3-22-84

Date: March 20, 1984

Subject: EPA Registration Number: 2724-298
Zoecon RF-200 Pressurized Spray

From: Orlando F. Graham
FHB/ISB E 3/22/84

To: Lisa Gardner
Product Manager (17)

Applicant: Zoecon Industries
A Division of Zoecon Corporation
12200 Denton Drive
Dallas, Texas 75234

Active Ingredients:

Isopropyl (E,E)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	0.03%
Pyrethrins	0.20%
Piperonyl butoxide, technical	1.00%
N-octyl bicycloheptene dicarboximide	1.00%
Inert Ingredients	97.77%

Background: Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Primary Dermal Irritation Studies. Data under EPA accession number 252259. Dermal Sensitization referenced in a previous submission. Studies conducted by Toxigenics, Inc. Method of support not indicated.

Recommendations:
(1) FHB/ISB finds these data ~~acceptable~~ acceptable to support conditional registration of this product. However in the Acute Inhalation Study since an LC50 was not ~~submitted~~, it could only be determined that the ~~eye~~ toxicity category is no worse than II - WARNING.

(2) The appropriate signal word is (DANGER)?

Label:
(1) Precautionary statements must precede signal word.
(2) The precautionary statements must be revised to include "DANGER. Corrosive; causes skin burns. May be fatal if inhaled. Harmful if swallowed."
(3) The statement of practical treatment must be revised to include "If on skin wash with plenty of soap and water and get medical attention"
(4) The storage and disposal statement must be revised similar to following: "Pesticide, spray mixture, or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resource Conservation and Recovery act."

Review:
(1) Acute Oral Toxicity Study: Toxi-Genics, Inc.; Study # 410-103; August 27, 1982.

Procedure: Five male and five female rats received 5.1gm of the test material orally. Observations made hourly on day of dosing, then twice daily thereafter for 14 days post treatment.

Necropsy performed on all animals

Results: No mortalities. Clinical signs reported included lethargy, loose stools, yellow brown stained fur. Necropsy report revealed a solitary, red-brown, crusted discoloration of the skin in the cervical region; and solitary, red depression on the lung of one male; another male had diffuse red exudate in the abdominal cavity and torn liver with clotted blood. LD50 greater than 5.1 gm.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(2) Acute Dermal Toxicity Study: Toxi Genics, Inc.; Study # 410-1024; September 15, 1982.

Procedure: Five male and five female New Zealand rabbits received 5.1 g/kg of the test material at abraded skin sites under occlusive wrap for 24 hour exposure. Observations made daily for 14 days after treatment. Necropsy performed on all animals.

Results: No mortalities. Clinical signs reported included loose stools, yellow/brown stained fur, vocalization when handled, emaciated, white discharge in eye; erythema, edema, atonia, desquamation, concaceous, fissured; eschar formation, white exudate at the areas of fissures, blisters, pimple-like eruptions. Necropsy report revealed multiple, focal, red or red-brown discoloration of skin at treated sites, thickened diffuse

abn, sloughing of epidermis of treated areas, multiple, focal, clear cysts in both kidneys of one male. LD50 greater than 5.1 gm.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(3) Acute Inhalation Toxicity Study: Toxi Lenics, Inc.; Study # 420-1196; July 7, 1983.

Procedure: Five male and five female rats weighing between 214 and 292 gm were exposed for 4 hours to an gravimetric ~~conc~~ concentration of 0.06 mg/l (nominal concentration = 5.27 mg/l). Average mass median diameter and geometric standard deviation was 0.4 u and 2.25 respectively. Temperature ranged between 70 and 75°F with relative humidity ranging between 37 and 58%. Observations made every 15 minutes during first hour of exposure and every 30 minutes for remainder of exposure time, then twice daily for 14 days post exposure. Necropsy performed on all ~~test~~ animals. Another group of five male and five female rats weighing between 188 and 289 gm were treated in a similar fashion as the previously mentioned group except no test material was used. These animals served as controls.

Results: No mortalities reported. Clinical signs reported included irregular breathing, exophthalmus, tremors in test animals. No clinical signs reported in controls. Necropsy report revealed

lung and kidney abnormalities; subpleural multifocal inflammatory changes; perbronchial inflammation involving bronchial mucosa; pulmonary interstitial edema; alveolar aggregates of pulmonary macrophages; unilateral renal hydronephrosis; pyelitis; [illegible] multifocal aggregates of mononuclear cells in the hepatic sinusoids; multifocal hepatocellular necrosis; focal hepatocellular vacuolative degeneration; a multifocal vacuolative degeneration of the [illegible] epithelium in a female test animal. Similar conditions noted in necropsy report of control animals.

Study Classification: Core Minimum Data. LC50 must be submitted.

Toxicity Category: II - WARNING

(4) Eye Irritation Study: Toxi Genics, Inc.; Study # 410-1026; September 1, 1982.

Procedure: One rabbit received 100 mg of the test material in one eye each. The treated eyes of three of the rabbits were washed with lukewarm water. Observations were made at 24, 48, and 72 hours, and 7 days after treatment.

Results: At 24 hours 6 animals of the unwashed group had redness (M6=1), but had cleared by 48 hours. No corneal opacity or iris irritation noted in any of the animals.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(5) Primary Dermal Irritation Study: Toxi Services, Inc.; Study # 410-1025; September 3, 1982.

Procedure: Six rabbits with intact skin received 0.5 g of the test material under occlusive wrap for 4 hour exposure. Observations were made at 24, 48 and 72 hours, 4, 5, 6 and 7 days after treatment.

Results: At 24 hours, 4/6 slight to moderate erythema (scores of 1, 2 and 3) and 4/6 slight edema (scores of 1). At 72 hours, 6/6 well defined to severe erythema (scores of 2, 3 and 4) and 4/6 slight to moderate edema (scores of 1, 2 and 3); ~~Eschar~~ eschar formation also noted. Moderate to severe reactions persisted through day 5. By day 6 ~~irritation~~ had begun to reverse itself. Desquamation reported on days 6 and 7.

PDIS ?

Study Classification: Core Guideline Data

Toxicity Category: I - DANGER