

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

6-12-86

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-MAY 2 2 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

£ 412/86

MEMORANDUM

SUBJECT: EPA File Symbol 100---

Ridomil PC 11G Gran Pungicide

FROM: Mary L. Waller

Mary L. Waller Pungicide-Herbicide ranch

Technical Support Section

Registration Division (TS-767C)

TO:

Henry M. Jacoby, PM 21 Fungicide-Herbicide Branch

Registration Division (TS-767C)

APPLICANT: Agricultural Division

Ciba-Geigy Corporation

P.O. Box 18300

Greensboro, NC 27419

ACTIVE INGREDIENTS:

BACKGROUND:

The registrant has submitted an acute oral, acute dermal, acute inhalation, primary eye irritation, primary skin irritation, and dermal sensitization studies. The studies were conducted by Ciba-Geigy Pharmaceutical's Division. The data Accession Number is 259739. The method of support is owner submission.

RECOMMENDATION:

PHB/TSS finds all the studies acceptable provided the registrant verifies that the product tested is identical (both actives and inert ingredients) to EPA File Symbol 100-AAU. The signal word is CAUTFON.

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LABELING: The proposed labeling is acceptable as submitted.

REVIEW:

(1) Acute Oral Toxicity Study: Ciba-Geigy Pharmaceutical's Division; Report No. 284-84; January 4, 1985.

PROCEDURE:

Five male and five female CD rats were administered a single oral dose of 5000 mg/kg of 10% test material suspended in 3% cornstarch. Animals were observed regularly on the day of dosing and twice daily on days 2 to 14. Animals were weighed prior to dosing and on days 8 and 14. All animals were submitted to gross necropsy.

RESULTS:

No deaths occurred. The LD $_{50}$ for males and females was reported to be > 5000 mg/kg. Toxic symptoms observed were hypoactivity, stains around mouth, and soft feces. All toxic symptoms had cleared by day 2. There were no significant findings at gross necropsy.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category IV - CAUTION.

(2) Acute Dermal Toxicity Study: Ciba-Geigy Pharmaceutical's Division, Report No. 288-84; January 2, 1985.

PROCEDURE:

Five male and five female New Zealand White rabbits were administered a single topical dose of 2010 mg/kg of test material which was moistened with purified water and applied as a slurry to a previously shaven test site on the animals' flanks under occlusive wrap. After 24 hours of exposure, each test site was washed with tapwater and dried with a paper towel. Animals were weighed prior to dosing and on days 8 and 15. Animals were observed daily for 15 days, and skin irritation was noted at 24 and 48 hours. All animals were necropsied.

RESULTS:

No deaths occurred. The LD50 was reported to be > 2010 mg/kg. No toxic symptoms were noted and no significant findings were noted at gross necropsy.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(3) Acute Inhalation Toxicity Study: Ciba-Giegy Pharmaceutical's Division, Report No. 84285; April 8, 1985.

Procedure:

Five male and five female Sprague-Dawley rats were exposed for 4 hours in a stainless steel inhalation exposure chamber to an average gravimetric concentration of 2.1 mg/L of test material. A control group of five males and five females was exposed to air under similar conditions. Chamber concentration and particle size was measured hourly. Animals were observed twice daily for 18 days. Body weights were recorded prior to dosing and on days 8, 15, and 19. All animals were necropsied.

RESULTS:

One out five females died during exposure. The LC50 for males and females was reported to be > 2.1 mg/L. Toxic symptoms observed were dyspnea, lacrimation, rasping, rhinorrhea, chromorhinorrhea, salivation, soft feces, and test substance coating the animals. Toxic symptoms subsided by day 3. Gross necropsy of the one mortality revealed a diffusely whitened lung and in another animal from the test group the right kidney was distorted.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(4) Primary Eye Irritation Study: Ciba-Geigy Pharmaceutical's Division; Report No. 290-84; January 7, 1985.

PROCEDURE:

Nine New Zealand White rabbits each received 100 mg of test material instilled in the lower conjunctival sac of the right eye. The eyes of three animals were rinsed after 30 seconds and eyes of the other six animals were rinsed after 24 hours. The left eye (untreated) served as the control. Eye irritation was graded at 1, 24, 48, and 72 hours after test material instillation. Animals' eyes

were examined using fluorescein stain prior to treatment and after 24-hour reading. Body weights were recorded prior to treatment and at day 3.

RESULTS:

Animals in the washed group exhibited redness (3/3 = 1) at 1 and 24 hours. All irritation had subsided by 48 hours. Animals in the unwashed group exhibited eye irritation as follows: at 24 hours, corneal opacity (1/6 = 5), iris irritation (2/6 = 5), and conjunctivae redness (3/6 = 2, 3/6 = 1). All irritation had cleared by 48 hours.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(5) Primary Skin Irritation Study: Ciba-Geigy Pharmaceutical's Division; Report No. 283-84; December 28, 1984.

PROCEDURE:

Three male and three female New Zealand White rabbits each received 0.5 g of test material applied to a previously shaven test site on the right side of the animals' backs. The test site was kept under occlusive wrap for 4 hours. A site on the left side of each animal was treated similarly with a blank patch and served as a control site. After exposure, the test site was cleaned with a moist paper towel to remove excess test material. Animals were observed and skin irritation was scored 24, 48, and 72 hours.

RESULTS:

No skin irritation or toxic effects were noted. The primary skin irritation score was 0.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category IV - CAUTION.

(6) Dermal Sensitization Study: Ciba-Geigy Pharmaceutical's Division; Report No. 301-84; February 12, 1985.

PROCEDURE:

Two groups of ten guinea pigs each were clipped free of hair (as needed) on the left dorsal flank, and each group received induction treatments consisting of 0.5 g of test material moistened with water or 0.5 ml of 0.05% 1-chloro-2,4-dinitrobenzene (CNDB). Induction treatments were administered on days 1, 3, 6, 8, 10, 13, 15, 17, 20, and 22 for 6 hours of exposure under occlusive wrap. After each exposure period, wraps and any remaining material was washed from the test site. Two weeks later, a challenge dose identical to an induction dose was administered to the right flank of the sensitized test groups and the sensitized positive control Two additional groups of 10 guinea pigs each were treated with 0.5 g of test material moistened with water of 0.5 ml of 0.05% CNDB. Animals were observed daily for general appearance, behavior, and excreta. Body weights were recorded prior to dosing on day 1 and on days 8, 15, 29, 36, and 38. Skin irritation was scored prior to dosing, 24 hours after each induction treatment, and 24 and 48 hours after the challenge dose.

RESULTS:

One animal in the nonsensitized test group and one animal from the sensitized positive control group died. Deaths were reported to be unrelated to treatment. No skin irritation occurred in the sensitized test group during the induction phase or after the challenge dose and no irritation occurred in the nonsensitized test group after the challenge dose. Three out of nine animals in the sensitized positive control group exhibited scattered mild erythema on days 21 and 23 during the induction phase and 8/9 exhibited erythema after the challenge dose. No irritation occurred in the nonsensitized positive control group after the challenge dose.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizer.

People stander

Ridomil® PC 11G

006030

Granular Fungicide

ACCEPTED
with COMMENTS
in EPA Letter Dates:

For the control of damping-off diseases of cotton and pod rot diseases of peanuts

FEB 26 1986

Under the Federal Insecticide, Fungicide, and Rodenticid tet as amended, to the letter of the Programme of t

50 Pounds Net Weight

Ridomil PC 11G is a granular fungicide

Keep Out of Reach of Children

Caution

See additional precautionary statements on back of bag.

See directions for use on back of bag.

EPA Reg. No. 100-

EPA Est. 100-

Control No.

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CIBA-GEIGY

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DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

FAILURE TO FOLLOW THE DIRECTIONS FOR USE AND PRECAUTIONS ON THIS LABEL MAY RESULT IN POOR DISEASE CONTROL OR CROP INJURY.

General Information

Ridomil PC 11G is a granular fungicide containing 1% metalaxyl and 10% PCNB (pentachloronitrobenzene). Metalaxyl is a systemic fungicide which provides control of damping-off of cotton and pod rot of peanuts caused by Pythium spp. PCNB is a protectant fungicide which provides control of damping-off of cotton and pod rot of peanuts caused by Rhizoctonia solani, and suppression of pod rot caused by Sclerotium rolfsii.

Note: Metalaxyl is a systemic fungicide having a specific mode of action. Metalaxyl could be subject to development of resistant strains of fungi. Development of resistance cannot be predicted. Therefore, CIBA-GEIGY cannot assume liability for crop damage resulting from resistant strains of fungi. Consult with your State Agricultural Experiment Station or Extension Service Specialist for guidance or ways to control any possible metalaxyl resistant strains of fungi which may occur.

Cotton

Ridomil PC 11G will control damping-off, seed and seedling rot diseases caused by <u>Pythium</u> spp. and <u>Rhizoctonia solani</u>. For best results, use high quality seed and plant into a properly prepared seedbed.

Apply 10 lbs. of Ridomil PC llG per 13,000 linear feet of row at the time of planting. Adjust the application equipment so the granules are mixed with the soil surrounding the seed.....

Note: Do not allow the feeding or grazing of cotton foliage by livestock, or illegal residues may result.

Rotation Crops

When Ridomil PC 11G is used for disease control in cotton, do not rotate to any root crop within 12 months following application, or illegal residues may result.

Peanuts

Ridomil PC 11G will control pod rot caused by Pythium spp.
and Rhizoctonia solani, and suppress Sclerotium rolfsii. For best results, <a href="Ridomil PC 11G should be used in a program with cultural practices that aid in the control of pod rot.

Apply 100 lbs. of Ridomil PC llG per 13,000 linear feet of row at pegging. Adjust the application equipment so the granules are distributed over the row in a band approximately 14 inches wide.

Note: Do not allow the feeding or grazing of peanut foliage \overline{by} livestock, or illegal residues may result.

Rotation Crops

When Ridomil PC llG is used for disease control in peanuts, do not rotate to any root crop within 12 months following application. Small grain cover crops may be planted the fall following treatment provided they are plowed down and not used for food or feed. Corn, cotton, tomatoes and tobacco may be planted the year following treatment. Other crops may be planted 18 months following application.

Storage and Disposal

<u>Pesticide</u>

Store in a dry place. Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment. Open dumping is prohibited. Wastes resulting from the use of this product are toxic. Improper disposal of unused pesticide, spray mixture, or rinsate is a violation of federal law. Pesticide, spray mixture, or rinsate that cannot be used according to label instructions must be disposed of according to federal, state or local procedures. For guidance in proper disposal methods, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office.

Container Disposal

Completely empty bag into application equipment. Dispose of empty bag in a sanitary landfill or by incineration, or by open burning, if allowed by state and local authorities. If burned, keep out of smoke.

For minor spills, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire or other emergency, call (919) 292-7100 day or night.

Precautionary Statements

Hazards to Humans and Domestic Animals

CAUTION

Harmful if absorbed through the skin or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Statement of Practical Treatment

If in eyes: — Flush eyes with plenty of water. Call a physician if irritation persists.

If on skin: Wash with plenty of soap and water. Get medical attention.

If inhaled: Move to fresh air.

Environmental Hazards

This product is toxic to fish. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes.

Ridomil® trademark of CIBA-GEIGY Corporation for metalaxyl

*1985 CIBA-GEIGY Corporation Agricultural Division CIBA-GEIGY Corporation Greensboro, NC 27419

CGA

September 13, 1985

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