UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATE: May 1, 1980

SUBJECT: EPA Registration No. 538-RAR
Proturf Fungicide VII: Caswell #

FROM: Deloris Graham DGH 5/27/80
EHB/TSS E 5/27/80

TO: Henry Jacoby
Product Manager (21)

Applicant: O. M. Scott and Sons Company
Marysville, Ohio 43040

Active Ingredient: Triadimefon 1-(4-chloro-phenonxy)-3,3-dimethyl-1-(1,2,4-triazol-1-yl)-butan-2-one 0.59%

Inert Ingredients: 99.41%

Background:

An Acute Oral, Acute Dermal, Eye and Skin Irritation Studies were submitted in support of the conditional registration of this product. The Alternate Method of Support is used. These studies were conducted by Raltech Scientific Services, Inc., Madison, Wisconsin. The Accession Number is 241971.

Recommendations:

1. The Acute Oral, Acute Dermal, Eye and Skin Irritation studies submitted in support of the conditional registration of this product are acceptable. However; for future submission,

   a. In the Skin Irritation Study you ~~must report~~ response data must be individually per animal at 24 and 72 hours.

2. Must submit an Acute Inhalation Study.

3. FHB/TSS has no objections to the conditional registration of this product provided an acceptable Acute Inhalation Study is submitted.

4. As determined by the data submitted the appropriate signal word is WARNING.

5. Please note that further labeling revisions may be necessary upon submission of the Acute Inhalation Study.

6. Under the heading "Procedure" for the Acute Oral Study (page 1) please clarify hours observed (1, 2, 5? and 4 hours).

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EPA FORM 1320-6 (REV 3-76)

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Label:

1. In the precautionary statement revise "Get medical attention if irritation persists" to "For eyes, get medical attention."

Review:

1. Acute Oral Toxicity Study: Raltech Scientific Services, Inc.; January 9, 1980; Lab. No. 763204.

Procedure: 5M and 5F Sprague - Dawley rats (222 to 250g) received a dosage of 5.0g/Kg as a mixture in corn oil. Observations were made at 1, 2, (5?) and 4 hours after dosing and daily thereafter for 14 days. Necropsy performed on animals. Body weights were recorded.

Results: No mortalities. Diarrhea present in some animals at 0-4 hours but had subsided by day 1. All animals appeared normal at 1-14 days. All animals gained weight. Necropsy revealed lungs: moderate, diffuse, raised white areas, dark red and mottled, dark red with white pinpoint foci; right anterior lung adhered to thoracic wall on a 3mm area; left kidney: round, has a thin connective tissue attachment to gastro-intestinal mesentery; thymus: hemorrhagic areas. LD50 for females and males is greater than 5g/Kg.

Study Classification: Core Guideline Data

Toxicity Category: IV-CAUTION

2. Acute Dermal Toxicity Study: Raltech Services, Inc.; Feb. 7, 1980; Lab. No. 763204

Procedure: 5M and 5F New Zealand white rabbits (2301 to 3000g) received a 2.0g/Kg dose of the test material on abraded sites under occlusive wrap for 24 hours. Observations were made daily after dosing for 14 days. Body weights were recorded. Necropsies were performed on all animals.

Results: No mortalities. All animals gained weight. At day 1, 7/10 animals had very slight erythema; 1/10 had very slight edema. By day 4, all irritation had cleared. On day 6, 1/10 animals exhibited desquamation, but had cleared by day 7. Other symptoms include loose stool in 1/10 animals on day 4, but had subsided by day 5.

9/10 animals had no visible abnormalities on necropsy. One animal had a hemorraghic area extending from left kidney to sublumbar region. LD50 is greater than 2.0g/Kg in both males and females.

Study Classification: Core Guideline Data

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Toxicity Category: III-CAUTION

3. Eye Irritation Study: Raltech Scientific Services, Inc., January 17, 1980; Lab No. 763204.

Procedure: Nine New Zealand white rabbits received 0.1g of the test material in one eye. Six rabbits had unwashed eyes and three rabbits had washed eyes. Observations were made at 24, 48, 72 and 96 hours and at 7 days after treatment. Body weights were recorded.

Results: 5/6 unwashed eyes had corneal opacity (5/6 = 5, 1/6 = 10, 1/6 = 43.75, 1/6 = 50) and iris irritation (5/6 = 5), on day 1. Corneal opacity persisted through 72 hours and iris irritation through day 4. Conjunctival redness and chemosis persisted through day 4, but discharge had subsided by day 4. On day 7, all unwashed eyes had no corneal opacity or irritation.

In washed eyes at 24 hours, no corneal opacity, 1/6 had iris irritation (1/6 = 5); 3/6 had conjunctival redness (3/6 = 1). All scores were zero at day 7.

Study Classification: Core Guideline Data

Toxicity Category: II-WARNING

4. Skin Irritation Study: Raltech Scientific Services, Inc.; January 9, 1980; Lab. No. 763204.

Procedure: 3M and 3F New Zealand white rabbits were administered a 0.5 gm dose of the test material at 2 abraded and 2 intact areas per rabbit under occlusive wrap for 24 hours. Observations were made at 24 and 72 hours.

Results: At 24 hours, Primary Dermal Irritation Score = 0.2 and at 72 hours was 0.0. Primary Dermal Irritation Index = 0.1.

Study Classification: Core Minimum Data. Must report response data individually per animal at 24 and 72 hours.

Toxicity Category: IV - CAUTION

RID 5711-93

TRIADIMEFON TOX REVIEWS

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.
