6-4-91

MRID No. 417768-01

DATA EVALUATION RECORD

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

2. **TEST MATERIAL:** Propanil-4-Isophorone Formulation; 44% active ingredient (as determined by performing laboratory); a dark liquid.

3. **STUDY TYPE:** Freshwater Invertebrate Acute Flow-Through Toxicity Test. Species Tested: Daphnia magna.

4. **CITATION:** Burgess, D. 1990. Acute Flow-Through Toxicity of Propanil-4-Isophorone Formulation to Daphnia magna. ABC Final Report No. 37770. Performed by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri. Submitted by Propanil Task Force, c/o John M. Wise Associates, Liberty, Missouri. EPA MRID No. 417768-01.

5. **REVIEWED BY:**

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

Signature: Rosemary Graham Mora
Date: 5/30/91

6. **APPROVED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
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Signature: Louis M Rifici
Date: 6/4/91

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

Signature:
Date:

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute flow-through toxicity test for freshwater invertebrates. The 48-hour EC_{50} of Propanil-4-Isophorone Formulation was 1.2 mg/l, therefore this formulation is classified as moderately toxic to Daphnia magna. The NOEC, based on the absence of sublethal effects, was 0.59 mg/l.

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Daphnia magna (<24 hours old) were obtained from populations cultured at the testing facility (originally obtained from the Columbia National Fisheries Research Laboratory, Missouri). The cultures were maintained in a temperature controlled area (20°±2°C) on a 16-hour daylight photoperiod with 30-minute dawn and dusk simulations. The daphnids were fed green algae (Selenastrum capricornutum) supplemented with a Tetramin®/cereal leaves/yeast suspension.

B. **Test System:** The test system was a 500-ml proportional diluter apparatus. Test vessels were glass beakers with a solution volume capacity of 1-L. Each beaker drained through a notched drain covered with 50-mesh stainless steel screen. The test vessels were immersed in a temperature-controlled bath, set to maintain 20°±1°C. The diluter delivered test solutions to each vessel (via 14-gauge hypodermic needles) at an average rate of 6.1 volume replacements every 24-hours.

The dilution water, a blend of reverse-osmosis water and ABC well water, had a total hardness of 160-180 mg/l as $CaCO_3$.

The test photoperiod was the same as that used for culturing with a light intensity of 50-70 footcandles.

C. **Dosage:** Forty-eight-hour acute flow-through test. Five nominal test concentrations (0.12, 0.24, 0.50, 1.0, and 2.0 mg/l), based on results of a range-finding study, were used in the study. A dilution water control and a solvent (0.01 mL acetone/L) control were also used.

Diluter stock solution was prepared by diluting 1.9995 g of formulated test substance to 100 ml with acetone, creating a concentration of 20,000 mg/l.

D. **Design:** Ten daphnids were randomly assigned and distributed to each exposure vessel (4 replicate vessels/concentration). The daphnids were not fed during the 48-hour test period.

Observations of survival and abnormal effects were made every 24 hours. Temperature, dissolved oxygen concentration (DO), and pH were measured in the controls, high, medium and low concentrations at test initiation and in all test concentrations at test termination. Temperature in the water bath was monitored continuously. The hardness of all concentrations was determined at test termination.

At 0 and 48 hours, 10 mL of test solution were collected from each vessel and pooled by concentration. The concentration of Propanil-4-Isophorone was determined by high pressure liquid chromatography (HPLC).

E. **Statistics:** The LC_{50} (EC_{50}) value and 95% confidence limits were determined using a computer program developed by Stephan (1977).

12. **REPORTED RESULTS:** Results of HPLC analyses indicated mean measured concentrations were <0.202, 0.27, 0.59, 1.1, and 2.3 mg/l of formulated test substance (Table 3, attached). The measured concentrations were fairly consistent between sampling days and the test material was not detected in the lowest tested concentration.

The 24-hour and 48-hour LC_{50} values (95% confidence interval) for Propanil-4-Isophorone Formulation based on "mortality" were 2.1 mg/L (1.8-2.6 mg/L) and 1.2 mg/l (1.0-1.3 mg/L), respectively. The 48-hour dose-response slope was calculated to be 5.4. Statistical analyses were based on the mean measured concentrations: 0.27, 0.59, 1.1, and 2.3 mg/l. The 48-hour no-effect-concentration based on the lack of mortality or other abnormal effects was considered to be 0.59 mg/l. Signs of lethal and/or sublethal effects were observed in the 0.27, 1.1, and 2.3 mg/l test concentrations (Table 6, attached). The effects demonstrated in 0.27 mg/l test solution were not attributed to effects of the toxicant.

The dissolved oxygen concentrations in this study ranged from 7.5 to 8.0 mg/l which represented 86 and 92% saturation at 20°C, respectively. The pH range was 7.7-7.8. Constant monitoring demonstrated min/max temperatures of 19.6-21.2°C. The total hardness was 110-112 as $CaCO_3$.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** No conclusions were presented in the report.

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A GLP compliance statement was included in the report indicating that the data and report prepared for this study were produced and compiled in accordance with EPA Good Laboratory Practice Standards. This statement was signed by the Study Director and representatives of the study sponsor.

A Quality Assurance Statement was included and signed by representatives of the Quality Assurance Unit of the preforming 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, but deviated from the SEP and Subdivision E as follows:

The report did not indicate aeration of the blended water prior to test initiation. Reconstituted water should be aged one to two weeks and intensely aerated prior to use.

The length of the acclimation period of the test organism to test conditions was not indicated in the report. A seven-day acclimation period to test conditions is recommended.

The length of time between solution preparation and test initiation was not reported.

The test material was not identified by Lot or Batch number.

The test material is 56% inert or carrier ingredients. A control containing the concentration of inert or carrier ingredients equivalent to that found in the highest tested concentration should have been included in the test design.

No observations of pretest mortality or health of the source culture(s) were given in the report.

First instar test organisms should be from the fourth or later broods of a given parent. The author did not indicate which brood was the source of the test animals.

The test concentrations selected for this study were not 60% of the next highest concentrations as recommended in the SEP.

4 8

The report did not indicate the depth of test solution maintained in test vessel.

The study employed five test concentrations, however the lowest nominal concentration (0.12 mg/l) was below the detectable limit. The author conducted statistical analyses using only the four concentrations within the detection limit.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal to calculate the EC_{50} value and 95% confidence interval. The reviewer's results were the same as the LC_{50} values presented by the author.

C. **Discussion/Results:** Given the results of the controls, it is probable that the above mentioned deviations did not affect the results of the study.

The study was conducted using a formulated test product (44% active ingredient), therefore the results of the study should be used for environmental risk assessment of the formulated product only.

The study is scientifically sound and meets the requirements for an acute flow-through toxicity test using Daphnia magna. The 48-hour EC_{50} was 1.2 mg/l, which indicates that Propanil-4-Isophorone is moderately toxic to Daphnia magna. This classification applies only to the whole material as tested. The NOEC, based on the lack of toxicant-related sublethal effects, was 0.59 mg/l.

D. **Adequacy of the Study:**

(1) Classification: Core (for formulated substance).

(2) Rationale: N/A.

(3) Repairability: N/A.

15. **COMPLETION OF ONE-LINER:** Yes, May 6, 1991.

✓ Sent 5/6

Rosemary Graham Mora Propanil-4-Isophorone Formulation Daphnia magna
05-06-91

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
3.3	40	33	82.5	0
		5	7.5	
.23	40	0	0	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 1.002848

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	4.296495E-02	1.175635	1.039159	1.33456

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	2.169436	6.109127	2.222359E-03

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 4.548022
95 PERCENT CONFIDENCE LIMITS =-2.150762 AND 11.24681

LC50 = 1.202578
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = .6322239
95 PERCENT CONFIDENCE LIMITS = 0 AND 1.45478

RIN 1876-95

PROPANIL EEB - REVIEW

Page____ is not included in this copy.

Pages 7 through 8 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.

__V__ 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.

Shaughnessey # 028201 Chemical Name Propanil-4-Isophorone Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validation Status

48-Hour EC_{50}	44%	EC_{50} = 1.2 ppm* (95% C.L. Moving Average 1.0, 1.3) Control Mortality (%) = 0
		Solvent Control Mortality (%) = 0
		Species:
		Slope = 5.4 # Animals/Level =
		Temperature = 20-21°C
		Lab: Analytical Bio-Chemistry Labs.
		48-Hour Dose Level pp m*/(% Effect)
		( ), ( ), ( ), ( ), ( )
		MRID # 41776801
		Comments: *Based on mean measured concentrations of formulated test ~~product~~ substance.
			RDM 5/6/91	Core

96-Hour LC_{50}	_____	LC_{50} = pp (95% C.L.) Control Mortality (%) = Solvent Control Mortality (%) = Species: Slope = # Animals/Level = Temperature = Lab: 96-Hour Dose Level pp /(% Mortality) ( ), ( ), ( ), ( ), ( ) MRID # Comments:	_____	_____