

US EPA ARCHIVE DOCUMENT

MEMORANDUM

EPA File Symbol: 69117-1 Pointer Insecticide
DP Barcode: D230827
Chemical: 129099 Imidacloprid
Test Material: Pointer Insecticide, is a yellowish liquid,
batch: 6030138/96JGSO45
From: Lawrence A. Fried, Biologist
Precautionary Review Section
Registration Support Branch (7505W)
Registration Division *Lawrence A. Fried
10-30-96*
To: Dennis Edwards, Jr., Product Manager, Team 19
Portia Jenkins, Team Reviewer, Team 19
Applicant: 69117 Arborsystems Inc.
Performing Lab: Cosmopolitan Safety Evaluation, Inc.
P.O. Box 71
Lafayette, NJ 07848

FORMULATION FROM LABEL

| <u>Ingredient(s)</u> | <u>% by wt.</u> |
|------------------------|-----------------|
| Imidacloprid | 5.00 |
| Inerts | 95.00 |
| Total | 100.00 |

BACKGROUND

Arborsystems Inc. has submitted primary eye (441376-01) and primary dermal (441376-02) studies on Pointer Insecticide. These data were submitted in order to support the amendment of the current precautionary labeling. PRS will provide the primary review of these studies.

RECOMMENDATION

81-4. Eye Irritation: Category II. The submitted study is acceptable.

81-5. Dermal Irritation: Category IV. The submitted study is acceptable.

LABEL RECOMMENDATION: For eye irritation and dermal irritation only. The following information should be used by the PM to amend the Pointer Insecticide precautionary label.

SIGNAL WORD: WARNING

PRECAUTIONARY STATEMENTS:

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF SWALLOWED: Call a physician or Poison Control Center. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

IF IN EYES: Hold eyelids open and flush with steady, gentle stream of water for 15 minutes. Get medical attention.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: D. Edwards
MRID No.: 441376-01
Author: G. Robbins

Reviewer: Fried
Report No.: D3472
Report Date: 09-19-96

Conclusion:

Toxicity Category: II
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure (Deviations from §81-4): None

Testing Facility: Cosmopolitan Safety Evaluation, Inc.

Test Material: Pointer Insecticide, is a yellowish liquid,
batch: 6030138/96JGS045

Test Animal: Rabbit; New Zealand White; 3/sex

Age: Young adult (3-6 months)

Weight: 2.1 to 2.5 kg.

Source: Laboratory Colony (Branchville)

Test Conditions: Six healthy young adult albino rabbits were used. One eye of each rabbit was dosed with 0.1 ml of the test substance, the other eye remaining untreated as a control. The animals were observed consistently over a 17-day period.

Results: Corneal involvement at 48 and 72 hours was observed. At 72 hours all eyes showed opacity (grade 1 or 2), iritis (grade 1) and conjunctival redness (grade 1) and chemosis (grade 1) usually with excessive discharge. On day-10, three eyes were normal. The other three eyes had very faint opacity; in two eyes there was no dye retention and no iritis but in one eye there was still a small central area of dye retention on the cornea, with neovascularization from the limbus toward the slight opacity. On day-14, two eyes had slight opacity, with vascularization from the limbus, but no dye retention or iritis. None of the conjunctivae were positive for irritation. All effects cleared by 17 days.

DATA REVIEW FOR DERMAL IRRITATION TESTING (§81-5)

Product Manager: D. Edwards
MRID No.: 441376-02
Author: G. Robbins

Reviewer: Fried
Report No.: E3472
Report Date: 09-18-96

Conclusion:

Toxicity Category: IV
Classification: acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations from §81-5: None

Testing Facility: Cosmopolitan Safety Evaluation, Inc.

Test Material: Pointer Insecticide, is a yellowish liquid,
batch: 6030138/96JGS045

Test Animal: Rabbit, New Zealand White
Age: Young adults
Weight: 2.1-2.4 kg
Source: Laboratory colony (Branchville)

Test Conditions: A 0.5 ml dose of test substance was applied to the application site for 4 hours on each of six rabbits. The degree of irritation was graded at approximately 1 hour after removal of the wraps and then at 24, 48 and 72 hours using a modification of the method of Draize and a primary irritation score was calculated.

Results: There was no immediate sign of discomfort on application. Approximately 45 minutes after patch removal there was slight irritation characterized by erythema (grade 1) at all sites and edema (grade 1) at three sites. Over the next three days the irritation tended to resolve and at 72 hours four test sites appeared normal and the remaining two test sites showed only very slight erythema (grade 1). The residual signs had subsided by day-4 when all test sites appeared normal. There was no systemic pharmacotoxic effect and no evidence of any injury in depth.

ACUTE TOX ONE-LINER

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 Chemical: 129099 Imidacloprid
 Applicant: 69117 Arborsystems Inc.
 Test Material: Pointer Insecticide, is a yellowish liquid,
 batch: 6030138/96JGSO45
 Date: October 30, 1996

| Study, Animal, Test Laboratory, Study #, Date | MRID No. | Results | Tox. Cat. | Core Grade |
|---|-----------|--|--------------|---------------|
| Eye Irritation, Rabbit, Cosmopolitan Safety Eval., Inc., NJ, #D3472, 09-19-96 | 441376-01 | Slight corneal opacity observed on day-14. All effects cleared by 14 days. | II | A |
| Dermal Irritation, Rabbit, Cosmopolitan Safety Eval., Inc., NJ, #E3472, 09-18-96 | 441376-02 | At 72 hours slight erythema observed. | IV | A |

A = Acceptable