FR-761

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

10-2-79

DATE: October 2, 1979

000761

SUBJECT: Vitavax EPA Reg. No. 400-124, CASWELL#165A

FROM: Alex Arce AA WSL
Toxicology Branch (TS-769)

10-4-79

TO: Diane Ierley
Product Manager#21

THRU: Dr. Adrian Gross, Chief
Toxicology Branch (TS-769)

Registrant: Uniroyal Chemical
Bethany, Ct.

Actic.. Requested: a) Change in signal word from "DANGER" to "WARNING" in the Basic and Collateral Labeling of Vitavax-30c. b) Review of toxicity data submitted in support of above mentioned. This request is an amendment of the previous request that was answered by Alex Arce on May 23, 1979 (Memo Arce to Jacoby). It was stated in the May 23 memo that in order to change the label signal word, Acute Oral Toxicity and Acute Inhalation tests were needed.

Recommendations:

a) The request for a change in the signal word from "DANGER" to "WARNING" is toxicologically supported.

b) The two toxicology studies currently submitted on Vitavax-30c are acceptable as follows:

Acute Oral Toxicity	LD_{50} > 5 g/kg	Tox. Cat. IV Core-Minimum
Acute Inhalation	LC_{50} > 5.6 mg/kg	Tox. Cat. III Core-Minimum

The material used in the 2 studies was Vitavax 30c; 11-16-67; Lot#8901161V and 8520157V: TANK N.3; Sample No. Composite BL9365CC0005.

~29% active of Vitavax alone

Chemical Name

Carboxin (ANSI) 5,6-dihydro-2-methyl-1-1,4-oxathin-3-carboxanilide

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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

1 of 3

Formulation

Active Ingredient	Percent by Weight
Vitavax Technical (Carboxin) 5,6-dihydro-2-methyl-N-phenyl-1,4-oxathin-3-carboxamide 97% active	32.90
Inert Ingredients	[redacted]

(Inert ingredients cleared under CFR 40 180.1001)

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Uses: For control of seed and seedling diseases.

Application Rate: To be diluted with water alone or combined with Captan or Thiram and to be applied as per label instructions.

Application Method: Apply mixture to seed. For use by professional seed processors only.

Toxicological Review of Studies Previously Submitted (Memo from Arce to Jacoby, May 23, 1979)

Study	Results	Tox. Cat.	Classification
Acute Dermal	LD_{50} > 5000 mg/kg	III	Core-Minimum
Skin Irritation	Severe	II	Core-Guidelines
Eye Irritation	Mild	III	Core-Guidelines

Toxicological Review of Studies Currently Submitted

a) Acute Oral Toxicity - Rats

Procedure

5 male and 5 female albino rats were dosed orally 5 g/kg body weight and observed for 14 days post-treatment.

Necropsies were performed and body weights were taken at intervals.

2

Results

Mortality: Acute Oral LD_{50} = > 5 g/kg

Signs of Toxicity: Decreased activity, Ataxia, Urinary Incontinence.

Necropsy: Lungs: Dark and mottled (1 Male); Spleen: Dark adn granular (1 Male), granular (4 Males and 5 Females); Kidney: Pale (3 Males), pale and mottled (1 Male).

Body Weight Changes: Unremarkable

Classification: Core-Minimum Data

The study was performed using only one dose level (5 g/kg). However the results give a clear indication of the oral toxicity of the material.

b) Inhalation Toxicity - Rats

Procedure

Five male and five female adult albino rats were exposed for one hour to an aerosol concentration of 5.6 mg test material per liter of air and observed for 14th day.

Body weights were recorded prior to exposure, at 7 days and on the 14th day. All animals were necropsies at the end of the study and the organs were microscopically examined.

A dust generation system equiped with a transvector jet (Vortex Corp., Cincinnati, Ohio) was used for this experiment.

Results

Mortality: Acute Inhalation LC_{50} > 5.6 mg/liter

Toxic Signs: Labored respiration, nasal discharge.

Body Weight Changes: Unremarkable

Necropsy: Lungs, described as being grayish with moderate or severe hemorrhage, cervical lymph nodes red. Other wise, normal.

Classification: Core-Minimum Data

Only one dose level was used in this study. The inhalation LC50 was found to be greater than 5.6 mg/kg. Thus, it gives a clear indication of the Inhalation toxicity of the material.

Toxicity Category: III

3