



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DD-775
TAR-2419

002819

Date: April 27, 1981

Subject: EPA File Symbol 538-RTD
Turf Builder Plus 2

From: Deloris F. Graham *PJM 4/24/81*
FHB/TSS

To: Richard Mountfort
Product Manager (23)

Applicant: O.M. Scott & Sons Company
Marysville, OH 43041
Attn: Michael P. Kelty

Active Ingredients:

2,4-Dichlorophenoxyacetic acid0.58%
2-(2-Methyl-4-chlorophenoxy)propionic acid.....0.58%
Inert Ingredients.....98.84%

Active Ingredients

2,4-Dichlorophenoxyacetic acid.....0.99%
2-(2-Methyl-4-chlorophenoxy)propionic acid.....0.99%
Inert Ingredients.....98.02%

Background: Submitted Acute Oral, Acute Dermal, Eye Irritation, and Skin Irritation studies on the low and high range of this product. Studies conducted by Hazleton Raltech, Inc., Raltech Scientific Services, and WARF Institute, Inc. Data under Accession Number 247096. Alternate method of support.

Recommendations:

- (1) FHB/TSS find all studies acceptable to support conditional registration of this product.
- (2) One eye irritation study is core supplementary; the dosage used to conduct the study must be submitted.
- (3) In the Acute Dermal Study, WARF 7082554, 4 test sites (2 abraded and 2 intact) per animal must be used.
- (4) The appropriate signal word is CAUTION.

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Label:

- (1) The statements "Do not contaminate feed or foodstuffs. Do not contaminate water used for irrigation or domestic purposes. Do not graze treated areas. Do not feed clippings to livestock." must be deleted from precautionary statements and placed in "Directions for Use."
- (2) Storage and disposal statements must appear under "Directions for Use."

Review: (low range, 0.58% a.i.)

(1) Acute Oral Toxicity Study: Hazleton Raltech, Inc.: RT# 917207; March 4, 1982.

Procedure: 5 M and 5 F rats weighing between 200 and 299 g received 2 g/kg of the test material. Observations were made daily for 14 days. Necropsy performed on all animals.

Results: No mortalities. Toxic signs included hypoactive and diarrhea. Necropsy revealed red exudate both eyes; mildly reddened thymus; mild hydrometra uterus. LD₅₀ greater than 5 g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

(2) Acute Dermal Toxicity Study: Hazleton Raltech, Inc.: RT# 917207; March 4, 1982.

Procedure: 5 M and 5 F New Zealand rabbits weighing between 2320 and 2956 g each received 2 g/kg of the test material at abraded skin sites under occlusive wrap for 24-hour exposure. Observations made daily for 14 days. Necropsy performed on all animals.

Results: No mortalities. Erythema, edema, desquamation and diarrhea observed. Necropsy revealed pitted cortical surface on kidneys. LD₅₀ greater than 2 g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(3) Eye Irritation Study: Hazleton Raltech, Inc.: RT# 917207; March 4, 1982.

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 30 seconds posttreatment. Observations were made at 24, 48, 72, and 96 hours, and 7 days.

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Results: At 24 hours, 4/6 animals of the unwashed group had corneal opacity (1/6 = 5, 1/6 = 7.5, 1/6 = 10, 1/6 = 20); 6/6 iris irritation (5/6 = 3), redness (1/6 = 2, 4/6 = 2.5, 1/6 = 3), chemosis (5/6 = 2, 1/6 = 2.5), discharge (1/6 = 1, 3/6 = 2, 1/6 = 3). At 96 hours, no corneal opacity or iris irritation; 6/6 redness (5/6 = 1, 1/6 = 1.5); 4/6 chemosis (3/6 = 0.5, 1/6 = 1). At 7 days, 4/6 redness (3/6 = 1, 1/6 = 1.5); 1/6 discharge (1/6 = 1). At 14 days, no corneal opacity or any irritation.

At 24 hours, 3/3 animals of the washed group had redness (2/3 = 1, 1/3 = 1.5); 1/3 chemosis (1/3 = 1). At 96 hours, 3/3 animals had redness (3/3 = 1). At 7 and 14 days no irritation.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

(4) Primary Dermal Irritation Study: Hazleton Raltech, Inc.; RT# 917207; January 11, 1982.

Procedure: Six New Zealand rabbits received 0.5 g of the test material at 2 abraded and 2 intact skin sites per animal under occlusive wrap for 24 hours exposure. Observation made at 24 and 72 hours posttreatment.

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

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

Review: (high range, 0.99% a.i.).

(1) Acute Oral Toxicity Study: Hazleton Raltech, Inc.; RT# 917208; February 20, 1982.

Procedure: 5 M and 5 F Sprague-Dawley rats weighing between 212 and 296 g received 5 g/kg of the test material. Observations were made at 1, 2.5, and 4 hours posttreatment, then daily for 14 days thereafter. Necropsy performed on all animals.

Results: No mortalities. Toxic signs included diarrhea. Necropsy revealed small amount of dried blood around nose; thymus mildly reddened; mild hydrometra uterus. LD₅₀ greater than 5 g/kg.

Study Classification: Core Guideline Data.

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Toxicity Category: IV - CAUTION.

(2) Acute Dermal Toxicity Study: Hazleton Raltech, Inc.; RT# 917208;
February 20, 1982.

Procedure: 5 M and 5 F New Zealand rabbits weighing between 2414 and 2824 g each received 2 g/kg of the test material at abraded skin sites under occlusive wrap for 24-hour exposure. Observations were made twice daily for 14 days. Necropsy performed on all animals.

Results: No mortalities. Toxic signs include possible respiratory congestion, soft stool, diarrhea, slight erythema, slight desquamation, and very slight edema in one animal. Ear mites in both ears observed in one animal.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(3) Eye Irritation Study: Raltech Scientific Services, Inc.; L.S. # 709040;
January 15, 1979.

Procedure: Nine rabbits were treated with test material as supplied. The treated eyes of three of the rabbits were washed 30 seconds posttreatment. Observations were made at 24, 48, and 72 hours and at 7 days.

Results: At 24 hours, 3/3 animals of the unwashed group had corneal opacity (5/6 = 5, 1/6 = 10); 5/6 iris irritation (5/6 = 5); 6/6 redness (2/6 = 1, 4/6 = 2), chemosis (3/6 = 1, 3/6 = 2), and discharge (2/6 = 1, 4/6 = 2). At 72 hours, 3/6 had corneal opacity (3/6 = 5); 4/6 redness (4/6 = 1); 2/6 chemosis (2/6 = 1). At 7 days, no corneal opacity, iris irritation or conjunctive irritation present.

At 24 hours, 1/3 animals of the washed group had corneal opacity (1/3 = 5), iris irritation (1/3 = 5); 3/3 redness (3/3 = 1), chemosis (3/3 = 1) and discharge (3/3 = 1). At 72 hours and 7 days, no corneal opacity, iris irritation or conjunctive irritation.

Study Classification: Core Supplementary Data. Dosage used must be submitted.

(4) Eye Irritation Study: WARF Institute, Inc.; WARF # 7082554.

Procedure: Nine rabbits received 0.1 g of the test material in one eye each. The treated eyes of three of the rabbits were washed 30 seconds posttreatment. Observations were made at 24, 48, and 72 hours.

Results: No irritation in washed or unwashed group at 24, 48, or 72 hours.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

(5) Primary Dermal Irritation Study: WARF Institute, Inc.; WARF # 7082554.

Procedure: 6 New Zealand rabbits received 0.5 g of the test material at one abraded and one intact skin site per animal under occlusive wrap for 24-hour exposure period. Observations were made at 24 and 72 hours posttreatment.

Results: No erythema or edema at 24 or 72 hours. Primary Irritation Score was zero.

Study Classification: Core Minimum Data. Four sites (2 abraded and 2 intact) must be used.

Toxicity Category: IV - CAUTION.

Mecoprop Scientific Reviews

Page _____ is not included in this copy.

Pages 6 through 16 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
 - ☒ A draft product label
 - ☐ The product confidential statement of formula
 - ☐ Information about a pending registration action
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 - ☐ The document is a duplicate of page(s) _____
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