

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

1. CHEMICAL: RH-7592 Technical.
Shaughnessey Number: Not available. 129 011
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: Anas platyrhynchos.
4. CITATION: Fletcher, D.W. 1988. 8-Day Acute Dietary Study with RH-7592 Technical in Mallard Ducklings. Prepared by Bio-Life Associates, Ltd., Neillsville, Wisconsin. Report No. 88RC-0019. Submitted by Rohm and Haas Company, Spring House, Pennsylvania. EPA Accession No. 410312-32.
5. REVIEWED BY:
Kimberly Rhodes
Associate Scientist
KBN Engineering and
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Signature: *Kimberly Rhodes*
Date: *June 20, 1989*
6. APPROVED BY:
Michael L. Whitten, M.S.
Wildlife Toxicologist
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Signature: *Michael L Whitten*
Date: *6-28-89*
Henry T. Craven, M.S.
Supervisor, EEB/HED
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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 mallard ducklings (Anas platyrhynchos) was 2,013 ppm active ingredient. Therefore, RH-7592 Technical is considered slightly toxic to mallards. The NOEC was 312 ppm active ingredient.
8. RECOMMENDATIONS: N/A

9. BACKGROUND:10. DISCUSSION OF INDIVIDUAL TESTS: N/A11. MATERIALS AND METHODS:

- A. Test Animals: Three-day old mallard ducklings (Anas platyrhynchos), which were phenotypically indistinguishable from wild birds, were received from a commercial supplier in Illinois. The birds were placed on a two day quarantine period to determine their suitability for testing and to acclimatize them to laboratory conditions. All birds were fed Purina^R 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 78 to 80°F with relative humidity between 71 and 76%. No birds died during the quarantine period and the birds appeared normal and active. 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, all birds were housed in 45.7-cm x 61.0-cm x 45.7-cm wire pens maintained over a concrete slab. 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 78 to 84°F with relative humidity between 51 and 76% 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 mallards 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 ducklings 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.

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 Mallard ducklings showed the acute dietary median lethal concentration (LC50) of the test material to be 2,110 ppm active ingredient with 95% confidence limits of 1,426 to 3,123 ppm active ingredient. The no-observed effect concentration (NOEC) was determined to be 312 ppm active ingredient. Cumulative mortality data are presented in Tables 2 and 3 (attached).

Sublethal effects (lethargy, anorexia and weakness) in the three highest test levels were observed during the first four days of testing. At the end of test day 5, the test birds were becoming more active, but appeared to be smaller in size than the vehicle control birds. On test day 6 through test termination, the birds were active, but remained smaller in size.

Gross necropsy examinations of the birds found dead during the study revealed pale livers and enlarged gall bladders in all birds. Gross pathological examinations of the four arbitrarily selected birds sacrificed from each group with survivors on test day 8 revealed no grossly visible abnormal tissue alterations.

Body weights on test day 5 were dose-correlatedly depressed in the 1,250 and the 2,500 ppm a.i. groups (Tables 5 and 6, attached). Test day 8 body weights were depressed only in the 2,500 ppm a.i. group. All other test group body weights were comparable to those of the vehicle controls.

Food consumption values during the test period in the 625, 1,250, 2,500 ppm a.i. test groups were dose-correlatedly depressed in comparison to those of the vehicle control groups. Food consumption values in the 2,500 ppm a.i. group were severely depressed during the five day test period and remained depressed during the three day recovery period. All other food consumption values in the test and vehicle control groups were comparable.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

The 8-day acute dietary LC50 of RH-7592 Technical was determined to be 2,110 ppm active ingredient with 95% confidence limits of 1,426 to 3,123 ppm active ingredient. The no-observed effect concentration (NOEC) was determined to be 312 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 size of the test pens (127,398 cm³) were smaller than the recommended size of 168,000 cm³.

o The SEP states that the brooder temperature should be about 35°C. During the test, the temperature in the brooding compartment of the pens ranged from 78 to 84°F (25.6 to 28.9°C).

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 2,013 ppm a.i. with a 95 percent confidence interval of 1,486 to 2,738 ppm a.i. which is similar to that reported by the author (i.e., 2,110 ppm a.i. with 95% confidence limits of 1,426 to 3,123 ppm a.i.). The slope of the dose-response curve was 5.0.
- C. Discussion/Results: The study results appear to be scientifically valid. The dietary LC50 value of RH-7592 Technical was determined to be 2,013 ppm active ingredient. Therefore, RH-7592 Technical is considered slightly toxic to mallard ducklings (Anas platyrhynchos). The NOEC was determined to be 312 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.

Study/Species/Lab/ Accession _____ Chemical X a.l. Results _____ Reviewer/ Date _____ Valid/ Stat _____

14-Day Single Dose Oral LD50 LD50 = . mg/kg (95% C.L.) Contr. Mort. (X) = _____

Species _____ Slope= _____ # Animals/Level= _____ Age (Days)= _____ Sex = _____

Lab _____ 14-Day Dose Level mg/kg/(% Mortality) _____

Acc. _____ Comments: _____

14-Day Single Dose Oral LD50 LD50 = mg/kg. (95% C.L.) Contr. Mort. (X) = _____

Species _____ Slope= _____ # Animals/Level= _____ Age (Days)= _____ Sex = _____

Lab _____ 14-Day Dose Level mg/kg/(% Mortality) _____

Acc. _____ Comments: _____

8-Day Dietary LC50 LC50 = ppm (95% C.L.) Contr. Mort. (X) = _____

Species _____ Slope= _____ # Animals/Level= _____ Age (Days)= _____ Sex = _____

Lab _____ 8-Day Dose Level ppm/(% Mortality) _____

Acc. _____ Comments: _____

8-Day Dietary LC50 LC50 = 2013 ppm (95% C.L.) Contr. Mort. (X) = 0

Species Anas platyrhynchos Slope= 5.0 # Animals/Level= 10 Age (Days)= 5 days N.R.

Lab Bio-Life Associates, LTD. 96.7% Sex = undetermined 6/20/89 Comp

Acc. 410312-32 8-Day Dose Level ppm/(% Mortality) 312 (0), 625 (0), 1250 (20), 2500 (60), 5000 (100)

Comments: Based on nominal concentrations. (Corrected for active ingredient)

48-Hour LC50 LC50 = pp (95% C.L.) Contr. Mort. (X) = _____

Species _____ Sol. Contr. Mort. (X) = _____

Lab _____ Slope= _____ # Animals/Level= _____ Temperature = _____

Acc. _____ 48-Hour Dose Level pp /(% Mortality) _____

Comments: _____

96-Hour LC50 LC50 = pp (95% C.L.) Con. Mort. (X) = _____

Species _____ Sol. Con. Mort. (X) = _____

Lab _____ Slope= _____ # Animals/Level= _____ Temp. = _____

Acc. _____ 96-Hour Dose Level pp /(% Mortality) _____

Comments: _____

96-Hour LC50 LC50 = pp (95% C.L.) Con. Mort. (X) = _____

Species _____ Sol. Con. Mort. (X) = _____

Lab _____ Slope= _____ # Animals/Level= _____ Temp. = _____

Acc. _____ 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.
- 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.

KIMBERLY RHODES RH-7592 TECHNICAL ANAS PLATYRHYNCHOS 06-20-89

| CONC. | NUMBER EXPOSED | NUMBER DEAD | PERCENT DEAD | BINOMIAL PROB. (PERCENT) |
|-------|----------------|-------------|--------------|--------------------------|
| 5000 | 10 | 10 | 100 | 9.765625E-02 |
| 2500 | 10 | 6 | 60.00001 | 37.69531 |
| 1250 | 10 | 2 | 20 | 5.46875 |
| 625 | 10 | 0 | 0 | 9.765625E-02 |
| 312 | 10 | 0 | 0 | 9.765625E-02 |

THE BINOMIAL TEST SHOWS THAT 625 AND 5000 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 2116.55

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

| SPAN | G | LC50 | 95 PERCENT CONFIDENCE LIMITS |
|------|----------|----------|------------------------------|
| 3 | .1144043 | 1971.069 | 1508.348 2649.212 |

RESULTS CALCULATED USING THE PROBIT METHOD

| ITERATIONS | G | H | GOODNESS OF FIT PROBABILITY |
|------------|----------|---|-----------------------------|
| 6 | .2701068 | 1 | .850371 |

SLOPE = 4.997019
95 PERCENT CONFIDENCE LIMITS = 2.399978 AND 7.594059

LC50 = 2013.404
95 PERCENT CONFIDENCE LIMITS = 1486.208 AND 2738.117

LC10 = 1121.448
95 PERCENT CONFIDENCE LIMITS = 541.3295 AND 1512.384
