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

006255

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

APR 2 1987

MEMORANDUM

SUBJECT: EPA File Symbol 2217-TEE
Trimec 871

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

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: PBI/Gordon Corporation
1217 West 12th Street
P.O. Box 4090
Kansas City, MO 64101

ACTIVE INGREDIENTS:
2-methyl-4-chlorophenoxyacetic acid 45.59%
2-(2-methyl-4-chlorophenoxy)propionic acid 20.40%
Dicamba (3,6-dichloro-o-anisic acid) 4.30%
INERT INGREDIENTS: 29.71%

BACKGROUND:

The applicant has submitted an acute oral, acute dermal, acute inhalation, primary eye irritation, primary dermal irritation, and dermal sensitization studies. The studies were conducted by Cosmopolitan Safety Evaluation, Inc. The data are not accessioned. The method of support is selective.

RECOMMENDATION:

FHB/TSS finds the data acceptable to support registration and the signal word is "DANGER" based on the Primary Eye Irritation Study.

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LABELING:

1. The Statement of Practical Treatment for eye exposure must be moved to the front panel and grouped with the signal word and child hazard warning as required for all exposure routes falling in the Toxicity I Category.

2. Revise Statement of Practical Treatment for oral exposure as follows:

   If Swallowed: Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol. Do not induce vomiting or give anything by mouth to an unconscious person.

3. Add the following remark below the the Statements of Practical Treatment:

   NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

REVIEW:

(1) Acute Oral Toxicity Study: Cosmopolitan Safety Evaluation, Inc.; Study No. 1471A; July 8, 1986.

PROCEDURE:

Three groups of five male and five female Sprague-Dawley rats were administered a single oral dose by gavage of either 316, 630, or 1256 mg/kg of test material. Animals were observed frequently during the first 5 hours following dosing and twice daily thereafter for 14 days. Body weights were recorded on day of dosing and at 7 and 14 days. Animals were necropsied upon discovery of death or at 14 days.

RESULTS:

No deaths occurred at 316 mg/kg. At 630 mg/kg, 1/5 males and 1/5 females died. At 1256 mg/kg, 4/5 males and 4/5 females died. The LD_{50} for males and females was reported to be 891 (603-1316) mg/kg.

Toxic symptoms included decreased locomotor activity, ataxia, chromorhinorrhea, chromodacryorrhea, prostration, perineal staining, and lacrimation. Gross necropsy revealed

slightly mottled livers, congested intestines containing reddish-brown viscose matter, and pale kidneys.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(2) Acute Dermal Toxicity Study: Cosmopolitan Safety Evaluation, Inc.; Study No. 1471B; July 8, 1986.

PROCEDURE:

Five male and five female New Zealand White rabbits were clipped free of fur on the trunk and 24 hours later, each animal received 2000 mg/kg of test material moistened with 7 ml of saline. The moistened mixture was applied to the clipped intact skin. The test site was covered with occlusive wrap for 24 hours. After exposure, the wrap and any residual material was removed. Skin irritation was scored at 24 hours and at 3, 7, and 14 days. Animals were weighed on day of dosing and at 7 and 14 days. Animals were observed for mortality and pharmacotoxic signs frequently on day of dosing and once daily thereafter for 14 days. Animals were necropsied upon discovery of death or at 14 days.

RESULTS:

There were no deaths. The LD_{50} was reported to be > 2000 mg/kg. Toxic symptoms observed were ataxia, prostration, and decreased locomotor activity. Animals exhibited very slight erythema and slight to moderate edema which subsided by day 7. No abnormalities were noted at gross necropsy.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(3) Acute Inhalation Toxicity Study: Cosmopolitan Safety Evaluation, Inc.; Study No. 1471C; August 12, 1986.

PROCEDURE:

Five male and five female Sprague-Dawley rats were exposed for 4 hours in a plexiglass exposure chamber to a mean gravimetrically measured concentration of 1.1 mg/L of test material. A control group of five males and five females was exposed to air under similar conditions. Animals were observed during exposure and at 1, 3, and 5 hours following exposure and once daily thereafter for 14 days. Body weights were recorded prior to dosing and on days 2, 3, 4, 7, and 14. Animals were necropsied at study conclusion.

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RESULTS:

No deaths occurred. The LC_{50} was reported to be > 1.1 mg/L. Toxic symptoms were sluggish response, ataxia, chromorhinorrhea, and depressed activity. Gross necropsy of one male revealed patchy pleurisy of the left lung.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(4) Primary Eye Irritation Study: Cosmopolitan Safety Evaluation, Inc.; Study No. 1471D; July 8, 1986.

PROCEDURE:

Six albino rabbits which were found to be free of ocular injury or irritation were each administered 0.1 g of test material. The test material was placed inside the lower lid of one eye and the eye was then held shut for 1 minute. The other untreated eye served as the control. Eye irritation was scored at 1, 24, 48, and 72 hours and at 7, 10, 14, and 21 days.

RESULTS:

Eye irritation was scored as follows: at 24 hours, corneal opacity (4/6 = 20, 2/6 = 15), iris irritation (6/6 = 5), conjunctivae redness (2/6 = 2, 4/6 = 1) and chemosis (2/6 = 3, 3/6 = 2, 1/6 = 1); at 7 days, corneal opacity (1/6 = 60, 4/6 = 40, 1/6 = 20), iris irritation (5/6 = 5), conjunctivae redness (6/6 = 1), chemosis (2/6 = 2, 4/6 = 1), vascularization (5/6) and pannus (1/6); at 14 days, corneal opacity (1/6 = 60, 3/6 = 40, 2/6 = 20), conjunctivae redness (6/6 = 1), chemosis (5/6 = 1), vascularization (5/6) and pannus (1/6); and at 21 days, corneal opacity (4/6 = 30, 2/6 = 15), conjunctivae redness (3/6 = 1), chemosis (2/6 = 1), vascularization (6/6) and pannus (1/6).

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category I - DANGER.

(5) Primary Skin Irritation Study: Cosmopolitan Safety Evaluation, Inc.; Study No. 1471E; July 8, 1986.

PROCEDURE:

Six albino rabbits were clipped free of fur on the dorsal surface and approximately 24 hours later, each animal received 0.5 g of test material moistened with 0.6 ml of saline. The

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test sites were covered with occlusive wrap and after exposure, the wrap was removed and the residual material was removed using a clean moistened paper towel. Skin irritation was scored at 24, 48, and 72 hours.

RESULTS:

At 72 hours, 6/6 animals exhibited very slight erythema with superficial desquamation and 1/6 animals exhibited very slight edema. The Primary Irritation Score is 1.0.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category IV - CAUTION.

(6) Dermal Sensitization Study: Cosmopolitan Safety Evaluation, Inc.; Study No. 1471F; July 8, 1986.

PROCEDURE:

Ten male albino guinea pigs were clipped free of fur on the right side and at least once a week thereafter. Twenty-four hours after the first clipping, each animal received the first of three induction treatments which were administered once a week for 3 weeks and consisted of 0.5 g of test material (moistened with 0.6 ml of saline) applied to a clipped test site on the right side under occlusive wrap for 6 hours of exposure. After each exposure, the wrap was removed and the test site rinsed with warm water. After 2 weeks, animals were challenged at both the treated side and a virgin test site on the other side of the animal. Skin irritation was scored at 24 and 48 hours after each induction treatment and challenge treatment. Known sensitizers have been tested under the same conditions in the past.

RESULTS:

Skin irritation was scored as follows: After first induction treatment, 10/10 animals exhibited very slight erythema and 8/10 animals exhibited very slight edema; after second induction treatment, 9/10 animals exhibited very slight erythema, 1/10 animals exhibited well-defined erythema, and 8/10 animals exhibited very slight edema; and after the third induction treatment, 10/10 animals exhibited very slight erythema and 7/10 animals exhibited very slight edema. Twenty-four hours after challenge, 10/10 animals exhibited very slight erythema and 9/10 animals exhibited very slight edema at the previously treated test site and 10/10 animals exhibited very slight erythema and 5/10 animals exhibited very slight edema at the virgin test site.

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STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizer.

MCPP Toxicology review

Page _____ is not included in this copy.

Pages 7 through 9 are not included in this copy.

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

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___ Sales or other commercial/financial information

X A draft product label

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