BB-1188

8-2-82

Date: August 2, 1982

005383

Subject: EPA Registration No. 400-115
Vitavax - 25DB

From: Deloris F. Graham DFG 8/9/82
FHB/TSS
E 8/9/82

To: Henry Jacoby
Product Manager (21)

Applicant: Uniroyal Chemical Company
Crop Protection Research and Development
74 Amity Road
Bethany, CT 06525

Active Ingredient:
Carboxin (5,6 dihydro-2-methyl-1,4-
oxathiin-3-carboxanilide).....25%
Inert Ingredients.....75%

Background: Submitted Acute Oral, Acute Dermal, Primary Dermal, and Dermal Sensitization studies in compliance with the Vitavax Registration Standard. Studies conducted by Food and Drug Research Laboratories and by Hazleton Raltech, Inc. Data under accession number 247772. Method of support not indicated.

Recommendations:

(1) FHB/TSS finds these data acceptable to support the conditional registration of this product and fulfill requirements set forth in the Vitavax Registration Standard.

(2) A previously submitted Eye Irritation Study was acceptable to fulfill that requirement, so an additional one was not submitted with these data.

Label:

(1) The "If swallowed" statement must be revised to include "If swallowed, give large quantities of water and induce vomiting by placing finger in back of throat. Never give anything by mouth to an unconscious person."

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(2) The "Keep out of lakes, ponds, and streams" must be revised to read, "Do not apply directly to water."

Review:

(1) Acute Oral Toxicity Study: Food and Drug Research Laboratories: FDRL #7211A; April 6, 1982.

Procedure: 4 groups consisting of 5M and 5F rats received one of the following doses: 1.0, 2.52, 6.35 and 16.0 g/kg. Observations made twice daily for 15 days posttreatment. Necropsy performed on all animals.

Results: At 2.52 g/kg, 2/5 M and 1/5 F died; at 6/35 g/kg, 3/5 M and 1/5F died; at 16.0 g/kg, 5/5 M and 5/5 F died. Toxic signs included ataxia, decreased activity, lacrimation. Necropsy revealed intestines contained bloodlike viscous liquid. LD_{50} for males was 4 g/kg with 95% confidence limits of 1.8 to 8.87 g/kg. LD_{50} for females was 6.69 g/kg with 95% confidence limits of 3.43 to 19.36 g/kg. Combined male and female LD_{50} was 5.18 g/kg with 95% confidence limits of 3.36 to 8.47 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III-CAUTION

(2) Acute Dermal Toxicity Study: Food and Drug Research Laboratories, FDRL #7211A; February 8, 1982.

Procedure: 5M and 5F rabbits weighing between 2.0 and 4.0 kg received 2 g/kg of the test material at abraded skin sites under occlusive wrap for 24 hours exposure. Observations made twice daily for 15 days. Necropsy performed on all animals.

Results: No mortalities. No toxic signs or abnormalities at necropsy. LD_{50} greater than 2 g/kg.

Study Classification: Core Guideline Data

Toxicity Category: III-CAUTION

(3) Primary Dermal Irritation Study: Food and Drug Research Laboratories; FDRL #7211A; January 27, 1982.

Procedure: Six New Zealand rabbits received 0.5 g of the test material at 2 abraded and 2 intact skin sites per animal under occlusive wrap for 24 hours exposure. Observations made at 24 and 72 hours after dosing.

Results: No irritation present at 24 or 72 hours. Primary Irritation score was zero.

Study Classification: Core Guideline Data

Toxicity Category: IV-CAUTION

(4) Dermal Sensitization Study: Hazleton Raltech, Inc.; RT Lab. No. 928087; April 8, 1982.

Procedure: Eighteen male guinea pigs weighing between 508 and 596 grams were used. The animals were divided into three groups consisting of a vehicle control group of four guinea pigs, a naive control groups of four guinea pigs and a treated group of ten guinea pigs. Ethyl alcohol was used as a vehicle control, and naive control untreated until challenge dose. The animals received three applications per week for three weeks for a total of nine applications. Two weeks following the ninth sensitizing dose, a challenge dose was administered. The initial treatment was 0.5 ml of the appropriate material. Observations were made at 24 and 48 hours after each application.

Results: Erythema and edema ranged from light to well defined during the sensitizing phase. Two animals did not exhibit erythema and eight did not exhibit edema reactions to the test macerial. None of the animals reacted to the test material following the challenge application.

None of the animals of the naive control group reacted to the test material following challenge application.

Two animals responded to vehicle control with slight erythemas during the sensitizing phase. One animal reacted to the vehicle control with a slight erythema response following the challenge application. No response seen in any other animal.

Based upon results, the test material Vitavox Technical is not considered a skin sensitizer on guinea pigs.

Study Classification: Core Guideline Data

Toxicity Category: Nonsensitizing

VITAVAX®-25 DB
FUNGICIDE

ACCEPTED

AUG 14 1979

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 400-115

[redacted]
UNIROYAL
[redacted]

COMPOSITION

Active Ingredient (% by weight)	
Carboxin (5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide)*	25%
Inert Ingredients	75%
Total	100%

*U.S. Patent Nos. 3,249,499 - 3,393,202 - 3,454,391

KEEP OUT OF REACH OF CHILDREN.

DANGER

STATEMENT OF PRACTICAL TREATMENT

If swallowed: Induce vomiting and see a physician.

If inhaled: See a physician if an abnormal reaction occurs.

If on skin: Wash thoroughly with soap and water.

If in eyes: Immediately flush eyes with plenty of water. See a physician.

See left side panel for additional precautionary statement.

Mfg. by UNIROYAL CHEMICAL - Division of UNIROYAL, INC.
Naugatuck, Connecticut 06770
EPA Establishment No.
EPA Registration No. 400-115-AA

7-7-79

NET WEIGHT:

LOT NO. _____

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

DANGER

Corrosive, causes eye damage. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash hands and face thoroughly with soap and water after use and before eating or smoking. Consumption of alcoholic beverages increases the possibility of harm.

Environmental Hazards

This product is toxic to fish. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

Physical or Chemical Hazards

Do not use or store near 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.

STORAGE AND DISPOSAL

1. **PROHIBITIONS**
   Do not contaminate water, food or feed by storage or disposal or by cleaning of equipment. Open dumping is prohibited. Do not reuse empty container.
2. **PESTICIDE DISPOSAL**
   Pesticide, spray mixture or rinsate that cannot be used or chemically reprocessed should be disposed in a landfill approved for pesticides or buried in a safe place away from water supplies.
3. **CONTAINER DISPOSAL**
   Dispose of in an incinerator or landfill approved for pesticide containers, or bury in a safe place.
4. **GENERAL**
   Consult Federal, State or local disposal authorities for approved alternative procedures such as limited open burning.
5. **STORAGE**
   Store in a dry location.

DIRECTIONS FOR USE

Vitavax-25DB Fungicide is a ready to use seed treatment fungicide. It has been formulated to be applied directly to seed in the planter. The recommended rate (see below) should be thoroughly mixed with the seed in the planter to insure proper coverage.

CORN

Vitavax-25DB Fungicide controls seed rots and provides systemic control of seedling diseases on corn. Vitavax-25 DB Fungicide should be applied directly to the seed in the planter at a rate of 4-6 ounces per 100 pounds of seed.

WHEAT, OATS AND BARLEY

Use 4-6 ounces of Vitavax-25DB per 100 pounds of seed as a planter box application for the control of various seeding diseases and for loose and covered smut on wheat. For bunt control on wheat the higher rate is recommended.

USE RESTRICTIONS.

Do not use treated seed for food, feed or oil purposes. Do not graze or feed livestock on treated areas for six weeks after planting.

COMPATIBILITY

Vitavax-25DB Fungicide can be applied to seed that has previously been treated with other seed protectant fungicides such as captan or thiram.

COMPATIBILITIES — Observe all cautions and limitations on labeling of all products used in mixture with this product.

IMPORTANT NOTICE — Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with the directions and instructions specified on the label under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product, contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to seller, and buyer assumes the risk of any such use.