12-3a 9-5-91

MRID No. 417760-01

DATA EVALUATION RECORD

1. **CHEMICAL:** Propanil-3,4-Dichloropropionilide. Shaughnessey No. 028201.

2. **TEST MATERIAL:** Propanil; Batch No. 01; 98 ±2% active ingredient; a blue-gray crystal.

3. **STUDY TYPE:** Marine Fish Acute Flow-Through Toxicity Test. Species Tested: Sheepshead Minnow (Cyprinodon variegatus).

4. **CITATION:** Sousa, J.V. 1990. (Propanil) - Acute Toxicity to Sheepshead Minnow (Cyprinodon variegatus) Under Flow-Through Conditions. SLI Report No. 90-02-3227. Prepared by Springborn Laboratories, Inc., Wareham, Massachusetts. Submitted by The Propanil Task Force, c/o John M. Wise, Liberty, Missouri. EPA MRID No. 417760-01.

5. **REVIEWED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature:

Date:

6. **APPROVED BY:**

Louis M. Rifici, M.S.
Associate Scientist
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Date:

Henry T. Craven, M.S.
Supervisor, EEB/HED
USEPA

Signature: Dan Barlow

Date: 9-5-91

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute flow-through toxicity study. The 96-hour LC_{50} of Propanil for Cyprinodon variegatus was 4.6 mg a.i./L, based on mean measured concentrations. Therefore, Propanil is classified as moderately toxic to sheepshead minnow. The NOEC, based on the lack of sublethal effects, was 0.72 mg a.i./L.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

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5. **REVIEWED BY:**

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Date: 5/30/91

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Signature: Louis M Rifici
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Date:

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8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

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11. **MATERIALS AND METHODS:**

A. **Test Animals:** The test organisms were obtained from Aquatic Biosystems, Inc., Colorado. The fish were maintained in natural seawater with a salinity of 30-34 parts per thousand (ppt), a pH range of 7.3-7.5, and a dissolved oxygen range of 71-77%. The temperature was maintained at 21-23°C. The photoperiod was 16-hour light/8-hour dark. The fish were fed a commercial flake food daily ad libitum. The fish were maintained in this environment for a minimum of 14 days.

A representative sample of 30 fish had a mean wet weight of 0.29 g (0.12-0.62 g) and a mean total length of 26 mm (20-32 mm).

B. **Test System:** The test system consisted of a continuous flow serial diluter, a temperature controlled water bath, and 14 aquaria (39 X 20 X 25 cm) with 19.5 cm standpipes to regulate volume. The total volume in each aquarium was 15 L. The flow rate was adequate to fully exchange the solution in each tank 6.5 times every 24-hours. The aquaria were impartially positioned in the water bath which was designed to maintain the test temperature at 22°±1°C. The photoperiod during the test was the same as that used during the holding period with a light intensity of 30-80 footcandles (approximately 330-880 lux).

C. **Dosage:** Ninety-six-hour flow-through test. Based on the results of a preliminary test, five nominal concentrations were used (2.6, 4.3, 7.2, 12.0, and 20.0 mg a.i./L). In addition, a dilution water control and a solvent control (74 µL acetone/L) were employed. The author adjusted the concentrations to reflect 100% active ingredient (based on 98% of active ingredient in the test material).

A stock solution was prepared by diluting 69.39 g of Propanil to 250 mL with acetone, resulting in a concentration of 272 mg a.i./mL. The test substance stock solution was pumped into the mixing chamber of the diluter. A concentration equal to the highest test concentration was produced in the mixing chamber which was subsequently diluted with test dilution water to produce the remaining test concentrations. A similar system was used for the solvent control. Each solvent replicate received the greatest amount of solvent introduced into the test aquaria.

D. **Design:** Ten fish were selected and distributed to each replicate aquarium. Each concentration level consisted of two replicate aquaria, resulting in 20 fish per test level or control. At any level, the organism loading concentration per liter of test solution was less than 0.03 g.

Mortality, biological observations, and the presence or absence of precipitates were noted every 24 hours. Dead fish were removed at each 24 hour observation. The dissolved oxygen, pH, salinity, and temperature were measured daily in all control and test concentration replicates. The temperature was also measured continuously using a minimum/maximum thermometer.

Chemical analyses of solution from Day 0 and 4 of the test were performed to verify the actual concentrations.

E. **Statistics:** Three statistical analyses were applied to the mortality data, 1) moving average angle, 2) probit, and 3) binomial probability. For this test the binomial method was used to report the LC_{50} (Stephan, 1977, 1982).

12. **REPORTED RESULTS:** Records of test parameters are presented in Table 1 (attached). Results of analyses of the exposure concentrations are presented in Table 2 (attached). The mortality and observation data based on mean measured concentrations are presented in Table 3 (attached). Table 4 (attached) summarizes the LC_{50} values.

Based on chemical analyses for active ingredient, the mean measured concentrations were 0.72, 1.9, 3.4, 5.8, and 8.8 mg a.i./L. Measured concentrations were fairly consistent between sampling days.

"Following 96 hours of exposure, 100 and 95% mortality was recorded in the two highest mean measured concentrations of Propanil tested (8.8 and 5.8 mg a.i./L, respectively). During the same period, no mortality was observed in the remaining treatment levels (3.4, 1.9, and 0.72 mg a.i./L Propanil, respectively.) Sublethal effects (e.g. lethargic behavior, loss of equilibrium) were observed among fish exposed to 3.4 and 1.9 mg a.i./L Propanil."

The 96-hour LC_{50} was 4.6 mg a.i./L (95% confidence limits of 3.4 and 5.8 mg a.i./L). The NOEC, based on the absence of sublethal effects, was 0.72 mg a.i./L.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** "Based on criteria established by EPA (1985), Propanil is classified as moderately toxic to Cyprinodon variegatus."

A Good Laboratory Practice Compliance Statement was included in the report, indicating that the study was in accordance with GLP regulations with the following exceptions: "stability , characterization and verification of the test substance identity and maintenance of records on the test substance is the responsibility of the test Sponsor." This statement was signed by representatives of the performing laboratory and the sponsor. In addition, a Quality Assurance Unit Statement was presented in the report and sign by a quality assurance representative of the performing laboratory.

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, except for the following deviations:

The test organisms were "selected and distributed" into the test chambers. The SEP recommends random assignment of test organisms to test chambers.

The recommended photoperiod for a fish acute toxicity study is 16-hour light/8-hour dark with a 15- to 30-minute transition period. No transition period was mentioned in the report.

The pH of the test conditions (7.8-8.0) deviated from SEP guidelines (8.0-8.3).

The raw data from the min/max thermometer were presented in the report. The author indicated that this data demonstrated a temperature range of 19-26°C during the last 24 hours of the test period. The SEP recommends a temperature 22°$\pm$1°C.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC_{50} value and obtained the same results as the author (see attached printout).

C. **Discussion/Results:** Deviations listed in Section 14A probably did not affect the results of the study. However, the registrant should take measures in future studies to ensure that the test temperature is maintained within the recommended limits.

This study is scientifically sound and meets the guideline requirements for a acute flow-through toxicity study. The 96-hour LC_{50} of 4.6 mg a.i./L (95% confidence interval of 3.4-5.8 mg a.i./L), based on mean measured concentrations, indicates that Propanil is moderately toxic to sheepshead minnow. The NOEC was 0.72 mg a.i./L, the lowest concentration tested.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

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

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

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, May 4, 1991.

Page_____ is not included in this copy.

Pages 7 through 11 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.

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.

Rosemary Graham Mora Propanil Cyprinodon variegatus 05-03-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
8.8	20	20	100	9.536742E-05
5.8	20	19	95	2.002716E-03
3.4	20	0	0	9.536742E-05
1.9	20	0	0	9.536742E-05
.72	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.4 AND 5.8 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 4.599287

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.

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Shaughnessey # 028201 Chemical Name Propanil 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}	98+2%	LC_{50} = 4.6 ppm* (95% C.L. binomial) (3.4, 5.8) Control Mortality (%) = 0 Solvent Control Mortality (%) = 0		
Species: Cyprinodon variegatus		Slope = — # Animals/Level = 20 Temperature = 22	Kelly 5/4/91	Core
Lab: Springborn Labs		96-Hour Dose Level ppm* /(% Mortality) 0.72 (0), 1.9 (0), 3.4 (0), 5.8 (95), 8.8 (100)		
MRID # 417760-01		Comments: *Based on mean measured concentrations.		

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