

DATA EVALUATION RECORD

1. CHEMICAL: RH-7592 Technical.  
Shaughnessey Number: Not available. 129011
2. TEST MATERIAL: RH-7592 Technical; Lot No. BPP-3-1786R;  
96.7% active ingredient; a white solid.
3. STUDY TYPE: Freshwater Fish Flow-through Acute Toxicity  
Test. Species Tested: Bluegill (Lepomis macrochirus).
4. CITATION: Swigert, J.P. 1988. Acute Flow-through Toxicity  
of RH-7592 Technical to Bluegill Sunfish (Lepomis  
macrochirus). Prepared by Analytical Bio-Chemistry  
Laboratories, Inc., Columbia, Missouri. Report No. 88RC-  
0024. Submitted by Rohm and Haas Company, Spring House, PA.  
Accession No. 410735-06.
5. REVIEWED BY:  
  
Kimberly Rhodes  
Associate Scientist  
KBN Engineering and  
Applied Sciences, Inc.  
  
Signature: *Kimberly Rhodes*  
Date: *June 13, 1989*
6. APPROVED BY:  
  
Prapimpan Kosalwat, Ph.D.  
Staff Toxicologist  
KBN Engineering and  
Applied Sciences, Inc.  
  
Signature: *P. Kosalwat*  
Date: *June 14, 1989*  
  
Henry T. Craven  
Supervisor, EEB/HED  
USEPA  
  
Signature: *Henry T. Craven*  
Date: *11/27/89*  
*11-27-89*
7. CONCLUSIONS: This study appears scientifically sound and  
fulfills the Guideline requirements for an acute 96-hour  
flow-through toxicity test using a warmwater fish species.  
The 96-hour LC50 of RH-7592 Technical to bluegill (Lepomis  
macrochirus) was 0.68 mg a.i./L based on mean measured  
concentrations. Therefore, RH-7592 Technical is classified  
as highly toxic to bluegill. The NOEC was determined to be  
0.42 mg a.i./L after 96 hours.
8. RECOMMENDATIONS: N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. MATERIALS AND METHODS:

A. Test Animals: Bluegill (*Lepomis macrochirus*) were obtained from a commercial supplier in Missouri. The fish were maintained at the testing facility in well water and were fed newly hatched brine shrimp or a commercially available fish food daily. Bluegill were removed from the culture and placed in the temperature acclimation unit 48 hours prior to test initiation. During this time, the fish were held without food. The bluegill used as the control group during this study had a mean weight of 0.21 ( $\pm$  0.042) grams and a mean length of 22 ( $\pm$  1.3) millimeters at test termination.

B. Test System: A proportional diluter system described by Mount and Brungs, utilizing a Hamilton Micro Lab 420 syringe dispenser, was used for the intermittent introduction of RH-7592 Technical test solutions and diluent water into each test chamber. The proportional diluter system used for the project was set to provide test levels approximately 50 percent dilutions of each other.

The diluter delivered 0.5 liter of test solution or control water to the test vessels at an average rate of 8.0 times per hour over the course of the study. This flow rate was sufficient to replace the 15-liter volume of each replicate within the test chambers 6.4 times per day. The test chambers were immersed in a temperature controlled water bath held at  $22 \pm 1^\circ\text{C}$ . The laboratory environment was maintained on a 16-hour daylight photoperiod.

Dilution water for the bluegill test was a blend of reverse osmosis water and ABC well water characterized as having a pH of 7.1 - 7.9, total hardness of 40 - 48 mg/L as  $\text{CaCO}_3$ , total alkalinity of 44 - 56 mg/L  $\text{CaCO}_3$  and specific conductance of 100 - 160 umhos/cm.

C. Dosage: 96-hour flow-through acute test.

D. Design: Based on the results of a preliminary test, a control, solvent control, and five nominal RH-7592 concentrations of 0.25, 0.50, 1.0, 2.0, and 4.0 mg a.i./L were tested. Each test concentration and

control was replicated twice with ten fish per test vessel. The test was initiated when fish were impartially distributed to each test vessel after the flow-through system had been running for approximately 24 hours. The concentration of acetone in the solvent control (0.1 mL of acetone in 1 liter of water) was equivalent to that received by the highest test concentration.

All concentrations were observed once every 24 hours for mortality and abnormal effects. The water quality parameters (temperature, dissolved oxygen and pH) were measured in each concentration and control at 0, 48, and 96 hours of testing. Analytical samples were collected from each test level and the diluter stock at 0 and 96 hours of the exposure.

- E. **Statistics:** The concentration of toxicant lethal to 50% of the population (LC50's) and 95% confidence intervals was determined at 24-, 48-, 72-, and 96-hour exposure periods by the computer program developed by Stephan et al. (1978).

12. **REPORTED RESULTS:** Mortality and behavioral observations during the acute flow-through toxicity test of RH-7592 to bluegill are shown in Table 5 (attached). The mean measured concentrations of RH-7592 Technical were 0.13, 0.18, 0.42, 0.92 and 2.2 mg a.i./L. The mean measured concentrations ranged from 36% to 79% of the nominal concentrations. A white precipitate was noted in the diluter mixing cell and in the three highest test concentrations at 0-hour and in all concentrations after 24-hours indicating that not all of the RH-7592 Technical was going into solution.

Water chemistry parameters measured at 0, 48, and 96 hours were within the specified limits for conducting aquatic toxicity tests. Temperature ranged from 21 to 23°C, dissolved oxygen ranged from 7.4 to 9.3 mg/L (representing 87 and 109% saturation at 21°C), and pH ranged from 7.3 to 8.1.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The 24-, 48-, 72-, and 96-hour LC50 values for RH-7592 Technical were 0.92, 0.80, 0.70 and 0.68 mg a.i./L, respectively, based upon mean measured concentrations. The slope of the 96-hour dose-response line was 7.5. Behavioral/sublethal effects (e.g., loss of equilibrium, fish on bottom of test chamber, surfacing, and quiescence) were noted among the fish in the 0.92 and 2.2 mg a.i./L test

concentrations. Given these behavioral/sublethal effects, a no-observed effect concentration (NOEC) of RH-7592 Technical to bluegill was determined to be 0.42 mg a.i./L. This conclusion is supported by the lack of mortality or behavior/sublethal effects at the test concentrations of 0.13, 0.18 and 0.42 mg a.i./L.

Quality Assurance and Good Laboratory Practice Regulation Statements were included in the report, indicating that the study was conducted in accordance with the FIFRA Good Laboratory Practice Standards 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 protocols recommended by the Guidelines, but deviated from the SEP as follows:

- o The SEP states that "test vessels should be described as to construction material and size, as well as depth and volume of solution." The test vessels were not described in this report.

- o The ASTM (1980 and 1988) standard protocols state that "the concentration of toxicant in the test chambers should be measured as often as practical during the test. At a minimum, the concentration of toxicant must be measured in (a) each chamber concurrently at least once during the test, preferably near the beginning of the test; (b) except for the control treatment, each test chamber (especially for those toxicant concentrations closest to the  $LC_{50}$  or  $EC_{50}$ ) at least one additional time during the test, on a schedule designed to give reasonable confidence in the concentration of toxicant in the test chambers, . . . and (c) at least one appropriate chamber whenever a malfunction is detected in any part of the metering system. In this study the concentrations of toxicants were measured only in the "A" replicates (control A, 1A, 2A, etc.) at the beginning of the test and only in the "B" replicates (control B, 1B, 2B, etc.) at the end of the test. At no time were the concentrations in all chambers measured concurrently.

- o The SEP recommends that fish be acclimated to study conditions for at least two weeks prior to testing. The bluegill were removed from the culture tank and placed in the temperature acclimation unit 48 hours prior to test initiation.

- o The SEP states that individual fish should weigh between 0.5 and 5 grams. The fish used in this study weighed between 0.132 and 0.319 grams.

- o The SEP states that each designated treatment group should be exposed to a concentration of toxicant that is at least 60% of the next highest concentration. Each designated treatment group for the test was only 50% of the next highest concentration.

The toxicity report did not provide the following information required by the SEP:

- o Percent of mortality 48 hours prior to test initiation.

- o The SEP recommends a 16-hour light and an 8-hour dark photoperiod with a 15- to 30-minute transition period between light and dark. The report did not state whether a 15- to 30-minute transition period between light and dark was maintained.

**B. Statistical Analysis:** The reviewer used EPA's Toxanal computer program to calculate the LC50 values. These calculations are attached. The binomial test provides a 96-hour LC50 value of 0.68 mg a.i./L with a 95 percent confidence interval of 0.42 to 0.92 mg a.i./L which is the same as that reported by the author.

**C. Discussion/Results:** Although the study appears to be scientifically valid, the 96-hour LC50 value is based upon the mean of measured RH-7592 Technical concentrations. Due to the fact that using the mean of the measured concentration is improper (since measurements were not made in accordance with established standards), the LC<sub>50</sub> value thus calculated is invalid. The reviewer used EPA's Toxanal computer program to calculate the LC<sub>50</sub> values using 1) the mean concentration values as used in the report, 2) the measured concentration values of the "A" replicates only, and 3) the measured concentration values of "B" replicates only. The 96-hour LC<sub>50</sub> value, based on the

mean measured RH-7592 Technical concentrations, was estimated to be 0.68 mg a.i./L with a 95 percent confidence interval of 0.42 to 0.92 mg a.i./L which is the same as that reported by the author. The 96-hour LC<sub>50</sub> value, based on the actual measured RH-7592 Technical concentrations of the "A" replicates, was estimated to be 0.62 mg a.i./L with a 95 percent confidence interval of 0.39 to 0.83 mg a.i./L. The 96-hour LC<sub>50</sub> value, based on the actual measured RH-7592 Technical concentrations of the "B" replicates, was estimated to be 0.74 mg a.i./L with a 95 percent confidence interval of 0.46 to 1.0 mg a.i./L. In light of the similarity of the calculated LC<sub>50</sub> values, the study author's value, LC<sub>50</sub> of 0.68 mg a.i./L, will be accepted. Therefore, RH-7592 Technical is classified as highly toxic to bluegill (Lepomis macrochirus). The no-observed effect concentration (NOEC) was determined to be 0.42 mg a.i./L mean measured concentration.

**D. Adequacy of the Study:**

- (1) **Classification:** Core.
- (2) **Rationale:** Although the test procedures deviated from the guidelines, the reviewer does not believe they significantly affected the toxicity results.
- (3) **Repairability:** N/A.

**15. COMPLETION OF ONE-LINER FOR STUDY:** Yes, 06-06-89.

Shaugnessy No. Not availableChemical Name RH-7592  
Technical

Chemical Class \_\_\_\_\_

Page \_\_\_\_\_ of \_\_\_\_\_

Study/Species/Lab/  
Accession \_\_\_\_\_Chemical  
X a.l.

Results

Reviewer/  
Date \_\_\_\_\_Valid  
Sta \_\_\_\_\_14-Day Single Dose Oral LD<sub>50</sub>LD<sub>50</sub> = \_\_\_\_\_ mg/kg ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = \_\_\_\_\_ # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

14-Day Dose Level mg/kg/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

14-Day Single Dose Oral LD<sub>50</sub>LD<sub>50</sub> = \_\_\_\_\_ mg/kg. ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = \_\_\_\_\_ # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

14-Day Dose Level mg/kg/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

8-Day Dietary LC<sub>50</sub>LC<sub>50</sub> = \_\_\_\_\_ ppm ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = \_\_\_\_\_ # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

8-Day Dose Level ppm/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

8-Day Dietary LC<sub>50</sub>LC<sub>50</sub> = \_\_\_\_\_ ppm ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = \_\_\_\_\_ # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

8-Day Dose Level ppm/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

48-Hour LC<sub>50</sub>LC<sub>50</sub> = \_\_\_\_\_ pp ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_  
Sol. Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = \_\_\_\_\_ # Animals/Level = \_\_\_\_\_ Temperature = \_\_\_\_\_

Lab \_\_\_\_\_

48-Hour Dose Level pp/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

96-Hour LC<sub>50</sub>LC<sub>50</sub> = 0.68 ppm ( 95% C.L. ) Binomial method: Contr. Mort. (X) = 0  
Sol. Contr. Mort. (X) = 0Species Lepomis macrochirus

Slope = N/A # Animals/Level = 20 Temp. = 22 ± 1 °C

Lab 96.7%96-Hour Dose Level ppm/(X Mortality)  
0.15 ( 0 ) , 0.18 ( 0 ) , 0.42 ( 0 ) , 0.92 ( 90 ) , 2.2 ( 100 )Acc. 410735-06

Comments: Based on mean measured concentrations

96-Hour LC<sub>50</sub>LC<sub>50</sub> = \_\_\_\_\_ pp ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_  
Sol. Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = \_\_\_\_\_ # Animals/Level = \_\_\_\_\_ Temp. = \_\_\_\_\_

Lab \_\_\_\_\_

96-Hour Dose Level pp/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

RIN 3477-95

EEB FENBUCONAZOLE REVIEW

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Pages \_\_\_\_\_ through \_\_\_\_\_ 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.



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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
2.2	20	20	100	9.536742E-05
.92	20	18	90	2.012253E-02
.42	20	0	0	9.536742E-05
.18	20	0	0	9.536742E-05
.13	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .42 AND .92 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 .6767549

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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Harry A. Winnik

LC<sub>50</sub> BASED ON "A" REPLICATE MEASURED CONCENTRATIONS

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1.9	10	10	100	9.765625E-02
.83	10	9	90	1.074219
.39	10	0	0	9.765625E-02
.18	10	0	0	9.765625E-02
.13	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT .39 AND .83 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 LC<sub>50</sub> FOR THIS SET OF DATA IS .6161175

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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Harry A. Winnik *LC50 BASED ON "B" REPLICATA MEASURED CONCENTRATIONS*  
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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
2.6	10	10	100	9.765625E-02
1	10	9	90	1.074219
.46	10	0	0	9.765625E-02
.19	10	0	0	9.765625E-02
.13	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT .46 AND 1 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 .7361127

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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