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

00514R

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Date: October 5, 1984
Subject: EPA File Symbol: 7501-IT
Gustapon Vitavax - PCNB Flowable Fungicide
From: Deloris F. Graham
FHB/TSS
To: Henry Jacoby
Product Manager (21)
Applicant: Gustafson, Inc.
P.O. Box 660065
Dallas, TX 75266-0065

Active Ingredient:
Carboxin (5,6-dihydro-2-methyl-
1,4-oxathiin-3-carboxanilide 17A
Pentachloronitrobenzene 17A
Inert Ingredients 56A

Background: Submitted Acute Oral, Acute Dermal, Acute Inhalation, Eye Irritation and Skin Irritation Studies. Studies conducted by Product Safety Labs. Method of support not indicated.

Recommendation:

- (1) FHB/TSS finds these data acceptable to support conditional registration of this product.
- (2) Acute Dermal Sensitization Study was not submitted. One must be submitted or data to support waiver.
- (3) Appropriate signal word is CAUTION.

Label:

- (1) Additional labeling may be necessary upon submission of Dermal Sensitization data.

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Review:

(1) Acute Oral Toxicity Study: Product Safety Labs.; Report No. T-3449; December 8, 1983.

Procedure: Five male and five female rats weighing between 200-300 grams received a 5.0 g/kg dose of the test material orally. Observations made daily for 14 days after treatment. Necropsy performed on all animals.

Results: 1/5 M died. Toxic signs were not noted in any animals. Necropsy report revealed pulmonary hemorrhage; intestinal hemorrhage. Discolored spleen in male that died. Slight pulmonary hemorrhage in one female that was sacrificed. All other animals reported unremarkable at necropsy. LD₅₀ reported to be greater than 5.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

(2) Acute Dermal Toxicity Study: Product Safety Labs.; Report No. T-3535; January 27, 1984.

Procedure: Five male and five female New Zealand rabbits weighing between 2.3 and 3.0 kg received 2.0 g/kg of the test material under occlusive wrap for 24-hour exposure period. Observations made for 14 days after exposure. Necropsy performed on all animals.

Results: No mortalities, toxic signs or abnormalities at necropsy reported. LD₅₀ reported to be greater than 2.0 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(3) Acute Inhalation Toxicity Study: Product Safety Labs.; Report No. T-3536; January 27, 1984.

Procedure: Five male and five female Wistar rats weighing between 200 and 300 g were exposed for 4 hours to a total of 6.8 g (estimated concentration 18.9 mg/liter/hour, nominal, determined gravimetrically). Observations made for 14 days after exposure. Necropsy performed on all animals.

Results: No mortalities or toxic signs reported. Discolored spleen in 1/5 F reported at necropsy. LD₅₀ reported to be greater than 18.9 mg/liter/hour, nominal, determined gravimetrically.

Study Classification: Core Minimum Data.

Chamber conditions (temperature, humidity, etc.) must be submitted.

Toxicity Category: IV - CAUTION

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(4) Eye Irritation Study: Product Safety Labs.; Report No. T-3517; January 18, 1984.

Procedure: Nine New Zealand rabbits recieved 0.1 ml of the test material in one eye each. The treated eyes of three of the rabbits were washed with lukewarm water thirty seconds after treatment. Observations made at 24, 48 and 72 hours after treatment.

Results: No corneal opacity or iris irritation reported. At 24 hours 2/6 animals of the unwashed group and 1/3 of the washed group had hyperemia (2/6=1) (1/3=1) 2/6 chemosis (2/6=1), Irritation had cleared by 72 hours.

Study Classification: Core Guideline Data

Toxicity Category: III - CAUTION

(5) Primary Skin Irritation Study: Product Safety Labs.; Report No. T-3518; January 18, 1984.

Procedure: Six New Zealand rabbits received 0.5 ml of the test material at two abraded and two intact skin sites per rabbit under occlusive wrap for 24-hour exposure. Observations were made at 24 and 72 hours and at 4 and 7 days after treatment.

Results: At 24 hours, 4/6 had slight to erythema (scores of 1) and 2/6 slight edema (scores of 1). At 72 hours, 5/6 slight to well-defined erythema (scores of 1 and 2) and no edema. Primary Irritation Score reported to be 0.44.

Study Classification: Core Guideline Data

Toxicity Category: IV - CAUTION

Carboxin science review

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Pages 4 through 5 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
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
 - The document is not responsive to the request
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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.
