

BB-1186  
TXR-757

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DATE: May 23, 1979

SUBJECT: Vitavax-30c

EPA Reg. #400-124

CASWELL#165A

FROM: Alex Arce  
Toxicology Branch TS-769

AA

TO: Henry Jacoby  
Product Manager#21

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

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Registrant: Uniroyal Chemical

Action 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 the above mentioned.

Recommendation:

- a) The request for a change in the signal word from "Danger" to "Warning" is not toxicologically supported, and can not be granted until Acute Oral and Acute Inhalation studies are submitted.
- b) The three toxicological studies submitted on Vitavax-30c are acceptable as follows:

<u>Study</u>	<u>Results</u>	<u>Tox. Cat.</u>	<u>Classification</u>
Acute Dermal	LD50 > 5000 mg/kg	III	Core-Minimum
Skin Irritation	<u>Severe</u>	II	Core-Guidelines
Eye Irritation	Mild	III	Core-Guidelines

Rationale for requesting Acute Oral and Acute Inhalation studies with Vitavax-30c prior to requested signal word change.

The Skin Irritation Study, submitted on behalf of the request, using Vitavax-30c (29.52% active ingredient) indicates severe irritation.

Studies using 34 and 97% active ingredients of the product, revealed mild irritation, and no irritation, respectively. The inert ingredients used in Vitavax-30c are different than the one used in the 34% active ingredient (Vitavax Flowable).

It is suspected that one of the inert ingredients in Vitavax 30c causes the severe irritation. Thus, an Acute Oral LD50 and Acute Inhalation Toxicity, studies using VITAVAX-30c are needed in order to evaluate the potential toxicity that the new added inert ingredient may cause.

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The material used in the 3 studies was Vitavax 30c; 11-16-67; Lot#8901161V and 8520157V; Tank No. 3; Sample No. Composite: BL9365 CC 0005.

Chemical Name:

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

Formulation

Active Ingredient

% by Weight

Vitavax Technical (Carboxin) 5,6-dihydro-2-methyl-N-phenyl-1,4-oxathin-3-carboxamide  
97% active

32.90

Inert Ingredients



(Inert ingredients cleared under CFR 40.180.1001)

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 Submitted

The three submitted studies were performed at the Food & Drug Research Laboratories Inc, of Waverly, New York, Project No. 6135, dated as follows:

Primary Skin Irritation	-	January 29, 1979
Eye Irritation	-	February 6, 1979
Dermal Toxicity	-	February 6, 1979

1. Primary SKin Irritation - Rabbits

Scope

Six adult white albino rabbits were dosed dermally with 0.5 mls of the test material in the abraded and intact areas of their backs under occlusion and observed at 24 and 72 hours post application.

The study follows the established guidelines.

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INERT INGREDIENT INFORMATION IS NOT INCLUDED

Result

The product induced a severe irritation that lasted for longer than 72 hours.

Conclusions

Classification: Core-Guidelines Data  
TOX Category: II

2. Eye Irritation Study - RabbitsScope

Nine adult white rabbits were dosed with 0.1 ml of the test material instilled in their eyes. The eyes of six animals were unwashed after instillation. The other 3 were washed 4 seconds after instillation. Untreated eyes served as controls. Observations were performed at 24, 48 and 72 hours and 7 days. The study follows the established guidelines.

Results

The product induce a mild conjunctival irritation that lasted for 72 hours in 4 animals washed eyes and one unwashed.

Conclusions

Classification: Core-Guidelines Data  
TOX Category: III

3. Acute Dermal Toxicity Study - RabbitsScope

5 male and 5 female adult New Zealand white rabbits were dosed with 5 g/kg body weight of the material, on the abraded and intact areas of their backs: (2 males and 3 females intact, 3 males and 2 females abraded).

The material was introduced under a square gauze patch, secured with plastic wraps and masking tape, and it was in contact for 24 hours post application. Observations lasted for 14 days post application.

Results

Mortality: None, LD50 > 5.0 g/kg  
Toxic Signs: ataxia, decreased activity, nasal discharge.  
Body Weights: Unremarkable

Necropsy

Lungs: 3 males showed signs attributable to dosing.

Spleen: Dark, (5 males and 2 females)  
Pale, (1 female)

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Results:

Kidneys: Pale (3 males and 2 females)

Stomach: Full and vascularized (2 males and 5 females)

Bladder: Full and vascularized (2 males and females)

Conclusions

Classification: Core-Minimum Data

Only one dose level used. No explanation if there <sup>were</sup> moribund animals. No observations reported on survivors although the study lasted for 14 days and the Necropsy findings were severe.

Tox Category III: CAUTION

TOX/HED:th:RD Initial WDYKSTRA:5-16-79

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