REVIEWER

005615

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 28 1986

MEMORANDUM

TO: Tim Gardner, 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

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

Subject:

Dimilin - EPA Reg. # 37100-8/ER/1F2507/1H5301/37100-EUP-T.

Caswell #: 346A

TOX project numbers: 1493/94/95/96/97.

Action requested:

Review data for tolerance on citrus and for Registration Standard requirements.

Recommendation:

1. A tolerance of 0.5 ppm in citrus, 0.3 ppm in dried citrus pulp, 20 ppm in citrus oil and 0.05 ppm in meat, milk and eggs was approved in the review of 4/29/85, R. Jaeger, PP # 1F2507. Data considered in support of those tolerances likewise support the present request.

2. Toxicity data accompanying the action have been reviewed and the DERs are attached. The results are summarized as follows:

   - Acute Oral LD_{50} in the Rat - > 5000 mg/kg
   - Acute Dermal LD_{50} in the Rat - > 2000 mg/kg
   - Rabbit Primary Eye Irritation - PII = 1/8; mild irritant.
   - Rabbit Primary Dermal Irritation - Non-irritating.

3. No Registration Standard data gaps have been filled by these studies.

DATA EVALUATION REPORT

Dimilin (diflubenzuron)

STUDY: Acute Oral LD_{50} in the Rat

LABORATORY: Duphar B. V., Weesp, The Netherlands.

STUDY NUMBER & DATE: 56645/30/84 March 1985. T.S.M. Koopman.

ACCESSION NUMBER: 261488

MATERIAL TESTED: Diflubenzuron VC-90 (contains 92.2% dimilin).

ANIMALS: SPF rats, 160 - 200 gm.

METHODS:

Housing conditions - Standard GLP.

Feed ad libitum after a 16 hour pre-treatment fasting period.

Water - ad libitum.

Dosing: 5 male and female rats per dose group were gavaged with 5000 mg/kg of test material or 500 mg/kg of excipients in 1 % tragacanth following a five day acclimatization period.

Observations - for mortality and toxic effects were made at 1/2 hour, 1.5, 3, 6, 24 and 48 hours, and on days 2 through 10 and on day 14.

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

Autopsy - at termination.

RESULTS:

Mortality: No animals expired during the study.

Clinical Signs: None reported.

Body weight gain: No treatment effects reported.

Autopsy: No relevant effects reported.

CONCLUSIONS:

Acute Oral LD_{50} is > 5000 mg/kg.

TOXICITY CATEGORY:

III.

CORE RATING:

Guideline.

DATA EVALUATION REPORT

Dimilin (diflubenzuron)

STUDY: Acute Dermal LD_{50} in the Rat

LABORATORY: Duphar B. V., Weesp, The Netherlands.

STUDY NUMBER & DATE: 56645/31/84 March 1985. T.S.M. Koopman.

ACCESSION NUMBER: 261488

MATERIAL TESTED: Diflubenzuron VC-90 (contains 92.2% dimilin).

ANIMALS: SPF male and female rats, 5 per sex per group.

METHODS:

Housing conditions - Standard GLP.

Feed ad libitum after a 16 hour pre-treatment fasting period.

Water - ad libitum.

Dosing: 5 male and female rats per dose group were exposed to 2000 mg/kg of test material or 200 mg/kg of excipients in 1 % tragacanth following a five day acclimatization period. The test site was depilated (about 10 % of the total surface area) and the test material was applied in a volume of 4 ml. The site was occluded for a period of 24 hours. The dressing was removed and the site wiped dry.

Observations - for mortality and toxic effects were made at 1/2 hour, 1, 1.5, 3, 6, 24 and 48 hours, and on days 2 through 10 and on day 14.

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

Autopsy - at termination.

RESULTS:

Mortality: No animals expired during the study.

Clinical signs: None.

Body weight gain: No treatment effects reported.

Autopsy: No relevant effects reported.

CONCLUSIONS:

Acute Dermal LD_{50} is > 2000 mg/kg.

TOXICITY CATEGORY: III.

CORE RATING: Guideline.

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DATA EVALUATION REPORT

Dimilin (Diflubenzuron)

STUDY: Rabbit Primary Eye Irritation Study

LABORATORY: Duphar B. V., Weesp, The Netherlands.

STUDY NUMBER & DATE: 56645/29/84 March 1985. T.S.M. Koopman.

ACCESSION NUMBER: 261488

MATERIAL TESTED: Diflubenzuron VC-90 (contains 92.2% dimilin).

ANIMALS: New Zealand White Rabbits.

METHODS:

Animals were examined with a slit lamp to determine condition of the eyes. 100 mg of test material was introduced into the left conjuntiva of each rabbit. Treated eyes were not rinsed. Injury was scored according to the Draize method initially, and at 1, 24, 48 and 72 hours.

RESULTS:

Slight conjunctival redness and chemosis was reported in each animal at 1 and 24 hours. A PII of 1/8 is calculated.

CONCLUSIONS:

VC-90 is a very mild eye irritant.

CORE RATING:

Guideline.

TOXICITY CATEGORY:

III

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DATA EVALUATION REPORT

Dimilin (Diflubenzuron)

STUDY: Primary Dermal Irritation in the Rabbit.

LABORATORY: Duphar B. V., Weesp, The Netherlands.

STUDY NUMBER & DATE: 56645/44/84 March 1985. T.S.M. Koopman.

ACCESSION NUMBER: 261488

MATERIAL TESTED: Diflubenzuron VC-90 (contains 92.2% dimilin).

ANIMALS: 6 New Zealand White Rabbits

METHODS:

A suitable area of the back was clipped and 0.5 gm of the test material was moistened with 1 % tragacanth, then placed under a 6 cm square of aluminum foil. The animals were immoblized during the 4 hour exposure period. The patches were removed and the skin was wiped dry. The dermal reactions were evaluted by the Draize method at 30 - 60 minutes and at 24, 48 and 72 hours.

RESULTS:

No erythema or edema was reported in any animal.

CONCLUSIONS:

VC-90 is not a dermal irritant.

CORE RATING:

Guideline.

TOXICITY CATEGORY:

III.