

Memorandum

000341

Date: March 27, 1981

Subject: EPA File Symbol: 2724-EOG Zoecon RF-184 House & Kennel Fogger
Caswell #28AAA, 508, 328

From: B. T. Backus
IRB/TSS

To: Mr. George LaRocca
Product Manager 15

Applicant: Zoecon Industries
12200 Denton Drive
Dallas, TX 75234

Active Ingredients:

Methoprene.....	0.150%
Propoxur.....	1.000%
DDVP.....	0.470%
DDVP-related compounds.....	0.030%
Inert Ingredients:.....	98.350%

Background:

Product is a fogger, for use indoors against fleas, ticks, roaches, ants, flies, spiders and flying moths.

Comment and Recommendation:

1. IRB/TSS has no objection, on the basis of hazard to humans and domestic animals, to the conditional registration of this product under the cite-all method of support with the labeling revisions indicated below.

Labeling:

1. There should be a STATEMENT OF PRACTICAL TREATMENT, preferably under that heading, with something like the following:

IF SWALLOWED: Drink a glass or two of water and induce vomiting by touching finger to back of throat or administration of syrup of ipecac. Get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Atropine is antidotal only if signs of cholinesterase inhibition are present.

IF INHALED: Remove to fresh air.

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

IF ON SKIN: Wash thoroughly with soap and water.

2. With a statement of practical treatment similar to the above the proposed "In case of eye contact, immediately flush eyes with plenty of water. Get medical attention. For skin wash with plenty of water" appearing in the Precautionary Statements can be deleted.

Review:

The following studies were conducted on the liquid obtained by spraying the aerosol as proposed for registration into a chilled beaker. The following studies were conducted by Elars Bioresearch Laboratories, Inc. 225 Commerce Drive, Fort Collins, Co 80524. They were received at EPA 12-19-80 and are in Acc. 244215.

1. Acute Oral LD50 Toxicity Study Zoecon RF-184 Fogger. (Acute Oral LD50 - Rat). Project No. 1605-D, dated 12/16/80.

Procedure: Based on results of a preliminary study, groups of 5M, 5F albino rats were orally gavaged at dosage levels of 1.3, 1.7, 2.0 and 3.5 g/kg, with 14-day observation, sacrifice and necropsies.

<u>Results:</u>	Dosage Level g/kg	Mortalities	
		M	F
	1.0	0/5	2/5
	1.3	0/5	3/5
	1.7	0/5	1/5
	2.0	2/5	4/5
	3.5	3/5	5/5

Oral LD50 (M) = 3.40 (1.18-9.81) g/kg; oral LD50 (F) = 1.32 (0.553-3.17) g/kg;
combined oral LD50 = 2.16 (1.25-3.73) g/kg.

Symptoms: excessive salivation, quivering, lethargy, piloerection, bloody ocular discharge, labored respiration. Rats that died had congested, hemorrhagic lungs, dark livers, hemorrhagic stomach and intestinal walls. Necropsies of survivors were unremarkable.

Study Classification: Core Minimum Data (composition of condensate not given).

Product Classification: Tox. Cat. III

2. Acute Dermal Toxicity Study Zoecon RF-184 Fogger (Acute Dermal LD50 - Rabbit). Project No. 1605-C, dated 11/13/80.

Procedure: Groups of 5M, 5F NZ white rabbits, 2-3 kg, received 24-hr occluded dermal exposure to dosage levels of 2.1, 4.25, 5.1, 6.0 and 7.0 g/kg, with 14-day observation, survivor sacrifice and gross necropsies.

<u>Results:</u>	Dosage Level	Mortalities	
		M	F
	g/kg		
	2.1	0/5	0/5
	4.25	2/5	0/5
	5.1	2/5	3/5
	6.0	1/5	2/5
	7.0	2/5	2/5

Dermal LD50 = 7.41 g/kg, with 95% confidence limits of 3.47 to 15.83 g/kg. Subjects in four highest dosage levels appeared to be in immediate pain at start of dosage, with subsequent labored breathing, excessive salivation and cyanotic appearance. Test sites appeared red and swollen at 24 hrs. Skin of application sites eventually became crusted, dried and cracked. Animals dying had congested and enlarged lungs, excessive salivation, diarrhea, cyanosis and red and swollen skin at application site. Sacrificed survivors showed damaged skin at test site.

Study Classification: Core Minimum Data (composition of condensate not reported).

Product Classification: Tox. Cat. III (95% confidence limits extend down to 3.47 g/kg).

3. Primary Dermal Irritation Zoecon RF-184 Fogger (Primary Dermal Irritation - Rabbit). Project No. 1605-A, dated 11/25/80.

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

Results: Max. score for erythema = 1 at 24 and 72 hrs; present at most sites. Very little edema noted. PDIS = 0.67.

Study Classification: Core Minimum Data (exact composition of condensate not reported).

Product Classification: Tox. Cat. IV

4. Primary Eye Irritation Study Zoecon RF-184 Fogger. (Primary Eye Irritation - Rabbit). Project No. 1605-B, dated 11/26/80.

Procedure: 0.1 ml was applied to one eye of each of 9 rabbits; 3 eyes were flushed for one minute with warm water starting 30 seconds after application. Other 6 eyes remained unwashed.

Results: Corneal opacity in 3/6 unwashed, 3/3 washed eyes. Only one eye still showed any irritation at 7 days, and even this was clear at 13 days.

Study Classification: Core Minimum Data (composition of condensate not reported).

Product Classification: Tox. Cat. II

The following study was conducted on the product as proposed for registration (in its aerosol form) at Hazleton Laboratories America Inc., 9200 Leesburg Tpk, Vienna, Va. 22180.

5. Preliminary Report Acute Inhalation Toxicity Study in Rats RF-184 Fogger (R & D 8559). (Acute Inhalation LC50 - Rat). Project No. 777-138, dated 12/4/80.

Procedure: 5M, 5F white rats were exposed to a nominal concentration of 5.83 mg/L for 4 hrs, with subsequent 14-day observation, sacrifice and necropsy.

Results: No mortalities. Gravimetric concentration determinations indicated solids made up between 8.67 and 11 ug/L. Approximately 35% of the particles collected were under 4.7 um. Symptoms included slightly rapid breathing at 1 hr and clear discharge in the nasal after 3 hrs. Slightly rapid breathing persisted through day 2. All subjects had normal weight gains.

Exposed animals exhibited higher incidence of darkened lymph nodes and kidney lesions than unexposed controls. However, it is not possible to state whether or not this was treatment-related.

Comment: Measured concentrations of solids were between 8.67 and 10 ug/L. If these were due to the active ingredients in this formulation (1.65% of total formulation) subjects were being exposed to an actual concentration of $10 \text{ ug/L} \div 0.0165 = \text{about } 600 \text{ ug/L}$.

Study Classification: Core Supplementary Data. Additional information will be eventually supplied, which would presumably include chemical analysis of material that was collected. Indication from this study is that product is certainly no worse than toxicity category II by this exposure route.

Byron T. Backus 3/27/81
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IRB/TSS

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Propoxur Toxicology Reviews

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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
- ☒ A draft product label
- ☐ The product confidential statement of formula
- ☐ Information about a pending registration action
- ☐ The document is a duplicate of page(s) _____