

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:** Marine Shrimp Static Acute Toxicity Test.
Species Tested: Mysidopsis bahia
4. **CITATION:** Murphy, D. 1990. A 96-Hour Static Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia). Laboratory Study No. 108A-105A. Prepared by Wildlife International Ltd., Easton, MD. Submitted by Agricultural Division, Ciba-Geigy Corporation, Greensboro, NC. EPA MRID No. 416091-10.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
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KBN Engineering and
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Signature: *Louis M Rifici*
Date: *4/16/91*

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
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Signature: *P. Kosalwat*
Date: *4/17/91*

Henry T. Craven, M.S.
Supervisor, EEB/HED
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Signature: *Henry T. Craven*
Date: *4/23/91*

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute, static toxicity test for saltwater shrimp. Based on measured concentrations, the 96-hour LC₅₀ of Prometon for mysid shrimp was 17.7 mg a.i./L. Therefore, Prometon is classified as slightly toxic to mysid shrimp. The NOEC, based on the lack of significant mortality, was determined as 4.44 mg a.i./L.
8. **RECOMMENDATIONS:** N/A

9. BACKGROUND:10. DISCUSSION OF INDIVIDUAL TESTS: N/A11. MATERIALS AND METHODS:

A. Test Animals: Young mysid shrimp (Mysidopsis bahia) were obtained from in-house cultures. Females containing embryos with eyespots were separated from the culture 24 hours prior to the initiation of the test. Newly-released mysids were collected using wide-bore, disposable, polyethylene pipettes. Water temperature in the culture unit was 24.0° to 25.0°C and changes in water temperature did not exceed 3°C in any 72-hour period. The holding water had a pH of 7.9 and the salinity was 25 parts per thousand (ppt). The shrimp were free from signs of disease during the holding period.

B. Test System: The test chambers were 2-L glass beakers containing 1 L of test solution. The test solution depth was approximately 8 cm. The test chambers were immersed in a temperature-controlled water bath set to 25°±1°C. The laboratory environment was maintained on a 16-hour daylight photoperiod with 30-minute dawn and dusk simulations. Natural seawater, collected at Indian River Inlet, DE, was aerated and filtered (0.2 µm) before use as test dilution water. The salinity of the dilution water was 25 ppt and the pH was 8.1.

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 further with solvent and sonicated for an additional 20 minutes. The volume was adjusted to 100 mL and the solution swirled by hand. An appropriate amount of the stock solution was mixed with dilution water in Teflon®-lined 25-L polyethylene aquaria and the resulting solutions were gently mixed with a teflon-coated stirring rod. No precipitates were observed in the solutions.

C. Dosage: Ninety-six-hour static test. Six nominal concentrations (2.3, 4.7, 9.4, 18.8, 37.5, 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:** Mysid shrimp were impartially removed from holding tanks and distributed to plastic cups containing 5 mL of dilution water until each cup contained 10 individuals. The cups were dipped into the test chambers to release the shrimp. Two replicates were used, for a total of 20 individuals per concentration. A third replicate chamber was used (for the negative control, 2.33, 17.7, and 72.4 mg/L treatments) so water chemistry measurements could be made at 48 hours without disturbing the shrimp.

Observations of mortality and sublethal responses were made every 24 hours. The shrimp were fed live brine shrimp nauplii during the test.

The dissolved oxygen (D.O.) and pH were measured in each replicate of all concentrations and the controls at the beginning and end of the test and in the separate water chemistry chambers at 48 hours. The temperature of one of the control chambers was monitored continuously and each replicate of the test concentrations was 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 2.33, 4.44, 8.07, 17.7, 33.1, and 72.4 mg a.i./L. These values represent 86 to 101% of nominal concentrations (Table 1, attached).

The responses of mysid shrimp are given in Table 3 (attached). The 96-hour LC_{50} based on measured concentrations was 15.8 mg/L (95% C.I. = 12.0-21.1 mg/L). The slope of the concentration-response curve was 2.4. Lethal effects were observed at all concentrations. The no-observed-effect concentration (NOEC) was given as 4.44 mg/L.

Dissolved oxygen ranged from 6.0 to 7.6 mg/L in the vessels containing mysids. The pH values ranged from 7.9 to 8.2. The temperature was 24.4°-24.7°C throughout the test.

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

The author categorized Prometon as slightly toxic to mysid shrimp.

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, ASTM E 729-80 or Subdivision E guidelines as follows:

The concentration of each solution was approximately 50% of the next highest concentration. The SEP recommends that each concentration be 60% of the next highest concentration.

The recommended temperature for mysid shrimp toxicity tests is $22^{\circ}\pm 1^{\circ}\text{C}$. The temperature used in the study was approximately 25°C .

The salinity of the dilution water in the study was 25 ppt. The recommended salinity for estuarine shrimp is 10-17 ppt and for marine shrimp is 30-34 ppt.

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. Test should be initiated within 30 minutes of test solution preparation.

- B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC_{50} value and obtained a 48-hour LC_{50} of 17.7 with 95% confidence limits of 14.3 and 22.2 (see attached printout) by the moving average method. Of the three methods employed by the software, the results from moving average method gave the narrowest confidence interval for the LC_{50} .
- C. **Discussion/Results:** The water solubility of the test material was given in the report as 750 mg/L at 20°C . Considering the procedure used to get the material into

solution in triethylene glycol and the potential for complications resulting from the use of solvents in toxicity tests, the use of solvent in this test is questionable. The study report does not give any reasons why a stock solution was prepared in triethylene glycol. Concentrated stock solutions could have been made in test dilution water and thus removed solvent effects from the responses observed in the test.

This study is scientifically sound and meets the guideline requirements for a static acute saltwater shrimp toxicity study. The 96-hour LC_{50} of 17.7 mg a.i./L (based on measured concentrations) classifies Prometon as slightly toxic to mysid shrimp. The NOEC was determined as 4.44 mg a.i./L based on the lack of significant mortality.

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.

RJN-0334-94 PROMETON REVIEWS (088807)

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.

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY, THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

LOUIS M. RIFICI PROMETON MYSIDOPSIS BAHIA 2-25-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
72.4	19	19	100	1.907348E-04
33.1	19	14	73.6842	3.178405
17.7	19	8	42.1053	32.3803
8.07	19	5	26.3158	3.178405
4.44	19	0	0	1.907348E-04
2.33	19	0	0	1.907348E-04

THE BINOMIAL TEST SHOWS THAT 4.44 AND 72.4 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 20.61858

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	5.442779E-02	17.74362	14.24734	22.19759

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY	
4	9.364286E-02	1	.3789693	

SLOPE = 3.048325
 95 PERCENT CONFIDENCE LIMITS = 2.115503 AND 3.981146

LC50 = 17.9572
 95 PERCENT CONFIDENCE LIMITS = 13.94914 AND 23.37002

LC10 = 6.880442
 95 PERCENT CONFIDENCE LIMITS = 4.199957 AND 9.346048

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Shaughnessy No. 80804

Chemical Name Prometon Chemical Class _____ Page 1 of 1

Study/Species/Lab/
Accession _____ Chemical
_____ & a.i.

Reviewer/
Date _____ Validation/
Status _____

14-Day Single Dose Oral LD50

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

Species _____

Lab _____

Acc. _____

Comments:

14-Day Single Dose Oral LD50

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

Species _____

Lab _____

Acc. _____

Comments:

8-Day Dietary LC50

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

Species _____

Lab _____

Acc. _____

Comments:

8-Day Dietary LC50

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

Species _____

Lab _____

Acc. _____

Comments:

48-Hour LC50

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

Species _____

Lab _____

Acc. _____

Comments:

96-Hour LC50

LC50 = 17.7 ppm * 95% C.L. MOVING AVERAGE (14.3 - 22.2) Contr. Mort. (X) = .5
Sol. Contr. Mort. (X) = 5
Slope = N/A # Animals/Level = 20 Temp. = 25°C
96-Hour Dose Level ppm/(X Mortality)
2.33 (.5), 4.44 (5), 8.07 (30), 17.7 (45), 33.1 (75), 72.4 (100)

Species MYSIDOPSIS bahia

Lab Wildlife International LTD 98.5%

Acc. MRD 416091-10

Comments: measured concentration

96-Hour LC50

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

Species _____

Lab _____

Acc. _____

Comments:

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