

7-20-83

Date: July 14, 1983

Subject: EPA File Symbol 538-RIL
Proturf Pythium Control

005135

From: Deloris P. Graham *DFG 7/20/83*
FHB/TSS *E 7/20/83*

To: Henry Jacoby
Product Manager (21)

Applicant: O. M. Scott & Sons Company
Attn: Michael P. Kelty
Marysville, Ohio 44131

Active Ingredient:

Metalaxyl M-(2,6-Dimethylphenyl)-N-
(2,6-Dimethylphenyl)-N-methoxyacetyl)

alanine, methyl ester..... 1.21%
Inert Ingredients..... 98.79%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Primary Skin Irritation Studies. Studies conducted by Hazleton Raltech, Inc. Data under Accession Number 249999. Alternate Method of Support used.

Recommendation:

1. FHB/TSS finds these data acceptable to support conditional registration of this product.
2. An Acute Inhalation Study was not submitted and one must be submitted and/or cited or a justification as to why this study is not necessary.
3. The appropriate signal word is CAUTION.

Label:

1. The statement "Do not contaminate feed or foodstuffs. Do not feed clippings to livestock. Keep children and pets off treated area until material has been washed off the foliage and the area is completely dry" must be deleted from precautionary statements and placed under the heading "Directions for Use."

Review:

1. **Acute Oral Toxicity Study:** Hazleton Raltech, Inc.; Lab. #730974; January 20, 1983.

Procedure: 5M and 5F Sprague-Dawley rats weighing between 200 and 289 g received 5 g/kg of the test material orally. Observations were made for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities. Toxic signs observed include diarrhea, brown stained anal area. Necropsy revealed lungs - diffuse, pinpoint, gray foci on all lobes, small raised area on right caudal lobe, dark red with white center; liver - liver-like protrusion, spherical in shape, adhered to diaphragm; thymus - reddened on right side. LD₅₀ greater than 5.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

2. Acute Dermal Toxicity Study: Hazleton Raltech, Inc.; Lab. #730974; January 20, 1983.

Procedure: Five male and five female New Zealand rabbits weighing between 2573 and 2926 grams received 2 g/kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure. Observations were made daily for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities. Erythema, edema, atonia, desquamation, fissuring and coriaceousness noted. No other toxic signs noted. Necropsy revealed treated skin crusty; left salivary gland reddened. LD₅₀ greater than 2 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

3. Skin Irritation Study: Hazleton Raltech, Inc.; Lab. #730974; January 10, 1983.

Procedure: Six New Zealand rabbits received 0.5 g of the test material on two abraded and two intact skin sites per animal under occlusive wrap for 24 hour exposure. Observations were made at 24 and 72 hours after treatment.

Results: At 24 hours, 6/6 slight to well defined erythema (scores of 1, 1.5 and 2.0) and slight to well defined edema (scores of 1, 1.5 and 2.0). At 72 hours, 6/6 had slight to well defined erythema (scores of 1, 1.5 and 2.0) and 4/6 slight edema (score of 1). Dermal Irritation Score = 1.3.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

4. Eye Irritation Study: Hazleton Raltech, Inc.; Lab. #730974; January 13, 1983.

Procedure: Nine New Zealand rabbits received 0.1 g of the test material in one eye each. The treated eyes of three of the rabbits were washed with lukewarm water 30 seconds after treatment. Observations were made at 24, 48, 72 and 96 hours and at 7 days after treatment.

Results: At 24 hours, 4/6 animals of the unwashed group had corneal opacity (2/6=5, 1/6=10, 1/6=11.25) and no corneal opacity in 3/3 animals of the washed group; 5/6 iris irritation (5/6=5); 6/6 and 3/3 conjunctive redness (1/6=1, 5/6=3)(1/3=1.5, 2/3=2); 5/6 chemosis (2/6=2, 3/6=3); 5/6 and 1/3 discharge (2/6=1, 1/6=1.5, 2/6=2.5)(1/3=1).

At 96 hours, 1/6 corneal opacity (1/6=11.25); 5/6 and 1/3 conjunctive redness (4/6=1, 1/6=2)(1/3=1); 2/6 chemosis (1/6=1, 1/6=1.5) and 1/6 discharge (1/6=1).

At 7 days, corneal opacity and all other irritation had cleared.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

METALAXYL

Page _____ is not included in this copy.

Pages 4 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.
