

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: Bluegill Sunfish (Lepomis macrochirus).
4. **CITATION:** Murphy, D. 1990. A 96-Hour Static Acute Toxicity Test with the Bluegill (Lepomis macrochirus). Laboratory Study No. 108A-103A. Prepared by Wildlife International Ltd., Easton, MD. Submitted by Agricultural Division, Ciba-Geigy Corporation, Greensboro, NC. EPA MRID No. 416091-07.
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> <i>4/23/91</i> Date:
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 bluegill sunfish was 41.5 mg a.i./L. Therefore, Prometon is classified as slightly toxic to bluegill. The NOEC, based on the lack of sublethal effects, was determined as 1.36 mg a.i./L.
8. **RECOMMENDATIONS:** N/A

6 hrs

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. MATERIALS AND METHODS:

- A. Test Animals: Juvenile bluegill sunfish (Lepomis macrochirus) from the same year class were obtained 56 days prior to the test from a commercial supplier in Brady, NE. The fish were maintained in well water and fed frozen brine shrimp, flake food, and a commercially available salmon starter. The temperature in the holding unit was 13° to 17°C and changes in water temperature did not exceed 3°C in any 72-hour period. The holding water had a pH of 6.7 to 8.4, an alkalinity of 195 mg/L as CaCO₃, and a hardness of 146 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 and fasted for 48 hours prior to the test. Feeding was discontinued during the acclimation period. No mortality occurred during acclimation.

Mean weight and length of 10 control fish were 0.73 (0.51-0.93) g and 30 (28-32) mm.

- B. Test System: The test chambers were Teflon®-lined, 25-L polyethylene aquaria filled with 15 L of test solution. The test solution depth was approximately 16.5 cm. The test aquaria were immersed in a temperature-controlled water bath set to 22±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 18.3007 g of Prometon to 75 mL of triethylene glycol in a 100-mL volumetric flask. The mixture was sonicated for 15 minutes, diluted to near volume with solvent and sonicated for an additional 20 minutes. This solution was diluted to 100 mL and mixed by hand. An appropriate amount of the stock solution was added to

each test chamber and the resulting solutions were gently mixed with a teflon-coated stirring rod.

- C. **Dosage:** Ninety-six-hour static test. Five nominal concentrations (1.9, 4.8, 12.0, 30.0, and 75.0 mg/L), a dilution water control and a solvent control (0.42 mL triethylene glycol/L) were used. The concentrations made were based on the percent active ingredient in the test material.
- D. **Design:** Bluegill were impartially distributed to each aquarium, two aquaria per concentration, for a total of 20 fish per concentration. Biomass loading rate was 0.49 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 and the controls 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 1.36, 3.42, 9.34, 29.3, and 58.8 mg a.i./L. These values represent 71 to 98% of nominal concentrations (Table 1, attached).

The responses of bluegill are given in Table 2 (attached). The 96-hour LC_{50} based on measured concentrations was 41.5 mg/L (95% C.I. = 29.3-58.8 mg/L). Sublethal or lethal effects were observed at 3.42, 9.34, 29.3 and 58.8 mg/L. The no-observed-effect concentration (NOEC) was given as 1.36 mg/L.

Dissolved oxygen ranged from 6.8 to 9.0 mg/L. The pH values ranged from 6.9 to 7.6. The temperature was 21.0°-22.4°C throughout the test.

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

The author categorized Prometon as slightly toxic to bluegill.

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:

Each selected nominal concentration was less than 60% of the next highest concentration. The SEP recommends that each concentration be at least 60% of the next concentration.

The fish were held in well water with a hardness of 146 mg/L as CaCO₃ and a temperature of 13° to 17°C and then acclimated to the test conditions (hardness of 40-48 mg/L and temperature of 22±1°C) for 48 hours. The recommended acclimation period for bluegill 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).
- 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 bluegill 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 41.5 mg a.i./L (based on measured concentrations) classifies Prometon as slightly toxic to bluegill. The NOEC was

determined as 1.36 mg a.i./L based on the lack of 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.

LOUIS M. RIFICI PROMETON LEPOMIS MACROCHIRUS 2-24-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
58.8	20	20	100	9.536742E-05
29.3	20	0	0	9.536742E-05
9.34	20	0	0	9.536742E-05
3.42	20	0	0	9.536742E-05
1.36	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 29.3 AND 58.8 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 41.5071

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

6

Shanghai No. 80804

Study/Species/Lab/
Accession
14-Day Single Dose Oral LD50

Chemical
X a.i.

Results

Reviewer/
Date
Validation
Status

Species _____
Lab _____
Acc. _____

LD50 = mg/kg (95% C.L.) Contr. Mort. (X) = _____
Slope = # Animals/Level = _____ Age (Days) = _____
Sex = _____
14-Day Dose Level mg/kg/(X Mortality)
(), (), (), (), ()

Comments:

14-Day Single Dose Oral LD50
Species _____
Lab _____
Acc. _____

LD50 = mg/kg. (95% C.L.) Contr. Mort. (X) = _____
Slope = # Animals/Level = _____ Age (Days) = _____
Sex = _____
14-Day Dose Level mg/kg/(X Mortality)
(), (), (), (), ()

Comments:

8-Day Dietary LC50
Species _____
Lab _____
Acc. _____

LC50 = ppm (95% C.L.) Contr. Mort. (X) = _____
Slope = # Animals/Level = _____ Age (Days) = _____
Sex = _____
8-Day Dose Level ppm/(X Mortality)
(), (), (), (), ()

Comments:

8-Day Dietary LC50
Species _____
Lab _____
Acc. _____

LC50 = ppm (95% C.L.) Contr. Mort. (X) = _____
Slope = # Animals/Level = _____ Age (Days) = _____
Sex = _____
8-Day Dose Level ppm/(X Mortality)
(), (), (), (), ()

Comments:

48-Hour LC50
Species _____
Lab _____
Acc. _____

LC50 = pp (95% C.L.) Contr. Mort. (X) = _____
Sol. Contr. Mort. (X) = _____
Slope = # Animals/Level = _____ Temperature = _____
48-Hour Dose Level pp/(X Mortality)
(), (), (), (), ()

Comments:

96-Hour LC50
Species Lepomis macrochirus
Lab Wildlife International Ltd.
Acc. MEID 416091-07

LC50 = 41.5 $\frac{\mu}{m}$ (95% C.L. binomial) Contr. Mort. (X) = 0
Sol. Contr. Mort. (X) = 0
Slope = N/A # Animals/Level = 20 Temp. = 21-22°C
96-Hour Dose Level ppm/(X Mortality)
1.36 (0), 3.42 (0), 9.34 (0), 29.3 (0), 58.8 (100)

LR 2/28/91 CR CR

Comments: measured concentrations

96-Hour LC50
Species _____
Lab _____
Acc. _____

LC50 = pp (95% C.L.) Contr. Mort. (X) = _____
Sol. Contr. Mort. (X) = _____
Slope = # Animals/Level = _____ Temp. = _____
96-Hour Dose Level pp/(X Mortality)
(), (), (), (), ()

Comments:

RIN-0334-94 PROMETON REVIEWS (08804)

Page _____ is not included in this copy.

Pages 8 through 9 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.
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 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
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