

US EPA ARCHIVE DOCUMENT

6-12-78

EEE BRANCH REVIEW

DATE: IN 2/2/78 OUT 6/12/78 IN _____ OUT _____
FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 400-81

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED _____

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCTS(S): I, D, H, F, N, R, S _____

DATA ACCESSION NO(S). _____

PRODUCT MGR. NO. 21 (Wilson)

PRODUCT NAME(S) Vitavax technical

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COMPANY NAME Uniroyal Chemical

SUBMISSION PURPOSE Data Submission Only

CHEMICAL & FORMULATION 5,6-Dihydro-2-methyl-1,4-Oxathiin-3-

carboxanilide. 99% active (The test material was assayed as 99% active in a 1977 analysis- Personal communication with Uniroyal liaison).

100.0 Pesticidal Use

Data submission only

101.0 Chemical and Physical Properties

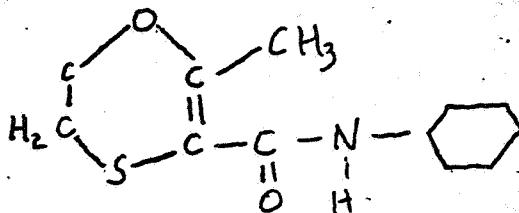
101.1 Chemical Name

5,6-Dihydro-2-methyl-1,4-oxathiin-3-carboxanilide

101.2 Common Names

Vitavax, Carboxine, D735, DCMO, F735

101.3 Structural Formula



101.5 Physical State

Vitavax is a non-volatile, off-white crystal.

101.6 Solubility (From 7/8/75 review by Scott C. Fredericks)

In Water

170 ppm in distilled water

In Acetone

600,000 ppm

In Ethanol

110,000 ppm

103.0 Toxicological Properties

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103.1.2 Avian Acute Toxicity

DATA REVIEW NUMBER: ES-VII-C

TEST: Acute oral, LD₅₀, with a wild waterfowl

SPECIES: Mallard duck

RESULTS: LD₅₀ with (95% confidence limits) = 6094.2
(2012.4 - 18454.9 mg/kg)

CHEMICAL: Vitavax technical (99% a.i.)

TITLE: Acute oral LD₅₀ - Mallard duck. Vitavax
technical. Final report.

ACCESSION NO: No accession number

STUDY DATE: June 16, 1977

RESEARCHER: Joann B. Beavers and Robert Fink:
Wildlife International

REGISTRANT: Uniroyal Chemical

VALIDATION CATEGORY: ~~Invalid~~ Core. The LD₅₀ should
be accepted as greater than 2000 mg/kg. (Rev. Conn. R. Tucker.
CATEGORY REPAIRABILITY: Wildlife International has
been given permission to use an eight-day post-
dosing observation period and the section has
agreed to accept studies on 14-day old birds
when the resulting LD₅₀ is greater than 3000 mg/kg.
The use of extrapolated LD₅₀ values is not accept-
able to this section, however, and forty percent
mortality was the highest percentage mortality
achieved in this study.

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Subacute Toxicity

DATA REVIEW NUMBER: ES-VII-D

TEST: Eight-day dietary LC₅₀ - bobwhite quail

SPECIES: Bobwhite quail

RESULTS: Ten birds were used at each treatment level. No deaths occurred at 4,640 ppm and two occurred at 10,000 ppm. Wildlife International concluded that the LC₅₀ was greater than 10,000 ppm.

CHEMICAL: Vitavax technical (99% active ingredient)

TITLE: Eight-day dietary LC₅₀ - bobwhite quail.
Vitavax technical. Final report.

ACCESSION NO: No accession number.

STUDY DATE: June 17, 1977

RESEARCHER: Joann B. Beavers and Robert Pink:
Wildlife International, LTD.

REGISTRANT: Uniroyal Chemical

VALIDATION CATEGORY: Core

CATEGORY REPAIRABILITY: The Environmental Safety staff has agreed to accept LC₅₀ avian tests in which no deaths occur at exposure levels of 5,000 ppm. There were no deaths in this test at levels of 4,640 ppm. This was judged to be sufficiently close to the 5,000 ppm cut-off point. The data do support the conclusion that the LC₅₀ is greater than 10,000 ppm. as is shown below:

When ten bobwhite quail were subjected to a dose of 10,000 ppm, two mortalities occurred. This set of observations lends statistical support to Wildlife International's claim that the LC₅₀ is greater than 10,000 ppm. This claim is explored in the following calculations by determining the likelihood of two deaths occurring out of ten animals dosed with the LC₅₀ level of a toxicant.

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The group of test birds, number one through ten, can respond in 2^{10} or 1024 different ways. Some of the responses are shown below:

Bird #	1	2	3	4	5	6	7	8	9	10
Response 1	D	S	S	S	D	S	S	S	S	D
2	S	D	D	S	D	S	D	S	D	S
3	D	D	D	S	S	S	S	S	D	D
+	-	-	-	-	-	-	-	-	-	-
+	-	-	-	-	-	-	-	-	-	-

1024

D = Mortality
S = Survivor

If we assume that 10,000 ppm was the dietary LC₅₀ level then each bird exposed to this level had an equal chance of surviving or dying. It also follows that each of the 1024 different responses is equally probable.

Of the 1024 equally probable responses there are 45 that include only two mortalities. This can be determined by the equation shown below (Adapted from Mosteller, et al., 1961).

$$\frac{N!}{r!(N-r)!} = \frac{10!}{8!(2)!} = \frac{3628800}{(40320)(2)} = 45$$

Where: N = Total number of birds
r = Number of survivors
N-r = Number of survivors

The probability of two mortalities and eight survivors occurring after an exposure to the LC₅₀ concentration is, therefore $\frac{45}{1024}$ or 0.044. This is a very low probability and it indicates that Wildlife International is probably correct in stating that 10,000 ppm was less than the LC₅₀.

Mosteller, F., R. Rourke, and G. Thomas, Jr. 1961.
Probability with statistical applications.
Addison - Wesley Publishing Company.
Reading, Mass. 478 pp.

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103.1.3 Fish - Acute Toxicity

DATA REVIEW NUMBER: ES-VII-G

TEST: 96-hr. LC₅₀ with a coldwater fish

SPECIES: Rainbow trout

RESULTS: 96-hr. LC₅₀ with confidence limits (95%)=
2.0 (1.6 - 2.5) ppm.

CHEMICAL: Carboxin (99% active ingredient)

TITLE: Acute toxicity of vitavax technical, Lot BL 8108 to the bluegill sunfish, Lepomis macrochirus Rafinescue and rainbow trout, Salmo gairdneri Richardson.

ACCESSION NO: No accession number

STUDY DATE: May 25, 1977

RESEARCHER: W. J. Kuc and George A. Carv: Union Carbide

REGISTRANT: Uniroyal

VALIDATION CATEGORY: Core

CATEGORY REPAIRABILITY: The fish used in this test were too small (average weight 0.28 grams), but the LC₅₀ is corroborated by previous, valid, Uniroyal, rainbow trout submissions.

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DATA REVIEW NUMBER: ES-VII-F

TEST: 96-hr. LC₅₀ with a warmwater fish

SPECIES: Lepomis macrochirus

RESULTS: 96-hr. LC₅₀ and (95% C.I.)=1.2(1.0-1.4)ppm

Test water characteristics:

pH7.47

Total hardness 44 mg/l (CaCO₃)

Temperature.....22.0 ±1°C.

CHEMICAL: Vitavax technical (99% active)

TITLE: Acute toxicity of Vitavax technical, Lot LB 8108 to the bluegill sunfish, Lepomis macrochirus Rafinesque and rainbow trout Salmo gairdneri Richardson.

ACCESSION NO: None given

STUDY DATE: May 25, 1977

RESEARCHER: William J. Kuc: Union Carbide Environmental Services

REGISTRANT: Uniroyal Chemical

VALIDATION CATEGORY: Core

ABSTRACT: Five concentrations, a control and a solvent control were used in the determinations.

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DATA REVIEW NUMBER: ES-VII-H

TEST: 48-hr. LC₅₀ with an aquatic invertebrate

SPECIES: Daphnia magna

RESULTS: 48-hr. LC₅₀ = 84.4 mg/l (95% C.I.=73.1-97.6)

Test water quality characteristics:

Temperature..... 17 ±1°C

Hardness..... 42 mg/l (CaCO₃)

pH..... 7.45

CHEMICAL: Vitavax

TITLE: Acute toxicity of vitavax technical to the water flea Daphnia magna Straus

ACCESSION NO: No accession number

STUDY DATE: April 20, 1977

RESEARCHER: Algirdas G. Vilkas: Union Carbide Corporation

REGISTRANT: Uniroyal Chemical

VALIDATION CATEGORY: Core

ABSTRACT: Five concentrations of Vitavax, a control, and a solvent control were used in this test.

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Office of Pesticide Administration

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Conclusions

The following fish and wildlife toxicity tests are the minimum data necessary to make an environmental safety evaluation of a pesticide with an outdoor use pattern:

- A. Subacute dietary LC₅₀ for a wild waterfowl.
- B. Subacute dietary LC₅₀ for an upland game bird.
- C. Acute oral LD₅₀ for either a wild waterfowl or an upland game bird.
- D. Acute LC₅₀ for a coldwater fish (96 hr.).
- E. Acute LC₅₀ for a warmwater fish (96 hr.).
- F. Acute LC₅₀ for an aquatic invertebrate.

Uniroyal's recent data submissions relate to these minimum data requirements in the following manner:

- 1. The June 17, 1977 bobwhite quail study by Wildlife International can be used to fill data requirement (B).
- 2. The June 16, 1977 mallard duck study by Wildlife International is inadequate to fill data requirement (C), because derivation of LD₅₀ by extrapolation is unacceptable. *RKH* ~~to a level greater than 40 percent was observed in this test.~~
- 3. The May 25, 1977 rainbow trout study by Union Carbide fills data requirement (D).
- 4. The May 25, 1977 bluegill sunfish study by Union Carbide fills data requirement (E).
- 5. The April 20, 1977 Daphnia magna study by Union Carbide fills data requirement (F).

RKH
Robert K. Hitch Date: June 12, 1978
Environmental Safety Section
EEEB-RD WH 567

QWA

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