

9-1-92

MRID No. 405313-01

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Isoxaben.
Shaughnessey No. 125851.
- 2. **TEST MATERIAL:** Isoxaben (N-(3-(1-ethyl-1-methylpropyl)-5-isoxazolyl)-2,6-dimethoxybenzamide) technical; Gallery® 75 dry flowable (75% active ingredient); Lilly Serial No. 121607.
- 3. **STUDY TYPE:** Non-Target Plants: Seedling Emergence Phytotoxicity Test. Species Tested: Corn, Sorghum, Barley, Wheat, Rice, Barnyardgrass, Green Foxtail, Cheatgrass, Wild Oat, Morningglory, Velvetleaf, Common Ragweed, Soybean, Cotton, Jimsonweed, Lambsquarter, Redroot Pigweed, Black Nightshade, Cocklebur, Sicklepod, Prickly Sida, Blackgrass, Annual Ryegrass, Browntop Panicum, Cucumber.
- 4. **CITATION:** Saunders, D.G., T.W. Waldrep and D.H. Mowrey. 1987. Potential for Injury to Nontarget Plants from Application of Isoxaben. Laboratory Project ID. No. EWD8732. Conducted by Lilly Research Laboratories, Greenfield, IN. Submitted by Elanco Products Co. EPA MRID No. 405313-01.

5. **REVIEWED BY:**

 Mark A. Mossler, M.S.
 Agronomist
 KBN Engineering and
 Applied Sciences, Inc.

Signature: *Mark A. Mossler*
 Date: *2/7/92*
Chalee Seem 9/1/92

6. **APPROVED BY:**

 Michael L. Whitten, M.S.
 Staff Scientist
 KBN Engineering and
 Applied Sciences, Inc.

Signature: *Michael L. Whitten*
 Date: *2/7/92*

Henry T. Craven, M.S.
 Supervisor, EEB/EFED
 USEPA

Signature: *Henry T. Craven*
 Date: *9/1/92*

7. **CONCLUSIONS:** This study is not scientifically sound and does not meet the guideline requirements for a Tier 2 seedling emergence non-target plant phytotoxicity test. Lack of phytotoxicity and emergence ratings as well as improper species selection invalidated this study. The

13 hrs

NOEC, EC₂₅ and EC₅₀ for cocklebur (the most sensitive species based on EC values) were <0.06, 0.002, and 0.02 ppmw, respectively.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

- A. **Test Plants:** Dicotyledon plants were represented by thirteen species from multiple families (see section 3). Monocotyledon plants were represented by twelve species from one family.
- B. **Test System:** Soil (clay loam, 2.7% organic matter content) was dried and the test material added as the soil was mixed in a modified cement mixer. Seeds were planted in 4-inch diameter pots and covered with treated soil. After planting, the pots were watered and placed in a greenhouse maintained at 70-85°F. A 12-hour photoperiod was maintained using supplemental lighting. The pots were sub-irrigated as needed.
- C. **Dosage:** The highest test solution was prepared by diluting an appropriate amount of the test material in a 1:1 acetone:ethanol solution which was further diluted to the appropriate concentration in deionized water containing 1000 ppm Toximul R and S. The final soil concentrations to which the plants were exposed ranged between 0.03 and 4 ppm (0.01 and 1.33 lb ai/A).
- D. **Design:** Each treatment/crop combination was replicated three times. Two sets of controls were used for each test species. Plant fresh weight was recorded 21 days after treatment.
- E. **Statistics:** The EC₂₅ and EC₅₀ were computed by regression of the fresh weight of the test plants against the log of the dose. If the goodness of fit value (R^2) was not greater than or equal to 0.64, the fit was declared inadequate and EC values were not determined. Confidence intervals (95%) were calculated using techniques established for internal standard calibration curves.

12. **REPORTED RESULTS:** "Isoxaben was applied at five nonzero levels in all cases but two; grain sorghum was applied at nine levels, and morningglory at four levels. Three replicates of each plant species were used for each nonzero level of isoxaben. Six replicates of each plant species were used as controls except in seven cases; morningglory (4), annual ryegrass (5), jimsonweed (5), redroot pigweed (5), and sicklepod (5), cucumber (9), and grain sorghum (24). Fresh weight control data were used to calculate the median fresh weight for each plant species and the 25 and 50 percent reduction in fresh weight was also calculated. These reductions served as the 25 and 50 percent detrimental effects."

"Estimated doses and 95% confidence intervals were calculated for those plant species for which R^2 was greater than 0.64 (Table III, attached)."

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** For crops that were planted in isoxaben pre-plant incorporated soil, cucumber and soybean were most sensitive based on fresh weights. Corn, cotton, grain sorghum, and rice had intermediate sensitivity, and barley and wheat were most tolerant. For grass weeds that were planted in isoxaben pre-plant incorporated soil, annual ryegrass, barnyardgrass, blackgrass, browntop panicum, and green foxtail were most sensitive, while cheatgrass and wild oat were most tolerant to isoxaben based on fresh weights. For broadleaf weeds that were planted in isoxaben pre-plant incorporated soil, black nightshade, cocklebur, common ragweed, jimsonweed, lambsquarters, morningglory, and pigweed were very susceptible. Sicklepod and velvetleaf were intermediate in sensitivity and prickly sida was the most tolerant of isoxaben. Phytotoxicity (particularly to broadleaf weeds) was anticipated because isoxaben is a potent herbicide and maximum activity is observed pre-plant incorporated in the laboratory. Isoxaben is generally safe when applied to established plants, particularly ornamental and woody plants.

A statement was included in the report indicating that the study was not subject to Good Laboratory Practices at the time of performance and was not monitored by the Quality Assurance Unit.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**
- A. **Test Procedure:** The test procedures followed the SEP and Subdivision J guidelines except for the following:

No lot numbers, seed sources, or germination ratings were reported.

Only one measure of phytotoxicity (fresh weight) was assessed. At least two parameters (usually one qualitative and one quantitative) must be measured.

The no-observed-effect concentrations (NOEC) were not determined for fresh weight.

Seedling emergence was not evaluated at one, two, and three or four weeks after treatment.

The species of crops selected for the tests were partially incorrect. Tests must be conducted with six species of dicots (from at least four families) and must include soybean and a root crop. Four species of monocot must be tested (from at least two families) and must include corn. This test did not include a dicot root crop or a second family monocot.

Illuminance, photoperiod and humidity were not reported.

The number of seeds planted per pot was not specified.

B. **Statistical Analysis:** Probit analysis and analysis of variance (coupled with Dunnett's test) were used by the reviewer to determine the EC values and NOEC, respectively, of cocklebur fresh weight (the most sensitive species based on EC values). The reviewer obtained similar but slightly less conservative EC values than the authors (see attached printouts). The NOEC was determined to be less than 0.06 ppmw, the lowest concentration tested.

C. **Discussion/Results:** The objective of a Tier 2 emergence test is to quantitate the amount of damage that occurs when the plants are in their most vigorous and sensitive stage of development. The authors did not report emergence or the number of plants per pot, and consequently, the reviewer has no idea as to the amount of damage sustained in the early phase of the study. The results from the regression analyses of fresh weight are presented in Table III.

Of the 25 species tested, EC values were able to be computed based on fresh weight for 17 of the test

species. The EC₅₀s of the 17 species (in ppmw), in increasing sensitivity to isoxaben, are as follows:

wild oat (1.3) < barley (0.68) < wheat (0.58) < cheatgrass (0.52) < sorghum (0.42) < cotton (0.41) < rice (0.32) < corn (0.31) < prickly sida (0.27) < velvetleaf = annual ryegrass (0.19) < blackgrass = sicklepod (0.15) < cucumber (0.14) < soybean (0.11) < jimsonweed (0.05) < cocklebur (0.02).

The EC₂₅ values were similar in trend to the EC₅₀s.

This study is not scientifically sound and does not meet the guideline requirements for a Tier 2 seedling emergence non-target plant phytotoxicity test. The NOEC, EC₂₅ and EC₅₀ for cocklebur (the most sensitive species based on EC values) were <0.06, 0.002, and 0.02 ppmw, respectively.

D. Adequacy of the Study:

- (1) **Classification:** Invalid.
- (2) **Rationale:** Lack of phytotoxicity and emergence ratings as well as improper species selection invalidated this study.
- (3) **Repairability:** No.

15. COMPLETION OF ONE-LINER: N/A.