8.26.92

MRID No. 417832-02

DATA EVALUATION RECORD

1. **CHEMICAL:** Oxytetracycline.
Shaughnessey No. 006304.

2. **TEST MATERIAL:** Oxytetracycline HCl; R02202-51010; 90.9% active ingredient; a yellow powder.

3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test. Species Tested: *Oncorhynchus mykiss*.

4. **CITATION:** Murphy, D. and G.T. Peters. 1991. Oxytetracycline Hydrochloride: A 96-Hour Static Acute Toxicity Test With the Rainbow Trout (*Oncorhynchus mykiss*). Laboratory Study No. 260A-103. Prepared by Wildlife International Ltd., Easton, MD. Submitted by Pfizer, Incorporated, New York, NY. EPA MRID No. 417832-02.

5. **REVIEWED BY:**

Sara R. Ager
Ecological Effects Branch
Environmental Fate and Effects Division

Sara R. Ager 8/20/92

6. **APPROVED BY:** (for KFA reviewed)

Ann Stavola 8/26/92

Ann Stavola
Ecological Effects Branch
Environmental Fate and Effects Division

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 116 mg ai/l (based on measured concentrations) classifies oxytetracycline hydrochloride as practically non-toxic to rainbow trout. The NOEC was 116 mg ai/l.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Juvenile rainbow trout (*Oncorhynchus mykiss*) were obtained as eyed eggs from a commercial

supplier in McMillin, WA. The young trout were raised in the laboratory (for 93 days) in well water and fed a commercially available salmon starter mash and salmon starter. The temperature in the holding unit was 11-13.6°C and changes in water temperature did not exceed 3°C in any 72-hour period. The holding water had a pH of 7.7 to 8.6, the alkalinity ranged from 170 to 190 mg/l as $CaCO_3$ and the hardness ranged from 114 to 168 mg/l as $CaCO_3$. The fish were free from signs of stress and disease during the holding period.

The fish were acclimated to the test conditions for 48 hours. Feeding was discontinued 48 hours before the test. There was no mortality during the 48 hours immediately before the test.

Mean weight and length of 10 control fish were 1.5 (1.1-2.0) g and 44 (39-48) mm.

B. **Test System:** The test chambers were Teflon®-lined, 50-l polyethylene aquaria filled with 45 l of test solution. The test solution depth was approximately 25 cm. The test aquaria were immersed in a temperature-controlled water bath set at 12 ±1°C. The laboratory environment was maintained on a 16-hour daylight photoperiod (46 footcandles) with 30-minute dawn and dusk simulations. Soft reconstituted water, prepared from well water that had been deionized, was aerated and filtered (0.2 m) before use. A typical batch of reconstituted water has a hardness of 40-48 mg/l as $CaCO_3$, an alkalinity of 30-35 mg/l as $CaCO_3$, and a pH of 7.3 to 7.5.

A stock solution was prepared by adding 15 g of the test material to 5 l of reconstituted water. An appropriate amount of stock solution was added to each test chamber (containing 45 l of dilution water), the volume brought to 47 l, and the resulting solutions gently mixed with a teflon-coated stirring rod.

C. **Dosage:** Ninety-six-hour static test. Five nominal concentrations [14.1, 23.6, 39.3, 65.5, and 109 mg active ingredient (ai)/l] and a dilution water control were used.

D. **Design:** Within 1.1 hours of solution preparation, rainbow trout were impartially distributed in twos to each aquarium for a total of 10 individuals per concentration. Biomass loading rate was 0.34 g/l. The fish were not fed during the test. Observations of

mortality and sublethal responses were made every 24 hours.

The dissolved oxygen (D.O.) and pH were measured in all concentrations and the control every 24 hours. The temperature of the negative control aquarium was monitored continuously and the temperature of all chambers was measured at the beginning and end of the test.

Samples were taken to determine the concentration of the test material in the water. The samples were frozen and sent to Hazleton Laboratories America, Inc., for analysis by microbial zone inhibition (Association of Official Analytical Chemists, 1990).

E. **Statistics:** No statistical analysis was conducted by the authors.

12. **REPORTED RESULTS:** The mean measured concentrations were 15.8, 24.1, 39.7, 69.4, and 116 mg ai/l (Table 1, attached).

One fish in the control jumped out of the tank within 48 hours. There was no mortality or sublethal responses at any tested concentration. The 96-hour LC_{50} based on measured concentrations was >116 mg ai/l. The no-observed-effect concentration (NOEC) was given as 116 mg ai/l.

The hardness and alkalinity of the test dilution water were 40 and 37.5 mg/l as $CaCO_3$, respectively, and the pH was 7.4 at the beginning of the test. Dissolved oxygen ranged from 8.4 to 9.8 mg/l. The pH ranged from 6.2 to 7.5. The temperature was 11.5-12.5°C throughout the test.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors categorized oxytetracycline hydrochloride as practically non-toxic to rainbow trout.

Quality Assurance and Good Laboratory Practice Regulation Statements were included in the report and analytical appendix, indicating that the studies were conducted in accordance with 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 SEP, except for the following:

The fish were held in well water with a hardness of 114-168 mg/l as $CaCO_3$ and a temperature of 11-13.6°C and then acclimated to the test conditions (hardness of 40 mg/l and temperature of 12 ±1°C) for 48 hours. The recommended acclimation period for rainbow trout is at least two weeks.

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

B. **Statistical Analysis:** Upon review of the mortality data, the reviewer concurs that the LC_{50} was greater than 116 mg ai/l and that the NOEC was 116 mg ai/l.

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC_{50} of 116 mg ai/l (mean measured concentrations) classifies oxytetracycline hydrochloride as practically non-toxic to rainbow trout. The NOEC was determined to be 116 mg ai/l based on the lack of mortality and sublethal effects.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 4-15-92.

Page 5 is not included in this copy.

Pages _____ through _____ are not included in this copy.

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.

Shaughnessey # 006304 Chemical Name Oxytetracycline hydrochloride 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 (%) =		
Species:		Slope = # Animals/Level = Temperature =		
Lab:		48-Hour Dose Level pp /(% Effect) ( ), ( ), ( ), ( ), ( )	_____	_____
MRID #		Comments:		
96-Hour LC_{50}	90.9%	LC_{50} = >116 ~~pp~~ mg ai/l* 95% C.L. (N/A) Control Mortality (%) = 10% Solvent Control Mortality (%) = n/a		
Species: Oncorhynchus mykiss		Slope = N/A # Animals/Level = 10 Temperature = 11.5-12.5 °C		
Lab: Wildlife International		96-Hour Dose Level ~~pp~~ mg ai/l* /(% Mortality) 15.8 (0), 24.1 (0), 39.7 (0), 69.4 (0), 116 (0)	M. Mossler 4/15/92	Core
MRID # 41783 2-02		Comments: NOEC = 116 mg ai/l* *. based on mean measured concentrations		