3-9-94

MRID No. 429186-21

DATA EVALUATION RECORD

FILE COPY

1. **CHEMICAL:** Fipronil (M & B 46030).
Shaughnessey Number: 129121.

2. **TEST MATERIAL:** Fipronil M & B 46030 Technical; Lot No. JJW-2092/1; >95% purity; white powder.

3. **STUDY TYPE:** 71-2. Avian Dietary LC_{50} Test.
Species Tested: Mallard Duck (*Anas platyrhynchos*).

4. **CITATION:** Pedersen, C.A. 1993. M & B 46030 Technical: 22-Day Acute Dietary LC_{50} Study in Mallard Ducklings. Study performed by Bio-Life Associates, Ltd., Neillsville, Wisconsin. Laboratory Project No. 89 DC 132. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, North Carolina. EPA MRID No. 429186-21.

5. **REVIEWED BY:**

Gary E. Schultz, M.S.
Associate Scientist
Engineering and
Applied Sciences, Inc.

Signature: Gary E Schultz
Date: January 20, 1994

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 1/20/94

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

Signature: Goodyear
Date: 3 n 94

2/22/94

3/9/94

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the requirements for an avian dietary acute toxicity test. The birds were fed test diets for 5 days, followed by a basal diet for 17 days (observation period). No mortality or sublethal effects occurred at diet concentrations of ≤1250 ppm ai. The LC_{50} was greater than 5000 ppm ai which classifies M & B 46030 as practically non-toxic to mallard ducks. The NOEC was 1250 ppm ai (1090 ppm ai mean measured concentration).

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Mallard ducklings (*Anas platyrynchos*), phenotypically indistinguishable from wild birds, were obtained when 2 days old from Whistling Wings, Inc., Hanover, Illinois. The birds were acclimated to the facilities for 6 days, and were 8 days old at test initiation. All birds were fed Purina® Game Bird Startena® during the quarantine period. Birds exhibiting abnormal behavior or physical injury during acclimation were not used in the study.

B. **Test System:** Birds were housed in wire pens in a thermostatically-controlled room. The pens measured 91.4 x 61.0 x 45.7 cm. During the test, the average temperature ranged from 21.7° to 26.7°C and the relative humidity ranged from 73% to 100%. Fluorescent lighting provided a 24-hour photoperiod throughout the study.

The treatment diets were prepared by dissolving the test substance (50.0 g) in 140.0 g acetone. This solution was then incorporated into 9,450 g of a basal diet (Purina® Game Bird Startena®). This 5,000 ppm ai diet was the highest test concentration. The remaining six diets were prepared by serial dilution of the highest concentration diet. The vehicle control diet was prepared by mixing 140.0 g acetone into 9.5 kg basal diet. Feed was presented each of the 5 test days from the diets prepared at test initiation. Water from a well was supplied *ad libitum*.

C. **Dosage:** Twenty-two day dietary LC_{50} test. Nominal dietary concentrations were 39, 156, 312, 625, 1250, 2500, and 5000 ppm ai. A vehicle control was also included.

D. **Design:** Ten birds were arbitrarily assigned to each pen (1 pen per treatment and 5 pens for the vehicle control). The birds were fed test diet or vehicle control diet for 5 days (exposure period) followed by basal diet for 17 days (observation period). Observations were made daily to ascertain the presence or absence of clinical signs indicative of test material effect. Inspections were made daily for mortalities, abundance of food and water, and food spillage.

A complete gross pathological examination was performed on the two birds that died during the study and four birds arbitrarily selected from the control and each of the seven treatment groups at test termination.

Body weights by group were measured at 0-hour on test day 1. Birds were individually weighed on day 22 of the test. Average feed consumption was determined by group for days 1-5, 6-10, 11-15, 16-20, and 21-22.

Immediately after diet preparation, samples were taken from the control, 39, 156, 312, 1250, and 5000 ppm diet for concentration verification. Samples were also taken from top, middle,and bottom of the 5000 ppm diet for homogeneity analysis. Stability samples were stored in the test room during the exposure period. All samples were frozen and sent to Hazleton Laboratories America, Inc., Madison, WI, for analyses using high performance liquid chromatography.

E. **Statistics:** The LC_{50} value was estimated by a visual inspection of the mortality data since only one mortality occurred in the treatment groups.

12. **REPORTED RESULTS:** Results of the homogeneity and stability analyses indicated that the test substance was uniformly mixed and stable in the diet (Table 5, attached). Measured concentrations ranged from 82.4% to 94.3% of nominal values.

One death each was recorded in the vehicle control group 3 (on day 20) and the 5000 ppm treatment group (on day 4). No mortalities occurred in any other groups. The LC_{50} value was determined to be in excess of 5000 ppm ai.

There were no clinical signs of toxicity in the vehicle control, 39, 156, 312, 625, and 1250 ppm ai treatment groups. Clinical signs of toxicity noted in the 2500 and 5000 ppm treatment groups were lethargy, anorexia and smallness in size. Total remission of all clinical signs was achieved in survivors by the end of test day 5.

Average body weights (Table 3, attached) on day 22 in the 312 and 625 ppm treatment groups were depressed when compared to other groups. However, these differences were not considered to be treatment-related because no differences were noted in the 1250, 2500, and 5000 ppm groups.

Food consumption values in the 2500 and 5000 ppm treatment groups were slightly reduced during the exposure period (Table 4, attached).

Gross pathological examination of the 1 dead bird in the vehicle control group showed a cloudy, pale yellow fluid in the pericardium, a hard yolk sac and slightly pale kidneys. No pathological abnormality was observed in any other bird examined.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The LC_{50} of M & B 46030 Technical was determined to be greater than 5000 ppm ai. The no-observed-effect concentration (NOEC) was 1250 ppm ai. Based upon the results of this study, M & B 46030 Technical would be classified as practically non-toxic to mallard ducks.

Quality Assurance and Good Laboratory Practice (GLP) compliance statements were included in the report, indicating that the study was conducted in accordance with GLP standards as set forth in 40 CFR Part 160.

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

A. **Test Procedure:** The test procedures were generally in accordance with Subdivision E, ASTM, and SEP guidelines with the following exceptions:

Birds were initially weighed by group. The guidelines recommend that the birds be weighed individually.

The relative humidity exceeded the recommended 80% for 20 of the 22 days in the study.

No negative control was included in the test. However, the reviewer will accept this study since no sublethal effects and only one mortality out of 50 birds occurred in the vehicle control group.

B. **Statistical Analysis:** Since only one mortality occurred in the treatment groups during the test, the LC_{50} value was estimated by visual inspection.

C. **Discussion/Results:** The analysis of the highest concentration diet at test initiation showed an average of 4480 ppm ai, while the analysis of the same diet left in the test room for 5 days (during the exposure period) resulted in a concentration of 4979 ppm ai. The mean measured concentration for the highest test

concentration was therefore 4730 ppm ai. Since only one mortality occurred in this test group, the LC_{50} was >4730 ppm ai and was believed to be >5000 ppm ai, which classified M & B 46030 as practically non-toxic to mallard ducks.

After review of the mortality, bird weight, and feed consumption data, the reviewer concurs that the NOEC was 1250 ppm ai nominal concentration (1090 ppm ai measured concentration).

This study is scientifically sound and fulfills the requirements for an avian dietary acute toxicity test.

D. Adequacy of the Study:

(1) **Classification:** Core

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. COMPLETION OF ONE-LINER: Yes, January 14, 1994.

Final Revised

Page _____ is not included in this copy.

Pages 6 through 11 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ 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.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

__√__ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.