1965-774
TXR-000035

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: August 4, 1980

000035

SUBJECT: EPA Registration Number: 538-72
Super Turf Builder Plus 2 for Grass: Caswell # 315 & 559

FROM: Deloris F. Graham DFG 8/14/80
FHB/TSS E 8/26/80

TO: Richard Mountfort
Product Manager (23)

Applicant: O.M. Scotts & Sons Company
Attention: Gerald L. Born
Marysville, OH 43040

Active Ingredient:
2,4-Dichlorophenoxyacetic acid..... 0.55%
2-(2-methyl-4-chlorophenoxy)propionic acid..... 0.55%

Inert Ingredients:..... 98.90%

Background:

Submitted new eye toxicology data changing the precautionary statements from CAUTION to WARNING, requesting an alternate inert ingredient and minor label revisions.

Recommendations:

1. FHB/TSS agrees with the applicant that the correct signal word for the product tested is WARNING, however, the study does not state whether the test substance was the original formulation or the alternate formulation as proposed. Please submit clarification of this point.

2. In the pesticidal/fertilizer formulations, each formulation proposed and any inerts, other than the fertilizer grades must be identical; i.e. surfactants, wetting agents, etc. for registration under the same registration number.

3. It could not be determined if the change in signal word from CAUTION to WARNING based on the change in eye irritancy is directly related to the change in inert ingredients. If

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this change in eye irritancy is due to the change in inert ingredients then this application for amended registration is not appropriate. Please see CFR 40-162.21(a)(i).

4. FHB/TSS objects to the proposed changes until test substance is identified and the appropriate method of submission is determined.

Label:

1. Reserve labeling comments until test substance is identified and the appropriate method of submission is determined.

Review:

1. Eye Irritation Study: Raltech Scientific Services, Inc.; March 19, 1980, Rt Lab. Number 772285.

Procedure:

9 New Zealand white rabbits received a 0.1g dose of the test material in one eye of each rabbit. After 30 seconds, the treated eyes of three rabbits were washed for 1 minute with lukewarm water. Observations were made at 24, 48, 72 and 96 hours and at 7 and 14 days after treatment.

Results:

At 24 hours - 3/6 animals in the unwashed group had corneal opacity (3/6 = 5), 6/6 iris irritation (6/6 = 5), 6/6 conjunctival redness (1/6 = 1, 2/6 = 1.5, 2/6 = 2.0, 1/6 = 2.5), 6/6 conjunctival chemosis (1/6 = 1.0, 5/6 = 1.5) and 5/6 conjunctival discharge (4/6 = 1.0, 1/6 = 1.5). At 72 hours, 1/6 had corneal opacity (1/6 = 5), no iris irritation, 5/6 conjunctival redness (4/6 = 1, 1/6 = 1.5), 3/6 conjunctival chemosis (2/6 = 1.0, 1/6 = 1/5), and 1/6 conjunctival discharge (1/6 = 0.5). At 7 days, 1/6 corneal opacity (1/6 = 2.5) and 1/6 iris irritation (1/6 = 5), all other irritation clear. On day 14 all irritation clear.

At 24 hours - 3/3 animals in the washed groups had corneal opacity (2/3 = 5, 1/3 = 7.5), 3/3 iris irritation (3/3 = 5), 3/3 conjunctival redness (1/3 = 1, 2/3 = 2), 3/3 conjunctival chemosis

(1/3 = 0.5, 1/3 = 1.5, 1/3 = 2.0), and 2/3 conjunctival discharge (1/3 = 1.0, 1/3 = 1.5). At 72 hours, no corneal opacity or iris irritation, or conjunctival discharge, but 2/3 animals had conjunctival redness (2/3 = 1) and 1/3 conjunctival chemosis (1/3 = 1). At day 7, all irritation had cleared.

Study Classification:

Core Minimum Data. Test substance must be clearly identified.

Toxicity Category:

II - WARNING

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Mecoprop Scientific Reviews

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Pages 4 through 9 are not included in this copy.

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 product 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.