Eye Irritation Study in Rabbits (#802-509) Eurofins Product Safety labs, Dayton, NJ 08810. Study Number 31304 dated 2-11-2011 MRID 48432201 unpublished.

SPONSOR: Lilly Miller Brands

EXECUTIVE SUMMARY: (MRID 48432201) A primary eye irritation test was conducted on rabbits with EPA Reg.No. 802-509. One-tenth of a milliliter of the test substance (as received) was instilled into the right eye of three healthy female (young adult) NZW rabbits . The left eye served as the untreated control. Ocular irritation was evaluated by the Draize method at 1, 24, 48, 72 hours and at 17 days post instillation.

One hour after test substance instillation, all three treated eyes showed corneal opacity and conjunctivitis. By 48 hours, iritis also developed in one animal and remained until day 4. A reddish discharge was noted for one animal at 48 hours. One animal showed pannus (day 10-14). All animals were free of ocular irritation by Day 17 (study termination).

Based on this study this product is classified as a severe eye irritant.

This eye study is classified as Acceptable. It does satisfy the guideline requirement for an acute EYE study (OPPTS 870.2400) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

Positive Incidence in Rabbit Eyes

Lesion	Time/hrs/days								
	1 hour	24 hrs	48 hrs	72 hrs	day 4	day 7	day 10	day 14	day 17
Corneal opacity	3/3	3/3	3/3	3/3	3/3	3/3	1/3	1/3	0/3
Iritis	0/3	0/3	1/3	1/3	1/3	0/3	0/3	0/3	0/3
Conjunctivitis	3/3	3/3	3/3	3/3	3/3	2/3	0/3	0/3	0/3
Severity or irritation/ mean score	25.0	23.0	22.0	20.7	22.3	16.0	8.3	7.0	0.0

A. Observations: One hour after test substance instillation, all three treated eyes showed corneal opacity and conjunctivitis. By 48 hours, iritis also developed in one animal and remained until day 4. A reddish discharge was noted for one animal at 48 hours. The overall incidence of irritation decreased thereafter. One animal showed (day 10-14) pannus. All animals were free of ocular lesions by Day 17 (study termination).

B. Results: The test substance is severely irritating to the rabbit eye.

C. Reviewer's conclusions: The test substance is mildly irritating. It is classified in EPA Toxicity Category II for primary eye irritation.

1. DP BARCODE: 388612
2. PC CODE: 034902
3. CURRENT DATE: July 18, 2011
4. TEST MATERIAL: #802-509

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Primary eye irritation study/Tox Monitor Labs/#31304/2-11-11	48432201	severe irritant	II	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived