3-27-86

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

006262

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 19 1985

MEMORANDUM

SUBJECT: EPA File Symbol: 538-ENG
Proturf Fluid Fung[illegible]e II

FROM: Deloris F. Graham 3/27/86
Technical Support [illegible]ection
Fungicide-Herbicid[illegible] Branch
Registration Division (TS-767C)

E 3/27/86

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: O.M. Scott & Sons Company
14310 Scottslawn Road
Marysville, OH 43041

ACTIVE INGREDIENTS:

960 AA Triadimefon, 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone	16.0%
375 AA Metalaxyl, N-2(2,6-Dimethylphenyl)-N-(methoxyacetyl)alanine, methyl ester	16.0%
INERT INGREDIENTS:	68.0%

BACKGROUND:

Submitted Acute Oral, Acute Dermal, Eye Irritation, Primary Dermal Irritation, and Dermal Sensitization Studies. Studies conducted by Hazleton Laboratories America, Inc. Studies under Accession Number 258183, "Selective" method of support used.

RECOMMENDATION:

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

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2. An Acute Inhalation Study was not submitted and one must be submitted or data to support waiver.

3. The appropriate signal word is DANGER.

LABEL: No labeling comments.

REVIEW:

(1) Acute Oral Toxicity Study: Hazleton Laboratories; Sample No. 40700723; August 29, 1984.

PROCEDURE:

Five groups consisting of five male and five female Sprague-Dawley rats each received one of the following doses of test material: 1.00, 1.64, 2.56, 3.20, or 5.00 g/kg. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

At 1.64 g/kg, 4/5 F; at 2.56 g/kg, 2/5 M and 5/5 F; at 3.20 g/kg, 4/5 M and 5/5 F died; at 5.00 g/kg, 5/5 M and 5/5 F died. Toxic signs reported included hypoactive, hypersensitive to touch, brown-stained hair coat, prostration, ataxia, red stain around eyes, nose, and mouth, tonic convulsions, piloerection, yellow-stained abdomen, dyspnea, mydriasis, swollen face, decreased limb tone, ulcerated upper lip, excessive salivation, yellow-stained anal region, black stain around eyes and nose, and black-stained anal area. Necropsy report revealed uterus - enlarged, each horn filled with clear fluid; lungs - multifocal firm, grey areas on all lobes; stomach - distended with thick orange fluid, nonglandular mucosa diffusely red; tail and hind feed appear cannibalized and necrotic; stomach - distended with yellow creamy material; intestinal tract - contains white and tan creamy material which has a gasoline-like odor. LD_{50} for males reported to be 2.75 g/kg with 95% confidence limits between 2.16 and 3.50 g/kg. LD_{50} for females reported to be 1.36 g/kg with 95% confidence limits between 1.05 and 1.77 g/kg.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

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(2) Acute Dermal Toxicity Study: Hazleton Laboratories; Sample No. 40700723; August 7, 1984.

PROCEDURE:

Five male and five female New Zealand rabbits received 2.0 g/kg of the test material under occlusive wrap for 24-hour exposure. Observations made for 14 days posttreatment. Necropsy performed on all animals.

RESULTS:

No mortalities or toxic signs reported. Necropsy report indicated two animals with crusted, thickened, and/or reddened treated skin. LD_{50} reported to be greater than 2.0 g/kg. Erythema, edema, atonia, desquamation, consciousness, fissuring, eschar, subcutaneous hemorrhage, blanching, and exfoliation also noted.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: III - CAUTION.

(3) Eye Irritation Study: Hazleton Laboratories; Sample No. 40700723; August 13, 1984.

PROCEDURE:

Six New Zealand rabbits received 0 1 ml of the test material in one eye each. Observations made for 21 days posttreatment.

RESULTS:

At 24 hours, 6/6 had corneal opacity (6/6 = 20); 5/6 iris irritation (5/6 = 5); 6/6 conjunctive redness (1/6 = 2, 5/6 = 3), chemosis (1/6 = 2, 4/6 = 3, 1/6 = 4) and discharge (4/6 = 2, 2/6 = 3); iris injected, blanching of conjunctivae, purulent and clear discharge also noted.

At 7 days, 6/6 corneal opacity (1/6 = 15, 1/6 = 20, 4/6 = 40) and pannus, iris irritation (6/6 = 5), redness (2/6 = 2, 4/6 = 3), chemosis (5/6 = 3, 1/6 = 4), and discharge (1/6 = 1, 4/6 = 2, 1/6 = 3). Iris injected and purulent discharge noted.

At 21 days, 6/6 had corneal opacity (2/6 = 5, 1/6 = 15, 3/6 = 20); 3/6 had pannus; 2/6 iris irritation (2/6 = 5); 5/6 redness (2/6 = 2, 3/6 = 3), and chemosis (4/6 = 3, 1/6 = 4); 3/6 discharge (3/6 = 1). Iris injected, corneal epithelial peeling, and granulation scar tissue also noted.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: I - DANGER.

(4) Preliminary Dermal Irritation Study: Hazleton Laboratories; Sample No. 40700723; August 1, 1984.

PROCEDURE:

Six New Zealand rabbits received 0.5 ml of the test material at intact skin sites under occlusive wrap for 4-hour expcsure period. Observations made for 7 days posttreatment.

RESULTS:

At 24 hours 6/6 animals had well-defined erythema (scores of 2) and 5/6 slight to moderate edema (scores of 1, 2, and 3). At 72 hours, 6/6 had slight to moderate erythema (scores of 1, 2, and 3) and 5/6 slight to moderate edema (scores of 1, 2, and 3). Fissuring noted at 96 hours; erythema and edema persisted. All irritation except fissuring in 1/6 animals had cleared by day 7.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITIY CATEGORY: III - CAUTION.

(5) Dermal Sensitization Study: Hazleton Laboratories; Sample No. 40700724; September 24, 1984.

PROCEDURE:

During induction phase a group of 10 male guinea pigs received 3 (once a week for 3 weeks) 0.4 ml topical applications of a 1.0% w/v concentration of the test material in distilled water; another group of 4 male guinea pigs were treated in same manner as previous group except a 0.3% w/v concentration of 2,4-dinitrochlorobenzene (positive control) in 80% ethanol/distilled water. Two weeks after third induction phase application, a challenge dose was administered to the test group and to 10 naive control animals (male guinea pigs) at the same concentration as used in induction phase. However, the positive control group was challenged with a 0.1% w/v of 2,4-dinitrochlorobenzene in acetone. Observations made at 24 and 48 hours after each application.

RESULTS:

Two test group animals displayed slight weight loss; however, no irritation was produced during induction phase or challenge dose. One animal in naive control group had slight irritation at challenge. Due to moderate to severe reaction produced by 2,4-dinitrochlorobenzene, a sensitizing reaction is indicated thereby confirming it as a positive control. Since no irritation was produced in test group, it is concluded that this product is not a sensitizing agent.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Nonsensitizing.

METALAXYL

Page_____ is not included in this copy.

Pages 6 through 9 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.