8-2-78

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(116)

DATE: August 2, 1978

SUBJECT: Vitavex, EPA Reg. No. 400-113, Data to add to files. Amended Pesticide Registration.

FROM: J. Doherty, Toxicology Branch

TO: Eugene Wilson, Product Manager #21

Registrant: Uniroyal Chemical Company
74 Amity Road
Bethany, Connecticut 06525

Product: Vitavax-17 Flowable Fungicide

Summary of Toxicological Data Submitted

Oral LD_{50} rat	5 ml/kg	IV	Minimum
Dermal LD_{50} rabbit	20 gm/kg	IV	Minimum
Inhalation LC_{50}	20 mg/l	IV	Minimum
Skin irritation	.08	III or IV	Temp Invalid
Eye irritation	corneal opacity noted	II	Minimum

Review of Studies Submitted

All studies by Food and Drug Research Laboratories, Inc. , Waverly, New York.

A. Acute Oral LD_{50}, #5495c, September 9, 1977

Ten young adult rats (5M or 5F) were dosed orally with 5 ml/kg of VITAVAX- 17 and observed. The experiment was conducted twice.

A total of 4 of the 20 rats died, therefore the product is category IV. Symptoms observed during the test period were decreased activity, ataxia, urinary maintenance. Necropsy findings were mottled lungs, and liver and pale kidneys.

This test is CORE MINIMUM.

B. Acute Dermal Toxicity in rabbits, #5495c, July 6, 1977.

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20 gm/kg of VITAVAX-17 were applied to the backs of acclimated rabbits according to 16CFR 1500.40.

None of the ten rabbits died. The product is category IV. Symptoms observed were decreased activity and anorexia.

This test is Core Minimum.

C. Acute Inhalation, September 15, 1977, 5481B.

10 rats (5M and 5F) were placed into a 75 liter chamber with an air supply of 10 liters/min. The test material (VITAVAX-17) was atomized into the chamber at a rate calculated to be 20/mg/l. The rats were exposed for one hour.

None of the 10 rats died. No note worthy symptoms develcped during or after exposure. The product is Category IV. This test is Core Minimum. The particle size was not determined nor was the chamber periodically sampled.

D. Dermal Irritation

Apparently a page is missing, no date or experiment number is given. The method used is not available nor the amount applied stated.

The results show a Draize score of 0.08 with cnly one rabbit developing edema (mild) after 12 hours of expcsure to its abraded skin.

Temporaily INVALID. The procedure and amount applied must be clarified.

E. Eye irritation, November 18, 1976, 524le.

The method used is referenced as 16CFR 1500.42. Apparently .100 ml of test material (VITAVEX-17) was instilled into the eye of each of six rabbits.

Corneal opacity that was reversed by the 7th day developed and conjunctiva irritation that persisted for 7 days developed in a single rabbit. The other 5 rabbits had maximum scores of 14/110 12/110, 12/110, 12/110 and 14/110.

The presence of corneal opacity and persistent irritation requires a category II classification. Since this was in a single rabbit only it may not be significant. If the product is sought for general use classification or if the amendment is to change the signal word, an additional test may be necessary.

This test is Core Minimum.

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Recommendation and Remarks

1. No recommendation was sought.

2. The amendment was not specified and therefore Toxicology Branch is unable to comment.

3. The dermal irritation study is temporary INVALID.

4. The eye irritation study may have to be repeated if a CAUTION is to be supported (no label was included in this package).

HED/TOX:init: Reto Engler 7/27/78
gjl
8/7/78