BL-145
TXR-750

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

000750

DATE: January 27, 1978

SUBJECT: Vitavax Flowable Fungicide
Caswell#165A

EPA Reg.#400-107
Shaughnessy#090201

FROM: William Greear WG Greear
Toxicology Branch

E for WNB 2/3/78

TO: Dr. Wilson
Product Manager #21

Recommendations

The acute oral LD_{50}, dermal LD_{50}, inhalation LC_{50}, eye and skin irritation studies are adequate and designated core studies. The labeling proposed is adequate.

*No RPAR criteria have been exceeded.

Review

1. Primary Skin Irritation of Vitavax Flowable Fungicide Lot# BL7960 - (Food and Drug Research Laboratories, Report#5294$_b$ 12/3/76, submitted by Uniroyal on 12/16/77, Acc#232545)

The back of each of 6 adult albino rabbits was shaved free of hair. Intact skin was exposed on the left half of the shaved area, and abraded skin on the right half. 0.5 ml of the test material was placed on both intact and abraded skin. Patches were removed after 24 hours and observations recorded. Readings were again made at 72 hours.

Results

P.I. = 3.71/8.00
TOX Category: III
Classification: Core-Minimum Data
(1) readings were not made on 2 intact and 2 abraded skin sites.

2. Primary Eye Irritation of Vitavax Flowable Fungicide Lot#BL7960 - (Food and Drug Research Laboratories, Report#5294$_b$, 12/3/76, submitted by Uniroyal on 12/16/77, Acc#232545)

The study was performed on 6 young adult albino rabbits according to the procedure described in 16 CFR 1500.42. Ocular reactions were scored at 24, 48 and 72 hours and at 7 days.

Results

No ocular reactions were observed.

TOX Category: IV

EPA FORM 1320-6 (REV. 3-76)

Classification: Core-Guideline
(1) an eye wash study is not necessary.

3. Acute Dermal LD_{50} of Vitava Flowable Fungicide Lot#BL8229 - (Food and Drug Research Laboratories, Report #5481$_a$, 6/28/77, submitted by Uniroyal on 12/16/77, Acc#232545)

The acute dermal toxicity study was conducted on 10 adult albino rabbits as described in 16 CFR 1500.40. One dose level of 20 ml/kg was tested.

Results

$LD_{50} > 20$ ml/kg (no deaths occurred)
Toxic Signs: decreased activity
Necropsy: not performed
TOX Category: IV
Classification: Core-Minimum Data
(1) necropsies were not performed.

4. Acute Oral LD_{50} of Vitavax Flowable Fungicide BL8229 - (Food and Drug Research Laboratories, Report #5481$_a$, 6/28/77, submitted by Uniroyal on 12/16/77, Acc#232545)

5 male and 5 female BLU: (LE) BR Long-Evans rats, weighing 200-300g, were administered 5 ml/kg of the test material, by gavage. The animals were observed daily for 14 days.

Results.

$LD_{50} > 5.0$ ml/kg (2/10 animals succumbed)
Toxic Signs: ataxia, decreased activity, emaciation
Necropsy: not performed
Classification: Core-Minimum Data
(1) this study in conjunction with the study performed on 9/9/77, adequately demonstrate the LD_{50} to be in excess of 5 ml/kg. No further testing is necessary.

5. Acute Oral LD_{50} of Vitavax Flowable Fungicide BL8599 - (Food and Drug Research Laboratories, Report #5481$_a$, 9/9/77, submitted by Uniroyal on 12/16/77, Acc#232545)

Same protocol as in #4, except that 20 rats were employed. In addition necropsies were performed.

Results

$LD_{50} > 5$ ml/kg (3/20 animals succumbed)
Toxic Signs: ataxia, urinary incontinence, nasal discharge.
Necropsy: mottled lungs, liver and kidneys; vascularization of skin; congested and vascularized G.I. tract.
TOX Category: IV

Classification: Core-Minimum Data
(1) refer to #4

6. Acute Inhalation LC_{50} of Vitavax Flowable Fungicide BL8229 - (Food and Drug Research Laboratories, Report#5481$_a$, 9/15/77, submitted by Uniroyal on 12/16/77, Acc#232545)

5 male and 5 female BLU: (SD) Sprague-Dawley albino rats, weighing 200 to 300 g, were exposed in a 75L chamber to a nominal concentration of 20 mg/L of the test material (atomized) for a period of 1 hour. The animals were observed daily for a period of 14 days.

Results

LC_{50} > 20 mg/L (no deaths occurred)
Toxic Signs: decreased activity and ataxia during exposure.
Necropsy: not performed
TOX Category: IV
Classification: Core-Minimum Data
(1) necropsies were not performed.

Typists: TH

3