

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: November 14, 1977

SUBJECT: Whitmire Tick & Flea Spray for Dogs EPA Reg. #499-129
Caswell#160 (Carbaryl)

FROM: William Dykstra, Ph.D
Toxicology Branch

11/14/77, WBD E 11/15/77

TO: Frank Sanders, PM #12

Action Type: Amendment with DATA

Product Manager: Frank T. Sanders, (12)

Recommendations:

1. A comparison of the eye and skin toxicity studies of the proposed CO₂ formula and the present fluorocarbon formula shows that skin irritation produced by either formula requires only a caution signal word. However, the primary eye irritation studies show that the proposed CO₂ formula will require a danger signal word, with appropriate statements, and the current fluorocarbon formula requires a warning signal word. Therefore, it is recommended that the amendment not be accepted.
2. It is recommended that if the proposed CO₂ formula be registered, only a restricted use with a danger signal word be allowed.
3. It is recommended that the current fluorocarbon formula label be changed from caution to warning signal word. After the signal word warning on the front panel, the statement "Keep out of Reach of Children" should be written (as it appears). Also, on the side panel, the signal word WARNING should appear followed by "DO NOT SPRAY IN OR NEAR DOG'S EYES. IF EYES ARE EXPOSED TO SPRAY, WASH THOROUGHLY WITH WATER." This warning statement should appear before the other precautionary statements.

Review: Toxicity Studies (Scientific Associates, Inc., S. A. #228860, 5/26 submitted by Whitmire Research Labs, Inc.

1. Dermal Irritation Tests in Rabbits using proposed CO₂ formulation.

Methods: According to acceptable guidelines on both intact and abraded skin

Results: Moderate Irritation at 72 hours.

Classification: Core-Minimum DATA

TOX Category: III Caution

2. Eye Irritation Test in Rabbits using proposed CO₂ formula.

Methods: 0.1 ml of liquid was instilled into conjunctival sac of six New Zealand albino rabbits. The affected eyes of three rabbits remained unwashed and the affected eyes of the other three rabbits were, after 20 sec exposure, washed with tap water.

Results: In the unwashed eyes, rabbits eyes showed ^{wed} corneal opacity at 7 days with ocular damage in the form of erthema, chemosis, iritis and discharge. In the was eyes, rabbits eyes also showed irreversible corneal opacity after 7 days.

Score: 35/110 + 40.3/110

Classification: Core-Minimum DATA

Toxicity Category: I DANGER

3. Dermal Irritation Test in Rabbits using (present fluorocarbon formula).
Method similar to part 1.

Results: P. I. = 1.35, not a primary irritant. Mild irritation at 72 hours.

Classification: Core-Minimum DATA

Tox Category: IV Caution

4. Eye Irritation Test in Rabbits (using Present fluorocarbon formula).

Procedure: Same as in part 2, test material is liquid.

Results: one out of six rabbits had corneal opacity at 7 days. All six rabbits showed conjunctival irritation at 7 days.

Score: 38.7/100 + 15.3/110

Classification: Core-Minimum DATA

Toxicity Category: II WARNING