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UNITED S TES ENVIRONMENTAL PROTECTIC GENCY HED ©

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DATE: July 17, 1979

SUBJECT: EPA File Symbol: 538-RLL TURF BUILDER PLUS HALTS
Caswell #357

FROM: B.T. Backus
IRB/TSS

TO: Mr. Richard Mountford
Acting Product Manager 25

Applicant: O.M. Scott & Sons
Marysville, OH 43040

Active Ingredient:
S-(O,O-Diisopropyl phosphorodithioate) ester of N-(2-Mercaptoethyl) benzenesulfonamide.....2.98%....3.58%....4.78%
Inert Ingredients:.....97.02%...96.42%...95.22%

Background:

The applicant is referring to CFR40, 162.21(a)(1), regarding varying fertilizer-pesticide combinations and conditions under which these may be registered under a single EPA Reg. No. Additionally, acute toxicology data have been submitted on both the high and low percentages of proposed active ingredient. The applicant is also supporting this application with the cite-all method of support.

Recommendations:

1. The submitted Acute Oral LD50, Acute Dermal LD50, Dermal and Eye Irritation studies on both the 2.98% and 4.78% active ingredient formulations are acceptable for registration purposes. However, the applicant should be informed that the Acute Dermal LD50 Toxicity Study with 4.78% a.i. was extremely marginal in that only 4 unabraded animals were used. The study is acceptable only because of the relatively high dosage level used, lack of toxicological symptoms, and because it shows the same result as the study on a high dosage of the 2.98% a.i. formulation.

2. The appropriate signal word is WARNING, based on the eye effects.

3. IRB/TSS has no objection, on the basis of incremental hazards to man and the environment, to issuance of a conditional registration for these proposed pesticide-fertilizer combinations with the labeling revisions indicated below.

Labeling:

1. The Hazard to Humans and Domestic Animals statement should be revised to something like the following:

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WARNING: Causes eye irritation. Do not get in eyes. If in eyes, flush with plenty of water and get medical attention. May be harmful if swallowed. Wash after handling. Do not contaminate feed or foodstuffs. Do not graze treated area. Do not feed clippings to livestock.

2. The Environmental Hazards statement should be revised to something like the following:

   This pesticide is toxic to fish. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

3. The Storage and Disposal statement can be revised to something like the following:

   Do not reuse empty container. Wrap container and put in trash.

4. The heading "Directions for Use" should appear on the appropriate place on the label, followed by the statement: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

Review:

The following acute toxicological studies were conducted on the proposed formulation with 2.98% active ingredient by Raltech Scientific Services, Inc. (formerly WARF INSTITUTE, INC.), P.O. Box 7545, Madison WI 53707. Reference No. F-8649, Batch No. 7-327-1HL; Warf Inst. No. 7120441. Cover sheet dated March 6, 1978. Received 4-24-79 and in EPA Acc. 238215.

1. Acute Oral LD50 (rat)

   Procedure: 10M (av. 200 gms) and 10F (av. 180 gms) received, by stomach tube, 5 gm/kg of the test material as a 1:4 suspension in corn oil, and were observed 14 days with sacrifice and gross post-mortem examination.

   Results: No mortalities. No symptoms noted. Necropsy indicated nothing remarkable. Animals, on average, gained weight. Oral LD50 above 5 gm/kg.

   Study Classification: Core Minimum Data

   Product Classification: Tox. Cat. IV

2. Acute Dermal Toxicity (rabbit)

   Procedure: 4M,4F (2458-3152 gm) New Zealand white rabbits were dermally exposed to a 20 gm/kg dosage level. Material was applied under a rubber sleeve, which remained in place for 24 hrs during which the animals were immobilized. Animals were subsequently observed for 2 weeks, then sacrificed, with a gross post-mortem examination.

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Although the protocol indicates that "Abraded animals marked by astericks (sic)..." the report does not identify any individual subjects as having abraded skin.

Results: No mortalities. No toxic signs noted. Most animals, with exception of 2 males, maintained or gained weight. Necropsies unremarkable. Dermal LD50 above 5 gm/kg (FR43, #163, Aug. 22, 1978, p. 37345).

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III (FR43, #163, Aug. 22, 1978, pp. 37356-37357).

3. Skin Irritation (rabbit)

Procedure: 0.5 gm was applied to 2 sites (1 abraded, 1 intact) on each of 6 rabbits, with 24-hr occluded exposure. Draize scoring at 24 and 72 hrs.

Results: No irritation. All scores zero. Primary Skin Irritation Index=0.

Study Classification: Core Minimum (no indication product was moistened with physiological saline) Data

Product Classification: Tox. Cat. IV

4. Eye Irritation Study in Rabbits

Procedure: 0.1 gm was instilled in one eye of each of 9 rabbits; 6 were unwashed, 3 were washed with distilled water (how long?) 30 seconds after instillation. Eyes examined at 24, 48, 72 (but not 96) hrs and at 7 days.

Results: Corneal opacity in 4/6 unwashed, 1/3 washed eyes at 24 hrs, with all eyes recovering on days 2-3. All scores zero on day 7.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. II:WARNING

The following acute toxicological studies were conducted on the proposed formulation with 4.78% a.i. by Raltech Scientific Services, Inc. Ref. No. F-8286, 8-16-3-HL, Cover sheet dated March 6, 1978; Received 4-29-79; in EPA Acc. No. 238215.

5. Acute Oral Toxicity in Rats

Procedure: 10M (av. 196 gms) and 10F (av. 170 gms) Sprague-Dawley rats received, by stomach tube, 5 gms/kg of the test material administered as a 1:4 w/v slurry in corn oil. They were then observed 14 days with

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sacrifice and gross post-mortem examination.

Results: No mortalities. Animals, on average, gained weight. Necropsy indicated 1F had slight kidney mottling, otherwise nothing remarkable. Oral LD50 above 5 gm/kg.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

6. Acute Dermal Toxicity (rabbit)

Procedure: 2M, 2F New Zealand white rabbits, 2795-3315 gms, were dermally exposed to 20 gm/kg of test material, moistened with physiological saline and applied under a rubber sleeve. They were observed 14 days, sacrificed and grossly examined.

Results: No mortalities. All animals gained weight. 1M, 2F showed slight kidney pitting or mottling. Dermal LD50 above 5 gm/kg (FR43, #163, Aug. 22, 1978, p. 37345).

Study Classification: Normally, a Dermal LD50 study utilizing only 2M and 2F would be classified as Core Supplemental Data. However, in this case the high exposure level, lack of toxicological effects, and similarity to the study which utilized 2.98% a.i. formulation, all indicate a fairly low order of toxicity by this exposure route. Therefore this allows us to classify the study as Core Minimum Data.

Product Classification: Tox. Cat. III (FR43, #163, Aug. 22, 1978, pp. 37356-37357).

7. Skin Irritation (rabbit)

Procedure: 0.5 gm was applied to 2 sites (1 intact, 1 abraded) on each of 6 rabbits with 24-hr occluded exposure. Draize scoring at 24 and 72 hrs.

Results: No irritation. All scores zero.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV

8. Eye Irritation Study in Rabbits

Procedure: 0.1 gm was instilled in one eye of each of 9 rabbits (6 unwashed, 3 washed beginning 20 seconds after instillation), with scoring at 24, 48, 72 hrs and 7 days.

Results: Corneal opacity in 1/6 unwashed, 1/3 washed eyes at 24 hrs.

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However, an additional 4/5 unwashed eyes are indicated as having sloughing of from 25-75% of corneal epithelium at 24 hrs. No Draize scoring presented.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. II: WARNING

Byron T Backus 7-17-79

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PAGES 6 THROUGH 10 ARE NOT INCLUDED. THOSE PAGES CONSISTED OF DRAFT LABELING.