

BB-775
TXR-3137

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: January 11, 1982

003137

SUBJECT: EPA Registration Symbol 533-RLT
Super Plus 2 For Grass

FROM: Deloris F. Graham
FHB/TSS

TO: Richard Mountfort
Product Manager (23)

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

Active Ingredients: (F-8517)
2,4-Dichlorophenoxyacetic acid..... 0.680%
2-(2-Methyl-4-chlorophenoxy) propionic acid..... 0.680%
Dicamba 3,6-Dichloro-o-anisic acid..... 0.027%
Inert Ingredients.....98.613%

Active Ingredients: (F-8655)
2,4-Dichlorophenoxyacetic acid..... 1.370%
2-(2-Methyl-4-chlorophenoxy) propionic acid..... 1.370%
Dicamba 3,6-Dichloro-o-anisic acid..... 0.055%
Inert Ingredients.....97.205%

Background: Submitted Acute Oral, Dermal, Eye Irritation, and Skin Irritation data on the high and low ends of the range of active ingredients which the inerts vary but actives will remain constant. Data under accession number 246283. Alternate method of support used. An Acute Inhalation Study was not submitted.

Recommendation:

1. FHB/TSS finds these data acceptable to support conditional registration of this product.
2. The appropriate signal word is "CAUTION."

Label:

1. The statement "Do not contaminate feed and foodstuffs" must be deleted from precautionary statements and placed under "Directions For Use."

1/28/82

2. The other labeling comments are adequate as proposed.

Review: (F-9517)

1. Acute Oral Toxicity Study: Raltech Scientific Services; RT #862787; October 2, 1981.

Procedure: 5M and 5F Sprague-Dawley rats weighing between 201 and 245 grams received a 5g/kg dose of the test material. Observations made daily for 14 days. Necropsy performed on all animals.

Results: No mortalities. No toxicological signs. Necropsy revealed mild hydrometra of uterus in 1F animal. LD50 greater than 5g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

2. Acute Dermal Toxicity Study: Raltech Scientific Services; RT #862787; October 2, 1981.

Procedure: 5M and 5F New Zealand rabbits weighing between 2302 and 2777 g received 2 g/kg at abraded skin sites under occlusive wrap. Observations were made at end of 24-hour exposure period, then daily for remainder of 14 days. Necropsy performed on all animals.

Results: No mortalities. Erythema, edema desquamation, fissuring observed. Necropsy revealed lungs reddened in 4/10 animals; all other animals normal. LD50 greater than 2 g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

3. Eye Irritation Study: Raltech Scientific Services; RT #862787; October 2, 1981.

Procedure: 9 New Zealand rabbits received 0.1 g of the test material in one eye each. The eyes of three of the rabbits was washed for 1 minute, 30 seconds posttreatment. Observations were made at 24, 48, 72, and 96 hours, 7 and 14 days.

Results: At 24 hours in unwashed group, 3/6 corneal opacity (3/6=5); 6/6 iris irritation (6/6=5), redness (2/6=1.5, 1/6=2, 1/6=2.5, 2/6=3), chemosis (1/6=1.5, 2/6=2, 3/6=3), discharge (1/6=1.5, 3/6=2, 1/6=2.5, 1/6=3). At 96 hours, no corneal opacity or iris irritation; 6/6 redness (1/6=1, 5/6=1.5); 3/6 chemosis (3/6=1). At day 7, 6/6 redness (4/6=1, 2/6=1.5). At day 14, 4/6 redness (2/6=0.5, 2/6=1).

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At 24 hours in washed group, 3/3 corneal opacity (2/3=2.5, 1/3=5), iris irritation (3/3=1); redness (2/3=2, 1/3=2.5), chemosis (1/3=1.5, 1/3=2, 1/3=3), discharge (1/3=1, 1/3=2, 1/3=3). At day 4, no corneal opacity or iris irritation, 3/3 redness (2/3=1, 1/3=1.5), chemosis (3/3=1). At 7 days, 2/3 redness (2/3=1). At day 14, 2/3 redness (1/3=0.5, 1/3=1).

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION ?

4. Primary Dermal Irritation Study: Raltech Scientific Services; RT #862787; October 2, 1981.

Procedure: 6 New Zealand rabbits received 0.5g of test material at 2 abraded and 2 intact skin sites per animal under occlusive wrap for 24 hour exposure. Observations were made at 24 and 72 hours posttreatment.

Results: Slight to well-defined erythema (scars 1 and 2) and slight edema (scars 1 and 1.5) at 24 hours. Slight erythema and edema in 4/6 animals with score of 1 at 72 hours.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

Review: (F-8688)

1. Acute Oral Toxicity Study: Raltech Scientific Services; RT #862788; October 2, 1981.

Procedure: 5M and 5F Sprague-Dawley rats weighing between 200 and 235g received a 5 g/kg dose of the test material. Observations made daily for 14 days. Necropsy performed on all animals.

Results: No mortalities. Diarrhea, ataxia, lacrimation, and tremors also observed. Necropsy revealed mild hydrometra of uterus in 2F animals and left lobe of thymus severely reddened in 1M animal. LD50 greater than 5g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

2. Acute Dermal Toxicity Study: Raltech Scientific Services; RT #862788; October 2, 1981.

Procedure: 5M and 5F New Zealand white rabbits weighing between 2307 and 2694g received 2g/kg of the test material at abraded skin sites under occlusive wrap for 24-hour exposure. Observations were made at end of 24-hour exposure period and daily thereafter for remainder of 14 days.

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Results: No mortalities. Erythema, edema, desquamation, fissuring, diarrhea, and soft stool observed. Necropsy revealed lungs mildly reddened; cecum flaccid, filled with liquid fecal material, areas of solid fecal material appeared to be adhered to mucosal lining; animal appears thin, with minimal amount of body fat; perineum stained with fecal material. LD50 greater than 2g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

3. Eye Irritation Study: Raltech Scientific Services; RT #862788; October 2, 1981.

Procedure: 9 New Zealand rabbits received 0.1g of test material in one eye each. The eyes of three of the rabbits were washed for 1 minute, 30 seconds posttreatment. Observations were made at 24, 48, 72, and 96 hours and 7 days.

Results: At 24 hours in unwashed group, 6/6 corneal opacity (1/6=1.25, 1/6=2.5, 2/6=5, 1/6=7.5, 1/6=12.5); 5/6 iris irritation (5/6=5); 6/6 redness (1/6=1.5, 5/6=2), chemosis (1/6=1, 1/6=1.5, 3/6=2, 1/6=2.5), 5/6 discharge (2/6=1.5, 3/6=2). At 96 hours, 1/6 corneal opacity (1/6=10), iris irritation (1/6=5); 6/6 redness (5/6=1, 1/6=1.5); 1/6 chemosis (1/6=1). At day 7, no corneal opacity, iris or conjunctive irritation present.

At 24 hours in washed group, 3/3 corneal opacity (2/3=5, 1/3=7.5), iris irritation (3/3=5), redness (2/3=1.5, 1/3=2), chemosis (1/3=1, 1/3=1.5, 1/3=2), discharge (2/3=1, 1/3=2). At 96 hours, 3/3 redness (3/3=1), no corneal opacity or iris irritation present. At 7 days, all redness had cleared.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION ⁷

4. Primary Dermal Irritation: Raltech Scientific Services; RT #862788; October 2, 1981.

Procedure: 6 New Zealand rabbits received 0.5g of the test material at 2 abraded and 2 intact skin sites per animal under occlusive wrap for 24-hour exposure. Observations made at 24 and 72 hours.

Results: Slight to well-defined erythema (scores 1 and 2) and slight edema (score of 1) at 24 hours. At 72 hours, slight erythema and edema (scores 1 and 1.5). At 96 hours, slight erythema and edema (scores 1 and 1.5).

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

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Mecoprop Scientific Reviews

Page _____ is not included in this copy.

Pages 5 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
 - ☐ FIFRA registration data
 - ☐ The document is a duplicate of page(s) _____
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