## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

002027

DATE: May 27, 1981

SUBJECT: EPA File Symbol: 538-RAI

Improved Super Turf Builder Plus 2: Caswell #

Deloris F. Graham AFB 4/1/81
FHB/TSS

E 6/2/6/ FROM:

TO: Richard Mountfort Product Manager (23)

> Applicant: O.M. Scott and Sons Marysville, Ohio 43041

Active Ingredient:

2,4-Dichlorophenoxyacetic acid..... Inert Ingredients.....

Background: Submitted revised precautionary labeling and petition to change signal word from WARNING to CAUTION based on Policy and Criteria Notice 2161.2. Million of support med material.

## Recommendation:

(1) Based on the re-evaluation of the Eye Study initially submitted and the new criteria set forth in Policy and Criteria Notice 2161.2. the appropriate signal word is CAUTION.

## Review:

(1) Eye Irritation Study: Raltech Scientific Services, Inc.: RT Lab. #759034; December 18, 1979.

Procedure: 9 New Zealand white rabbits received a 0.1g dose of the test material in one eye of each rabbit. The animals were divided into two groups, Group I consisting of 6 rabbits with treated washed eyes and Group II consisting of 3 rabbits with treated washed eyes.

Observations were made at 24, 48, 72 and 96 hours, and at 7 days after treatment. If injury present at day 7, observations were made at 14 and 21 days.

Results: In Group I at 24 hours, 6/6 animals had corneal opacity (1/6 = 1.25, 1/6 = 2.5, 1/6 = 5.0, 1/6 = 7.5, 2/6 = 15), 5/6 iris irritation (5/6 = 5) and 6/6 conjunctive redness (1/6 = 1.5, 3/6 = 2.0, 2/6 = 2.5),chemosis (2/6 = 1.5, 2/6 = 2.0, 2/6 = 2.5) and discharge (1/6 = 1.0, 1/6)= 1.5, 2/6 = 2.0, 1/6 = 2.5, 1/6 = 3.0). Corneal opacity present through day 21, iris irritation and conjunctival irritation present through day 7.

In Group II at 24 hours, 3/3 animals had corneal opacity (1/3 = 7.5, 1/3)= 11.25, 1/3 = 15.0), 3/3 iris irritation (3/3 = 5), 3/3 conjunctive

rednass (1/3 = 1.5, 1/3 = 2.0, 1/3 = 2.5), chemosis (2/3 = 1.5, 1/3 = 2.5) and discharge (2/3 = 1.0, 1/3 = 2.0). Corneal opacity clear at 48 hours; iris irritation persisting through 48 hours. Conjunctive redness through 96 hours. Other symptoms observed included blanching, purulent discharge, clear discharge.

Study Classification: Core Guideline Data.

Toxicity Category: (III - CAUTION) to category I DANCER Milely

(2) Eye Irritation Study: Cannon Laboratories, Inc.; May 28, 1980. 3/83

Procedure: 9 New Zealand white rabbits received a 0.1g of the test material instilled into one eye of each rabbit. Animals were divided into two groups, Group I consisting of 6 animals with treated unwashed eyes. Observations were made at 24, 48 and 72 hours as well as 4, 7, 10, 13, 16, 19 and 21 days after instillation of the test material.

Results: At 24 hours in Group I, 6/6 animals had corneal opacity (1/6 =  $\frac{5}{1}$ ,  $\frac{1}{6}$  =  $\frac{10}{5}$ ,  $\frac{3}{6}$  =  $\frac{15}{1}$ ,  $\frac{1}{6}$  =  $\frac{20}{1}$ ; 6/6 iris irritation (6/6 = 5); 6/6 conjunctival redness (6/6 = 5), chemosis (4/6 = 2, 2/6 = 3) and discharge (6/6 = 3). Corneal opacity persisted through day 19. Iris irritation cleared by day 7 and conjunctival irritation by day 13.

At 24 hours in Group II, 2/3 corneal opacity (1/3 = 5, 1/3 = 15), 1/3 iris irritation (1/3 = 5), 3/3 conjunctive redness (3/3 = 2), chemosis (3/3 = 1) and discharge (3/3 = 1). Corneal opacity cleared by 72 hours, iris irritation by 48 hours and conjunctival irritation by day 7. Pannus was also observed.

Study Classification: Core Guideline Data.

Toxicity Category: (III - CAUTION)

Category I DANGER

(3) Eye Irritation Study: WIL Research Laboratories, Inc.; WIL - 80122; May 28, 1980.

Procedure: 9 New Zealand white rabbits received a 100 mg in the right eye of each animal. Animals were divided into two groups, Group I consisted of 6 animals with treated unwashed eyes, and Group II consisted of 3 animals with washed eyes. Observations were made frequently during the day of dosing and at least twice daily thereafter for 14 days.

Results: At 24 hours, 4/6 animals had corneal opacity (3/6 = 5, 1/6 = 10); no iris irritation; 6/6 conjunctive redness (3/6 = 2, 3/6 = 3); 6/6 conjunctive chemosis (5/6 = 2, 1/6 = 3) and 4/6 conjunctive discharge (2/6 = 1, 2/6 = 3). Corneal opacity clear in all animals except 1 on day 10. All conjunctive irritation clear by day 7.

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In Group II, no corneal opacity or iris irritation. 3/3 had conjunctive redness (2/3 = 1, 1/3 = 2) and chemosis (2/3 = 1, 1/3 = 2). All irritation clear by day 4.

Study Classification: Core Guideline Data

Toxicity Category: Toxicity Category: If - CAUTION I mot unut.

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