

2,4-D/TOX

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DATE: February 10, 1981

SUBJECT: Super Turf Builder Plus 2 for Grass
EPA Registration No. 538-72FROM: Sherell A. Sterling
FHB/TSSTO: Richard Mountfort
Product Manager (23)Registrant: O.M. Scott & Sons
Marysville, Ohio 43040

Active Ingredients:

2,4-Dichlorophenoxyacetic acid.....	0.68%
2-(2-methyl-4-chlorophenoxy)propionic acid.....	0.68%
Inert Ingredients.....	98.64%

Background: Data were submitted on this registered product in order to amend precautionary labeling. Currently, the signal word is DANGER based on eye irritation; the registrant requests the signal word to be changed to CAUTION. The registrant also supplied information on the accident history of this product. Acute Oral, Acute Dermal, Eye and Skin Irritation studies were conducted by Raltech Scientific Service, Inc. of Madison, Wisconsin. Also submitted were Eye Irritation studies conducted by Wil Research of Cincinnati, Ohio and Cannon Laboratories, Inc. of Reading, Pennsylvania. The method of support is "alternate."

Recommendations:

1. The Acute Oral, Acute Dermal, Eye and Skin Irritation studies conducted by Raltech are considered adequate and acceptable for conditional registration purposes.
2. The additional Eye Irritation studies conducted by Wil Research and Cannon Laboratories are adequate and acceptable for conditional registration purposes.
3. An Acute Inhalation study was not submitted for this formulation. If this study is not submitted, vapor pressure (if applicable) and particulate size representative of the product is necessary. Please see §163.81-3 of the Proposed Guidelines for Human Hazard Evaluation.
4. In most instances, the Agency bases toxicity categories on the "worst case" data. Due to the information on use history (no accidents), the type of formulation and use pattern, FHB/TSS is using the "best case" data to assign precautionary labeling.
5. FHB/TSS has no objection to the formulation change proposed here (F-9387). We note the Acute Inhalation deficiency, however.

Labeling Recommendations:

1. The registrant proposes the signal word WARNING. Based on the Eye Irritation study, FHB/TSS finds the signal word WARNING appropriate for this product.
2. Under the "Environmental Hazards" section the following statement must appear:

"Do not apply directly to lakes, streams or ponds."

3. Additional revisions may be necessary if additional data are submitted.

Review:

1. Acute Oral Toxicity; Raltech Lab. No. 757246; January 17, 1980; Acc. No. 243956.

Procedure: A group of 5 male and 5 female Sprague-Dawley rats (211-240g) each received 5g/kg dosages of "F9387." Animals were observed for 14 days. At termination of study, all animals were subjected to necropsies.

Results: No deaths. All animals appeared normal throughout study.
Necropsies revealed: lung - diffuse, pinpoint with white foci (1/5 male); mild hydrometra (3/5 female). LD50 > 5g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

2. Defined Dermal LD50; Raltech Lab. #757246; January 17, 1980; Acc. No. 243956.

Procedure: A group of 5 males, 5 females New Zealand white rabbits (2574-3000g) each received a dosage of 5g/kg of "F9387" at abraded sites. Test substance was moistened with 0.9% saline. Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days. All animals were subjected to necropsies.

Results: No mortalities; all animals appeared normal. LD50 > 5g/kg.
Observations included: slight to moderate erythema, desquamation and fissuring. Necropsies showed: liver - multifocal, firm, tan masses.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

3. Eye Irritation: Raltech #757246; January 17, 1980; Acc. No. 243956.

Procedure: 0.1g of "F9387" was applied into one eye of each of 9 New Zealand white rabbits. Three of the treated eyes were irrigated for one minute with lukewarm water starting no sooner than 30 seconds post-instillation. Draize scoring at 24, 48, 72, 96 hours; 7, 14 and 21 days.

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Results: In the unwashed eyes at 24 hours corneal opacity was observed in 3/6=5, 1/6=10, 2/6=12.5 and 6/6 with corneal epithelial peeling; iris irritated, injected in 6/6=5; redness in 6/6=3.0; chemosis in 1/6=2.5, 4/6=3.0, 1/6=3.5; discharge in 1/6=2.5, 5/6=3.0 and 6/6 with purulent discharge. At 7 days unwashed eyes showed corneal opacity in 1/6=5, 1/6=10; 3/6 showed corneal neovascularization; redness in 4/6=1, 2/6=2 and scar tissue noted on lower bulbar conjunctivae; chemosis in 1/6=1; discharge in 1/6=1 and purulent. At day 21, only irritation noted was corneal opacity in 1/6=2.5. Washed eyes exhibited at 24 hours; corneal opacity in 1/3=3.75 and 2/3=5 with corneal epithelial peeling in 3/3; iris injected with irritation in 3/3=5; redness in 3/3=2.5; chemosis in 2/3=2, 1/3=2.5; discharge in 2/3=1.5, 1/3=2.5 and 3/3 with purulent discharge. All washed eyes were clear at 7 days.

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER

4. Primary Skin Irritation; Raltech #757246; January 17, 1980; Acc. No. 243956

Procedure: Six New Zealand white rabbits each received 0.5g of "F9387" at each of 4 sites (2 abraded, 2 intact). The test substance was moistened with 0.9% saline. Animals were scored with Draize's method 24, 72 hours.

Results: At 24 hours, intact sites had slight erythema at 8/12 sites, edema - slight at 7/12 sites. Abraded sites showed slight to well-defined erythema at 10/12 sites; slight edema at 10/12 sites. By 72 hours intact sites all appeared normal; one abraded site showed slight erythema and edema. The Primary Irritation Index was 0.8

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

5. Primary Eye Irritation Study of "F-9387, Batch No. 9-190-1HL" on New Zealand Albino Rabbits; Cannon Lab. #F-7287; May 30, 1980; Acc. No. 243956.

Procedure: 0.1g of "F9387" was applied into one eye of each of 9 New Zealand white rabbits. Three of the treated eyes were irrigated for one minute with lukewarm water, 20 seconds post-instillation. Scoring at 24, 48, 72 hours; 4, 7, 10, 13, 16, 19, 21 days.

Results: At 24 hours unwashed eyes showed corneal opacity in 2/6=10, 1/6=20, 1/6=30, 1/6=40; iris irritation in 6/6=5; redness in 6/6=3; chemosis in 1/6=1, 5/6=2; discharge in 1/6=2, 5/6=3. At 7 days, 2/6=5 and 1/6=10 for corneal opacity with 3/6 with pannus; redness in 2/6=1. By day 21, corneal opacity in 2/6=5, 1/6=10 with pannus in 1/6.

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Washed eyes at 24 hours exhibited ^{corneal opacity in} 1/3=5, 1/3=10; iris irritation in 3/3=5; redness in 3/3=3; chemosis in 2/3=2, 1/3=3; discharge in 2/3=1, 1/3=2. All scores were zero by day 4.

Study Classification: Core Guideline Data.

Toxicity Category: I - DANGER

6. Acute Eye Irritation Study in Albino Rabbits with F-9387; Wil -.80123; July 9, 1980; Acc. No. 243956.

Procedure: 100^{mg} of "F9387" was applied into one eye of each of 9 New Zealand white rabbits. Three of the treated eyes were irrigated for 30 seconds with lukewarm water 20-30 seconds post-instillation. Scoring at 24, 48, 72 hours; 4, 7, 10 days.

Results: At 24 hours in unwashed eyes corneal opacity in 3/6=5, 1/6=10; redness in 1/6=1, 3/6=2, 2/6=3; chemosis in 2/6=2, 3/6=3, 1/6=4; discharge in 4/6=2, 2/6=3. At 7 days unwashed eyes showed corneal opacity in 1/6=5, redness in 1/6=1, chemosis in 1/6=1. All unwashed eyes were clear on day 10.

At 24 hours in the washed eyes corneal opacity was noted in 1/3=5; redness in 3/3=1; chemosis in 2/3=1, 1/3=2; discharge in 3/3=1. All eyes were clear by day 4.

Study Classification: Core Guideline Data.

Toxicity Category: II - WARNING