3-8-83

Date: March 8, 1983

Subject: EPA File Symbol: 538-RIG
Proturf Fluid Fungicide

005026

From: Deloris F. Graham
FHB/TSS E 3/9/83

To: Herdrey Pacoby
Product Manager (21)

Applicant: O. M. Scotts Company
Marysville, Ohio

Active Ingredients:
Thiophanate-methyl, Dimethyl [(1,2-phenylene) bis (iminocarbonothioyl)] bis [carbamate] . . . 19.65%
Iprodione, 3-(3,5-Dichlorophenyl)-N-(1-methyl ethyl)-2,4-dioxo-1-imidazolidinecarboxamide 19.65%
Inert Ingredients 60.70%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation and Skin Irritation Studies. Studies conducted by Hazleton Raltech, Inc. Data under accession number 249270. Alternate method of support.

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.

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(3) The appropriate signal word is CAUTION.

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Label:
(1) The statement "Do not contaminate feed or foodstuffs. Do not graze treated areas. Do not feed clippings to livestock" must be deleted from precautionary statements and placed ~~in~~ under "Directions For Use".

Reviewer:
(1) Acute Oral Toxicity Study: Hazleton Raltech, Inc.; RJ Lab. # 987196; September 23, 1982.

Procedure: Five male and five female rats received 5g/kg of the test material orally. Observations were made at 1, 25 and 4 hours after treatment, then daily thereafter for 14 days. Necropsy performed on all animals.

Results: No mortalities. Toxic signs observed included diarrhea, soft stools, hypoactivity, urine stained abdomen, hypersensitive to touch, tremors, lacrimation, ataxia, decreased limb tone, piloerection, brownish stained anal and urogenital area and miosis in one animal. Necropsy revealed - right axillary region - subcutaneous mass, firm, tan, red, lobular, 2.0 cm in diameter

nodes appears mildly enlarged; uterus - mild hydrometra. LD50 greater than 5g/Kg for males and females.

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Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

(2) Acute Dermal Toxicity Study: Hazleton Raltech, Inc; Lab.# 987196; September 9, 1982.

Procedure: Five male and five female rabbits recieved 2g/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, desquamation and fissuring noted. Necropsy revealed skin intact area reddened and mildly thickened; no other abnormalities. LD50 greater than 2g/Kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(3) Eye Irritation Study: Hazleton Raltech, Inc; Lab.# 987196; September 3, 1982.

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

Results: At 24 hours 2/6 animals of the unwashed group had corneal opacities (4/6=5); 2/6 iris

irritation (2/6=1); 4/6 and 3/3 animals of the washed group had redness (3/6=1.5, 3/6=2.0)(2/3=1.0, 1/3=1.5) 4/6+3 Chemosis (3/6=1.0, 1/6=1.5) (1/3=1.0) and discharge (4/6=1) (1/3=1).

At 96 hours 4/6 had redness (4/6=1); no other irritation present. Redness had cleared by day 7.

Study classification: Core Guideline Data -

Toxicity Category: III - CAUTION

(4) Skin Irritation Study: Hazleton Raltech, Inc.; RI lab.# 987196; August 29, 1982.

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

Results: At 24 hours, 6/6 erythema (4/6=1.0, 1/6=1.5, 1/6=2.0) and edema (4/6=1, 2/6=1.5). At 72 hours, 2/6 had erythema (4/6=1) and 1/6 edema (1/6=1), Primary Dermal Irritation Score was 0.8.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

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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.

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____ Sales or other commercial/financial information.

X A draft product label.

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