

5/24/93

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Fenvalerate.
Shaughnessey No. 109301.
- 2. **TEST MATERIAL:** MO 70616 Technical; Code #2-4-0-0; 98.8% active ingredient; a tan solid.
- 3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test.
Species Tested: Rainbow Trout (*Salmo gairdneri*).

4. **CITATION:** Forbis, A.D., L. Georgie, and D. Burgess. 1985. Acute Toxicity of MO70616 Technical to Rainbow Trout (*Salmo gairdneri*). Report No. 33175. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO. Submitted by E.I. du Pont de Nemours & Company, Inc., Wilmington, DE. EPA MRID No. 412330-01.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Louis M Rifici*
Date: *10/24/91*

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *P. Kosalwat*
Date: *10/24/91*

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

Signature: *Michael Rexrode* 5/18/93
Henry T. Craven 5/24/93

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for a static acute toxicity test. The test concentrations were measured but, since a detectable quantity of the test material was found in the solvent control (the dilution water control was not analyzed) and the analytical results were highly variable, some contamination of the analytical samples probably occurred during shipment. Since the analytical results were unreliable, nominal concentrations were used to compute the LC₅₀ value. The 96-hour LC₅₀ of 0.26 µg a.i./l classifies MO 70616 as very highly toxic to rainbow trout. The NOEC can be estimated as 0.1 µg a.i./l nominal concentration.

6 hrs

8. RECOMMENDATIONS: N/A.
9. BACKGROUND:
10. DISCUSSION OF INDIVIDUAL TESTS: N/A.
11. MATERIALS AND METHODS:

A. Test Animals: Rainbow trout (*Salmo gairdneri*) were obtained from a commercial supplier in McMillin, WA. The fish were maintained in culture tanks on a 16-hour daylight photoperiod for at least 2 weeks prior to testing. The fish were fed a commercially available fish food daily until 48 hours before the test. The condition of the fish was monitored daily and records of disease treatments were kept.

Mean weight and length of the control fish measured at the end of the test were 0.56 (± 0.17) g and 41 (± 3.3) mm. Biomass loading rate in the control was 0.37 g/l.

B. Test System: Vessels used in the test were 19-l glass containers filled with 15 l of soft reconstituted water (control) or test solution. The vessels were kept in a water bath set to maintain $12 \pm 1^\circ\text{C}$.

The dilution water was prepared by adding 48 mg NaHCO_3 , 30 mg $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$, 30 mg MgSO_4 , and 2 mg KCl to 1 liter of deionized water. This recipe was designed to yield a total hardness of 40-45 mg/l as CaCO_3 , a total alkalinity of 30-35 mg/l as CaCO_3 , and an initial pH of 7.2-7.6.

The test material was dissolved in acetone. The test solutions were prepared by adding appropriate amounts of stock solution directly to the test chambers.

The rainbow trout were not fed during the test.

C. Dosage: Ninety-six-hour static test. Based on a preliminary test, five nominal concentrations (0.032, 0.056, 0.10, 0.18, and $0.32 \mu\text{g a.i./l}$), a solvent control (0.02 ml acetone/l), and a dilution water control were used.

D. Design: Ten fish were randomly added to each test chamber, one chamber per concentration, within 30 minutes of test solution preparation. All chambers

were observed once every 24 hours for mortality and sublethal responses.

Samples from each test chamber were taken at 0 and 96 hours and sent to the Shell Development Company for analysis. The dilution water control was not measured. The concentration of MO 70616 was determined using gas-liquid chromatography.

E. Statistics: The 96-hour median lethal concentration (LC_{50}) and associated 95% confidence interval (C.I.) were calculated using a computer program developed by Stephan.

- 12. REPORTED RESULTS:** The measured concentrations are given in Table A (attached). A measurable quantity of MO 70616 was detected in the solvent control after 96 hours. The mean measured concentrations (reviewer calculated) were 0.023, 0.028, 0.046, 0.093, and 0.155 $\mu\text{g}/\text{l}$. These values represent 46-72% of nominal concentrations.

The mortality responses of the rainbow trout are given in Table 3 (attached). The 96-hour LC_{50} , based on nominal concentrations, was 0.26 $\mu\text{g}/\text{l}$ (95% C.I. = 0.20-0.38 $\mu\text{g}/\text{l}$). The 96-hour no-observed-effect concentration (NOEC), based on the lack of mortality and abnormal effects, was 0.10 $\mu\text{g}/\text{l}$.

The water quality measurements made during the test are given in Table 3 (attached).

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

The authors presented no conclusions.

Quality Assurance and Good Laboratory Practice statements were included in the report, indicating that the study was conducted in accordance with 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:

The test temperature was not monitored every six hours as recommended.

A 15 to 30-minute dawn and dusk simulation period is recommended in the SEP. A transition period was not used in the study.

The fish were acclimated to the dilution water and test temperature for 48-96 hours. The SEP recommends an acclimation period of at least two weeks.

Each selected nominal concentration was approximately 55% of the next highest concentration. The SEP recommends that each concentration be 60% of the next highest concentration.

- B. **Statistical Analysis:** The reviewer used EPA's Toxanal program and nominal concentrations to calculate the LC₅₀ value as 0.26 µg a.i./l (95% C.I. = 0.20-0.38 µg a.i./l). The slope of the concentration-response curve was 6.0 (see attached printout).
- C. **Discussion/Results:** A portion of the Appendix appears to be missing from the report. Several references to data located in the Appendix are made in the body of the report, but the data are missing.

The test material may have been unstable or volatile. The concentration of MO 70616 decreased by as much as 37% or increased by as much as 15% between the two sampling times. There may have been significant cross contamination because, after 96 hours, a measurable quantity of MO 70616 was detected in the solvent control. Unfortunately, the dilution water control was not sampled for analysis. If the mortality results were evaluated using only the test levels which had been measured analytically, this test would have no valid control.

In the sample analysis report (Appendix), the author states "It was impossible to determine whether the water (in the shipping container) was from the surrounding melted ice or sample leakage. Since some of the bottle caps were rather loose and the bottles packed upside down it is probable that both occurred." If there was exchange between the samples and the water from the melted ice, the analytical results must be considered invalid. Measured concentrations are not required in static tests and, since the test was scientifically sound, the study need not be classified "invalid" based on the analytical results alone.

However, the analytical measurements are valuable and their exclusion should not go without mention.

This study is scientifically sound but does not meet the guideline requirements for a static acute toxicity test. The analytical results were highly variable and probably do not represent the actual concentrations the fish were exposed to because of the apparent leakage and contamination of the samples with the ice water during shipping. Since the analytical results were unreliable, nominal concentrations were used to compute the LC₅₀ value. The 96-hour LC₅₀ of 0.26 µg a.i./l classifies MO 70616 as very highly toxic to rainbow trout. The NOEC can be estimated as 0.1 µg a.i./l nominal concentration.

D. Adequacy of the Study:

- (1) **Classification:** Supplemental.
- (2) **Rationale:** Some contamination of the analytical samples probably occurred during shipment, leading to analytical results which are highly variable. A measurable quantity of the test material was detected in the solvent control (the dilution water control was not analyzed).
- (3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 10-24-91.

Page is not included in this copy.

Pages 6 through 7 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.
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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.

RIFICI FENVALERATE SALMO GAIRDNERI 10-24-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.32	10	7	70	17.1875
.18	10	2	20	5.46875
.1	10	0	0	9.765625E-02
.056	10	0	0	9.765625E-02
.032	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 .2554269

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
1	.8025485	.2554268	.1725957 .6272444

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.4448145	1	.9896976

SLOPE = 5.955045
95 PERCENT CONFIDENCE LIMITS = 1.983363 AND 9.926728

LC50 = .2576157
95 PERCENT CONFIDENCE LIMITS = .1995786 AND .3835043

LC10 = .157655
95 PERCENT CONFIDENCE LIMITS = 6.440161E-02 AND .2026392

Shaughnessey # 109301 Chemical Name Fenvalerate Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID # _____ Chemical % a.i. _____ Results _____ Reviewer/ Validation Date _____ Status _____

48-Hour EC₅₀ _____ EC₅₀ - pp (95% C.L.) Control Mortality (%) - _____ Solvent Control Mortality (%) - _____

Species: _____ Slope - # Animals/Level - _____ Temperature - _____

Lab: _____ 48-Hour Dose Level pp / (% Effect) _____
() , () , () , () , ()

Comments: _____

96-Hour LC₅₀ 98.8 LC₅₀ - 0.26 pp_b (0.20 - 0.38) ^{95% C.L.} Rabbit Control Mortality (%) - 0

Solvent Control Mortality (%) - 0

Species: Salmo gairdneri Slope - 60 # Animals/Level - 10 Temperature - 12

Lab: Analytical Bio-chemistry 96-Hour Dose Level pp_b / (% Mortality) LMC Supplemental
10/29/91

MRID # 412330-01 Comments: pp_b = nominal concentrations of active ingredient

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