497E

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

JUL 28 1993

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: EPA ID #s 3125-URT, 3125-URA, Imidacloprid, Data to support changes in Tox. Category for eye irritation studies on 2 formulations.

Tox. Chem. No. 497E
PC No. 129059
DP Barcode: D188656, D188658
Submission: S436136, S436151

FROM: Marion Copley, DVM, DABT
Head, Review Section 4
Toxicology Branch 1
Health Effects Division (H7509C)

Marion Copley 7/23/93

TO: Jenkins/Edwards (PM 19)
Registration Division (H7505C)

THROUGH: Karl Baetcke, PhD
Chief, Toxicology Branch 1
Health Effects Division (H7509C)

Karl A. Baetcke 7/23/93

CONCLUSIONS

Toxicology Branch has evaluated the eye irritation (81-4) study for the 0.62 % G formulation (DER attached) and reevaluated the data evaluation report (DER) for the 2.5 % G formulation and concluded that the toxicity category is III for both formulations as stated by the registrant. The file and 1-liners for Imidacloprid will reflect this change from II to III.

ACTION REQUESTED

Miles Inc has requested that the toxicity category for the eye irritation study conducted on the 2.5 % technical be changed from II to III.

DISCUSSION

After reevaluating the DER (HED Doc. 009375, MRID 42055327) for the eye irritation study no. 89-335-DT (81-4) on the 2.5 % formulation it was determined that the Registrant is correct and the study should reflect a

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toxicity category of III. This is because scores of 1 for conjunctival effects are not considered to be positive effects. the original DER did not take this into consideration. Eye effects were resolved by 48 hours. No supplemental DER will be produced for this change.

The eye irritation study no. 89-335-DX (81-4) on the 0.62 % formulation supports a toxicity category of III. Eye effects were resolved within 7 days (DER attached).

Reviewed by: Marion Copley, DVM
Section 4, Tox. Branch 1 (H7509C)
for Secondary reviewer: Linnea Hansen, PhD
Section 4, Tox. Branch 1 (H7509C) 7/23/93

DATA EVALUATION REPORT

STUDY TYPE:	Primary Ocular Irritation - Rabbit (81-4)
TOX. CHEM. NO.:	497E
PC NO.:	129059
MRID NO.:	426744-02
TEST MATERIAL:	BAY NTN 33893 0.62 % Granular
SYNONYMS:	1-[(Chloro-3-puridinyl)methyl]-4,5-dihydro-N-nitro-1H-imidazol-2-amine Imidacloprid (proposed)
STUDY NO.:	92-335-PX
SPONSOR:	Miles Inc.
TESTING FACILITY:	Miles Inc., Ag. Division, Stilwell, Kansas 66085-9104
AUTHOR:	A.B.Astroff and S.D.Phillips
REPORT ISSUED:	10/12/92

CONCLUSION:

Mild irritation, resolved within 7 days

Toxicity Category: III

This study satisfies the guideline requirements (81-4) for Primary Ocular Irritation on the 0.62 % granular formulation and is acceptable for regulatory purposes.

MATERIALS:

1. **Test Compound:** BAY NTN 33893 0.62 % Granular
   Description: Grey Granules. Batch Nos.: 2 33005, 2030071
   Purity: 0.71 % a.i.
   Stability: Estimated at least two years

2. **Test Animals:** Species: Rabbit, Strain: New Zealand White:
   Age: 12 weeks (weight not given);
   Source: Small Stock Industries, Pea Ridge, Arkansas

3. **Environment:** Rabbits were housed individually in stainless steel cages suspended over bedding. Temperature: 18-24 °C;

Humidity: 40-70 %; Photoperiod: 12 hours light/dark; Food: approx. 125 g/day of Agway Prolab Rabbit Formula; Water: municipal ad libitum.

METHODS:

Test material, 0.11 g (0.1 ml), was placed into the conjunctival sac of the left eye in each of six adult rabbits (all males). The eye lids were held together for about one second. The right eye was not treated and served as a control.

Eyes were evaluated for corneal, iridal and conjunctival irritation at 1, 24, 48, and 72 hours following treatment using the Draize method. They were also examined 7 days post dosing if lesions persisted.

RESULTS AND DISCUSSION:

The results are on the attached table taken from the study report (p. 16). There were no corneal lesions in any rabbit. There was transient chemosis, discharge, iridal lesions (24 hr only) and conjunctival redness. All lesions were resolved by 7 days.

Signed Quality Assurance and Good Laboratory Practice statements were present.

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____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

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✓ FIFRA registration data.

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