Memorandum

Date: August 14, 1980

Subject: EPA File Symbol: 2724-EIT ZOECON RF-178 FOGGER
Caswell #28AAA, [redacted]

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%
Inert Ingredients [redacted].....99.85%

Background:

Proposed for use as a fogger. This product would be used in and around the home to kill pre-adult fleas.

Comments and Recommendations:

1. The acute oral LD50, dermal LD50, eye and dermal irritation, and inhalation studies submitted with this application are adequate and acceptable.

2. The toxicity of this product is, as would be expected, essentially [redacted]

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 uses with the labeling revisions as indicated below.

Labeling:

1. The product formulation can cause short-term (less than 7-day) corneal opacity, [redacted] Irritation [redacted] is still present at 7 days following exposure. The appropriate signal word is therefore WARNING, based on the potential eye hazard.

2. The appropriate statement following HAZARDS TO HUMANS AND DOMESTIC ANIMALS would be something like the following:

13
100

INERT INGREDIENT INFORMATION IS NOT INCLUDED

WARNING: Harmful if swallowed, inhaled or absorbed through skin. Avoid breathing vapor. Causes eye irritation. Do not get in eyes. Avoid contact with skin or clothes. In case of eye contact immediately flush with plenty of water. Get medical attention. For skin, wash with plenty of water. Get medical attention if irritation persists.

Review:

The following 4 studies were conducted by Elars Bioresearch Laboratories, Inc. 225 Commerce Drive, Fort Collins, Colorado 80524 on test material obtained by spraying contents of an aerosol can (product as proposed for registration) into a chilled inverted beaker, from which condensate dripped into a second beaker. Specific gravity of the test material was 1.29 gm/ml. The test material probably had approximately the following composition:

[redacted]	
Methoprene	0.2%

Studies were received at EPA July 11, 1980, and are in Acc. 242982.

1. Rat Acute Oral Toxicity; Proj. 1537-D, dated June 6, 1980.

   Procedure: Groups of 5M, 5F Sprague-Dawley rats (160-400 gms) received dosage levels of 1.0 and 6.45 g/kg, with 14-day observation, survivor sacrifice and gross necropsies.

   Results: No mortalities. No symptoms at 1.0 g/kg. At 6.45 g/kg all had lethargy, ataxia, respiratory rate reduction after dosage. Four animals had diarrhea days 1-2. "Slight" kidney congestion in 6 dosed a 1.0 g/kg; congested kidneys in 9 dosed at 6.45 g/kg. All gained weight over 14-day period.

   Study Classification: Core Minimum Data (material tested was not analyzed)

   Product Classification: Tox. Cat. IV

2. Acute Dermal Toxicity; Proj. No. 1537-C, June 25, 1980.

   Procedure: Groups of 5M, 5F NZ white rabbits with abraded skin received 24-hr occluded exposure to dosage levels of 2.1 and 5.1 g/kg, with 14-day observation, survivor sacrifice and gross necropsies. Concurrent control groups.

   Results: No mortalities in exposed animals. Most gained weight. Two rabbits died in one control group. One subject from 2.1 g/kg dosage level and 4 from the 5.1 g/kg level showed pitted, pale and/or congested kidneys.

   Study Classification: Core Minimum Data (material tested was not analyzed).

   Product Classification: Tox. Cat. IV

3. Primary Dermal Irritation; Proj. No. 1537-A; June 4, 1980

Procedure: 0.5 mls was applied to each of 4 sites (2 intact, 2 abraded) on each of 6 rabbits with 24-hr occluded exposure.

Results: Considerable response variation. Erythema scores and edema scores ranged from 0-3 at both 24 and 72 hrs. Average Irritation score 2.38 at 24 hrs; 3.00 at 72 hrs (there was an increase in edema between the 24 and 72 hr scoring). PDIS = 2.69. Two subjects still had slight erythema (score = 1) at some sites on 21st day.

Study Classification: Core Minimum Data (test material not analyzed).

Product Classification: Tox. Cat. III

4. Primary Eye Irritation; Proj. No. 1537-B, dated June 25, 1980.

Procedure: 0.1 ml test material was placed in one eye of each of 9 rabbits. Three eyes were flushed for 1 minute starting 30 seconds after application. Remaining 6 eyes were unwashed.

Results: Some corneal opacity noted in 3/6 unwashed, 1/3 washed eyes, but not present on 7th day. Slight conjunctival irritation was present in 4/6 unwashed, 0/3 washed eyes at 7 days. All scores zero by 7 (10) days.

Study Classification: Core Minimum Data (test material not analyzed)

Product Classification: Tox. Cat. II

The following study was conducted at Hazleton Laboratories Inc. 9200 Leesburg Tpk, Vienna VA 22180. It was submitted to Zoecon Corp. August 4, 1980; received at EPA 8-6-80.

5. Acute Inhalation Study in Rats. Interim Report. Proj. No. 777-131.

Procedure: 5M, 5F Sprague-Dawley rats were exposed to a nominal concentration of 5.03 mg/liter for 4 hours. Aerosol was generated from two Methoprene Fogger cannisters located inside the exposure chamber above the animals; a pneumatic activator produced a 1.25 second spray burst every 273 seconds for 4 hours. Four 15-minute aerosol samples were collected on preweighed Gelman DM-450 filters (sampling rate 10 liters/minute) beginning at 0.75, 1.75, 2.75 and 3.75 hours after exposure started. These filters were shipped in Teflon sealed glass vials on dry ice to Zoecon for methoprene content analyses. Particle size distribution of the non-volatile component of the aerosol was determined from 4 15-minute samples collected with Andersen 4-stage Mini-impactors.

Subjects were observed for 14 days following exposure, with survivor sacrifice and gross necropsy. There was a concurrent control (unexposed) group.

Results: No mortalities. All animals gained weight. Similar necropsy findings for both control and exposed groups.

Analysis of Gelman filters:

Filter Number	Weight Gain of Filter from Exposure (mg.)	Methoprene Analysis of Filter Paper (mg.) -GLC
1	1.13	1.53
2	1.06	1.20
3	1.37	1.48
4	1.34	1.34
		Av.1.39

Since the product is about 0.15% methoprene, 5.03 mg/liter (nominal conc)product would be a nominal conc. of 7.55 µg/liter of methoprene. Average of 1.39 mg in 150 liters (10 liters/min. x 15 liters) would be an average conc. of 9.27 µg/liter of methoprene, so the actual exposure was to a level about the same as the nominal concentration.

Mean mass aerodynamic diameter (MMAD) of the non-volatile component was about 2.35µ.

Study Classification: Core Minimum Data (no measurements made of the volatile aerosol components; no justification given for testing at 4 hrs and conc. of 5 mg/liter instead of 1 hour and 20 mg/liter).

Product Classification: Tox. Cat. IV

Byron T Backus 8/14/80

Byron T. Backus
IRB/TSS