UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

000288

MEMORANDUM

DATE: January 30,1981

SUBJECT: EPA File Symbol 1021-RUAA
ESDIOL INTERMEDIATE 2207
Caswell No. 25, 508, 613, 646

FROM: Cheryl A. Peterson
IRB/TSS

TO: Mr. Franklin D. R. Gee
Product Manager (17)

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

Active Ingredients:

S-bioallethrin [d-trans-chrysanthemum monocarboxylic acid ester of d-2-allyl-4-hydroxy-3-methyl-2-cyclopenten-1-one	0.300%
Other Isomers	0.023%
Baygon [o-Isopropoxyphenyl methylcarbamate]	4.000%
N-octyl bicycloheptenedicarboximide	2.000%
Petroleum Distillate	0.026%
Inert Ingredients	93.561%

Background:

This product is intended for manufacturing use only. The company has submitted an application for conditional registration of a new product. The "cite-all" method of support is being used, and acute oral, acute dermal, acute inhalation, primary eye irritation, skin sensitization and primary skin irritation studies have been submitted in support of the application.

1.79

Labeling:

(Specimen Label)

1. The appropriate signal word is CAUTION, as indicated by the applicant.

2. The Statement of Practical Treatment should appear after the Precautionary Statements, and should resemble the following:

   If Swallowed: Drink a glass of water. Do not induce vomiting. Get immediate medical attention.

   In case of eye or skin contact: Flush with plenty of water. Get medical attention if irritation continues.

   (The statement "Incase of contact immediately flush skin and eyes with plenty of water." should be deleted from the Precautionary Statement.

3. The statement KEEP OUT OF REACH OF CHILDREN followed by the word CAUTION should appear on the front panel.

(Product Label)

1. The appropriate signal word is DANGER, based on eye irriation.

2. The Statement of Practical Treatment under If Ingested should be similar to the following:

   Drink glass of water. Do not induce vomiting. Get immediate medical attention.

3. The statement of Practical Treatment under IF IN EYES should resemble the following:

   Flush with plenty of water. Get immediate medical attention.

4. The Precautionary Statements should be similar to the following:

   DANGER: Causes eye and skin irritation. May be harmful if swallowed. Do not inhale vapors. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash after using. Wash all contaminated clothing with soap and warm water before re-use. Do not contaminate feed or foodstuff.

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Recommendations:

1. The acute oral, acute dermal, primary skin irritation and dermal sensitization studies are acceptable.

2. The acute inhalation and both primary eye irritation studies have been classified Core Supplementary Data. Actual chamber concentration measurements and particle size data must be provided in acute inhalation studies. Three animals must have test eyes washed starting no sooner than 30 seconds after test material instillation with lukewarm water for 1 minute.

3. Previous experience with the action of the inert ingredients which would be the cause of eye irritation in this product indicates that the hazard presented by exposure to the eye would place this product in Toxicity Category I. A 21-day eye irritation study which includes eye washes may indicate a lower toxicity category, such information would be useful in further evaluation of the toxicity classification of this product.

4. IRB/TSS would have no objection on the basis of hazard to man or domestic animals to the conditional registration of the above product with the labeling revisions indicated below.

Review:

The following studies were conducted by Biosearch, Inc., P.O. Box 8598, Philadelphia, PA 19101 for McLaughlin Gormley King Company on material identified as X-3384-79 [12.89% F-2207, 87.110% Petroleum Distillate, 0.042% S-bioallethrin, 0.005% other ingredients from S-bioallethrin, 0.258 MGK-264, 0.516% Baygon, 0.26% Inerts from Baygon, [redacted] F-2207 = 0.324% S-bioallethrin, 0.036% other ingredients from 90% Esbiol, 2.000% MGK-264, 4.000% Baygon, 0.200% inerts per Baygon, [redacted] They were received by EPA on 12-3-80, and are in Accession No. 244253. It was designated project number 79-1773A.

1. Acute Oral LD50-Rat. Dated: 11-12-79

Procedure: 5 groups of 5M, 5F Sherman-Wistar, albino rats each received via stomach syringe exposure to 1.0 g/kg, 2.0 g/kg, 4.0 g/kg, 8.0 g/kg or 16.0 g/kg test material. There was a 14-day observation period with survivor sacrifice and necropsy.

Results: LD_{50} in M & F = 11.3 g/kg (95% Conf. Lim. = 8.0-16.0 g/kg). Clinical signs included ataxia and drooling. 5M, 5F died Day 1 at 16.0 g/kg. Necropsy showed nothing remarkable. Survivors, on the average, gained weight during the observation period.

Study Classification: Core Minimum Data (Individual weight measurements should be recorded 3-4X weekly).

Product Classification: Tox. Cat. IV.

2. Acute Dermal LD_{50}-Rabbit. Dated: 11-12-79

Procedure: 4 groups of 4M, 4F albino rabbits (unspecified strain) each received 24-hour, occluded exposure to 4.0 g/kg, 8.0 g/kg., 16.0 g/kg and 20.0 g/kg test material. There was a 14-day observation period with survivor sacrifice and necropsy.

Results: LD_{50} = 11.3 (95% Conf. Lim. = 8.0-16.0) g/kg. Survivors, on the average, gained weight during the observation period. 4M, 4F died Day 1 at 16.0 and 20.0 g/kg. Clinical signs included tremors, ataxia, diarrhea and drooling. Necropsy showed nothing remarkable.

Study Classification: Core Minimum Data (Individual clinical signs and weights should be recorded).

Product Classification: Tox. Cat. III.

3. Primary Skin Irritation-Rabbit. Dated: 11-12-79.

Procedure: 6 albino rabbits each received 24-hour, occluded exposure to 0.5 g test material on an abraded and an intact skin area. Observations were made at 24 and 72 hours.

Results: Primary Irritation Index: 5.67. Moderate edema and minor erythema were evident in all animals at 72 hours.

Study Classification: Core Guideline Data

Product Classification: Tox. Cat. II.

4. Acute Inhalation LC_{50}-Rat. Dated: 11-12-79.

Procedure: 5M and 5F albino rats received 1 hour exposure to a nominal conc. of 22.6 mg/l test material. Air flow was 10 l/min. Rats were placed in a 70 l, all-glass chamber. Material was administered as supplied. There was a 14-day observation period, with survivor sacrifice and necropsy.

Results: No mortalities. LC_{50} is greater than a 1 hour exposure to a nominal conc. of 22.6 mg/l. No clinical signs were reported. Necropsy revealed nothing remarkable. Animals, on the average, gained weight during the observation period.

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Study Classification: Core Supplementary Data (Actual chamber concentration measurements and particle size measurements were not provided).

5. Primary Eye Irritation-Rabbit. Dated: 11-12-79.

Procedure: 6 albino rabbits each received 0.1 gm test material in the right eye. Observations were made at 1, 2, 3, 5, 7 and 14 days. No wash was given.

Results: No corneal opacity. No conjunctivitis.

Study Classification: Core Supplementary Data (3 additional animals did not receive eye wash after application of test material to the eye).

6. Contact Dermal Irritation/Sensitization-Guinea Pig. Dated: 11-15-79.

Procedure: 10 M albinc guinea pigs each received 24-hour occluded exposure to 0.5 gm test material on intact skin. Animals were allowed to rest for a day. This sequence was repeated. This was done for a total of 10 applications. The animals had a 2 week rest period, and then a challenge application was put on skin sites differing from the original test sites. The challenge remained on for 24 hours. Observations were made 24 hours after each application was removed, and 24 and 48 hours after the challenge was removed.

Results: Not an irritant. No edema. No erythema. [illegible]

Study Classification: [Core Supplementary Data, Skin Irritation: the test material must be applied to 2 intact and 2 abraded sites on each animal.] Core Minimum Data: Dermal sensitization study.

Product Classification: Not a sensitizer under conditions of this test.

The following test was conducted on material identified as F-2207 as supplied.

7. Primary Eye Irritation-Rabit. Dated: 11-12-79.

Procedure: 6 albino rabbits each received 0.1 gm test material in the right eye. Observations were made at 1, 2, 3, 5, 7, and 14 days. No wash was given.

Results: All animals showed moderate corneal opacity at 14 days. All animals showed moderate ~~erythema~~ [illegible] at 14 days.

Study Classification: Core ~~Supplementary~~ Minimum Data (3 animals did not receive eye wash after application of test material).

Propoxur Toxicology Reviews

Page _____ is not included in this copy.

Pages 6 through 9 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

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