5-6-82

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

002821

MEMORANDUM

Date: May [illegible]82

Subject: EPA File Symbol 100-[illegible]E
Ridomil 5G Fungicide

From: Deloris F. Graham
FHB/TSS

E 5/6/82

To: Henry Jacoby
Product Manager (21)

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

Active Ingredients:
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. All studies except the Acute Inhalation study conducted by Stillmeadow, Inc. The Acute Inhalation Study conducted by ToxiGenics. Data under accession number 247083. Method of support not submitted.

Recommendations:

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

2. The appropriate signal word is CAUTION.

Label:

1. The precautionary statements must precede directions for use.

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2. The "If swallowed" must be revised similar to the following statement.

> If swallowed, drink large quantities of water and induce vomiting by placing fingers in back of throat and call a physician or contact local poison control center. Never give anything by mouth to an unconscious person.

Review:

1. Acute Oral Toxicity Study: Stillmeadow, Inc.; Project #2264-81; October 9, 1981.

   Procedure: 5M and 5F Sprague-Dawley rats weighing between 200 and 300 grams received 5070 mg/kg of the test material. Observations made three times on day of treatment, then daily for 14 days thereafter. Necropsy performed on all animals.

   Results: No mortalities. Toxic signs included activity decrease, ptosis, polyuria, ataxia. Necropsy revealed pleural cavity filled with hard mass of yellow pus; yellow patches throughout lungs. LD50 greater than 5070 mg/kg.

   Study Classification: Core Guideline Data.

   Toxicity Category: IV - CAUTION.

2. Acute Dermal Toxicity Study: Stillmeadow, Inc.; Project #2265-81; October 5, 1981.

   Procedure: Each of 5M and 5F New Zealand rabbits weighing between 2.35 and 2.85 kg received 2010 mg/kg of the test material at abraded skin sites under occlusive wrap for 24-hour exposure. Observations were made at 1, 3, 6 and 24 hours posttreatment, then daily through 14 days. Necropsy performed on all animals.

   Results: No mortalities. Slight erythema and brown discoloration of test site hairs observed. At necropsy in one animal both kidneys polycystic. LD50 greater than 2010 mg/kg.

   Study Classification: Core Guideline Data.

   Toxicity Category: III - CAUTION.

3. Acute Inhalation Toxicity Study: ToxiGenics; Study #420-0759; December 30, 1981.

   Procedure: 5M and 5F rats weighing between 213 and 291 grams were exposed for 4 hours to a gravimetric concentration of 2.62 mg/l (nominal concentration was 30.6 mg/l) of the test material. Particle size was 1.98

micrometers with standard deviation of 2.45 micrometers. Temperature was 77.7°F. Observations were made every 15 minutes during first hour of exposure, then at least every 30 minutes during the remainder of the exposure. Necropsy performed on all animals. A group of control animals were treated in a similar manner, except no test material was used.

Results: No mortalities. Poor coat quality, irregular breathing were the toxic signs observed. In untreated control, damp, red-stained fur observed. At necropsy no abnormalities in treated animals. At necropsy of control animal right pelvis kidney dilated and diffused, lung depression, diffuse and red. LC50 greater than 2.62 mg/l gravimetric concentration.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

4. Eye Irritation Study: Stillmeadow, Inc.; Project #2266-81; September 29, 1981.

Procedure: Nine New Zealand rabbits received 100 mg of the test material in one eye each. The treated eyes of three of the rabbits were washed thirty seconds posttreatment. Observations were made of 1, 24, 48 and 72 hours and at 7 days after treatment.

Results: At 24 hours, 6/6 animals of the unwashed group had redness (3/6=1, 3/6=2); 4/6 chemosis (4/6=1) and 2/6 discharge (2/6=1). At day 4, 2/6 had redness (2/6=1). At day 7, all irritation had cleared.

At 24 hours, 2/3 animals of the washed group had redness (2/3=1). At day 4, all irritation had cleared.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

5. Primary Dermal Irritation Study: Stillmeadow, Inc.; Project #2267-81; September 24, 1981.

Procedure: Six New Zealand rabbits received 0.5 g of the test material at 2 abraded and 2 intact skin sites per animal under occlusive wrap for 24-hour exposure. Observations made at 24 and 72 hours.

Results: At 24 hours, 6/6 animals had erythema (6/6=1) and 1/6 edema (1/6=1). No irritation at 72 hours.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

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6. Dermal Sensitization Study: Stillmeadow, Inc.; Project #2268-81; November 11, 1981.

Procedure: A group of ten guinea pigs were treated with 50.0% w/v slurry of the test material in deionized water as a test group. A group of ten guinea pigs were treated with a 0.05% w/v solution in ethanol of 2,4-dinitrochlorobenzene as a positive control. The animals were treated on each of the first ten treatment days by introducing 0.5 ml of the appropriate material beneath a gauze patch secured by adhesive dressing. The entire trunk of the animal was then wrapped with clear polyethylene film to secure the patches. Each animal was then placed in a restraint for approximately six hours. On day 35 (final treatment), all animals were treated in an identical manner as in the previous ten treatment days, with the addition of a second test site receiving 0.5 ml of the test material. Observations were made at 24 hours after treatment for each test site.

Results: The average skin reaction scores for the positive control was 0.1 for initial treatment (Day 0) and 2.3 for the final treatment (Day 35). A sensitizing reaction in guinea pigs was produced by 2,4-dinitrochlorobenzene (0.05% w/v solution in ethanol).

The average skin reaction scores for the test group was 0.2 for the initial treatment (Day 0) and 0.2 for the final treatment (Day 35). The 50.0% w/v slurry of Ridomil 5G in deionized water did not produce a sensitizing reaction in guinea pigs.

Study Classification: Core Minimum Data. Observations made at 24 and 48 hours after each application.

Toxicity Category: Nonsenitizing.

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METALAXYL

Page_____ is not included in this copy.

Pages 5 through 9 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

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