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TXR-677

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

000877

624A

DATE: September 9, 1980

SUBJECT: Goosegrass/Crabgrass Control for Bermudagrass
EPA File Symbol: 538-RAU

FROM: Sherell A. Sterling SAS 9-16-80
FHB/TSS E 9/24/80

TO: Robert Taylor
Product Manager (25)

Applicant: O. M. Scott & Sons Co.
Attn: Gerald L. Born
Marysville, OH 43040

Active Ingredient:
Oxadiazon..... 5.25%
Bensulide..... 1.31%
Inert Ingredients.....93.44%

Background: Acute Oral, Acute Dermal, Eye and Skin Irritation studies were submitted in support of this conditional registration. The studies were conducted by Raltech Scientific Services, Inc. of Madison, Wisconsin. These studies are included under Accession No. 242661. The "alternate" method of support is used. In a phone conversation between S. Sterling and Dr. Michael Kelty of O. M. Scott, Dr. Kelty stated that "F9197" is Goosegrass/Crabgrass Control for Bermudagrass; written confirmation will be forthcoming.

Recommendations:

1. The Acute Oral, Acute Dermal, Eye and Skin Irritation studies are considered adequate and acceptable for conditional registration purposes.

2. An Acute Inhalation study was not submitted. Please refer to §163.81 -3 of the "Proposed Guidelines for Human Hazard Evaluation" to determine if this study is required. If the study is not required, please submit this determination along with the information used in making this determination.

3. Please note that for any product which contains a cholinesterase inhibitor, such as this product, an Acute Delayed Neurotoxicity study is required. This study is outlined under §163.81-7 of the enclosed "Proposed Guidelines."

4. FHB/TSS objects to the conditional registration of this product until an acceptable Acute Delayed Neurotoxicity study is submitted and the following labeling revisions are made.

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Labeling Recommendations:

1. Based on the Eye Irritation study, the appropriate signal word is WARNING as proposed by the applicant.

2. The "Hazards to Humans and Domestic Animals" section must be revised to the following (or similar) statements:

> "Warning. Causes eye irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid inhalation."

3. The following (or similar) statements are required; they may appear on the label in the "Hazards to Humans and Domestic Animals" section or, preferably, as a separate section. This separate section must be preceded by the heading "Statement of Practical Treatment."

> "If swallowed, drink one or two glasses of water and induce vomiting by touching back of throat with finger. Get medical attention. Never give anything by mouth to an unconscious person."
>
> "If in eyes, wash with water for at least 15 minutes. Get medical attention."
>
> "If on skin, wash with soap and water. Remove contaminated clothing. Wash clothing before reuse."

4. The statement "Do not contaminate feed or foodstuffs" is a general restriction. It must appear in the general restriction section of the labeling under the "Directions for Use."

5. The "Environmental Hazards" must be revised as follows:

> "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

6. Further labeling recommendations will be made when the requested data are submitted.

Review:

1. Acute Oral Toxicity; Raltech #9313077; March 18, 1980.

Procedure: A group of 5M, 5F Camm Sprague-Dawley rats received a dosage of 5.0 g/kg of "F9197" in corn oil. Subsequently, 8M and 8F Charles River rats received dosages of 2.56, 4.00 and 6.25 g/kg of "F9197" in corn oil; 5M and 5F Charles River rats were dosed at 5.0 g/kg of "F9197" in corn oil. The animals were observed for 14 days. All animals were subjected to necropsies. Animals tested were 200-299 g.

Results: The Charles River rat mortalities were reported as: 1/8M and 1/8F at 2.56 g/kg, F death was due to mechanical misadministration of test material; 0/8M and 2/8F at 4.0 g/kg, 1/8F deaths due to misadministration; 1/5M and 0/5F at 5.0 g/kg, M death due to misadministration; 0/8M and 0/8F at 6.25 g/kg. The Camm strain showed the following mortalities: 2/5M and 5/5F at 5.0 g/kg. Symptoms included: diarrhea, hypoactivity, miosis, urine stained abdomen, decreased limb tone, ataxia, lacrimation, fasciculation, hypersensitivity to sound, bradypnea, tremors. The following were observed at necropsy: at highest dosage 2F with hemorrhagic areas on bladder, 1F with masses on uterus. The necropsies for the Camm strain showed the following symptoms for "in study" mortalities (only 3 survived): blood around eyes and nose, hemorrhagic areas on mucosal surface of stomach, stomach-cardia mucosa thickened and hemorrhagic. LD_{50} for Camm strain is less than 5.0 g/kg; LD_{50} for Charles River rats was greater than 6.25 g/kg.

Study Classification: Core Minimum Data. Total of 4 deaths due to "mechanical misadministration" of test material.

Toxicity Category: III-CAUTION. Noting the difference in LD_{50} for the 2 strains of rats, category III is appropriate. Also, we note that this product contains a cholinesterase inhibitor; Camm strain showed symptoms attributable to cholinesterase inhibition.

2. Acute Dermal Toxicity; Raltech #9313077; March 18, 1980.

Procedure: 5M, 5F New Zealand white rabbits (2538-2983 g) were exposed to 2 g/kg of "F9197" which had been moistened with 0.9% saline solution. Exposure sites on all animals were abraded. Animals were observed for 14 days. All animals were subjected to necropsies.

Results: Mortalities reported were: 1/5M and 0/5F. Symptoms included erythema (8/10) and edema (2/10); dehydration, hypoactivity, ataxia, diarrhea, decreased limb tone. Necropsy showed the following (alteration of pathology only noted in males): lungs - covered with gelatinous exudate; heart - pale and covered with exudate; liver - multifocal, firm tan masses. Histopathology report showed all skin to be normal; 2/10 rabbits with "insignificant" mild chronic inflammation of outer dermis. LD_{50} is greater than 2.0 g/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

3. Primary Eye Irritation; Raltech #9313077; March 18, 1980.

Procedure: 0.1 g of "F9197" was instilled into one eye of each of 9 New Zealand white rabbits. Three of the rabbits' eyes were irrigated with lukewarm water for 1 minute, 30 seconds after instillation of "F9197." The eyes were scored using the Draize method at 24, 48, 72, 96 hours; 7, 14 and 21 days.

Results: At 24 hours the unrinsed eyes exhibited corneal opacity in 2/6=2.5, 1/6=10 and 1/6=18.75 with corneal epithelial peeling in 1/6; iris irritation in 2/6=5 and injected; conjunctival redness in 2/6=1, 1/6=2, 3/6=3 (with petite hemorrhage); chemosis in 1/6=1, 1/6=1.5, 2/6=3, 1/6=3.5; discharge in 2/6=1 and 2/6=2 (all purulent). By 7 days, unwashed eyes showed 1/6=5 with corneal opacity, epithelial peeling in 1/6; redness in 1/6=1. All eyes were clear at 21 days in the unrinsed group.

The washed group at 24 hours showed no corneal opacity; iris irritation 1/3=5; redness in 1/3=1, 1/3=2, 1/3= chemosis in 1/3=1, 1/3=1.5, 1/3=2; purulent discharge in 1/3=1. All washed eyes were clear at 7 days.

Study Classification: Core Guideline Data

Toxicity Category: II-WARNING

4. Primary Dermal Irritation, Raltech #9313077; March 18, 1980.

Procedure: 6 New Zealand white rabbits were exposed to 1.5 g of "F9197" moistened with 0.9% sterile saline solution. Each rabbit was exposed at 4 sites, 2 abraded and 2 intact, under occlusive wrap for 24 hours. Scoring at 24, 72 hours.

Results: At 24 hours at abraded sites erythema described as 5/12=0.5, 4/12=1, 1/12=1.5 and 1/12=2; edema at 2/12=0.5, 3/12=1, 1/12=1.5. Intact sites at 24 hours showed erythema at 3/12=0.5 and 4/12=1; edema at 3/12=0.5, 1/12=1. All scores were zero at 72 hours. The Primary Irritation Index was 0.5.

Study Classification: Core Guideline Data

Toxicity Category: IV-CAUTION

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