2,4-D/TOX

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Releasable

DATE: September 18, 1980

SUBJECT: EPA File Symbol 538-RLI
Turf Builder with Plus 2: Caswell # 315 and 559

FROM: Deloris F. Graham D.G. 9/25/80
FHB/TSS
E 9/25/80

TO: Richard Mountfort
Product Manager (23)

Applicant: O. M. Scott & Sons Company
Attention: Gerald L. Born
Marysville, OH 43041

Active Ingredients:

2,4 dichlorophenoxy acetic acid	1.15%
2-(2-Methyl-4-chlorophenoxy) propionic acid	1.15%
Inert Ingredients:	97.70%

Background:

Submitted Acute Oral and Skin Irritation studies on sample F-6560, Batch No. 3-109-1; Acute Dermal study on sample F-6560, Batch No. 4-219-12-DY; Acute Oral, Acute Dermal, Skin and Eye Irritation studies were submitted on fertilizer base sample. These data are under Accession No. 242865. Referenced data under EPA Registration Nos. 464-453 and 464-454. Alternate method of support is used.

Recommendations:

1. FHB/TSS finds the Acute Oral (F-8480), Acute Dermal (Fertilizer base, F-8480), Dermal Irritation (Fertilizer base, F-8480), and the Dermal Irritation (F-6560, Batch 3-109-1) studies are acceptable to support the products on which they were conducted. However, for future submission please note:

   a. In the Acute Oral Study (Fertilizer base, F-8480),

      Response data and necropsy reports must be submitted individually for each animal.

   b. In the Acute Dermal study (Fertilizer base, F-8480),

      Response data and necropsy reports must be submitted individually for each animal.

c. In the Dermal Irritation Study (Fertilizer base, F-8480),

Four sites (two abraded and two intact) per animal must be used.

d. In the Dermal Irritation Study (F-6560, Batch No. 3-109-1).

Four sites (two abraded and two intact sites) per animal must be used.

2. FHB/TSS finds the Acute Oral (F-6560, Batch No. 3-109-1), Acute Dermal Study (F-6560, Batch No. 4-219-12-DY) and the Eye Irritation Study (Fertilizer base, F-8480) not acceptable to support the registration of product on which the study was conducted.

a. In the Acute Oral Study (Sample F-6560, Batch No. 3-109-1),

(1) Response data and necropsy reports must be submitted individually for each animal.

(2) Male and female animals must be used.

(3) LD_{50} and 95% confidence limits for males and females must be submitted separately.

b. In the Acute Dermal Study (F-6560, Batch No. 4-219-12-DY),

(1) Must use equal number of male and female animals, at least five animals per sex.

(2) Response data and necropsy reports must be submitted individually for each animal.

c. In the Eye Irritation Study (Fertilizer base, F-8480),

Nine rabbits (six rabbits with treated, unwashed eyes and three rabbits with treated, washed eyes) must be used.

3. FHB/TSS was unable to determine which product was being registered.

4. Acute toxicity data must be submitted on product being registered.

5. Under the Alternate Method of Support data cited must be on an identical formulation.

6. FHB/TSS objects to the conditional registration of this product until the product being registered is clearly identified and all the necessary acute toxicity data are submitted.

Note to PM:

1. Product being registered must be clearly identified.

2. Data must be submitted on formulated product.

3. Data referenced are not identical products.

Label:

Labeling comments reserved until identification of product and a sample label is submitted.

Review:

1. Acute Oral Toxicity Study: WARF Institute, Inc. (Sample F-6560, Batch No. 3-109-1) April 30, 1973

   Procedure:

   Three groups, each consisting of six Sprague-Dawley rats (150-250g) were administered one of the following doses 5, 10, and 20 g/kg. Observations were made for two weeks.

   Results:

   At 5 and 10g/kg no mortalities. At 20g/kg 4/6 animals died. Estimated oral LD_{50} between 10 and 20g/kg.

   Study Classification: Core Supplementary Data

   a. Must submit response data and necropsy reports individually for each animal.

   b. Male and female animals must be used.

   c. LD_{50} and 95% confidence limits for males and females must be submitted separately.

2. Acute Oral Toxicity Study: WARF Institute, Inc., (Fertilizer base, control No. F-8480), October 20, 1977. WARF No. 7082556.

   Procedure:

   10M and 10F Sprague-Dawley rats received a 5g/kg dose of the test material. Observations were made hourly for 5 hours after dosing and twice daily thereafter for two weeks. Necropsy examination performed on all animals.

Results:

2/10F died. No other signs of toxicity noted. As indicated by average total body weight male animals gained weight and female animals lost weight. Necropsy revealed mildly mottled kidneys, a few congested lungs. Oral LD_{50} for M&F greater than 5 gm/kg.

Study Classification: Core Minimum Data.

Must submit response data and necropsy reports individually for each animal.

Toxicity Category: IV-CAUTION

3. Acute Dermal Toxicity Study: WARF Institute, Inc. (Sample F-6560, 4-219-12-DY), September 13, 1974. WARF No. 4082302.

Procedure:

2M rabbits received 8g/kg dose of the test material by injection under occlusive wrap. The animals were immobilized for a 24-hour period after treatment. Observations were made for two weeks.

Results:

Animal gained weight. Dermal LD_{50} was in excess of 8g/kg.

Study Classification: Core Supplementary Data

a. Must submit response data and necropsy reports individually for each animal.

b. Must use equal number of male and female animals.

4. Acute Dermal Toxicity Study: WARF Institute, Inc. (Fertilizer base, F-8480) October 20, 1977; WARF No. 7082556.

Procedure:

3M and 3F New Zealand white rabbits (2.0 to 3.0 kg) received a 21g/kg dose of the test material at abraded skin sites under occlusive wrap for 24-hour exposure. Observationswere made hourly for 5 hours after treatment was indicated and twice daily thereafter for the remainder of the two week observation period.

Results:

1/3F died. No other signs of toxicity. Majority of surviving animals gained weight. Necropsy revealed dark and mottled lungs, livers, and kidneys. Dermal LD_{50} was in excess of 21 g/kg for males and females.

Study Classification: Core Minimum Data

Must submit response data and necropsy report individually for each animal.

Toxicity Category: III-CAUTION

5. Eye Irritation Study: WARF Institute, Inc. (Fertilizer base, F-8480) October 20, 1977; WARF No. 7082556.

Procedure:

0.1 ml of the test substance was administered into one eye of each of three rabbits. Eyes were flushed with distilled water 20 seconds after instillation of the test material. Observations were made at 24, 48 and 72 hours after treatment.

Results:

No corneal opacity, iris irritation, nor conjunctival irritation at 24, 48 and 72 hours.

Study Classification: Core Supplementary Data

Must use nine rabbits (six rabbits with treated, unwashed eyes and three rabbits with treated, washed eyes).

6. Dermal Irritation Study: WARF Institute, Inc. (Fertilizer base, F-8480) October 20, 1977, WARF No. 7082556.

Procedure:

Six New Zealand white rabbits (2.5 to 3.5 kg) received a 0.5 gm dose of the test material at one abraded and one intact site per animal under occlusive wrap for 24 hours. Observations were made at 24 and 72 hours after dosing.

Results:

No erythema or edema at either site at 24 and 72 hours. Dermal Irritation Index was zero.

Study Classification: Core Minimum Data

Must use four sites (two abraded and two intact) per animal.

Toxicity Category: IV-CAUTION

7. Dermal Irritation Study: WARF Institute. Inc. (Sample F-6560, Batch No. 3-109-1) May 21, 1973. WARF No. 3043133.

Procedure:

Six white rabbits received 0.5 gm of the test material at one abraded and one intact site per animal under occlusive wrap for 24 hours. Observations were made at 24 and 72 hours.

Results:

No irritation, all readings were negative. Dermal Irritation Score was zero.

Study Classification: Core Minimum Data

Four sites (2 abraded and two intact) per animal must be used.

Toxicity Category: IV-CAUTION