Accession No. 410312-31

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 Single-Dose Oral Toxicity Test.
   Species Tested: Colinus virginianus.

4. CITATION: Fletcher, D.W. 1988. 21-Day Acute Oral LD50 Study with RH-7592 Technical in Bobwhite Quail. Prepared by Bio-Life Associates, Ltd., Neillsville, Wisconsin. Report No. 88RC-0021. Submitted by Rohm and Haas Company, Spring House, Pennsylvania. EPA Accession No. 410312-31.

5. REVIEWED BY:

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

   Signature: Kimberly D. Rhodes
   Date: June 28, 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 Craven
   Date: 11/27/89
   11-27-89

7. CONCLUSIONS: This study is scientifically sound and fulfills the guideline requirements for an avian single-dose oral toxicity test. Under the conditions tested, the oral LD50 of RH-7592 Technical for bobwhite quail (Colinus virginianus) was greater than 2,150 mg a.i./kg of body weight. Therefore, RH-7592 Technical is considered practically non-toxic to bobwhite quail.

8. RECOMMENDATIONS: N/A

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bobwhite quail (Colinus virginianus), phenotypically indistinguishable from wild birds, were received from Oak Ridge Game Farm at 17 weeks of age. The quail were fed a 28% protein feed containing 100 grams of Bacitracin per ton. The supplier administered penicillin and aureomycin to the birds for three days in preparation for the stress of the trip to the testing facility. The birds were placed on a 19-day quarantine period to determine their suitability for testing and to acclimatize them to laboratory conditions. All birds were fed Purina Duck Grower W/O during the quarantine period. Lighting was provided by fluorescent lights which were left on 8 hours per day. The animal room temperature during the quarantine ranged from 64 to 72°F with relative humidity between 43 and 61%.

No birds died during the quarantine period. All 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. All birds were fasted (with water allowed) for approximately 18 hours prior to dosing at 0 hour on test day 1.

B. **Test System:** During testing, birds were housed in 53.3-cm x 45.7-cm x 38.1-cm wire pens. Lighting in the room was provided by fluorescent lights which were left on 8 hours per day. A thermostatically controlled, heated environment offered temperatures ranging from 64 to 68°F with relative humidity between 37 and 58% during the 21-day project.

C. **Dosage:** 21-day single-dose oral LD50 test.

D. **Design:** Ten bobwhite quail (five males and five females) were randomly assigned to a control group and each of two test groups. The two nominal dose levels used in this study were 1,470 and 2,150 mg a.i./kg of body weight. The doses for the individual test birds were gravimetrically measured and administered via gelatin capsules at 0 hour on test day 1. All birds received their respective doses of test material. The

control birds each received an empty gelatin capsule only.

The quail were individually weighed at 0 hour on test day 1, and on test days 3, 7, 14, and 21. Group food consumption values were recorded on test days 3, 7, 14, and 21.

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 (two male and two female) from each group were subjected to complete gross pathological examinations on test day 21.

E. **Statistics:** Statistical analysis to calculate the LD50 value was not performed since only 40% mortality occurred in the highest concentration during this study. Statistical analysis (ANOVA) of the body weights was performed at each weighing interval.

12. **REPORTED RESULTS:** The results of the 21-day acute oral LD50 study conducted with RH-7592 Technical in Bobwhite quail showed the acute oral median lethal-dose (LD50) of the test material to be in excess of 2,150 mg a.i./kg of body weight. No mortalities occurred in the control or the 1,470 mg a.i./kg test groups. Four mortalities (2 male and 2 female) occurred in the 2,150 mg a.i./L group (Table 3, attached). The first death (a male) was recorded within 20 hours post-dosing in the 2,150 mg a.i./kg group.

No abnormal behavioral reactions were noted in the control birds. Signs of toxicity noted in both treatment groups included lethargy, sitting, yellow-colored diarrhea, anorexia, and emaciation. Complete remission was noted on test day 11.

Gross pathological examinations of the four birds that died during the investigation revealed only emaciation of the female bird found dead on test day 7. Gross pathological examinations of the four arbitrarily selected birds (two males and two female) from each group at the close of the investigation revealed no abnormal tissue alterations.

Statistical analysis (ANOVA) of the body weights at each weighing interval revealed a statistically significant decrease in the test groups at all weighing intervals except 0 hour on test day 1 in comparison to the control group values. The individual body weight data collected during the investigation are presented in Table 4 (attached).

Severe food consumption depressions were noted during the first seven test days in the two test groups when compared to the control group. All other food consumption values were comparable to those of the control group.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: The acute oral LD50 of RH-7592 Technical was determined to be in excess of 2,150 mg a.i./kg of body weight.

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 in accordance with protocols recommended by the Guidelines.

B. Statistical Analysis: Statistical analysis was not needed since mortality was less than 50% during the study.

C. Discussion/Results: The study appears to be scientifically valid. The acute oral LD50 value of RH-7592 Technical was determined to be greater than 2,150 mg/kg of body weight. Therefore, RH-7592 Technical is considered practically non-toxic to bobwhite quail (Colinus virginianus).

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, June 22, 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	Valid Stat
14-Day Single Dose Oral LD_{50}		LD50 = . mg/kg (95% C.L.) Contr. Mort.(%)=		
Species	____	Slope= # Animals/Level= Age(Days)= Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
~~14~~ 21-Day Single Dose Oral LD_{50}		LD50 = >2,150 mg/kg. (95% C.L. N/A) Contr. Mort.(%)= 0		
Species Colinus virginianus	96.7%	Slope= N/A # Animals/Level= 10 Age(Days)= 138 days ~~K.R.~~ Sex = 5 Male 5 Female	10/22/09	Core
Lab Bio-Life Sciences, Ltd.		14-Day Dose Level mg/kg/(% Mortality) 1,470(0), 2,150(40), ( ), ( ), ( )		
Acc. 410312-31		Comments: Based on nominal concentrations corrected for active ingredient.		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab	____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab	____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
48-Hour LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Temperature =		
Lab	____	48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mor.(%)= Sol. Con. Mor.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mort.(%)= Sol. Con. Mort.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		

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RIN 3477-95

EEB FENBUCONAZOLE REVIEW

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