2-14-92

MRID No. 420096-05

DATA EVALUATION RECORD

1. **CHEMICAL:** Fenoxaprop-ethyl.
   Shaughnessey No. 128701.

2. **TEST MATERIAL:** Fenoxaprop-P-ethyl technical (HOE 046360); 95.6% active ingredient; a light-colored solid.

3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test. Species Tested: Rainbow Trout (*Salmo gairdneri*). 72-1

4. **CITATION:** Fischer, R. 1986. The Effect of HOE 046360 - Active Ingredient Technical (Code: HOE 046360 OH ZC96 0002) on *Salmo gairdneri* (Rainbow Trout) in a Static Acute Toxicity Test (Study No. Sg348/a, BBA/EPA Method). Laboratory Report No. A39607. Prepared by Hoechst AG, Federal Republic of Germany. Submitted by Hoechst Celanese Corporation, Somerville, NJ. EPA MRID No. 420096-05.

5. **REVIEWED BY:**

   Richard C. Petrie, Agronomist
   Ecological Effects Branch, Section 3
   Environmental Fate and Effects Branch

   Signature: R. C. Petrie
   Date: 2/04/92

6. **APPROVED BY:**

   Daniel Rieder, Head Section 3
   Ecological Effects Branch
   Environmental Fate and Effects Branch

   Signature: Daniel Rieder
   Date: 2-14-92

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for a static acute freshwater fish toxicity study. The test temperature (16 ±1°C) was higher than recommended for coldwater fish species and the test vessel construction material was not included in the report. The 96-hour LC_{50} of 0.58 mg/l (based on nominal concentrations) classifies fenoxaprop-p-ethyl as highly toxic to rainbow trout. The NOEC was determined as 0.32 mg/l based on lack of mortality and sublethal effects. ?

8. **RECOMMENDATIONS:** ~~Submission of the missing information is required to upgrade this study.~~ N/A.

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5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
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Signature: Mark A. Mossler

Date: 11/25/91

6. **APPROVED BY:**

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Signature: Louis M. Rifici

Date: 11/25/91

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

Signature:

Date:

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8. **RECOMMENDATIONS:** Submission of the missing information is required to upgrade this study.

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Fertilized rainbow trout (*Salmo gairdneri*) eggs were obtained from a commercial supplier in Germany. The trout were raised in the laboratory (for 3 months) and fed flake, live and frozen foods. The fiberglass holding tank (338 x 85 x 74 cm) received 170 l/hour of water and the solution depth was 55-60 cm. The temperature in the holding unit was 12 ±2°C. The holding water had a pH of 7.4 to 7.8. The fish were free from signs of disease during the holding period. However, 0.04% mortality occurred during the two weeks before test initiation.

The fish were acclimated to the test conditions and fasted for 96 hours. No mortality was witnessed. Mean weight and length of 10 fish were 1.3 g and 54 mm, respectively.

B. **Test System:** The test chambers were 59-l VA tanks filled with 50 l of test solution. The test solution depth was approximately 18 cm. The test tanks were kept in a temperature-controlled room at 16 ±1°C. The laboratory environment was maintained on a 16-hour daylight photoperiod. The test water was a mixture of tap water (70%) and deionized water (30%).

A stock solution was prepared by adding 0.203 g of fenoxaprop-p-ethyl to 4.06 ml of acetone. Secondary stocks were created in 25 ml of acetone and all of this stock was added to each 50-l chamber. The resulting amount of solvent was 0.5 ml acetone/l. The mixture was stirred thoroughly with a glass rod.

C. **Dosage:** Ninety-six-hour static test. Based on preliminary studies, nine nominal concentrations (0.1, 0.135, 0.18, 0.24, 0.32, 0.42, 0.56, 0.75, and 1.0 mg/l), a dilution water control and a solvent control were used. The concentrations made were not corrected for the percent active ingredient in the test material.

D. **Design:** Rainbow trout were randomly distributed to each chamber for a total of 10 individuals per

concentration or control. Biomass loading rate was 0.25 g/l. The fish were not fed and the water was not aerated during the test. Observations of mortality and sublethal responses were made every 24 hours. At each evaluation, dead fish were removed from the containers.

The dissolved oxygen (D.O.), temperature, and pH were measured in the controls and the low, middle, and high test concentrations at the start of the study and every 24 hours thereafter. The conductivity was measured in these same vessels at the start and end of the study. The temperature of the control and the 0.1 and 0.56 mg/l test concentrations were continuously monitored during the test.

A vessel containing 1.0 mg/l fenoxaprop-p-ethyl but no fish was sampled at 0, 2, 48, and 96 hours to measure the stability of the test material.

E. **Statistics:** The median lethal concentration (LC_{50}) and associated 95% confidence interval (C.I.) for each 24-hour interval were calculated using a computer program developed by Stephan et al. (1978).

12. **REPORTED RESULTS:** The stability test indicated that the amount of test material had declined to 84% of nominal after 48 hours and 60% after 96 hours (Table 7.3, attached). However, all results stated are based on unadjusted nominal rates.

The responses of rainbow trout are given in Table 6.2 (attached). Signs of toxicity included slower reaction, swimming on the bottom, narcosis, and spasms. The 96-hour LC_{50} based on nominal concentrations was 0.61 mg/l (95% C.I. = 0.42-0.75 mg/l). Sublethal or lethal effects were observed at concentrations greater than 0.32 mg/l. The no-observed-effect concentration (NOEC) was 0.32 mg/l.

Dissolved oxygen ranged from 8.4 to 10.7 mg/l. The pH values ranged from 8.0 to 8.2. The temperature was 15-16.3°C throughout the test. Conductivity was 446-464 μS/cm.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** No conclusions other than those stated were made by the author.

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 fish were acclimated to the test conditions for 96 hours. The guidelines recommend 2 weeks.

The results of preliminary studies were not given in the report.

The period between test solution preparation and the initiation of the test was not stated in the report. Tests should be initiated within 30 minutes of solution preparation.

It was not stated what material the test vessels were made of. The test vessels must be constructed of glass or stainless steel.

The temperature was kept at 16°C. The recommended test temperature for rainbow trout is 12°C.

A dawn/dusk lighting transition period was not used.

B. **Statistical Analysis:** Table 6.2 indicates that one fish was dead at 48 hours in the 0.42 mg/l exposure vessel. However, this fish was not counted as dead for the 72- and 96-hour time periods. The reviewer feels that this is a typographical error and that one fish was dead at this concentration. The reviewer used EPA's Toxanal program and the nominal concentrations to calculate the LC_{50} and obtained the same value (see attached printout). However, since probit analysis gave a slope for the toxicity, it was used rather than binomial probability.

C. **Discussion/Results:** Judging from the response of the control organisms, the short acclimation period did not modify the response of the rainbow trout in the test.

The author stated that the test vessels were VA tanks. However, the reviewer does not know what type of material these tanks were made of. If glass or steel vessels are not used, the concentrations of the test

solutions must be measured. A stability test was conducted in a vessel under identical climatic conditions. However, the author did not state if it was conducted in the same type of vessel (i.e., VA tank).

The temperature was 16 ±1°C. The recommended test temperature for coldwater fish is 12 ±1°C. Rainbow trout are sensitive species and the higher test temperature probably affected the response of the fish. The results should be interpreted with caution.

This study is scientifically sound but does not meet the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 0.58 mg/l (based on nominal concentrations) classifies fenoxaprop-p-ethyl as highly toxic to rainbow trout. The NOEC was determined as 0.32 mg/l based on lack of mortality and sublethal effects.

D. **Adequacy of the Study:**

(1) **Classification:** Supplemental.

(2) **Rationale:** The test temperature was higher than recommended and the author did not state what material was used to construct the test vessels or if the stability test was conducted in this same type of vessel.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 10-30-91.

FENOXAPROP

RIN 4731-95 P.C. 128701

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.

✓ 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.

MOSSLER FENOXAPROP-P-ETHYL RAINBOW TROUT 10-30-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1	10	10	100	9.765625E-02
.75	10	10	100	9.765625E-02
.56	10	2	20	5.46875
.42	10	1	10	1.074219
.321	10	0	0	9.765625E-02
.24	10	0	0	9.765625E-02
.18	10	0	0	9.765625E-02
.135	10	0	0	9.765625E-02
.1	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT .42 AND .75 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 .6139334

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.1144044	.5711923	.4999746	.6552171

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
9	.284362	1	.738623

SLOPE = 13.21

95 PERCENT CONFIDENCE LIMITS = 6.165687 AND 20.25431

LC50 = .5846913

95 PERCENT CONFIDENCE LIMITS = .5174998 AND .6612647

LC10 = .4685838

95 PERCENT CONFIDENCE LIMITS = .3498463 AND .5268985

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Shaughnessey # 128701 Chemical Name Fenoxaprop-ethyl Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
48-Hour EC_{50}	_____	EC_{50} = _____ pp (_____) 95% C.L. Control Mortality (%) = _____ Solvent Control Mortality (%) = _____ Slope = _____ # Animals/Level = _____ Temperature = _____ 48-Hour Dose Level pp /(% Effect) ( ), ( ), ( ), ( ), ( ) Comments:	_____	_____
96-Hour LC_{50}	95.6	LC_{50} = 0.58 mg/l* pp (0.52 - 0.66) 95% C.L. - probit Control Mortality (%) = 0 Solvent Control Mortality (%) = 0 Slope = 13.2 # Animals/Level = 10 Temperature = 16 °C 96-Hour Dose Level mg/l* pp /(% Mortality) 0.1 (0), 0.135 (0), 0.18 (0), 0.24 (0), 0.32 (0) 0.42 (10), 0.56 (20), 0.75 (100), 1.0 (100). Comments: NOEC = 0.32 mg/l* * Based on nominal concentration of total test material	M. Mossler 10/30/91	Supplemental

Species: Salmo gairdneri

Lab: Bioassay Inc.

MRID # 420096-05

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