Memorandum

021413

Date: 25 January 1982

Subject: EPA File Symbol: 1021-RUOE EVERCIDE INTERMEDIATE 2244
Caswell #844, 77A

From: B. T. Backus
IRB/TSS

To: Mr. Franklin Gee
Product Manager 17

Applicant: McLaughlin Gormley King Company
8810 Tenth Ave. North
Minneapolis, MN 55427

Active Ingredients:

| | |
|---|---|
| Tetramethrin | 10.00% |
| Fenvalerate | 6.26% |
| Heavy Aromatic Naphtha | 25.00% |
| Petroleum Distillate | 31.06% |
| Inert Ingredients: | 27.68% |

Background:

Product is proposed for formulating use only. One recommended product (a wasp and hornet killer) would have the following composition:

| | |
|---|---|
| Evercide Intermediate 2244 | 2.00% |
| [redacted] | |

Comments and Recommendations:

1. The toxicity studies received 6/15/81 are acceptable and adequate.

2. IRB/TSS has no objection, on the basis of hazards to humans and domestic animals, to the conditional registration of this product for the proposed uses with the labeling revisions indicated below.

Labeling:

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

2. The "IF SWALLOWED" statement of practical treatment for the EVERCIDE 2244 should be revised to something like:

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IF SWALLOWED: Call a physician or poison control center immediately. Do not induce vomiting because of aspiration hazard.

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

   CAUTION: Harmful if swallowed. Avoid inhalation of vapors. May cause eye irritation. Avoid contact with skin and eyes. Avoid contamination of food and feedstuffs.

4. We would prefer that the STORAGE AND DISPOSAL statement appear after the complete set of Instructions for Formulating.

The following revisions are applicable to the specimen (end-use) product label.

5. "May cause eye irritation" should be added to the statements under Hazards to Humans and Domestic Animals.

6. The "GENERAL CLASSIFICATION" should be deleted.

7. We would prefer that there be a separate STATEMENT OF PRACTICAL TREATMENT (under that heading) for this end-use product. Statements can be the same as those appearing on the label for the intermediate. [redacted] However, this end-use product would probably be in toxicity category III by this exposure route.

8. We would prefer that the STORAGE AND DISPOSAL statement appear following the complete set of Directions for Use.

Review:

The following studies were conducted on the product as proposed for registration (TL-2251) at Biosearch Inc. P.O. Box 8598, Philadelphia, PA 19101. Studies were received at EPA 6/15/81, and are in Acc. 245439.

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

   Procedure: Groups of 5M, 5F rats received oral dosages of 1, 2, 4, 8 or 16 g/kg with subsequent 14-day observation.

   Results:
   Mortality:

| Dosage Level (gm/kg) | Mortalities/Animals 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 |

Symptoms: Included lethargy, ataxia, drooling, trembling, convulsions. Deaths occurred up to 7 days after dosage, but survivors had essentially recovered by 8th day. Gross pathologies 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 weight data).

Product Classification: Tox. Cat. IV

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

Procedure: Groups of 4M, 4F rabbits were dermally exposed to 4, 8, 16 or 20 gm/kg, with 24-hr occluded exposure, subsequent 14-day observation.

| Results: | Dosage Level (gm/kg) | Mortalities/Animals Dosed M | F |
|---|---|---|---|
| Mortality: | 4.0 | 0/4 | 0/4 |
| | 8.0 | 0/4 | 0/4 |
| | 16.0 | 0/4 | 0/4 |
| | 20.0 | 3/4 | 1/4 |

Symptoms: Lethargy, depression, ataxia, drooling, occasional body tremors. More pronounced at higher dosage levels. Moderate irritation at all dosage levels lasting 7-8 days. Gross pathologies were unremarkable.

Dermal LD50 (M) = greater than 16 gm/kg, but less than 20 gm/kg.
Dermal LD50 (F) = greater than 20 gm/kg.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat.IV

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

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

Results: PDIS=3.54; scores higher at 24 hrs than at 72.

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 instilled in one eye of each of 6 rabbits, with no subsequent wash.

Results: Minimal conjunctival irritation in 4/6 rabbit eyes on day 1. All scored zero on day 2.

Study Classification: Core Minimum Data (no washed eyes)

Product Classification: Tox. Cat. III

The following studies were conducted on the proposed end-use product with the composition:

Neo-Pynamin (Tetramethrin), 90%.....0.2224
D-Trans Allethrin, 90%.....0.15
Fenvalerate,80%.....0.1564
Heavy Aromatic Naphtha.....0.5%

[redacted]

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

Procedure: 10M guinea pigs each received a series of 10 24-hr contact exposures to 0.5 mls of material, with occluded exposure. Each 24-hr contact period was followed by a 24-hr "rest period." There was a 2-week period following the 10th exposure, after which guinea pigs were challenged at a previously unused site, with readings at 24 and 48 hrs.

Results: No evidence of dermal sensitization

Study Classification: Core Minimum Data (no positive control; animals could have also been retested or challenged at the previously used application site).

Product Classification: Not a sensitizer under these circumstances

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

Procedure: 5M, 5F rats were exposed for one hour to a nominal concentration of 54.3 mg/L, with subsequent 14-day observation. Mass median diameter of the aerosol impacting on an Andersen sampler was calculated at 0.92 u, and the concentration was calculated to be 0.19 mg/L.

Results: No mortalities or symptoms observed.

Study Classification: Core Minimum Data. The 0.19 mg/L measured concentration would be the non-volatiles in this formulation, which represent about 1.03% of the total. This suggests the animals were actually exposed to 0.19 mg/L ÷ 0.0103 = 18.45 mg/L, with no adverse effects. This is toxicity category III by a factor of slightly more than 9x.

Product Classification: Tox. Cat. III

Byron T. Backus
IRB/TSS

Heavy aromatic naphtha toxicology review

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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

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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.

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