4-23-79 PR 1106 TXR-756

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 000756

DATE: April 23, 1979

SUBJECT: Vitavax-4G Caswell #165A 400-EUP-LI

FROM: Alex Acre
Toxicology Branch (TS-769)

TO: Henry Jacoby
PM#21/RD/OPP

THRU: Dr. Adrian Gross, Chief William M Butler for M. Adrian Gross
Toxicology Branch (TS-769)

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Petitioner: Uniroyal Chemical

Action Requested: Experimental Use Permit request for Vitavax-4G, a granular fungicide, for control of sclerotium rolfsii on peanuts.

4 studies are submitted for review:

Skin Irritation (Rabbits)	Vitavax 10G
Eye Irritation (Rabbits)	Vitavax 10G
Acute Oral LD50 (Rats)	Vitavax 10G
Acute Dermal LD50 (Rabbits)	Vitavax 10G

The studies submitted in support of an EUP were performed with VITAVAX-10G 400-RGN which is a granular formulation containing 10% active Vitavax. Vitavax-4G contains only 4.14% Technical.

The applicant submits that results of toxicity studies for VITAVAX-4G would be similar to those obtained with VITAVAX 10G and would also meet the requirements of Toxicity Category III.

This reviewer agrees with the rationale for using the data submitted (Data on Vitavax 10G) on behalf of an EUP for VITAVAX 4G.

Product formulation Vitavax 4G.

Active Ingredient	% by Weight
Vitavax Technical (carboxin)	4.14

5,6-Dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide

Inert Ingredients

[redacted]

The inert ingredients are exempted from tolerance. CFR 40 180.1001

174

Recommendations

(1) The toxicology data submitted are adequate to support an EUP for Vitavax 4G to be applied on peanuts for the control of Sclerotium rolfsii (also known as Southern Stem Rot, Southern Blight, or white mold).

(2) The results of analysis for Vitavax residue in the peanut meats contains less than 0.2 ppm. The established tolerance for Carboxin (common name for Vitavax) and its metabolites is 0.2 ppm (40 CFR 180.301).

Date Review

Summary of Tests submitted (Vitavax 10G)

Date Submitted	Test	TOX Category	Classification	Results
May 16, 1977	Skin Irritation (Rabbits)	IV	Core-Minimum	Negative (Non irrita
Aug. 16, 1977	Eye Irritation (Rabbits)	III	Core-Minimum	Mild irr tant
June 28, 1977	Acute Oral LD50 (Rabbits)	IV	Core-Minimum	>5 g/kg
June 28, 1977	Acute Dermal LD50 (Rabbits)	IV	Core-Minimum	>20 g/kg

Referenced Human Safety Data

The data includes all previously submitted toxicology data in support of: EPA Registrations#400-81, 400-80, 400-15 and 400-107.

All data submitted has been accepted in support of previous actions.

List of the previously accepted data:

Memo of 10-3-78 from D.W. Dykstra
" " 6-22-78 " D.W. Dykstra
" " 4-17-78 " D.W. Dykstra
" " 1-27-38 from W. Greear
" " 6-17-69 from J.C. Svirberly (petition)

Uses: Vitavax 4G,a granular fungicide to be used to aid control of Sclerotium rolfsii on peanuts.

2

Hazard Evaluation

The four studies submitted were performed at the Food & Drug Research Laboratory, Inc. of Waverly, New York, and can be found in EPA Accession Number 237329 dated 2-6-79.

Data Review

(1) Skin Irritation Study - Rabbits - Vitavax 10G.

Report Laboratory No.4580a, May 16, 1977.6 adult albino rabbits were dosed with 0.5 g of the material on abraded and intact areas of their dermis introduced under a square patch that was removed after 24 hours. Observations at 24 & 72 hours.

Results: Negative for irritation.

Classification: Core-Minimum Data

Toxicity Category: IV

(2) Eye Irritation Study - Rabbits - Vitavax 10G.

Report Laboratory No. 5180c, Aug. 16, 1976, 6 adult rabbits were treated with 100 mg of the material instilled into their eyes. It is not stated if both eyes were used. It is assumed that they did, since they followed the procedure described in 16 CFR 1500.42.

Observations were done for 24, 48 and 72 hours and at the 7th day.

Results

Minimal conjunctival irritation lasted till after the 7th day in 4 rabbits out of 6.

Classification: Core-Minimum Data

Note: - Studies done using higher concentrations, and washing the eye post application, did not improve the response of the irritation.

TOX Category: II

(3) Acute Oral Toxicity - Rats - Vitavax 10G.

Report Laboratory No. 5480a, 6-28-77, ten albino rats, 5 males and 5 females were dosed with 5 g.kg by oral intubation and observed for 14 days following treatment.

3

Results

Mortality: LD50 > 5 g/kg b.wt.

Symptoms: Decreased activity and ataxia.

Classification: Core-Minimum Data

TOX Category: IV

(4) Acute Dermal LD50 - Rabbits - Vitavax 10G.

Report Laboratory No. 580a, June 28, 1977, ten rabbits, sex not mentioned, were administered dermally dermally 20 g/kg of Vitavax 10G on intact and abraded skin sites and observed for 14 days post exposure.

The method followed is described in 16 CFR 1500.4.

It is assumed that the material was protected by an impervious cuff for 24 hours.

Results

Mortality: LD50 > 20 g/kg b.wt.

Symptoms: Decreased activity, anorexia

Classification: Core-Minimum Data

TOX Category: IV

TOX/HED:th:RD Initial WWOODROW:4-16-79