BB-1188

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

005810

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: October 17, 1985

SUBJECT: EPA File Symbol 7501-OL
Vitavax Pour-On

FROM: Deloris F. Graham
Technical Support Section
Fungicide-Herbicide Branch
Registration Division

TO: Henry Jacoby
Product Manager (21)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: Gustafson, Inc.
P.O. Box 660065
Dallas, TX 75266-0065

Active Ingredients:

5,6-Carboxin (5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide	6.4%
Thiram (tetramethylthiuram disulfide)	6.4%
Inert Ingredients	87.2%
	100.0%

BACKGROUND

Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation, Primary Dermal Irritation, and Dermal Sensitization Studies. Studies conducted by Food and Drug Research Laboratories, Inc. Studies under Accession Number 258471. Method of support not indicated.

RECOMMENDATIONS

1. FHB/TSS finds these data acceptable to support conditional registration of this product.

2. The appropriate signal word is CAUTION.

LABEL

1. The statement "Do not use or store near food or feed" should be deleted from Precautionary Statements and placed under the heading "Directions For Use."

2. Storage and Disposal statements must come under the heading "Directions For Use," subheading "Storage and Disposal."

REVIEW

1. Acute Oral Toxicity Study: Food and Drug Research Lab., Inc., FDRL Study No. 8253A; October 24, 1984.

   Procedure: Five groups consisting of five male and five female rats each received one of the following doses orally: 4.0, 5.57, 7.75, 10.78, or 15.0 g/kg. Observations made for 15 days postdosing. Necropsy performed on all animals.

   Results: At 5.57 g/kg, 1:5 M and 3:5 F died, at 7.75 g/kg, 4:5 M and 3:5 F died; at 10.78 g/kg, 5:5 M and 5:5 F died; at 15.0 g/kg, 5:5 M and 5:5 F died.

   Toxic signs reported included decreased activity, ataxia, salivation, diarrhea, wet-abdomen, gasping, and lacrimation. Necropsy report indicated yellow liquid in abdominal cavity; black streaks in lower stomach. LD_{50} for males reported to be 6.57 g/kg, with 95 percent confidence limits between 5.02 and 8.59 g/kg. LD_{50} for females reported to be 6.17 g/kg with 95 percent confidence limits between 4.44 and 8.04 g/kg. LD_{50} for males and females combined was reported to be 6.37 g/kg, with 95 percent confidence between 5.45 and 7.40 g/kg.

   Study Classification: Core Guideline Data

   Toxicity Category: IV - CAUTION

2. Acute Inhalation Toxicity Study: Food and Drug Research Lab., Inc., FDRL Study No. 8253; November 20, 1984.

   Procedure: Five male and five female rats were exposed for 4 hours to a 3.8 mg/L actual concentration. Particle size reported to be a mean of 8.4 µm. Temperature between 20 and 21 °C and relative humidity between 72 and 100 percent. Observations made periodically during exposure, then twice daily thereafter for 14 days. Necropsy performed on all animals.

Results: One out of five females died. Toxic signs reported included wet coat, decreased activity, respiratory irregularity, and alopecia. Necropsy report indicated dark red nasal passages noted in animal that died during study; no other irritation noted.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

3. Acute Dermal Toxicity Study: Food and Drug Research Lab., Inc.; FDRL Study No. 8253A; November 19, 1984.

Procedure: Five male and five female New Zealand rabbits recieved 2.0 g/kg of the test material under occlusive wrap for 24-hour exposure. Observations made frequently on day of dosing, then twice daily through day 15. Necropsy performed on all animals.

Results: No mortalities reported. Clinical signs reported included anorexia, decreased activity, diarrhea, soft stools, soft stools with mucous, nasal discharge. No abnormalities reported in necropsy findings. LD_{50} reported to be greater than 2.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

4. Eye Irritation Study: Food and Drug Research Lab., Inc.; FDRL Study No. 8253A; November 26, 1984.

Procedure: Nine rabbits recieved 0.1 mL of the test material in one eye each. The treated eyes of three of the rabbits were washed with physiological saline 30 seconds after treatment. Observations made at 1, 24, 48, and 72 hours after treatment. If injury persisted, eyes were examined at 4 days, then every 3 days until irritation subsided or until 21 days posttreatment.

Results: At 24 hours, 3:6 animals of the unwashed group and 2:3 of the washed group had iris irritation (3:6 = 5) (2:3 = 5); 6:6 and 2:3, conjunctive redness (3:6 = 1, 3:6 = 2) (2:3 = 1); 6:6 and 1:3 chemosis (4:6 = 1, 2:6 = 2) (1:3 = 1); 4:6, discharge (3:6 = 1, 1:6 = 2); irritation had cleared in all animals except 1:6 by day 4; 1:6 had slight redness (1:6 = 1) and chemosis (1:6 = 1). Redness and chemosis in this animal had cleared by day 7.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

5. Primary Dermal Irritation Study: Food and Drug Research Lab., Inc.; FDRL Study No. 8253A; October 24, 1984.

Procedure: Six New Zealand rabbits received 0.5 mL of the test material at two intact skin sites per rabbit under occlusive wrap for 4-hour exposure. Observations made at 1/2 hour after exposure period, then at 28, 52, and 76 hours after dosing.

Results: No irritation reported in any animal throughout observation period. Mean Primary Irritation Score reported to be zero.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

6. Dermal Sensitization Study: Food a d Drug Research Lab., Inc.; FDRL Study No. 8253; November 14, 1984.

Procedure: Ten male guinea pigs received three 0.5 mL applications of a 35 percent (w/v) aqueous solution of UBI 2359 flowable (test material) a week for a total of 10 induction phase applications. Three male guinea pigs served as naive control. Six male guinea pigs received three 0.5 mL applications of a 0.07 (w/v) solution of 1-chloro-2,4-dinitrobenzene (DNCB, positive control) a week for a total of 10 induction phase applications. Two weeks after 10 induction phase applications, challenge dose was applied. Observations made at 24 and 48 hours after each application.

Results: No irritation reported in test group or naive control group of animals during induction or challenge dose phases. However, positive control group showed irritation ranging from negative (0) to well-defined (2) irritation during induction phase and slight (1) to well-defined (2) erythema at challenge dose, thus producing no sensitizing response. It is therefore concluded that the test material does not produce a sensitizing response.

Study Classification: Core Guideline Data

Toxicity Category: Nonsensitizing

Carboxin science review

Page _____ is not included in this copy.

Pages 5 through 7 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

X A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.