3-4-87

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 24 ...

MEMORANDUM

SUBJECT: EPA File Symbol 3125-GTA
Bayleton 216 Concentrate

FROM: Deloris F. Graham DFG 3/4/87
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

E 3/4/87

TO: Lois A. Rossi, Acting PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Mobay Corporation
Agricultural Chemicals Division
P.O. Box 4913
Kansas City, MO 64120

ACTIVE INGREDIENT:
1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-
1,2,4-triazol-1-yl)-2-butanone 22%
INERT INGREDIENTS: 78%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation, and Dermal Sensitization Studies to support conditional registration of this product. Studies conducted by Mobay Chemical Corporation. Data under Accession Number 264276. Method of support not indicated.

RECOMMENDATIONS:

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

2. The appropriate signal word is DANGER.

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LABEL:

The "It Swallowed" statement submitted should be revised to include "do not induce vomiting."

REVIEW:

(1) Acute Oral Toxicity Study: Mobay Chemical Corporation; Report No. 698; December 12, 1985.

PROCEDURE:

A group of five female rats received a single 1000 mg/kg dose of the test material orally. Three groups consisting of five male and five female rats each received one of the following doses: 1300, 1600, or 1900 mg/kg. One group of five male rats received a single 1450 mg/kg dose. Observations made for 14 days postdosing. Necropsy performed on all animals.

RESULTS:

At 1000 mg/kg, 2/5 F died; at 1300 mg/kg, 4/5 F died; at 1450 mg/kg, 3/5 M died; at 1600 mg/kg, 3/5 F and 5/5 M died; at 1900 mg/kg, 5/5 F and 4/5 M died. Toxic signs reported included decreased activity, urine stain, ataxia, salivation, lacrimation, hyperactivity, corneal opacity, tremors, and convulsions. Necropsy report revealed white eye zone, ocular neovascularization, fluid-filled stomach and small intestines; pinpoint black foci in glandular stomach mucosa; autolysis, dark tail, dark bladder fluid, small soft testes, cannibalism, inguinal discharge, and malocclusion in addition to toxic signs. LD_{50} for females reported to be 1090 mg/kg with 95 percent confidence limits (between 753 and 1549 mg/kg). LD_{50} for males reported to be 1470 mg/kg (982 to 2192 mg/kg).

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(2) Acute Dermal Toxicity Study: Mobay Chemical Corporation; Report No. 680; October 15, 1985.

PROCEDURE:

Five male and five female rabbits with intact skin sites were dosed with a single 2000 mg/kg dose of test material. The treated sites were placed under occlusive wrap for 24-hour exposure period. Observations made for 14 days postexposure. Necropsy performed on all animals.

2

RESULTS:

No mortalities reported. Erythema was the only toxic sign reported. Necropsy report revealed dry and crusty skin at dosing site. LD_{50} reported to be greater than 2000 mg/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Acute Inhalation Toxicity Study: Mobay Chemical Corporation; Report No. 677; October 10, 1985.

PROCEDURE:

Three groups consisting of 10 male and 10 female rats each were exposed head only to analytical concentrations of 1836 mg/m^3 or 2295 mg/m^3 or conditioned air (control). Mean MMAD was reported to be 2.4 µm with geometric standard deviation of 2.4. Temperature reported to range between 21.5 and 24.9 °C, and relative humidity between 19.5 and 69.0 percent. Observations made for 14 days exposure. Necropsy performed on all animals.

RESULTS:

At 1836 mg/m^3, 1/10 rats died due to rat crawling forward in restrainer and suffocating itself and not due to test substance according to report submitted. At 2295 mg/m^3, 1/10 animals reported dead. Toxic signs reported included salivation, labored breathing, decreased activity, and opacity. Necropsy report revealed sporadic lesions such as multiple depressed lung zones, red submaxillary salivary glands, ventral abdominal alopecia, granular spleen, corneal zones, raised uterine zone and enlarged left cervical lymph node, red turbinates, bilateral lacrimation, red cervical lymph nodes, red lungs, tan nasal discharge, and urine-stained ventrum. LC_{50} reported to be greater than 2295 mg/m^3 (2.295 mg/L). No-observable-effect level reported to be 1836 mg/m^3.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(4) Eye Irritation Study: Mobay Chemical Corporation; Report No. 681; October 15, 1985.

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PROCEDURE:

Six rabbits received 0.1 ml of the test material in one eye each. Observations made for 56 days posttreatment.

RESULTS:

At 24 hours posttreatment, 5/6 rabbits had corneal opacity (4/6 = 5, 1/6 = 10), iris irritation (5/6 = 5), conjunctive redness (3/5 = 2, 2/5 = 3) and discharge (1/6 = 2, 4/6 = 3); 6/6 conjunctive chemosis (1/6 = 1, 1/6 = 2, 3/6 = 3, 1/6 = 4). At day 7, 4/6 had corneal opacity (2/6 = 5, 2/6 = 10); 2/6 iris irritation (2/6 = 5); 5/6 redness (3/6 = 1, 2/6 = 2); 4/6 chemosis (2/6 = 1, 1/6 = 2, 1/6 = 3) and discharge (3/6 = 1, 1/6 = 3). At 21 days, 3/6 had corneal opacity (2/6 = 5, 1/6 = 10); 1/6 redness (1/6 = 1); 3/6 chemosis (2/6 = 1, 1/6 = 2); 1/6 discharge (1/6 = 2). At 56 days, 3/6 had corneal opacity (3/6 = 5).

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: I - DANGER.

(5) Primary Dermal Irritation Study: Mobay Chemical Corporation; Report No. 679; October 15, 1985.

PROCEDURE:

Six rabbits with intact skin sites each received a 0.5 ml application of the test material under occlusive wrap for 4-hour exposure period. Observations made for 14 days posttreatment.

RESULTS:

At 24 hours posttreatment, 6/6 rabbits had well-defined erythema (6/6 = 2) and 1/6 slight edema (1/6 = 1). At 72 hours, 6/6 had slight to well-defined erythema (1/6 = 1, 5/6 = 2). Irritation cleared by day 14.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(6) Dermal Sensitization Study: Mobay Chemical Corporation; Report No. 688; November 21, 1985.

PROCEDURE:

Fifteen guinea pigs received 0.5 ml applications once a week for 3 weeks totaling three induction phase applications.

The first two applications were made using undiluted test material and the third using a 50 percent solution of test material in deionized water. Two weeks after third induction phase application a challenge dose was applied. Two weeks after challenge a rechallenge dose was applied to 15 animals of test group and an additional five animals of untreated negative control group. Observations made at 24 and 48 hours after each induction application and 48 and 72 hours after each challenge application.

RESULTS:

Slight to well-defined erythema noted throughout induction period. At 48 and 72 hours after challenge, slight to well-defined erythema produced in test group as well as naive control. However, the solvent blank tested was reported to have reached scores in excess of test material, but were not listed. At rechallenge with a 12.5 percent solution, slight to well-defined erythema in test group, but no irritation produced in naive control group. Therefore it is concluded that this product may cause a dermal sensitization reaction.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Sensitizing Agent.

RID 5711-93

TRIADIMEFON TOX REVIEWS

Page_____ is not included in this copy.

Pages 6e through 7 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.

__✓__ 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.
