5-24-93

MRID No. 412330-02

DATA EVALUATION RECORD

1. **CHEMICAL:** Fenvalerate.
Shaughnessey No. 109301.

2. **TEST MATERIAL:** MO 70616-3-6 1.9EC; Lot #3-6; 32% active ingredient (reviewer's calculation); a yellow liquid.

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 MO70616-3-6 1.9 EC to Rainbow Trout (*Salmo gairdneri*). Static Acute Toxicity Report No. 33177. Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO. Submitted by E.I. du Pont de Nemours & Company, Inc., Wilmington, DE. EPA MRID No. 412330-02.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
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Signature: Louis M. Rifici
Date: 10/24/91

6. **APPROVED BY:**

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

Henry T. Craven, M.S.
Supervisor, EEB/EFED
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Signature: Meadul Reynolds 5/1/93
Date: 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 using rainbow trout. 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. In addition, the table containing the analytical results may have been from another test using the same test material and bluegill sunfish. Based on nominal concentrations, the 96-hour LC_{50} of 0.51 µg a.i./l classifies MO 70616-3-6 1.9EC as very

6 hrs

highly toxic to rainbow trout. The NOEC can be estimated as 0.18 µg a.i./l nominal concentration.

8. **RECOMMENDATIONS:** See Section 14.D.(3).

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 0.54 (±0.09) g and 39 (±1.1) mm. Biomass loading rate in the control was 0.36 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°±1°C.

The dilution water was prepared by adding 48 mg $NaHCO_3$, 30 mg $CaSO_4.2H_2O$, 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 (0.18, 0.32, 0.56, 1.0, and 1.8 µg/l), a solvent control (0.01 ml acetone/l), and a dilution water control were used. The concentrations made were based on the total product.

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 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:** A measurable quantity of MO 70616 was detected in the solvent control after 96 hours. The mortality responses of the rainbow trout are given in Table 3 (attached). The 96-hour LC_{50}, based on nominal concentrations, was 1.6 µg/l using the binomial method. Confidence limits for the LC_{50} value could not be determined. Sublethal effects were observed at 1.0 and 1.8 µg/l. The no-observed-effect concentration (NOEC), based on the lack of mortality and abnormal effects, was 0.56 µg/l after 96 hours. One death occurring at 0.32 µg/l was considered aberrant.

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 percent active ingredient for the test material was not given in the report.

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.

The D.O. and pH of the control, solvent control, lowest and highest concentration were measured at 0, 48, and 96 hours. The SEP states that the D.O. and pH should be measured in the controls, and the high, medium, and low concentrations.

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.

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 nominal concentrations (adjusted for active ingredient) and EPA's Toxanal program to verify the author's results and obtained a 96-hour LC_{50} value of 0.51 µg a.i./l (see attached printout). No confidence limits could be computed.

C. **Discussion/Results:** The percent active ingredient in the test material was calculated by the reviewer using information provided in the Appendix of this report (page 15).

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 table (Table A, attached) containing the results of the analysis for the test material appears to list the results for the present study but is identified as "results of water analyses associated with the acute toxicity study of MO 70616 technical to bluegill sunfish performed at ABC Labs (Study #33174)." Given the importance of the measured concentrations in the LC_{50} determination, the source of the data in the table must be clarified.

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 using rainbow trout. The table containing the analytical results may have been from another test using the same test material and bluegill sunfish. The analytical results given in the Appendix 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 LC_{50} value. The 96-hour LC_{50} of 0.51 µg a.i./l classifies MO 70616-3-6 1.9EC as very highly toxic to rainbow trout. The NOEC can be estimated as 0.18 µg a.i./l nominal concentration.

D. <u>Adequacy of the Study</u>:

(1) **Classification:** Supplemental.

(2) **Rationale:** The table containing the analytical results may have been from another test using the same test material and bluegill sunfish. If the analytical results given in the table represent the concentrations in the present study, 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.

FENVALERATE Sh # 109301

Page_____ is not included in this copy.

Pages 7 through 8 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.

X 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.

RIFICI FENVALERATE SALMO GAIRDNERI 10-24-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.58	10	7	70	17.1875
.32	10	0	0	9.765625E-02
.18	10	0	0	9.765625E-02
.1	10	1	10	1.074219
.058	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 .5063717

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
7	5.02072	3.887652	8.631229E-03

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 2.988423

95 PERCENT CONFIDENCE LIMITS =-3.707725 AND 9.684569

LC50 = .569232

95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = .2139518

95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

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

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
96-Hour EC_{50}	32 Reviewer calculated	EC_{50} - 0.51 pp b* 95% C.L. binomial (N/A) Control Mortality (%) - 0 Solvent Control Mortality (%) - 0 Slope - N/A # Animals/Level - 10 Temperature - 12°C 48-Hour Dose Level pp b* /(% Effect) 0.058(0), 0.1 (10), 0.18(0), 0.32(0), 0.58(70)	LMR 10/24/91	Supplemental
Species: Salmo gairdneri Lab: Analytical Bio-chemistry MRID # 412330-02		Comments: *nominal concentrations adjusted for active ingredient.		

96-Hour LC_{50}		LC_{50} - pp 95% C.L. ( ) Control Mortality (%) - Solvent Control Mortality (%) - Slope - # Animals/Level - Temperature - 96-Hour Dose Level pp /(% Mortality) ( ), ( ), ( ), ( ), ( )		
Species: Lab: MRID #		Comments:		