

002407

Memorandum

Date: 18 January 1983

Subject: EPA File Symbol: 4758-RUA HILL'S HOLIDAY FLEA & TICK AEROSOL SPRAY  
Caswell #526

From: B. T. Backus  
IRB/TSS

To: Mr. William Miller  
Product Manager 16

Applicant: Pet Chemicals Inc.  
P.O. Box 660656  
7781 N.W. 73 CT  
Miami Springs, FL 33166

Active Ingredient  
d-Limonene.....5.00%  
Inert Ingredients:.....95.00%

Background:

Product is proposed for use on dogs and cats for control of ticks and fleas. The applicant has sent in acute oral LD<sub>50</sub>, acute dermal LD<sub>50</sub>, acute inhalation LC<sub>50</sub>, primary eye and dermal irritation, and guinea pig sensitization studies on the subject formulation.

Comments and Recommendations:

1. The acute oral LD<sub>50</sub>, acute dermal LD<sub>50</sub>, primary eye and dermal irritation, and guinea pig sensitization studies are acceptable, although there is some concern about the relatively low concentration at which the product was tested in the sensitization study.
2. The acute inhalation LC<sub>50</sub> study has been classified as supplementary data, as no measurements were reported as to actual concentrations (as opposed to nominal values) of the formulation or its active during the period of exposure.
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 comments as indicated below.

Labeling:

1. This product is in toxicity category IV with respect to potential oral hazards. Therefore, the statement: "Harmful if swallowed." as well as the if swallowed statement of practical treatment are not necessary. However, we can accept retention of these statements.

Review:

The following studies were conducted on the product as proposed for registration by M B Research Laboratories, Inc. Steinsburg & Wentz Roads, P.O. Box 203, Spinnerstown, PA 18968. Studies were received at EPA 11-23-82.

1. Acute Oral LD<sub>50</sub> - Rat. Project No. MB 81-5737 A; dated 1-20-82. In Acc. 248913.

Procedure:

5M, 5F Wistar albino rats received oral dosages of 5 g/kg, with subsequent 14-day observation.

Results: No mortalities. Symptoms included coma, flaccidness, ataxia, lethargy, dyspnea, ptosis, chromorhinorrhea or chromodacryorrhea, muzzle area stained brown. Most symptoms were observed only on the day of dosage and 24 hrs later. Subjects gained weight during two week observation period. Post-sacrifice necropsies were mostly unremarkable. Oral LD<sub>50</sub> above 5 g/kg.

Study Classification: Core Minimum Data (product is an aerosol, not certain how material was prepared for dosage).

Product Classification: Tox. Cat. IV

2. Acute Dermal LD<sub>50</sub> - Rabbit. Project No. MB 81-5737 B; dated 1-20-82. In Acc. 248912.

Procedure: 5M, 5F albino rabbits received 24-hr occluded dermal exposure to a dosage level of 2 g/kg, with subsequent 14-day observation.

Results: No mortalities. Symptoms seen included lethargy, ptosis, few feces, diarrhea and yellow nasal discharge. Severe dermal responses on day 7, with improvement in most animals by day 14. Dermal LD<sub>50</sub> above 2 g/kg.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

3. Primary Dermal Irritation - Rabbit. Project No. MB 81-5737 C; dated 1-20-82. In Acc. 248912.

Procedure: 0.5 ml was applied to each of 4 intact sites on each of 6 rabbits, with 4-hr occluded exposure. Scoring at 4 hrs and at 1, 3, 7 and 14 days.

Results: PDIS = 3.28 (average of 4, 24 and 72 hr scores). However, scores of 4 for erythema-eschar common at 7 days, but only slight irritation at 14 days.

Study Classification: Core Minimum Data

Product Classification: Tox. Cat. III

4. Primary Eye Irritation - Rabbit. Project No. MB 81-5737 D. In Acc. 248711.

Procedure: 0.1 ml was placed in the conjunctival sac of one eye of each of 9 rabbits. Three eyes were flushed with water for one minute starting 20-30 seconds after instillation. Remaining 6 eyes were unwashed.

Results: No corneal involvement. Some conjunctival irritation persistent in 6/6 unwashed, 3/3 washed eyes through day 2. All eyes cleared by day 7.

Study Classification: Core Minimum Data (product is an aerosol; not certain how material was prepared prior to testing).

Product Classification: Tox. Cat. III

5. Sensitization - Guinea Pig. Project No. MB 81-5737 F; dated 1-20-82. In Acc. 248909.

Procedure: A group of 10 male received a series of 10 intradermal injections (at the rate of 3/week) of a 0.01% dilution of the product in physiological saline, followed with a two-week rest period, and a challenge at a previously unused site.

Results: One animal died on day 4. No evidence of sensitization was seen during the induction period or on challenge.

Study Classification: Core Minimum Data (some concern about the considerable dilution of test material used in this study).

Product Classification: Not a sensitizer at this dilution. However, other studies have indicated d-Limonene is a weak sensitizer.

5. Acute Inhalation LC<sub>50</sub> - Rat. Project No. 81-5737; dated Dec. 29, 1981. In Acc. 248910.

Procedure: A group of 5M, 5F SD rats were exposed for 4 hrs to a nominal concentration of 5 mg/L, with subsequent 14-day observation. Particle size measurements taken during the run were 2.90 + 2.34 um and 3.55 + 2.23 um. No reporting as to actual concentration to which subjects were exposed.

Results: No mortalities. Behavior unremarkable during exposure; all rats gained weight afterwards.

Study Classification: Core Supplementary Data (No reporting as to actual concentration to which subjects were exposed).

Byron T. Backus 01-18-83

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IRB/TSS

FRONT PANEL

HILL'S HOLIDAY  
FLEA & TICK AEROSOL SPRAY

For Dogs & Cats

002407

ACTIVE INGREDIENTS:		
d-limonene		5.00%
INERT INGREDIENTS:		95.00%
	TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN  
CAUTION  
See additional precautions on side panel

Net Wt. 14 oz. (397 gm)  
EPA Reg. No. 4758-

SIDE PANEL

GUARANTEE

If this product fails to perform as claimed, mail this container with proof of purchase to Pet Chemicals Inc. FULL PURCHASE PRICE plus your return postage will be refunded by return mail.

PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS & DOMESTIC ANIMALS  
CAUTION

Do not get in eyes or on clothing. Harmful if swallowed. Avoid breathing vapors. Caution should be exercised when using on nursing animals. Do not use on animals under 1 month of age. Some individuals and pets may be sensitive to this product. Discontinue use if irritation develops. Wash hands with soap and water after using.

STATEMENT OF PRACTICAL TREATMENT

If swallowed - call a physician or Poison Control Center. It is preferable to induce vomiting under medical supervision because of aspiration hazard; otherwise give glass of water and induce vomiting by touching finger to back of throat. . . . .  
If on skin - wash off with soap and water. Get medical attention if irritation develops. . . . .  
If in eyes - flush with plenty of water. Get medical attention if irritation persists. . . . .

PHYSICAL OR CHEMICAL HAZARDS

Flammable. Keep away from heat or open flame. . . . .

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. . . . .

Hold tip of nozzle 4-6 inches from animal. Direct spray into hair. To insure penetration to skin, stroke against lay of hair. Be sure to include legs and feet. Do not spray near animal's eyes or on genital area, to avoid irritation. Spray animal's bedding to help control fleas. May be used as needed.

STORAGE AND DISPOSAL

Do not use or store near heat or open flame. Do not re-use empty container. Wrap empty container and place in trash collection.

EPA Est. No. 4758-FL-1

Cat. No. \_\_\_\_\_

Manufactured by  
PET CHEMICALS INC.  
P.O. Box 660656, Miami Springs, FL 33166