

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD

1. **CHEMICAL:** Prometon
Shaughnessey No. 80804
2. **TEST MATERIAL:** Prometon Technical; Batch Code 73152-ML-5664; ID # FL-872050 ARS-8114; 98.5% active ingredient; a white powder.
3. **STUDY TYPE:** Freshwater Fish Static Acute Toxicity Test.
Species Tested: Oncorhynchus mykiss
4. **CITATION:** Murphy, D. 1990. A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss). Laboratory Study No. 108A-102B. Prepared by Wildlife International Ltd., Easton, MD. Submitted by Agricultural Division, Ciba-Geigy Corporation, Greensboro, NC. EPA MRID No. 416091-08.
5. **REVIEWED BY:**

Louis M. Rifici, M.S. Associate Scientist II KBN Engineering and Applied Sciences, Inc.	Signature: <i>Louis M Rifici</i> Date: <i>4/16/91</i>
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6. **APPROVED BY:**

Pim Kosalwat, Ph.D. Senior Scientist KBN Engineering and Applied Sciences, Inc.	Signature: <i>P. Kosalwat</i> Date: <i>4/17/91</i>
Henry T. Craven, M.S. Supervisor, EEB/HED USEPA	Signature: <i>H. T. Craven</i> Date: <i>4/23/91</i>
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute, static toxicity test for freshwater fish. Based on measured concentrations, the 96-hour LC₅₀ of Prometon for rainbow trout was 19.6 mg a.i./L. Therefore, Prometon is classified as slightly toxic to rainbow trout. The NOEC, based on the lack of mortality and sublethal effects, was determined as 6.36 mg a.i./L.
8. **RECOMMENDATIONS:** N/A

9. BACKGROUND:10. DISCUSSION OF INDIVIDUAL TESTS: N/A11. 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 58 days) in well water and fed a commercially available salmon starter mash and salmon mash. The temperature in the holding unit was 9° to 12°C and changes in water temperature did not exceed 3°C in any 72-hour period. The holding water had a pH of 7.8 to 8.6, the alkalinity ranged from 150 to 195 mg/L as CaCO₃, and the hardness ranged from 112 to 160 mg/L as CaCO₃. The fish were free from signs of stress and disease during the holding period.

The fish were acclimated to the test conditions for 123.5 hours. Feeding was discontinued 48 hours before the test. Mortality was less than 1% during the 48 hours immediately before the test.

Mean weight and length of 10 control fish were 0.87 (0.64-1.12) g and 38 (35-41) mm.

- B. Test System: The test chambers were Teflon®-lined, 25-L polyethylene aquaria filled with 21-L of test solution. The test solution depth was approximately 23 cm. The test aquaria were immersed in a temperature-controlled water bath set to 12°±1°C. The laboratory environment was maintained on a 16-hour daylight photoperiod with 30-minute dawn and dusk simulations. Soft reconstituted water, prepared from well water that had been deionized, was aerated and filtered (0.2 µm) before use. A typical batch of reconstituted water has a hardness of 40-48 mg/L as CaCO₃, an alkalinity of 30-35 mg/L as CaCO₃, and a pH of 7.3 to 7.5.

A stock solution was prepared by adding 18.3043 g of Prometon to 75 mL of triethylene glycol in a 100-mL volumetric flask. The mixture was stirred for 19 hours, diluted to volume with solvent and stirred for an additional 2 hours. The solution was then sonicated for 15 minutes to obtain a clear solution. An appropriate amount of the stock solution diluted to 1-L with dilution water was added to each test chamber (containing 20-L of dilution water) and the resulting

solutions were gently mixed with a teflon-coated stirring rod.

- C. **Dosage:** Ninety-six-hour static test. Five nominal concentrations (4.7, 7.8, 13.0, 21.6, and 36.0 mg/L), a dilution water control and a solvent control (0.2 mL triethylene glycol/L) were used. The concentrations made were based on the percent active ingredient in the test material.
- D. **Design:** Rainbow trout were impartially distributed to each aquarium, two aquaria per concentration, for a total of 20 individuals per concentration. Biomass loading rate was 0.44 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 each replicate of all concentrations and the controls, every 24 hours. The temperature of one of the control aquaria was monitored continuously and each replicate of the test concentrations were measured at the beginning and end of the test.

Prometon concentrations were measured by gas chromatography from samples taken at test initiation.

- 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 measured concentrations were 4.97, 6.36, 11.4, 19.5, and 32.2 mg a.i./L. These values represent 82 to 106% of nominal concentrations (Table 1, attached).

The responses of rainbow trout are given in Table 2 (attached). The 96-hour LC_{50} based on measured concentrations was 19.6 mg/L (95% C.I. = 17.1-22.4 mg/L). Sublethal or lethal effects were observed at 11.4, 19.5, and 32.2 mg/L. The no-observed-effect concentration (NOEC) was given as 6.36 mg/L.

Dissolved oxygen ranged from 8.6 to 10.8 mg/L. The pH values ranged from 7.3 to 7.6. The temperature was 11.4°-12.5°C throughout the test.

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

The author categorized Prometon as slightly toxic to rainbow trout.

Quality Assurance and Good Laboratory Practice Regulation 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 held in well water with a hardness of 112-160 mg/L as CaCO₃ and a temperature of 9° to 12°C and then acclimated to the test conditions (hardness of 44 mg/L and temperature of 12°±1°C) for 5.15 days. 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.

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.

- B. Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC₅₀ value and obtained similar results (see attached printout). The slope of the probit line was 8.6.
- C. Discussion/Results:** Judging from the response of the control organisms (Table 2, attached), the short acclimation period did not modify the response of the rainbow trout in the test.

This study is scientifically sound and meets the guideline requirements for a static acute freshwater fish toxicity study. The 96-hour LC₅₀ of 19.6 mg a.i./L (based on measured concentrations) classifies Prometon as slightly toxic to rainbow trout. The NOEC was determined as 6.36 mg a.i./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, 02-28-91.

RIN-0334-94

PROMETON REVIEWS (088804)

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.

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
32.2	20	20	100	9.536742E-05
19.5	20	8	40	25.17223
11.4	20	1	5	2.002716E-03
6.36	20	0	0	9.536742E-05
4.97	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 11.4 AND 32.2 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 20.75519

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
3	.0513501	18.80796	16.36562 22.19801

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	.1761829	1	.550241

SLOPE = 8.58883
 95 PERCENT CONFIDENCE LIMITS = 4.983742 AND 12.19392

- LC50 = 19.62207
 95 PERCENT CONFIDENCE LIMITS = 17.11343 AND 22.3899

LC10 = 13.95977
 95 PERCENT CONFIDENCE LIMITS = 10.35022 AND 16.19797

Shanghai No. 80804

Chemical Name Prometon Chemical Class _____ Page 1 of 1

Study/Species/Lab/ Accession _____ Chemical g a.i. Results _____ Reviewer/Date _____ Validation Status _____

14-Day Single Dose Oral LD₅₀ LD₅₀ = mg/kg (95% C.L.) Contr. Mort. (X) = _____

Species _____ Slope = # Animals/Level = _____ Age (Days) = _____ Sex = _____

Lab _____ 14-Day Dose Level mg/kg/(% Mortality) _____

Acc. _____ Comments: _____

14-Day Single Dose Oral LD₅₀ LD₅₀ = mg/kg (95% C.L.) Contr. Mort. (X) = _____

Species _____ Slope = # Animals/Level = _____ Age (Days) = _____ Sex = _____

Lab _____ 14-Day Dose Level mg/kg/(% Mortality) _____

Acc. _____ Comments: _____

8-Day Dietary LC₅₀ LC₅₀ = ppm (95% C.L.) Contr. Mort. (X) = _____

Species _____ Slope = # Animals/Level = _____ Age (Days) = _____ Sex = _____

Lab _____ 8-Day Dose Level ppm/(% Mortality) _____

Acc. _____ Comments: _____

8-Day Dietary LC₅₀ LC₅₀ = ppm (95% C.L.) Contr. Mort. (X) = _____

Species _____ Slope = # Animals/Level = _____ Age (Days) = _____ Sex = _____

Lab _____ 8-Day Dose Level ppm/(% Mortality) _____

Acc. _____ Comments: _____

48-Hour LC₅₀ LC₅₀ = PP (95% C.L.) Contr. Mort. (X) = 0
Sol. Contr. Mort. (X) = _____

Species _____ Slope = # Animals/Level = _____ Temperature = _____

Lab _____ 48-Hour Dose Level pp/(% Mortality) _____

Acc. _____ Comments: _____

96-Hour LC₅₀ LC₅₀ = 19.6 * M (95% C.L. Probit) Contr. Mort. (X) = 0
Sol. Con. Mort. (X) = 0

Species Oncorhynchus mykiss Slope = 8.6 # Animals/Level = 20 Temp. = 12 ± 1°C

Lab Wildlife International Ltd. 98.5 LR Cre
2/28/91

Acc. MRID 416091-08 4.97 (0), 6.36 (0), 11.4 (5), 19.5 (40), 32.2 (100)

96-Hour LC₅₀ Comments: Measured concentrations

96-Hour LC₅₀ LC₅₀ = PP (95% C.L.) Contr. Mort. (X) = _____
Sol. Con. Mort. (X) = _____

Species _____ Slope = # Animals/Level = _____ Temp. = _____

Lab _____ 96-Hour Dose Level pp/(% Mortality) _____

Acc. _____ Comments: _____