BB-12/3
TAR-1191

tox

DATE: August 3, 1981

SUBJECT: Progrow Ornamental Herbicide II
EPA File Symbol 538-RTE

001191

FROM: Sherell A. Sterling
FHB/TSS

TO: Richard Mountfort
Product Manager (23)

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

Active Ingredients:

Oxyfluorfen	2.00%
Pendimethalin	1.00%
Inert Ingredients	97.00%

Background:

Acute Oral, Acute Dermal, Eye and Skin Irritation studies were submitted on an alternate formulation of this product. The alternate formulation for Progrow Ornamental Herbicide II is designated "F-9529." The method of support for this application for conditional registration is "alternate."

The labeling submitted for review with this application bears the signal word "WARNING." However, after checking a review of the original formulation F-9955 (see Sterling, May 11, 1981), it was determined that the signal word for both F-9955 and F-9529 is "CAUTION." The precaution- ary statements for these two products would be identical.

All studies submitted for this "alternate" formulation were conducted by Raltech Scientific Services of Madison, Wisconsin. The data were assigned Accession Number 245519.

Recommendations:

1. The Acute Oral, Acute Dermal, Eye and Skin Irritation tests are adequate and acceptable for the conditional registration of this formulation (F-9529).

2. An Acute Inhalation study was not submitted. In the cases of products where this study is not feasible, the vapor pressure and particulate size of the product are required for our records.

3. F-9529 and F-9955 have identical Toxicity Category ratings for the Acute Oral, Acute Dermal, Eye and Skin Irritation studies (Sterling, May 1, 1981).

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Labeling Recommendations:

1. The signal word must be changed from WARNING to CAUTION.

2. The "Hazards to Humans and Domestic Animals" section must be revised as follows:

   CAUTION. Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

   The required "Statement of Practical Treatment" is as follows:

   If in eyes: Flush with plenty of water. Get medical attention if irritation persists.

   The statement "Do not contaminate feed or foodstuffs" must appear under the "Directions for Use" as a general restriction.

3. Under the "Environmental Hazards," the statement "Keep out of lakes, ponds, or streams" must be replaced with "Do not apply directly to water."

4. The "Storage and Disposal" section must be revised as described in the enclosed storage and disposal information sheets.

Review:

1. Acute Oral LD50; Raltech #807123; November 6, 1980; Acc. No. 245519.

   Procedure: A group of 5M, 5F (217-259g) Sprague-Dawley rats each received a 5 g/kg dosage of "F-9529." The test substance was mixed with distilled water and administered via an animal feeding needle. Animals were observed for 14 days post-dosing. At termination of study, all animals were subjected to necropsies.

   Results: No mortalities were reported. Only symptom observed was diarrhea. Necropsy revealed mild hydrometra in uterus of 1/5F; lungs of 2/5F mildly reddened. The LD50 was greater than 5 g/kg for males, females.

   Study Classification: Core Guidline Data.

   Toxicity Category: IV - CAUTION

2. Acute Dermal LD50; Raltech #807123; November 6, 1980; Acc. No. 245519.

   Procedure: A group of 5M, 5F (2329-2998 g) New Zealand white rabbits each received 2 g/kg of "F-9529" at abraded skin sites. The 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.

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Results: No mortalities were observed. Observations included: slight erythema, slight edema, slight desquamation at skin sites; diarrhea. Necropsies revealed: 5/5M and 3/5F with lungs slightly reddened; 1/5F with diffuse cystic areas on cortical surface of kidneys. The LD50 for M, F was greater than 2 g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

3. Eye Irritation; Raltech #807123; November 6, 1980; Acc. No. 245519.

Procedure: Nine New Zealand white rabbits each received 100 mg of "F-9529" in one eye. Thirty seconds post-dosing, three of the eyes were rinsed with lukewarm water for one minute. Eyes were scored at 24, 48, 72 hours; 4, 7 days.

Results: At 24 hours, the unrinsed eyes exhibited corneal opacity in 1/6=5, 1/6=10; 2/6 with corneal epithelial peeling; iris injected and irritated in 3/6=5; redness in 3/6=2, 2/6=2.5, 1/6=3; chemosis in 2/6=1.5, 2/6=2, 2/6=2.5, 1/6=3; purulent discharge in 4/6=1, 1/6=1.5; 1/6=2. All unrinsed eyes were clear by day 7.

The rinsed eyes at 24 hours only exhibited redness in 3/3=2; and chemosis in 1/3=1, 2/3=1.5. All rinsed eyes were clear at day 7.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION

4. Skin Irritation; Raltech #807123; November 6, 1980; Acc. No. 245519.

Procedure: Six New Zealand white rabbits each received 0.5 g of "F-9529" at each of 4 sites. Of the 4 sites, 2 were abraded and 2 intact. The test substance was moistened with sterile 0.9% saline at application. Exposure was for 24 hours under occlusive wrap. Scoring was done at 24, 72 hours.

Results: At 24 hours, intact sites showed erythema in 3/12=1, 1/12=1.5 and edema in 1/12=1; abraded sites with erythema in 6/12=1, 1/12=1.5 and no edema. By 72 hours, all irritation at both intact and abraded sites had subsided. The Primary Irritation Index was 0.3.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

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Oxyfluorfen toxicology review

Page 4 is not included in this copy.

Pages _____ through _____ 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

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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.