

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

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OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

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SUBJECT: EPA File Symbol 3125-GAU APR | 5 1986

Bayleton 0.5% Granular EPA File Symbol 3125-GAG Bayleton 1% Granular

FROM: Mary L. Waller MM
Technical Support Section

Fungicide-Herbicide Branch Registration Division (TS-767C)

TO: Henry Jacoby, PM 21

Fungicide-Herbicide Branch Registration Division (TS-767C)

Applicant: Mobay Chemical Corp.

Agricultural Chemicals Division

P.O. Box 4913

Kansas City, MO 64120

ACTIVE INGREDIENT:

1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-

BACKGROUND:

The applicant has submitted an acute oral, acute dermal, acute inhalation, primary skin, and primary eye irritation study conducted on 3125-GAG to support both registrations. The studies were conducted by Mobay Chemical Corporation. The data Accession Number is 258091. The method of support is owner submission.

RECOMMENDATION:

FHB/TSS finds the acute oral, acute dermal, acute inhalation, primary dermal, and primary eye irritation studies

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acceptable to support registration of both products. A dermal sensitization study was not included with the data, and the registrant must submit this study. The signal word is "CAUTION."

The Product Manager should inform the registrant that for future acute inhalation studies, the LC₅₀ should be expressed in terms of actual concentration. LC₅₀ values expressed in terms of nominal concentration are unacceptable.

REVIEW:

(1) Acute Oral Toxicity Study: Mobay Chemical Corp.; Report No. 575; February 1, 1985.

PROCEDURE:

Two groups each consisting of five male and five female fasted rats received one of the following doses of test material via oral intubation: 1250 or 2500 mg/k. The 2500 mg/k dose was administered as two sequential 1250 doses spaced 30 minutes apart. Animals were observed twice daily for 14 days for mortality and toxic symptoms. At study conclusion, all animals were submitted for gross necropsy.

RESULTS:

One mortality occurred which was unrelated to treatment. Gross necropsy revealed that part of the test material had been inadvertently administered into the respiratory tract. The oral LD50 was reported to be > 2500 mg/k in rats of both sexes. Toxic symptoms observed included diarrhea, decreased activity, unthriftiness, salivation, lacrimation, and red nasal discharge. No gross lesions were observed at gross necropsy.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(2) Acute Dermal Toxicity Study: Mohay Chemical Corp.; Report No. 561; December 4, 1984.

PROCEDURE:

Five male and five female New Zealand white rabbits were shaved and 24 hours later, each animal received 2000 mg/k of test material applied to the shaven test site kept under occlusive wrap for 24 hours. Animals were restrained during exposure. After exposure the test site was wiped clean using

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a damp towel. Animals were weighed prior to study, and at 7 and 14 days. Animals were observed twice daily for 14 days for mortality and toxic symptoms. All animals were subjected to gross necropsy.

RESULTS:

No deaths, toxic symptoms, or gross lesions at necropsy were observed. Animals gained weight throughout study.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - Caution.

(3) Acute Inhalation Toxicity Study: Mobay Chemical Corp.; Report No. 586; February 12, 1985.

PROCEDURE:

Five male and five female Sprague-Dawley rats were exposed (head only) for 4 hours to a dust produced from the test material having a gravimetrically measured concentration of 6 to 21 mg/L. A control group of five males and five females was exposed to air for 4 hours under similar conditions. Animals were observed twice daily for 14 days. All animals were submitted for gross necropsy.

RESULTS:

No deaths occurred. The LC50 was reported to be 3150 mg/L (nominal concentration). The measured actual concentration was between 6.0 - 21 mg/L; therefore, we can assume that the LC50 is > 6.0 mg/L. Toxic symptoms included lacrimation and nasal and ocular irritation. Gross necropsy revealed one female with a severely dilated left renal pelvis and a depressed zone on the left kidney.

STUDY CLASSIFICATION: Core Minimum Data. See comments under Recommendation.

TOXICITY CATEGORY: Category IV - CAUTION.

(4) Primary Eye Irritation Study: Mobay Chemical Corp.; Report No. 560; December 4, 1984.

PROCEDURE:

Six New Zealand white rabbits each received 100 mg of the test material instilled in the left eye. The right eye served as the control. Eye irritation was scored at 1, 24, 48, and 72 hours and at day 8.

RESULTS:

Eye irritation at 24 hours was scored as follows: corneal opacity (3/6 = 20), iris irritation (6/6 = 1), conjunctivae redness (6/6 = 2), chemosis (1/6 = 2, 3/6 = 1), and discharge (1/6 = 2, 3/6 = 1). All irritation had cleared by day 8.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category III - CAUTION

(5) Primary Skin Irritation Study: Mobay Chemical Corp. Report No. 552; November 8, 1984.

PROCEDURE:

Six New Zealand white rabbits were shaved and approximately 20 hours later, each animal received 0.5 g of test material moistened with water and applied to a shaven test site. The test sites were kept under occlusive wrap for 4 hours, after which the wrap and any residual test material was removed. Skin irritation was scored at 30 minutes and at 24, 48 and 72 hours.

RESULTS:

No irritation occurred. The primary irritation index was 0.0.

STUDY CLASSIFICATION: Core Guideline Data

TOXICITY CATEGORY: Category IV - CAUTION

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