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

3-12-86

006207

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES
MAR 03 1986

MEMORANDUM

SUBJECT: EPA Registration Number 100-628
Ridomil 5G Fungi·

FROM: Deloris F. Graha[illegible] 3/12/86
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: CIBA-GEIGY Corporation
Agricultural Division
P.O. Box 18300
Greensboro, NC 27419

Active Ingredient:
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)
alanine methyl ester . . . . . 5.0%
Inert Ingredients . . . . . 95.0%

Background:

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation and Dermal Sensitization Studies. Studies conducted by CIBA-GEIGY and Stillmeadow, Inc. Data under Accession Number 258034. Method of support not indicated. Label submitted with review was stamped acceptable on November 25, 1985, prior to acute toxicity review on March 3, 1986.

Recommendations:

1. FHB/TSS finds these data acceptable to support conditional registration of this product.

2. The appropriate signal word is CAUTION.

Label:

Precautionary statements must appear on center front panel or on top side or back panel preceding Directions for Use.

Review:

1. Acute Oral Toxicity Study: CIBA-GEIGY: Study No. 832030; April 28, 1983.

Procedure:

One group consisting of five male and five female rats each received a single 5010 mg/kg dose of the test material. Another consisting of five male and five female rats each received a single of dose (10 ml/kg) of a 3 percent corn starch containing 0.5 percent Tween 80. Observations were made for 2 weeks posttreatment. Necropsy performed on all animals.

Results:

No mortalities, toxic signs or abnormalities at necropsy noted. $LD_{50}$ reported to be greater than 5010 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

2. Acute Dermal Toxicity Study: CIBA-GEIGY; Study No. 832066; July 18, 1983.

Procedure:

Five male and five female rabbits received 2010 mg/kg of the test material under occlusive wrap for 24-hour exposure. Observations made for 16 days posttreatment. Necropsy performed on all animals.

Results:

No mortalities, toxic signs or abnormalities at necropsy reported. $LD_{50}$ reported to be greater than 2010 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

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3. Acute Inhalation Toxicity Study: CIBA-GEIGY; Report No. 85023 (MIN 852118); April 23, 1985.

Procedure:

Five male and five female rats were exposed whole body to a 2.1 mg/liter gravimetric concentration for 4 hours. Average mass median diameter was 2.8 $\mu$m and geometric standard deviation 2.8. Chamber temperature ranged from 22 to 26 °C and relative humidity from 40 to 60 percent. Observations were made for 15 days postexposure. Necropsy performed on all animals. A second group of five male and five female rats were exposed to air only and served as control group.

Results:

No mortalities reported. Toxic signs reported included compound covering the body, lacrimation, chromodacryorrhea, rhinorrhea, chromorhinorrhea and stains around the nasal area. At necropsy pale kidneys noted in one treated male. No abnormalities reported in control group. $LC_{50}$ reported to be greater than 2.1 mg/l gravimetric concentration.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

4. Eye Irritation Study: CIBA-GEIGY; Study No. 832049; June 2, 1983.

Procedure:

Nine rabbits received 100 mg of the test material in one eye each. The treated eyes of three of the rabbits were washed with purified water for 1 minute 30 seconds after treatment. Observations at 1, 24, 48, 78 and 168 hours (7 days) after treatment.

Results:

At 24 hours, 5/6 of the unwashed group and 1/3 of the washed group had conjunctive redness (2/6 = 1, 1/6 = 2) (1/3 = 1); 4/6 conjunctive chemosis (4/6 = 1) and mild discharge in 6/6 + 3/3 animals. In unwashed animals blepharospasm, focal areas of subepithelial edema at lower quadrant, corneal surface rough. Irritation had cleared at 7 days.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

5. Primary Skin Irritation Study: CIBA-GEIGY; Study No. 832064; June 6, 1983.

Procedure:

Six rabbits received 0.5 gm of the test material at intact skin sites under occlusive wrap for 24-hour exposure period. Observations made at 30 to 60 minutes, at 24, 48 and 72 hours posttreatment.

Results:

No irritation reported in any animal throughout 72-hour observation period.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

6. Dermal Sensitization Study: Stillmeadow, Inc.; Project No. 2895-83; April 12, 1983.

Procedure:

Two groups consisting of ten male guinea pigs each were treated with one of the following substances: 500 mg of the test material moistened with 0.5 ml of deionized water or 0.05 percent w/v solution of 2,4-dinitrochlorobenzene in ethanol as a positive control. Applications using the patch method were made on alternate days for a total of 10 induction phase applications. Two weeks after tenth application a challenge dose was applied. Observations made at 24 hours after each application.

Results:

No irritation reported in test group during induction phase or at challenge dose. The irritation produced by the positive control was significantly greater at challenge to a

virgin skin site and original test skin site than after initial treatment thereby confirming 2,4-dinitrochlorobenzene as positive sensitizing agent.

Study Classification: Core Guideline Data.

Toxicity Category: Nonsensitizing.

METALAXYL

Page_____ is not included in this copy.

Pages 6 through 9 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.