11-27-89

Accession No. 410312-33

DATA EVALUATION RECORD

1. **CHEMICAL:** RH-7592 Technical.
   Shaughnessey Number: Not available. 129011

2. **TEST MATERIAL:** RH-7592 Technical; Lot No. BPP-3-1786R; T.D. No. 87-186; 96.7% active ingredient; a white powder.

3. **STUDY TYPE:** Avian Dietary LC50 Test.
   Species Tested: Colinus virginianus.

4. **CITATION:** Fletcher, D.W. 1988. 8-Day Acute Dietary Study with RH-7592 Technical in Bobwhite Quail. Prepared by Bio-Life Associates, Ltd., Neillsville, Wisconsin. Report No. 88RC-0020. Submitted by Rohm and Haas Company, Spring House, Pennsylvania. EPA Accession No. 410312-33.

5. **REVIEWED BY:**

   Kimberly Rhodes
   Associate Scientist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: Kimberly Rhodes
   Date: June 20, 1989

6. **APPROVED BY:**

   Michael L. Whitten, M.S.
   Wildlife Toxicologist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: Michael L. Whitten
   Date: 6-28-89

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

   Signature: Henry T. Craven 11/27/89
   Date: 11-27-89

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an avian dietary LC50 test. Under the conditions tested, the dietary LC50 of RH-7592 Technical for bobwhite quail (Colinus virginianus) was 4,050 ppm active ingredient. Therefore, RH-7592 Technical is considered slightly toxic to bobwhite quail. The NOEC was 625 ppm active ingredient.

8. **RECOMMENDATIONS:** N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. MATERIALS AND METHODS:

A. Test Animals: Bobwhite quail (Colinus virginianus), which were phenotypically indistinguishable from wild birds, were hatched from eggs collected from the colony of adult bobwhite quail at the testing facility. The birds were placed on a 14-day quarantine period to determine their suitability for testing and to acclimatize them to laboratory conditions. All birds were fed Purina® Game Bird Startena during the quarantine period. Lighting was provided by fluorescent lights which were left on 24 hours per day. The animal room temperature during the quarantine ranged from 94 to 103°F with relative humidity between 28 and 39%. Nineteen out of 177 birds died during the quarantine period. All other birds were normal and active during this time. Prior to initiation of the project, all birds were examined and their suitability for testing (based on general physical condition) was determined.

B. Test System: During testing, birds were housed in 45.7-cm x 61.0-cm x 45.7-cm wire pens. Lighting in the room was provided by fluorescent lights which were left on 24 hours per day. A thermostatically controlled, heated environment offered temperatures ranging from 95 to 104°F with relative humidity between 36 and 47% during the 8-day project.

C. Dosage: 8-day acute dietary LC50 test. RH-7592 Technical was incorporated into the diet via a premix with acetone.

D. Design: Ten bobwhite quail of undetermined sex were arbitrarily assigned to each of the five vehicle control groups and five test groups. The five nominal dietary concentrations used in this study were 312, 625, 1,250, 2,500, and 5,000 ppm active ingredient. The vehicle control diet was prepared by mixing 300 mL acetone into 13 kg stock diet.

Test diets were fed to the bobwhite quail for five consecutive days. After the five day test period, treated diets were removed and birds were offered untreated feed for a three day recovery period.

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Birds were weighed by group at 0-hour on test day 1 and on test days 5 and 8. Food consumption was recorded for each group for the five day test period and for the three day recovery 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.

All birds dying during the investigation and four arbitrarily selected birds from each group with survivors at the termination of the project were subjected to complete gross pathological examinations.

E. Statistics: The LC50 was calculated by employing a simplified method of Litchfield and Wilcoxon (1949).

12. REPORTED RESULTS: The results of the 8-day acute dietary LC50 study conducted with RH-7592 Technical in Bobwhite quail showed the acute dietary median lethal concentration (LC50) of the test material to be 4,050 ppm active ingredient with 95% confidence limits of 2,547 to 6,440 ppm active ingredient. The no-observed effect concentration (NOEC) was determined to be 625 ppm active ingredient. Cumulative mortality data are presented in Tables 2 and 3 (attached).

Sublethal effects (lethargy and anorexia) in the three highest test levels were observed during the first five days of testing. At the end of test day 6, the test birds were becoming more active, but appeared to be smaller in size than the vehicle control birds. On test days 7 and 8, the birds were active, but remained smaller in size.

Gross necropsy examinations of the seven birds found dead during the study and of the four arbitrarily selected birds from each group on test day 8 revealed no grossly visible abnormal tissue alterations.

At 0 hour (on test day 1) all control and test groups had average body weights of 33 or 34 grams (Tables 5 and 6, attached). Body weights on test day 5 and 8 were dose-correlatedly depressed in the 1,250, 2,500, and 5,000 ppm a.i. groups. The two lowest treatment groups (312 and 625 ppm a.i.) on test days 5 and 8 were comparable to those of the vehicle control groups.

Food consumption values during the test period in the three highest test groups (1,250, 2,500 and 5,000 ppm a.i.) were severely depressed in comparison to those of the vehicle control groups. Food consumption values in the two lowest treatment groups (312 and 625 ppm a.i.) were comparable to those of the vehicle control groups during testing. Food consumption values in the test groups were comparable to those of the vehicle control groups during the recovery period.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: The 8-day acute dietary LC50 of RH-7592 Technical was determined to be 4,050 ppm active ingredient with 95% confidence limits of 2,547 to 6,440 ppm active ingredient. The no-observed effect concentration (NOEC) was determined to be 625 ppm active ingredient.

A GLP compliance statement was included in the report and the study was audited by a QA unit. A statement of quality assurance was included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards: Pesticide Programs (40 CFR 160).

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

A. Test Procedure: The test procedures were generally in accordance with protocols recommended by the Guidelines, but deviated from the SEP as follows:

o The SEP states that individual body weight should be measured at the beginning and the end of the study. Body weights by group were measured in this study.

o The SEP states that the food consumption must be recorded at the beginning and end of the pretreatment, treatment, and observation periods. Food consumption at the beginning and end of pretreatment was not reported.

B. Statistical Analysis: The reviewer used EPA's Toxanal computer program to calculate the LC50 values. These calculations are attached. The probit method provides an 8-day dietary LC50 value of 4,954 ppm a.i. with a 95 percent confidence interval of 3,317 to 24,156 ppm a.i. which is similar to that reported by the author (i.e., 4,050 ppm a.i. with 95% confidence limits of 2,547 to 6,440 ppm a.i.). The slope of the dose-response curve was 3.2.

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C. Discussion/Results: The observed mortality did not follow the typical mortality pattern usually seen in similar tests. Six of ten birds died in the highest treatment group, while only a single mortality was seen in all other treatment groups combined. This accounts for the large confidence interval calculated with EPA's Toxanal program.

The study results appear to be scientifically valid. The dietary LC50 value of RH-7592 Technical was determined by the author to be 4,050 ppm active ingredient. Therefore, RH-7592 Technical is considered slightly toxic to bobwhite quail (Colinus virginianus). The NOEC was determined to be 625 ppm active ingredient.

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, June 20, 1989.

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Shaughnessey No. Not available | Chemical Name RH-7592 Technical | Chemical Class ____ | Page ____ of ____

Study/Species/Lab/Accession	Chemical % a.i.	Results	Reviewer/Date	Validity Status
14-Day Single Dose Oral LD_{50} Species ____ Lab Acc.		LD50 = . mg/kg (95% C.L.) Contr. Mort.(%) = Slope= # Animals/Level= Age(Days)= Sex = 14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
14-Day Single Dose Oral LD_{50} Species ____ Lab Acc.		LD50 = mg/kg. (95% C.L.) Contr. Mort.(%) = Slope= # Animals/Level= Age(Days)= Sex = 14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
8-Day Dietary LC_{50} Species Colinus virginianus Lab Bio-Life Associates, Ltd. Acc. 410312-33	96.7%	LC50 = 4,050ppm (95% C.L. 2,547 - 6,440) Contr. Mort.(%) = 0 Slope= N/A # Animals/Level= 10 Age(Days)= 14 days Sex = undetermined 06/20/89 Core 8-Day Dose Level ppm/(%Mortality) 312 (0), 625 (0), 1,250 (10), 2500 (0), 5000 (60) Comments: Based on nominal concentrations (corrected for active ingredient).	K.R	
8-Day Dietary LC_{50} Species Lab ____ Acc.		LC50 = ppm (95% C.L.) Contr. Mort.(%) = Slope= # Animals/Level= Age(Days)= Sex = 8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
48-Hour LC_{50} Species Lab ____ Acc.		LC50 = pp__ (95% C.L.) Contr. Mort.(%) = Sol. Contr. Mort.(%) = Slope= # Animals/Level= Temperature = 48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
96-Hour LC_{50} Species Lab ____ Acc.		LC50 = pp__ (95% C.L.) Con. Mor.(%) = Sol. Con. Mor.(%) = Slope= # Animals/Level= Temp.= 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
96-Hour LC_{50} Species Lab ____ Acc.		LC50 = pp__ (95% C.L.) Con. Mort.(%) = Sol. Con. Mort.(%) = Slope= # Animals/Level= Temp.= 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____

RIN 3477-95

EEB FENBUCONAZOLE REVIEW

Page____ is not included in this copy.

Pages 7 through 10 are not included.

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.

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____ 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.

KIMBERLY RHODES RH-7592 TECHNICAL COLINUS VIRGINIANUS 06-20-89

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
5000	10	6	60.00001	37.69531
2500	10	0	0	9.765625E-02
1250	10	1	10	1.074219
625	10	0	0	9.765625E-02
312	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 0 AND +INFINITY 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 4579.289

THE MOVING AVERAGE METHOD CANNOT BE USED WITH THIS DATA SET BECAUSE NO SPAN WHICH PRODUCES MOVING AVERAGE ANGLES THAT BRACKET 45 DEGREES ALSO USES TWO PERCENT DEAD BETWEEN 0 AND 100 PERCENT.

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
9	.5690085	1	.2353475

SLOPE = 3.165246

95 PERCENT CONFIDENCE LIMITS = .7776172 AND 5.552875

LC50 = 4953.541

95 PERCENT CONFIDENCE LIMITS = 3317.106 AND 24156.16

LC10 = 1966.452

95 PERCENT CONFIDENCE LIMITS = 374.2057 AND 2942.88

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