8-26-92

MRID No. 417832-03

DATA EVALUATION RECORD

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

2. **TEST MATERIAL:** Oxytetracycline HCl; Batch No. R02202-51010; 90.9% active ingredient; a yellow powder.

3. **STUDY TYPE:** Freshwater Invertebrate Static Acute Toxicity Test. Species Tested: *Daphnia magna*.

4. **CITATION:** Bellantoni, D.C., C.M. Holmes, and G.T. Peters. 1991. Oxytetracycline Hydrochloride: A 48-Hour Static Acute Toxicity Test With the Cladoceran (*Daphnia magna*). Laboratory Study No. 260A-101. Prepared by Wildlife International Ltd., Easton, MD. Submitted by Pfizer Incorporated, New York, NY. EPA MRID No. 417832-03.

5. **REVIEWED BY:**

Sara R. Ager, Biologist
Ecological Effects Branch
Environmental Fate and Effects Branch

Sara R. Ager 8/24/92

6. **APPROVED BY:**

Ann Stavola, Section Head
Ecological Effects Branch
Environmental Fate and Effects Branch

Ann Stavola 8/26/92

7. **CONCLUSIONS:** The 48-hour EC_{50} of >102 mg ai/l (based on measured concentrations) classifies oxytetracycline hydrochloride as practically non-toxic to *Daphnia magna*. The NOEC was 60.1 mg ai/l.

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The daphnids (*Daphnia magna*) used in the test were obtained from in-house cultures. The adult daphnids were fed a mixture of yeast, Cerophyll®, trout chow, and a suspension of *Selenastrum capricornutum*. Daphnids were cultured under the test conditions listed in Section 11.B. The daphnids in the

cultures were in good health and showed no signs of disease or stress. Neonates were obtained for testing by transferring individual adult daphnids to dilution water 24 hours prior to test initiation. First instar larvae (<24 hours old) from at least three different adults were chosen for the test.

B. Test System: The test chambers were 250-ml glass beakers containing 150 ml of test solution. The test solution depth was approximately 5 cm. The test chambers were positioned in a temperature-controlled water bath set to maintain 20 ±1°C. The laboratory environment was maintained on a 16-hour daylight photoperiod (25-50 footcandles) with 30-minute dawn and dusk simulations. Medium-hard well water with the characteristics listed in Table 2 (attached) was aerated and filtered (0.2 m) before use as dilution water.

A stock solution [5 mg active ingredient (ai)/l] was prepared by dissolving 1.3785 g of the test material in 250 ml of deionized water. Nominal test solutions were prepared by adding appropriate amounts of the stock solution to dilution water.

C. Dosage: Forty-eight-hour static test. Five nominal concentrations (13, 22, 36, 60, and 100 mg ai/l) and a dilution water control were used.

D. Design: Daphnids were impartially distributed to each test beaker by twos for a total of 10 individuals per concentration. Observations of mortality and immobility were made every 24 hours. The daphnids were not fed during the test.

The dissolved oxygen and pH were measured in all concentrations and the control at the beginning and end of the test. The temperature of the dilution water control was monitored continuously and each test chamber 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 measured concentrations were 12.1, 19.7, 35.6, 60.1, and 102 mg ai/l (Table 1, attached).

No mortality or sublethal responses were noted within the first 24 hours of the study. By test termination, 4 of the 10 daphnids in the highest treatment group were dead or immobilized. The remaining six daphnids of this group swam erratically. No mortality or sublethal effects were noted in the lower concentration test groups. The 48-hour EC_{50} based on measured concentrations was >102 mg ai/l. The no-observed-effect concentration (NOEC) was determined to be 60.1 mg ai/l, based on signs of toxicity, immobilization, and mortality observed at the 102 mg ai/l test level.

Dissolved oxygen ranged from 7.0 to 9.0 mg/l. The pH values ranged from 7.5 to 8.4. The temperature was 19.8-21.4°C throughout the test.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: The authors concluded that oxytetracycline hydrochloride was practically non-toxic to *Daphnia magna*.

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 results of preliminary studies, if any, 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.

The guidelines recommend using soft water (between 40-48 mg/L as $CaCO_3$). Water used in the study had a hardness of 132 mg/L as $CaCO_3$.

added

Only 10 organisms were used at each test level. For reliable results, at least 20 organisms should be used at each test level.

added

The storage conditions and expiration date was not supplied by Pfizer Incorporated.

The temperature varied slightly more than the recommended 1°C.

B. Statistical Analysis: Upon review of the mortality data, the reviewer concurs that the EC_{50} was greater than 102 mg ai/l and that the NOEC was 60.1 mg ai/l.

C. Discussion/Results: Although an inadequate number of organisms was used at each test level, this study is acceptable in demonstrating low toxicity to *Daphnia magna*. The 48-hour EC_{50} of >102 mg ai/l (based on measured concentrations) classifies oxytetracycline hydrochloride as practically non-toxic to *Daphnia magna*. The NOEC was determined to be 60.1 mg ai/l, based on signs of toxicity, mortality, and immobilization at the 102 mg ai/l test level.

added

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.

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