

US EPA ARCHIVE DOCUMENT

BB-1057
TR=2/1

Memorandum

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Date: March 2, 1981

Subject: EPA File Symbol: 2724-EOR Zoecon RF-190 Fogger
Caswell #28AAA, 652BB

From: B. T. Backus
IRB/TSS

To: Mr. Franklin Gee
Product Manager 17

Applicant: Zoecon Industries
12200 Denton Drive
Dallas, TX 75234

Active Ingredients:

Methoprene.....	0.15%
Permethrin.....	0.50%
Inert Ingredients:.....	99.35%

Background:

Product is a fogger. Proposed use would involve one ^{12 oz.} fogger for each 12,000 cubic feet (or 1,500 square feet), but "Additional units should be used for areas where mist might not flow."

Comments and Recommendations:

1. The acute oral LD50, dermal LD50, primary eye and primary dermal irritation studies are acceptable and adequate.
2. In the acute inhalation LC50 study, 61.6% of the collected material on chamber filters was methoprene and 38.4% was permethrin. Expected figures would be about 23% and 77% respectively. The analyzed amount of methoprene suggests exposure was to an actual concentration of 13.7 mg/liter, while that of permethrin suggests exposure to an actual concentration of about 2.6 mg/liter of product. Some explanation should be provided for this apparent discrepancy.
3. If a satisfactory explanation is given for the methoprene and permethrin figures in the inhalation LC50 study, IRB/TSS would have no objection, on the basis of acute toxicological considerations, to the conditional registration of this product for the proposed uses under the cite-all method of support with the labeling revisions indicated below.

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Labeling:

1. There should be a Statement of Practical Treatment (preferably under that heading) regarding eye exposure something like the following:

IF IN EYES: Flush with plenty of water. Get medical attention.

2. The HAZARDS TO HUMANS AND DOMESTIC ANIMALS statement should be revised to something like the following:

WARNING: May cause eye irritation. Do not get in eye. Avoid contact with skin and clothing. Harmful if inhaled. Avoid breathing vapors. Cover or remove fish tanks and bowls before use. Do not apply to humans or animals.

3. The phrase ~~on 2-5-80~~ additional units should be used for areas where mist might not fall should be deleted; or, alternatively, should be justified and possibly made somewhat more specific as to circumstances.

Review:

The following studies were conducted on the material obtained by condensing the aerosol (product proposed for registration) into a clean beaker. Studies were conducted at Elars Bioresearch Laboratories, Inc. 225 Commerce Drive, Fort Collins, Colorado 80524. Studies are in Acc. 244027.

1. Rat Acute Oral Toxicity; Project 1540-D, dated June 25, 1980.

Procedure: Groups of 5M, 5F albino rats, 150-300 gms, were orally dosed at 5.0 and 5.5 g/kg, with 14-day observation, survivor sacrifice, and gross necropsies.

Results: 1M, 1F died at 5 g/kg dosage level; female died during gavage. No mortalities at 5.5 g/kg. Symptoms included lethargy, ataxia and tremors. One rat in the 5.5 g/kg dosage level had thickening of the mucosa on the non-glandular esophageal region of stomach. Others were unremarkable on necropsy. All survivors gained weight. Oral LD50 in excess of 5.5 g/kg.

Study Classification: Core Minimum Data (no analysis on material administered).

Product Classification: Tox. Cat. IV

2. Acute Dermal Toxicity Zoecon Methoprene and Permethrin Fogger. Project No. 1540-C, dated July 21, 1980.

Procedure: Groups of 5M, 5F NZ white rabbits, 2-3 kg, with abraded skin, received a 24-hr occluded dermal exposure to dosage levels of 2.1 and 5.1 g/kg, with subsequent 14-day observation, sacrifice and necropsies.

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Results: No mortalities. Some erythema in 2.1 g/kg dosage level group, none in the 5.1 g/kg group (groups were tested on May 27, 1980 and June 19, 1980 respectively). Animals at 5.1 g/kg dosage level showed evidence of cutaneous lesions (apparently found on necropsy). No material-related systemic toxicity was observed. Dermal LD50 above 5.1 g/kg.

Study Classification: Core Minimum Data (no analysis on material administered).

Product Classification: Tox. Cat. IV

3. Primary Dermal Irritation Zoecon Methoprene and Permethrin Fogger. Project No. 1540-A, dated July 3, 1980.

Procedure: 0.5 ml test material was applied at each of 4 sites (2 intact, 2 abraded) on each of 6 NZ white rabbits, with 24-hr occluded dermal exposure.

Results: PDIS = 1.46. Erythema worse on day 3 (most scores 1-3) than on day 1; but considerable improvement by day 6.

Study Classification: Core Minimum Data (no analysis of material administered)

Product Classification: Tox. Cat. IV

4. Primary Eye Irritation Zoecon Methoprene and Permethrin Fogger, Project No. 1540-B. Dated July 3, 1980.

Procedure: 9 rabbits received 0.1 ml of test substance in one eye, with 3 eyes being flushed with water for 1 minute starting 30 seconds after instillation; other 6 eyes remained unwashed.

Results: Corneal opacity in 5/6 unwashed, 3/3 washed eyes at 24 hrs. All corneal opacity had cleared by day 7; only one rabbit eye showed any signs of irritation on day 7.

Study Classification: Core Minimum Data (no analysis of material administered)

Product Classification: Tox. Cat. II

The following study was conducted on the product as proposed for registration by Hazleton Laboratories America Inc. This study is in Acc. 244027.

5. Acute Inhalation Toxicity Study in Rats Methoprene and Permethrin Fogger. Project No. 777-133; not dated (study was terminated June 16, 1980).

Procedure: 5M. 5F Sprague-Dawley derived rats, 225-292 g, were exposed for 4.5 hrs to a nominal concentration of 5.3 mg/liter of aerosol product, with subsequent 14-day observation, survivor sacrifice and necropsies.

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Results: No mortalities. No significant symptomatology. Nothing remarkable found on necropsy. Four 15-minute aerosol samples were collected on Gelman-Metricel DM-450 membrane filters at a sampling rate of 10 liters/min. Filters were preweighed, dried after exposure, then reweighed, and were subsequently analyzed for methoprene and permethrin using GLC. Average weight gain of filters was 4.48 milligrams; or 5.02 milligrams (from analyses results). Of the 5.02 milligrams, 3.10 mgs was methoprene and 1.93 mgs was permethrin. Of the collected material then 61.6% was methoprene and 38.4% was permethrin; expected figures would be about 23% and 77% respectively. The amount of methoprene suggests exposure was to an actual concentration of 13.7 mg/liter of product, while that of permethrin suggests exposure was to an actual concentration of about 2.6 mc/liter. Zoecon Industries did the actual analyses on these filter papers.

Gravimetric analysis indicated a mean concentration of 29.87 ug/liter (this would be presumably of permethrin+methoprene). $29.87 \div 0.0065 = 4595$. Gravimetric analysis indicates then a product concentration of approximately 4.6 mg/liter. A similar figure (M=28.45 ug/liter) was obtained from the mini-impactor. The mean mass median diameter (MMAD) of the non-volatile component was slightly above 3.99 u.

Study Classification: Core Supplementary Data (until such time as the analytical inconsistency is satisfactorily explained).

Product Classification: Tox. Cat. III (tentative).

Byron T Backus 03/02/81

Byron T. Backus
IRB/TSS

Methoprene toxicology reviews

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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
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 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - A draft product label
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