

US EPA ARCHIVE DOCUMENT

3-11-94

MRID No. 429186-16

DATA EVALUATION RECORD

FILE COPY

- 1. **CHEMICAL:** MB 46030 (Fipronil).
Shaughnessey Number: 129121.
- 2. **TEST MATERIAL:** M & B 46030 technical; Lot No. JJW-2092/1;
96.8% purity; a white powder.
- 3. **STUDY TYPE:** 71-1A. Avian Single Dose Oral LD₅₀ Test.
Species Tested: Mallard Duck (*Anas platyrhynchos*).
- 4. **CITATION:** Pedersen, C.A. 1990. M & B 46030 Technical: 21-
Day Acute Oral LD₅₀ Study in Mallard Ducks. Study performed
by Bio-Life Associates, Ltd., Neillsville, Wisconsin.
Laboratory Project No. 89 DD 70. Submitted by Rhone-Poulenc
Ag Company, Research Triangle Park, North Carolina. EPA
MRID No. 429186-16.

5. **REVIEWED BY:**

Nicole U. Jurczyk, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Nicole U. Jurczyk*

Date: 1/12/94

6. **APPROVED BY:**

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

Signature: *Mark A. Mossler*

Date: 1/12/94

James J. Goodyear, Ph.D.
Project Officer, EEB/EFED
USEPA

Signature: *James J. Goodyear*

Date: 3 11 94

7. **CONCLUSIONS:** The study is scientifically sound and fulfills the requirements for an avian oral LD₅₀ test. The single dose oral LD₅₀ was greater than 2150 mg ai/kg, the highest concentration tested. This classifies the test material as practically non-toxic to mallard ducks. The NOEL was 2150 mg ai/kg.

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

9. **BACKGROUND:**

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

11. MATERIALS AND METHODS:

A. Test Animals: The birds used in the study were 35 week old mallard ducks (*Anas platyrhynchos*) obtained from Whistling Wings, Inc., Hanover, Illinois. All birds were from the same hatch and were phenotypically indistinguishable from wild birds. The birds were acclimated to the testing conditions for 15 days. All birds appeared to be in good health at initiation of the test.

B. Test System: The birds were housed indoors in pens constructed of wire mesh that were maintained over concrete. The pens measured 121.9 x 121.9 x 121.9 cm.

The photoperiod (maintained by a time clock) was ten hours of fluorescent light per day during the acclimation and test periods. The temperature in the test room ranged from 50°F to 76°F with relative humidity between 72% and 95%.

C. Dosage: Twenty-one-day single dose oral LD₅₀ test. Based on the results of preliminary testing, the dosages selected for definitive testing were 1470 and 2150 milligrams of active ingredient per kilogram of body-weight (mg ai/kg).

D. Design: The birds chosen for the definitive study were randomly assigned to two treatment groups and one control group. Ten birds (five female and five male) were assigned to each pen.

The birds were fasted for 19 3/4 hours prior to dosing. The test material was dispensed directly into gelatin capsules. Each treatment bird received its respective dose of the test material via four capsules. The control birds were each given four empty gelatin capsules. Each bird was individually weighed and dosed on the basis of milligrams of test material per kilogram of body weight.

All birds were fed Purina Duck Grower W/O. Food was supplied *ad libitum*, except for the fasting period prior to dosing. Water was available to the birds at all times.

Daily inspections were made throughout the study for mortalities, clinical signs of toxicity, abundance of food and water, and food spillage.

Birds were weighed individually at test initiation, days 3, 7, 14, and at test termination (day 21). Group food consumption values were recorded on test days 3, 7, 14, and 21.

The one bird that died during the investigation was subjected to a gross pathological examination. Four arbitrarily selected birds (two male and two female) from the control group and from each of the two treatment groups were subjected to gross pathological examinations on test day 21.

E. Statistics: There was only one mortality during the study. This mortality was believed to be unrelated to treatment. Therefore, no statistical methods were employed in determination of an LD₅₀ value.

- 12. REPORTED RESULTS:** No signs of toxicity were noted in the control or treatment birds throughout the investigation. One of the birds from the 1470 mg ai/kg group was found dead on day 6 of the study. The death was attributed to fighting among the birds in this group. Fighting was noted during test days 6 through 8 only. No mortalities occurred in the control or 2150 mg ai/kg groups.

Gross pathological examinations of the 12 arbitrarily selected survivors and of the one bird that died during the study revealed no abnormal pathological findings.

Statistical analysis of the body weights revealed no significant differences between the control and treatment birds at any of the weighing intervals. Food consumption values in the control and treatment groups were comparable throughout the investigation (Table 4, attached).

- 13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The acute oral LD₅₀ for the test material was determined to be greater than 2150 mg ai/kg. The no-observed-effect-level (NOEL) was determined to be 2150 mg ai/kg. Based on the results of this study, the test material would be classified as practically non-toxic to bobwhite quail.

Quality Assurance and Good Laboratory Practice statements were included in the report indicating conformance with GLP regulations as set forth in 40 CFR Part 160.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

- A. Test Procedure:** The test procedures were in accordance with Subdivision E and SEP guidelines.
- B. Statistical Analysis:** Since there were no treatment-related mortalities during the test, the LD₅₀ could not be calculated. Based on nominal concentrations, the LD₅₀ was greater than 2150 mg ai/kg.
- C. Discussion/Results:** Although the author reported that the one mortality occurred at the 1470 mg ai/kg treatment level, Table 3 (attached) indicated that this mortality occurred in the highest dosage group (2150 mg ai/kg). The reviewer assumes that the mortality listing in Table 3 is in error because Table 5 (attached) and the text of the report note the mortality as having occurred in the lower dosage group.

The occurrence of one death due to fighting among the birds raises the question of whether the birds were overcrowded. Crowding stress from inadequate cage facilities may result in aggressive behavior. The testing facility should review their husbandry practices to ensure that all precautions have been taken to avoid aggressive behavior by the test animals.

The study is scientifically sound and meets the requirements of an avian single dose oral LD₅₀ study. Based on nominal concentrations, the LD₅₀ was greater than 2150 mg ai/kg. This classifies the test material as practically non-toxic to mallard ducks. The NOEL was 2150 mg ai/kg.

- D. Adequacy of the Study:**
- (1) **Classification:** Core.
 - (2) **Rationale:** N/A.
 - (3) **Repairability:** N/A.

- 15. COMPLETION OF ONE-LINER:** Yes; January 5, 1994.

Final review

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Pages 5 through 7 are not included in this copy.

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