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

006152

7-16-87

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

~~JUL 10 1987~~

MEMORANDUM

SUBJECT: EPA Registration No. [illegible]5-427
Wilbur-Ellis Apron [illegible]ble

FROM: Mary L. Waller
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

7/16/87

TO: Lois A. Rossi, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Wilbur-Ellis Company
191 West Shaw Avenue, Suite 107
Fresno, CA 93704-2876

ACTIVE INGREDIENT:
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine, methyl ester 28.35%
INERT INGREDIENTS: 71.65%

BACKGROUND:

This product was registered by H. Jacoby on March 31, 1985 without a data review. Data were recently submitted to the Agency by the registrant after California informed the registrant that the appropriate signal word should be CAUTION and not WARNING. The registrant has submitted acute oral, acute dermal, acute inhalation, primary skin irritation, primary eye irritation, and dermal sensitization studies. The acute inhalation toxicity study was conducted by Leberco Testing, Inc. All other studies were conducted by Northview Pacific Laboratories, Inc. The data are not accessioned. The method of support was not indicated.

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RECOMMENDATION:

FHB/TSS finds the data acceptable provided the registrant certifies in writing that Wesco Nu-flow Apron (product tested) is identical to Apron Flowable (EPA Registration No. 2935-427). If there is any difference in the products, the data cannot be used at this time to support registration of 2935-427 and the product tested should be identified and the submission should be rerouted to FHB/TSS so that it can be determined whether the data can be used to support registration of 2935-427.

The signal word should be CAUTION and the product is classified as a sensitizer.

The Product Manager should inform the registrant that when conducting future dermal sensitization studies, skin irritation scores at 24 and 48 hours after each induction treatment should be submitted for each animal.

LABELING:

1. The signal word on the front and side panel should be revised to read "CAUTION."

2. Add the following sentence to the precautionary statements: "This product may cause an allergic skin reaction."

3. The Storage and Disposal instructions should appear immediately under or after the misuse statement under the Directions for Use or at the end of the Directions for Use.

REVIEW:

(1) Acute Oral Toxicity Study: Northview Pacific Laboratory, Inc.; Report No. X4J034-G; December 13, 1984.

PROCEDURE:

Four groups of male rats and five groups of female rats were each administered a single oral dose of test material by intubation as follows: Each group of male rats received either 3160, 3500, 4000, or 5000 mg/kg and each group of female rats received either 750, 1500, 2500, 4000, or 5000 mg/kg. All groups contained five animals except the male group which contained eight animals and received 5000 mg/kg. Animals were observed several times on day of dosing and daily thereafter for 14 days. Body weights were recorded on day of dosing and at 7 and 14 days. Animals were necropsied.

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RESULTS:

At 750 and 1500 mg/kg, 1/5 females died. At 2500, 4000, and 5000 mg/kg, 5/5 females died. At 3160 mg/kg, 2/5 males died. At 3500 mg/kg, 1/5 males died. At 4000 mg/kg, 3/5 males died. At 5000 mg/kg, 5/8 males died. The LD_{50} for males was reported to be 4250 (3541-5100) mg/kg. The LD_{50} for females was reported to be 1750 (1000-3063) mg/kg.

Toxic symtoms observed were convulsions, diarrhea, lethargy, paleness, scruffy coat, and salivation. Gross necropsy revealed abnormally colored lungs, stomachs filled with fluid, gas, or fluid-filled intestines, darkened and/or enlarged spleens and pink or red adrenals.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(2) Acute Dermal Toxicity Study: Northview Pacific Laboratory, Inc.; Report No. X4J034-G; December 13, 1984.

PROCEDURE:

Five male and five female New Zealand White rabbits were clipped free of hair on the dorsal surface. Twenty-four hours later, each animal was administered 2000 mg/kg of test material that was applied to the shaven skin and covered with nonocclusive wrap for 24 hours. After exposure, the wrap and residual test material were removed. Body weights were recorded prior to dosing and at 7 and 14 days. Animals were observed several times on the day of dosing and daily thereafter for 14 days. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred; therefore, it can be assumed that the LD_{50} is > 2000 mg/kg. No toxic symptoms were observed. Several males exhibited red areas on the lungs.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Primary Skin Irritation Study: Northview Pacific Laboratories, Inc.; Report No. X4J034-G; December 13, 1984.

PROCEDURE:

Six New Zealand White rabbits were clipped free of hair on the dorsal surface. Each animal received 0.5 ml of test

material that was applied to the clipped area and covered with nonocclusive wrap for 4 hours of exposure. After exposure, the wrap and residual test material were removed. Skin irritation was scored at 1, 24, 48, and 72 hours after removal of wrap.

RESULTS:

No irritation was observed.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(4) Primary Eye Irritation Study: Northview Pacific Laboratories, Inc.; Report No. X4J034-G; December 13, 1984.

PROCEDURE:

Six New Zealand White rabbits were each administered 0.1 ml of test material that was placed in the conjunctival sac of the right eye of each animal. The treated eye was held shut for approximately 1 second after test material administration. After 24 hours of exposure, the animal's treated eye was rinsed. Eye irritation was scored at 1, 24, 48, and 72 hours after exposure.

RESULTS:

At 1 hour, 3/6 animals displayed conjunctivae redness (2/6 = 2, 1/6 = 1). At 24 hours, all irritation had subsided.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(5) Acute Inhalation Toxicity Study: Leberco Testing, Inc.; Report No. U6J0136; November 17, 1986.

PROCEDURE:

Five male and five female Sprague-Dawley-derived rats were exposed for 4 hours in an inhalation chamber to a mean gravimetric concentration of 5.74 mg/L of test material. Animals were weighed prior to exposure and at 7 and 14 days. Animals were observed twice daily for 5 days during the first week and once daily during the second week. Animals were necropsied at study conclusion.

RESULTS:

No deaths occurred. Therefore, it can be assumed that the LC_{50} is > 5.74 mg/L. No toxic symptoms were observed. Gross necropsy revealed 9/10 animals had mottled lungs.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(6) Dermal Sensitization Study: Northview Pacific Laboratories, Inc.; Report No. X6K0056; December 15, 1986.

PROCEDURE:

A test group of 10 Hartley guinea pigs and a positive control group of 5 guinea pigs were clipped free of hair on the shoulder. Each animal received induction treatments that were administered 3 times a week for 2 weeks. The test group received 0.5 ml of test material and the positive control group received 0.5 ml of a 0.1% solution of 1-chloro-2,4-dinitrobenzene. Each induction treatment was applied to filter paper that was placed on the clipped area and covered with occlusive wrap for 6 hours of exposure. Animals were placed in restrainers during exposure. After each exposure the residual material was removed. Two weeks after the last induction treatment, each group was challenged using a virgin test site. Skin irritation was scored at 24 and 48 hours after challenge.

RESULTS:

After challenge, the test group exhibited slight patchy erythema, edema, and cracking of the skin. The positive control group exhibited slight patchy to moderate erythema.

STUDY CLASSIFICATION:

Core Minimum Data--see comments under Recommendation.

TOXICITY CATEGORY: SENSITIZER.

METALAXYL

Page_____ is not included in this copy.

Pages 6 through 7 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.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

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.