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

C06C85

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 20 87

MEMORANDUM

SUBJECT: EPA File Symbol 7364-UN
Algimycin GLB-X-II

FROM: Deloris F. Graham DFG 7/27/87 E 7/27/87
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

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

APPLICANT: Great Lakes Biochemical Company
6120 West Douglas Avenue
Milwaukee, WI 53218

ACTIVE INGREDIENTS:
Simazine: 2-chloro-4,6(ethylamino)-
5-triazine 3.0%
INERT INGREDIENTS: 97.0%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Eye Irritation, Dermal Irritation, Dermal Sensitization Studies and rationale for not submitting Acute Inhalation Study. Studies conducted by Hazleton Laboratories America, Inc. Data under EPA MRID Nos. 401904-01 through 05. Method of support not indicated.

RECOMMENDATION:

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

2. The rationale submitted in lieu of the acute inhalation study is sufficient to support waiver. Additional information such as sieve analysis of formulated product indicating particle size in

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relation to percent of product may support waiver. See Proposed Testing Guidelines, Section 81-3.

3. Based on data submitted appropriate signal word is CAUTION.

LABEL:

1. The subheading "CAUTION" under the "Directions For Use" heading must be deleted and replaced with another heading.

2. The precautionary statements should precede directions for use.

3. See attached copy for appropriate labeling procedure and format.

4. The statement "may cause allergic skin reaction" must be included in precautionary statements.

REVIEW:

(1) Acute Oral Toxicity Study: Hazleton Labs.; Project ID 70103654; March 10, 1987; EPA MRID No. 401904-01.

PROCEDURE:

Three groups consisting of five male and/or female rats each received one of the following doses: 4.0 (females only), 5.0, and 6.0 (females only) g/kg. Observations made for 14 days postexposure. Necropsy performed on all animals.

RESULTS:

At 4.0 g/kg, 2/5 F died; at 5.0 g/kg, 2/5 F died; at 6.0 g/kg, 5/5 F died. Toxic signs reported include hypoactivity, diarrhea, red-stained face, ataxia, yellow-stained genital region. Necropsy report revealed stomach - contains yellow fluid material; small intestines - contains yellow mucoid semifluid material; submandibular lymph nodes enlarged; lungs - mottled red and dark red; stomach - contains a clear fluid and white caseous material with multiple, red focal areas; perineum - stained brown; stomach - contains green and white, and brown and white fibrous material. LD_{50} for males reported to be greater than 5 g/kg. LD_{50} for females reported to be 4.8 g/kg with 95% confidence limits between 3.9 and 5.8 g/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(2) Acute Dermal Toxicity Study: Hazleton Labs; Project ID 70103655; March 17, 1987; EPA MRID No. 401904-02.

PROCEDURE:

Five male and five female rabbits each received 2 g/kg of the test material under occlusive wrap for a 24-hour exposure period. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

No mortalities, clinical signs, or abnormalities at necropsy reported. LD_{50} reported to be greater than 2.0 g/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Eye Irritation Study: Hazleton Labs.; Project ID 70103657; March 2, 1987; EPA MRID No. 401904-03.

PROCEDURE:

Six rabbits received 0.07 g (≈0.1 ml) of the test material in one eye each. Observations were made for 7 days posttreatment.

RESULTS:

At 1 hour posttreatment, 5/6 rabbits had iris irritation (5/6 = 5). At 24 hours posttreatment, 6/6 rabbits had conjunctive redness (6/6 = 2); 5/6 chemosis (5/6 = 1). Irritation had cleared by day 7.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(4) Primary Dermal Irritation Study: Hazleton Labs.; Project ID 70103656; March 6, 1987; EPA MRID No. 401904-04.

PROCEDURE:

Six rabbits with intact skin sites each received a 0.5 g moistened with 0.9% saline under occlusive wrap for a 4-hour exposure period. Observations made for 96 hours posttreatment.

RESULTS:

At 24 hours, 1/6 rabbits had slight erythema (1/6 = 1). Irritation clear at 48 hours posttreatment.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: IV - CAUTION.

(5) Dermal Sensitization Study: Hazleton Labs.; Project ID 70103658; April 14, 1987; EPA MRID No. 401904-05.

PROCEDURE:

Ten male guinea pigs received six 0.05 ml intradermal injections (one row of three on either side of animal midline) of the following: Freund's Adjuvant Solution; 5% w/v test material in sterile water and 5% w/v test material in Freund's Complete Adjuvant mixture. Six days after intradermal injection the test sites were pretreated with 10% w/w sodium lauryl sulfate in petrolatum 24 hours prior to a topical application of a 25% w/w suspension of test material in petrolatum. Two weeks after topical induction phase application, a challenge dose using 25% w/w suspension of the test material was applied to the test group and to naive control group. Observations made at 24 and 48 hours postapplication.

RESULTS:

Slight irritation in 2/10 guinea pigs at 24 hours post-challenge of test group; no irritation produced in naive control group. It was concluded that a mild sensitization response was produced.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Sensitizing agent.

Attachment

SIMAZINE

Page____ is not included in this copy.

Pages 5 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.

__X__ 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.