REVIEWER

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

005552

OCT 22 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Paul Schroeder, PM # 17
Insecticide/Rodenticide Branch
Registration Division TS-767C

THRU: R. B. Jaeger, Section Head
Rev. Sec. # 1/Toxicology Branch
Hazard Evaluation Division TS-769C RBJ/10/2/86

FROM: D. Ritter, Toxicologist
Rev. Sec. # 1/Toxicology Branch
Hazard Evaluation Division TS-769C

DLR 10-2-86
10/2/86

Subject:

Dimilin - EPA Reg. # 37100-ER/37100-EUP-T.

Caswell #: 346A.

TOX Project #: 2012.

Action Requested:

Review data submitted in support of EUP and Registration application for use on Citrus.

Our Response:

1. Toxicology Branch approved citrus tolerances of 0.5 ppm in whole fruit, 1.0 ppm in dried pulp and 75 ppm in citrus oil in our review of PP # 6G3349 and 6H5487, D. Ritter, 9/5/86. We reiterate that approval here.

2. A number of the toxicity studies submitted in this data package were previously submitted and evaluated in the S. Biscardi review of 9/26/77. We have attached DERs for those studies which have not been previously evaluated.

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DATA EVALUATION REPORT

DIFLUBENZURON VC-90

STUDY: Dermal LD_{50} in Rats.

LABORATORY: Duphar VP, Weesp, Netherlands.

STUDY NUMBER & DATE: 56645/31/84 March, 1985.

STUDY DIRECTOR: T. S. M. Koopman

ACCESSION NUMBER: 262505

MATERIAL TESTED: Diflubenzuron VC-90*

ANIMALS: SPF-derived rats, five males and five females per group.

METHODS:

Husbandry: Standard GLP.

Feed & Water: Available ad lib.

Following a five day acclimatization period the animals were shaved over the back and flank, a 2000 mg/kg dose of test material in 1 % tragacanth solution was applied to approximately 10 % of the shaved area. A control solution, containing only the excipients, was applied to another five animals per sex. The test sites were occluded with protective coverings and allowed to remain 24 hours, following which the dressings were removed and the test sites wiped clean.

Animals were observed at 0.5, 1.5, 3, 6, 24 and 48 hours, and daily thereafter (except on days 11, 12 and 13) for mortality, toxic signs and skin reactions for 14 days.

Body weights were obtained initially and on days 2, 7 and 14.

Animals were autopsied at termination at 14 days.

RESULTS:

Mortality - no animals died during the study.

Clinical signs - none were reported.

Body weights - slight loss occured in both treated and control in first two days but these returned to normal thereafter.

Post-mortem examination - negative for effect of dermal exposure to the test material.

CONCLUSIONS:

Dermal LD_{50} > 2000 mg/kg.

TOXICITY CATEGORY:

III.

CORE RATING:

Guideline.

DATA EVALUATION REPORT

DIFLUBENZURON VC-90

STUDY: Oral LD_{50} in Rats.

LABORATORY: Duphar VP, Weesp, Netherlands.

STUDY NUMBER & DATE: 56645/30/84 March, 1985.

ACCESSION NUMBER: 262505

MATERIAL TESTED: Diflubenzuron VC-90*

ANIMALS: SPF-derived rats, five males and five females per group.

METHODS:

Husbandry: Standard GLP.

Feed & Water: Available ad lib., except from 16 hours pre-dosing to 6 hours post-dosing.

Animals were given a single P.O. dose of test material in 1 % tragacanth solution. Animals were fasted 16 hours pre-exposure and for an additional 6 hours following treatment. Water was available ad lib. The test levels administered were 0 (500 mg/kg excipients) and 5000 mg/kg.

Animals were observed at 0.5, 1.5, 3, 6, 24 and 48 hours, and daily thereafter (except on days 11, 12 and 13) for mortality and toxic signs for 14 days.

Body weights were obtained initially and on days 2, 7 and 14.

Animals were autopsied at termination at 14 days.

RESULTS:

Mortality - none.

Toxic signs - none reported.

Body weights - no effect reported.

Gross necropsy - no evidence of effect.

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*CSF: 92.2 % Tech. dimilin, [redacted]

CONCLUSIONS:

Rat Oral LD_{50} > 5,000 mg/kg.

CORE RATING: Guideline.

TOXICITY CATEGORY: III

Reviewer: D. Ritter

DATA EVALUATION REPORT

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DIFLUBENZURON VC-90

STUDY: Rabbit Eye Irritation.

LABORATORY: Duphar VP, Weesp, Netherlands.

STUDY NUMBER & DATE: 56645/29/84 March, 1985.

ACCESSION NUMBER: 262505

MATERIAL TESTED: Diflubenzuron VC-90*

ANIMALS: SPF-derived rabbits, six males.

METHODS:

Husbandry - Standard GLP.

Feed and Water - available ad libitum.

Procedure:

Only those animals demonstrating no eye defects upon slit-lamp examination were used. 100 mg. test material was instilled into the left lower conjunctival sac. The right eye served as control. The exposed eyes were not rinsed.

Ocular damage was assessed using the scoring system of Draize at 1 hour, 24, 48 and 72 hours following exposure.

RESULTS:

The conjuntivae were slightly irritated for the first 48 hours; two rabbits exhibited a slight edema of the conjuntivae, which disappeared at 24 hours. No involvement of the cornea or iris was reported.

CONCLUSIONS:

PII < 0.1/8.0 a very mild irritant.

TOXICITY CATEGORY: III.

CORE RATING: Minimum.

DATA EVALUATION REPORT

DIFLUBENZURON VC-90

STUDY: Rabbit Dermal Irritation.

LABORATORY: Duphar VP, Weesp, Netherlands.

STUDY NUMBER & DATE: 56645/44/84 March, 1985.

ACCESSION NUMBER: 262505

MATERIAL TESTED: Diflubenzuron VC-90*

ANIMALS: SPF-derived rabbits, six males.

METHODS:

Husbandry - Standard GLP.

Feed and Water - available ad libitum.

Procedure:

The backs were shaved free of hair and 0.5 gm. the test material, slightly moistened with 1 % tragacanth solution was applied under a 6 cm^2 aluminum foil patch. The animals were restrained and the test sites were occluded with adhesive tape.

Four hours later the test sites were uncovered, wiped clean and scored for dermal irritancy after the method of Draize at 30 - 60 minutes and at 24, 48 and 72 hours.

RESULTS:

The investigators reported no erythema, irritation or edema in any test animal at any time.

CONCLUSIONS:

PII = 0/110. Not a dermal irritant to the unabraded unwashed skin.

CORE RATING:

Minimum.

TOXICITY CATEGORY:

III.