Doc. No. 1570

001530

Memorandum

Date: 17 March 1982

Subject: EPA File Symbol: 1021-RUIT EVERCIDE INTERMEDIATE 2245
Caswell #844, 25A, 77A,

From: B. T. Backus
IRB/TSS

To: Mr. Franklin Gee
Product Manager 17

Applicant: MGK Co.
8810 Tenth Ave. N.
Minneapolis, MN 55427

Active Ingredients:

25A —d-trans Allethrin.....6.75%
Related Compounds.....0.53%
77A —Cyano (3-phenoxyphenyl)methyl 4-chloro-alpha (1-methyletheyl) benzeneacetate.....6.26%
Heavy Aromatic Naphtha.....25.00%
Petroleum Distillate.....34.90%
Inert Ingredients.....26.56%

Background:

Product is proposed for formulating use only. Product is to be used at 2% by weight with appropriate solvents etc. in the manufacture of insect sprays.

Comments and Recommendations:

1. The acute oral LD50, dermal LD50, primary skin and eye irritation studies for EVERCIDE Intermediate 2245 are acceptable.

2. The dermal sensitization and inhalation LC50 studies on the proposed end-use product are acceptable.

3. IRB/TSS would have no objection, on the basis of hazard to humans and domestic animals, to the conditional registration of this product for the proposed use with the labeling revisions indicated below.

Labeling:

1. "Keep Out of Reach of Children" should be above the signal word CAUTION.

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2. The "IF SWALLOWED" statement of practical treatment should be revised to something like:

   Call a Physician or Poison Control Center. Do not induce vomiting because of aspiration hazard.

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

   CAUTION: Harmful if swallowed or absorbed through skin. Avoid inhalation of vapors. May cause eye irritation. Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling. Avoid contamination of food and feedstuffs.

4. We would prefer that the Storage and Disposal statement appear after the complete set of use instructions.

Review:

The following studies were conducted on the product (EVERCIDE Intermediate 2245) as proposed for registration. These studies were conducted by Biosearch Inc., P.O. Box 8598, Philadelphia PA 19101. Studies were received at EPA 12-21-81 and are in Acc. 247020.

Studies were conducted on EVERCIDE Intermediate 2244 - See Doc. No. 1570

1. Acute Oral LD50 - Rat. Project No. 81-2354A; dated 4-23-81.

   Procedure: Groups of 5M, 5F rats received oral dosage levels of 1.0, 2.0, 4.0, 8.0 or 16.0 gm/kg, with subsequent 14-day observation.

   Results: Mortalities

Dosage Level (gm/kg)	Mortalities/Rats Dosed M	F
1.0	0/5	0/5
2.0	0/5	0/5
4.0	0/5	0/5
8.0	3/5	3/5
16.0	5/5	3/5

   All deaths occurred within 6 days of dosage.
   Symptoms: Lethargy, ruffling and ataxia (at 2 gm/kg and above). At higher dosage levels tremors and convulsions.
   Necropsies were unremarkable.

   Oral LD50 (M) = 8.0 (5.7-11.2) gm/kg
   Oral LD50 (F) = 9.8 (6.1-15.9) gm/kg.

   Study Classification: Core Minimum Data (no individual body weights, not certain from report whether necropsies were performed on rats which died). 2

   Product Classification: Tox. Cat. IV (but probably presents an aspiration hazard from petroleum distillate).

2. Acute Dermal LD50 - Rabbit. Project No. 81-2354A; dated 4-23-81.

Procedure: Groups of 4M, 4F white rabbits received 24-hr occluded dermal exposure to 4.0, 8.0, 16.0 or 20.0 gm/kg, with subsequent 14-day observation.

Results: Mortalities

Dosage Level (gm/kg)	Mortalities/Rabbits Exposed M	F
4.0	0/4	0/4
8.0	0/4	0/4
16.0	0/4	0/4
20.0	3/4	1/4

All deaths occurred within 8 days of exposure.
Symptoms: At 8 gm/kg and above lethargy and depression. At highest level drooling and ataxia.
Dermal LD50 (M) = above 16 but less than 20 gm/kg.
Dermal LD50 (F) = above 20 gm/kg.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. IV (Dermal LD50 above 5 gm/kg)

3. Primary Dermal Irritation - Rabbit. Project No. 81-2354A; dated 4-23-81.

Procedure: 0.5 mls was applied at both an intact and an abraded skin site on each of 6 white rabbits, with 24-hr occluded exposure.

Results: PDIS = 3.54, with improvement seen between 24 and 72 hrs.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

4. Primary Eye Irritation - Rabbit. Project No. 81-2354A; dated 4-23-81.

Procedure: 0.1 ml was applied to one eye of each of 6 rabbits, with no wash.

Results: Slight conjunctival irritation in 4/6 rabbit eyes at 1 day; all scores zero at 2 days.

Study Classification:Core Minimum Data

Product Classification: Tox. Cat. III

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The following studies were conducted on the product diluted to 2%, the resulting formulation having the composition:

d-trans Allethrin	0.135%
Related Compounds	0.011%
Fenvalerate	0.125%
Heavy Aromatic Naphtha	0.500%
[redacted]	

5. Sensitization - Guinea Pig. Project No. 81-2354A; dated 4-23-81.

Procedure: 10M guinea pigs received a series of 10 24-hr occluded dermal exposures to 0.5 ml test material at 48 hr intervals, with challenge at a new test site two weeks after last exposure of initial series.

Results: 9/10 challenge site scores zero. 1/10 showed minimal erythema.

Study Classification: Core Minimum Data (no positive control)

Product Classification: Not a sensitizer

6. Acute Inhalation LC50 - Rat. Project No. 81-2354A; dated 4-23-81.

Procedure: 5M, 5F rats were exposed for 1 hr to a nominal concentration of 54.3 mg/L, with subsequent 14-day observation.

Results: No mortalities. Slight ruffling, depression, noted 2-3 hours after exposure ended. Mass median diameter was measured as 0.92 u; the concentration was calculated to be 0.19 mg/liter.

Comment: Most of this product is composed of solvents. The 0.19 mg/L would be the amount of actives together with the heavy aromatic naphtha (total percentage in this formulation: 0.771). 0.19 mg/L ÷ 0.00771 = ~~24.64~~ mg/L. (18.45 mg/L - amount of actives is ~1.03%)

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. ~~IV~~ III

Byron T Backus 05/17/82

Byron T. Backus
IRB/TSS

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INFORMATION WHICH MAY REVEAL THE IDENTITY OF AN INERT INGREDIENT IS NOT INCLUDED

Heavy aromatic naphtha toxicology review

Page _____ is not included in this copy.

Pages 5 through 6 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

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

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.
