3/11/94

MRID No. 429186-20

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: Bobwhite Quail (*Colinus virginianus*).

4. **CITATION:** Pedersen, C.A. 1993. M & B 46030 Technical: 22-Day Acute Dietary LC_{50} Study in Bobwhite Quail. Study performed by Bio-Life Associates, Ltd., Neillsville, Wisconsin. Laboratory Project No. 89 QC 135. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, North Carolina. EPA MRID No. 429186-20.

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 11 94

2/22/94
3/9/94

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirement 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 ≤19.5 ppm ai. The LC_{50} was 48.0 ppm ai which classifies M & B 46030 as very highly toxic to bobwhite quail. The NOEC was 19.5 ppm ai.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bobwhite quail (*Colinus virginianus*) were obtained as eggs from Oak Ridge Game Farm, Gravette, Arkansas. The eggs were hatched and held in an incubator for a 14 day quarantine period. All birds were from the same hatch and phenotypically indistinguishable from wild birds. All birds were fed Purina® Game Bird Startena® during the quarantine period. Thirty-five mortalities among 467 chicks occurred during this 14 day period, and no mortalities occurred during the last 5 days of the quarantine. The birds were 14 days of age at test initiation.

B. **Test System:** The birds were housed in wire pens in a thermostatically-controlled room. The pens measured 45.7 x 61 x 45.7 cm. During the test, the average temperature ranged from 32.2 to 46.7°C and the relative humidity ranged from 29 to 65%. A 24-hour fluorescent lighting photoperiod was used 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 the diet (9,450 g Purina® Game Bird Startena®) which resulted in a 5000 ppm ai premix. The highest test concentration of 625 ppm ai was prepared by mixing an appropriate amount of the premix in the diet. 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 stock diet. Feed was presented each day from the diets prepared at test initiation. Water from a well was supplied *ad libitum*.

C. **Dosage:** Twenty-two day dietary LC_{50} test. Dosage levels selected for the study were 4.9, 9.8, 19.5, 39, 156, 312, and 625 ppm ai. A vehicle control was also included.

D. **Design:** Ten chicks 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 32 birds that died during the study and four birds arbitrarily selected from the control and each of the four lowest dosage treatment groups at test termination.

Body weights by group were measured at 0-hour on day 1 and 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, 4.9, 19.5, 39, 156, and 312 ppm diet for concentration verification. Samples were also taken from top, middle,and bottom of the 4.9 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 calculated using the Litchfield and Wilcoxon method.

12. **REPORTED RESULTS:** Results of the homogeneity and stability analyses indicated that test substance was uniformly mixed and stable in the diet (Table 6, attached). Measured concentrations ranged from 71% to 91% of nominal values.

There were no clinical signs of toxicity or mortalities in the vehicle control, 4.9, 9.8, or 19.5 ppm ai treatment groups. At the 39 ppm and higher treatment concentrations, clinical signs of toxicity included lethargy, white-colored diarrhea, and anorexia. Total remission was achieved in the eight survivors of the 39 ppm treatment group by the end of test day 6. Two birds in the 39 ppm and all 30 birds in the 156, 312, and 625 ppm ai groups died between days 3 and 6 of the study (Table 3, attached).

Body weight gain and food consumption values (Tables 4 and 5, attached) in the three lowest dosage treatment groups were comparable to those in the control groups. Anorexia was noted in the 39 and 156 ppm treatment groups during the test period. Average body weight on day 22 in the 39 ppm treatment group was depressed in comparison to that in the vehicle control group.

No pathological abnormality was observed in any bird examined.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The LC_{50} of M & B 46030 Technical was determined to be 48.0 ppm ai with 95% confidence limits of 38.7-59.5 ppm ai. The no-observed-effect concentration (NOEC) was 19.5 ppm ai. Based upon the results of this study, M & B 46030 Technical would be classified as very highly toxic to bobwhite quail.

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

No negative control was included in the test. However, the reviewer will accept this study since no mortality or sublethal effects occurred in the vehicle control group.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to calculate the LC_{50} and 95% confidence limits. Measured concentrations were used in the calculation. The results were slightly less conservative than the author's, and would place the test material in a less toxic category. Therefore, the author's results will be used in this evaluation.

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for an avian dietary acute toxicity test. After 5 days of exposure to the test material and 17 days of observation, the LC_{50} was 48 ppm ai which classifies M & B 46030 as very highly toxic to bobwhite quail. The NOEC was 19.5 ppm ai based on the lack of mortality or sublethal effects.

D. **Adequacy of the Study:**

(1) **Classification:** Core

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

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

15. **COMPLETION OF ONE-LINER:** Yes, January 12, 1994.

GARY SCHULTZ FIPRONIL COTINUS VIRGINIANUS 1-12-94

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
257	10	10	100	9.765625E-02
140	10	10	100	9.765625E-02
35.5	10	2	20	5.46875
16.8	10	0	0	9.765625E-02
4	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 16.8 AND 140 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 54.67479

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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The calculation is based on measured concentrations.

Final Review

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