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Caswell #3B

MEMORANDUM

Date: January 7, 1981

Subject: MON 097
524-EUP-LA

From: Sherell A. Sterling
FHE/TSS

To: Robert Taylor
Product Manager (25)

Applicant: Monsanto Company
1101 - 17th Street, N.W.
Washington, D.C. 20036

Active Ingredient:
2-Chloro-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)-acetamide 86.4%
Inert Ingredients 13.6%

Background: Data were submitted with an application for an Experimental Use Permit. Data submitted included Acute Oral, Acute Dermal, Eye and Skin Irritation studies. These studies were conducted by Monsanto's Environmental Health Laboratory in St. Louis, Missouri.

Recommendations:

1. The Acute Oral, Acute Dermal, Eye and Skin Irritation studies are adequate and acceptable for conditional registration purposes. Hence, these studies are adequate support for an experimental use permit.

2. An Acute Inhalation study was not submitted for this product. This study must be conducted before data are considered complete for conditional registration purposes. Before conducting this study, please be sure to consult Section 163.81-3 of the enclosed "Proposed Guidelines for Human Hazard Evaluation."

1 of 48

Labeling Recommendations:

1. Based on the information submitted, the appropriate signal word is WARNING as proposed by the applicant.

2. The term "Practical Treatment" is the preferred subheading instead of "First Aid."

3. Additional revisions may be necessary if future data submissions warrant.

Review:

1. Acute Oral Toxicity of "MON 097" (8 lb/gal EC) to Rats; Environmental Health Lab. Report No. R 80-49; Oct. 15, 1980; Acc. No. 243802

   Procedure: Sprague-Dawley rats, M(262-296 g) and F (174-221g), received "MON 097" by oral intubation. In each dosage level, 5M and 5F animals were tested. After treatment, animals were observed for 14 days. All animals were subjected to necropsies.

   Results: At 1250 mg/kg, 0/5M and 2/5F died; at 1768 mg/kg, 0/4M(one traumatic intubation death) and 3/5F; at 2500 mg/kg, 0/5M and 2/5F; at 3536 mg/kg, 3/5M and 2/5F died; at 5000 mg/kg, 4/5M and 5/5F deaths. Observations reported convulsions, prostration, ataxia, lethargic appearance, salivation, body tremors, lacrimation, urine-stained fur, diarrhea, porphyrin around the nose, bloodlike discharge from eyes, dehydrated nose, emaciated appearance, ptosis, muscular weakness, self mutilation, tail swollen and discolored, shallow breathing, alopecia, and backflush of test material. Necropsy revealed necrotic yellow spots on liver; blood around mouth/nose; hemorrhaging of intestinal tract; gas in stomach/intestinal tract; hydronephrosis; material in thoracic cavity, stomach and intestinal tract.

   Study Classification: Core Guideline Data

   Toxicity Category: III-CAUTION

2. Acute Dermal Toxicity of "MON 097" (8 lb/gal EC) to Rats; Environmental Health Lab. Report No. R 80-48; October 15, 1980; Acc. No. 243802

Procedure: New Zealand white rabbits (2.26-3.36 kg) received dosages of MON 097 8 lb/gal EC under occlusive wrap with a 24 hour exposure. At each dosage level tested, 4 rabbits of each sex were tested, 2 with application site abraded and 2 intact. Animals were observed for 14 days post-application. Necropsies were performed on all animals.

Results: Deaths reported were: at 2000 mg/kg, 0/4M and 0/4F; at 2828 mg/kg, 1/4M and 0/4F; at 4000 mg/kg, 2/4M and 3/4F. LD50 for M was 3999 mg/kg with a 95% confidence limit of 1796-8907 mg/kg. LD50 for F was 3563 mg/kg with a 95% confidence limit of 3054-4156 mg/kg. The combined M and F LD50 was 3667 mg/kg with a 95% confidence range of 3017-4458. Observations during study included: hardening of skin in treatment area, convulsions, tremors of head, loss of balance, salivation, labored breathing, grinding of teeth, muscular weakness, ptosis, vocalization with convulsions, lacrimation, exophthalmia, defatting of skin in treatment area. Necropsy revealed: 3 with yellow areas on liver due to abcess of gall bladder; one rabbit with broken leg.

Study Classification: Core Guideline Data

Toxicity Category: III-CAUTION

3. Primary Eye Irritation of "MON 097" (8 lb/gal EC) to Rabbits; Environmental Health Lab. Report No. R 80-51; October 15, 1980; Acc. No. 243802

Procedure: 0.1 ml of "MON 097" 8 lb/gal EC was applied into one eye of each of 9 New Zealand white rabbits. Twenty seconds post-treatment, 3 rabbits' treated eyes were washed with physiological saline. Eyes were scored according to Draize's method at 24, 48, 72 hours; 4, 7 and 10 days or until irritation subsided.

Results: In the unwashed eyes at 24 hours corneal opacity was observed in 1/6=5, 2/6=15, 3/6=20; iris irritation in 5/6=5; conjunctival irritation in 1/6=6, 4/6=12, 1/6=18. All scores for unwashed eyes were zero by day 7.

The washed eyes at 24 hours showed corneal opacity in 1/3=5; no iris irritation; conjunctival irritation in 3/3=2. All scores for washed eyes were zero by 72 hours.

000899

Study Classification: Core Guideline Data

Toxicity Category: II-WARNING

4. Primary Skin Irritation of "MON 097" (8 lb/gal EC) to Rabbits; Environmental Health Lab. Report No. 80-50; October 15, 1980; Acc. No. 243802

Procedure: Six New Zealand white rabbits received 0.5 ml of "MON 097" 8 lb/gal EC at each of 4 sites, 2 abraded and 2 intact. Exposure was for 24 hours under occlusive wrap. Draize scoring at 24, 72 hours.

Results: At 24 hours, intact sites showed erythema in 6/12=1, 2/12=2; no edema. The abraded sites at 24 hours showed erythema in 7/12=1 and 1/12=2. At 72 hours erythema at intact sites was 5/12=1; at abraded sites, 7/12=1; no edema evident. The Primary Irritation Index was 0.6.

Study Classification: Core Guideline Data

Toxicity Category: IV-CAUTION

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Page_____ is not included in this copy.

Pages 5 through 48 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

X___ A draft product label.

____ The product confidential statement of formula.

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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
