

US EPA ARCHIVE DOCUMENT

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9-21-92

MRID No. 416420-01

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Iprodione.
Shaughnessey No. 109801.
- 2. **TEST MATERIAL:** Iprodione Technical; Lot No. 89062 01; 96.2% active ingredient; an off-white granular powder.
- 3. **STUDY TYPE:** Freshwater Invertebrate Flow-Through Acute Toxicity Test. Species Tested: *Daphnia magna*.
- 4. **CITATION:** McNamara, P.C. 1990. Iprodione Technical - Acute Toxicity to Daphnids (*Daphnia magna*) During a 48-Hour Flow-Through Exposure. SLI Report No. 90-7-3380. Prepared by Springborn Laboratories, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416420-01.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Louis M Rifici*
Date: *7/9/92*

6. **APPROVED BY:**

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

Signature: *Rosemary Graham Mora*
Date: *7/9/92*

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

Signature: *Henry T. Craven*
Date: *10/16/92*

7. **CONCLUSIONS:** This study is not scientifically sound. Immobilization in the dilution water control and solvent control averaged 5 and 10%, respectively, which did not meet the guideline requirements. The 48-hour EC₅₀ was 0.24 mg a.i./l, therefore, Iprodione technical is classified as highly toxic to daphnids. Since sublethal effects were observed at all exposure levels, an NOEC value could not be estimated.

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

9. **BACKGROUND:**

INVALID

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.**11. MATERIALS AND METHODS:**

A. Test Animals: *Daphnia magna* (≤ 24 hours old) were obtained from in-house cultures maintained under a 16-hour light photoperiod (light intensity = 40-45 ft-candles) at $20 \pm 2^\circ\text{C}$. The culture water was well water filtered through a resin column (Amberlite XAD-7) and a carbon filter to remove any organic contaminants then fortified to a hardness of 160-180 mg/l and an alkalinity of 110-130 mg/l as CaCO_3 . The pH was 7.9-8.3 and the conductivity was 400-600 $\mu\text{mhos/cm}$. The cultures were fed *Ankistrodesmus falcatus* and a trout food suspension once daily.

B. Test System: An intermittent-flow proportional diluter with a 60% dilution factor was used. An Iprodione stock solution (16 mg a.i./ml) was prepared in acetone and delivered to the diluter mixing chamber during each cycle resulting in the high nominal test concentration of 1.2 mg a.i./l. This solution was diluted to give the lower concentrations. The flow of test solution from the mixing/splitting chambers into the test chambers was restricted using glass capillary tubes (1 mm I.D.) to minimize turbulence in the chambers. Test solutions were delivered at an approximate rate of 6 volume replacements per day.

The test vessels were made of glass and contained a constant solution volume of 1.8 l. The test solution depth was approximately 14 cm. The diluter and exposure vessels were housed in a temperature-controlled laboratory ($20 \pm 1^\circ\text{C}$). The test area was illuminated at an intensity of 20-44 ft-candles using fluorescent tubes on a 16-hour light/8-hour dark photoperiod.

The dilution water was from the same source as that used in culturing. The water quality was described as a total hardness of 160 mg/l as CaCO_3 , an alkalinity of 110-120 mg/l as CaCO_3 , a pH of 8.2-8.3, and a conductivity of 500 $\mu\text{mhos/cm}$.

C. Dosage: Forty-eight-hour, flow-through, acute toxicity test. Based on preliminary testing, five nominal concentrations (0.16, 0.26, 0.43, 0.72, and 1.2 mg a.i./l), an acetone control (0.076 ml/l), and a dilution water control were selected for the test.

- D. **Design:** Two chambers were used for each concentration with ten impartially-selected daphnids per chamber. The number of immobilized daphnids observed was recorded daily. Observations of sublethal effects and of the physical characteristics of the test solutions were made at test initiation and every 24 hours thereafter. The daphnids were not fed during the test.

Dissolved oxygen concentration, pH, and temperature were measured once daily in all replicates. At test initiation, hardness, alkalinity, and conductivity in one replicate vessel of each level were determined. The temperature of one vessel was also monitored continuously using a minimum/maximum thermometer.

Water samples from both replicates of each concentration and the controls were taken daily. The concentration of Iprodione was determined using high performance liquid chromatography.

- E. **Statistics:** The 48-hour median effective concentration (EC_{50}) and associated 95% confidence interval (C.I.) were calculated using the moving average angle method.

12. **REPORTED RESULTS:** Based on day 1 and 2 measured concentrations, the mean measured concentrations were 0.075, 0.11, 0.17, 0.34, and 0.49 mg/l and averaged 43% of nominal (Table 3, attached). "Throughout the exposure period, the test solutions were clear and contained no visible sign of undissolved material."

Daphnid responses were presented in Table 4 (attached). All daphnids were immobilized at 0.49 mg/l and sublethal effects were observed at all exposure levels. Twenty percent immobilization occurred in a solvent control replicate and 10% occurred in a dilution water control replicate. The 48-hour EC_{50} was 0.25 mg a.i./l (95% C.I. = 0.21-0.31 mg a.i./l). The no-observed-effect concentration (NOEC) was 0.075 mg a.i./l.

The dissolved oxygen concentration during the test was 8.0 to 8.8 mg/l and the pH was 7.8 to 8.2. The results of continuous temperature monitoring established the test temperature was 19 to 23°C.

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

"Based on criteria established by U.S. E.P.A. (1985), Iprodione Technical would be classified as highly toxic to *Daphnia magna*."

Quality Assurance and GLP Compliance Statements were included in the report indicating adherence to USEPA GLP Regulations. The dates of study inspections were also included.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

- A. Test Procedure:** The test procedures generally adhered to the SEP, except for the following:

Immobilization in the control replicates ranged from 0 to 20% and averaged 5 and 10% in the dilution water control and solvent control, respectively. The SEP states that a flow-through test is unacceptable if more than 5% of the control daphnids die (i.e., are immobilized) during the study.

The temperature during the study (19-23°C) was occasionally higher than recommended (20 ±1°C).

The stock solution concentration was incorrectly reported as 16 mg a.i./l on page 12 of the report. The correct concentration was 16 mg a.i./ml.

- B. Statistical Analysis:** The reviewer used EPA's Toxanal program and the mean of all three daily measurements (Table 3, attached) to determine the 48-hour EC₅₀ value as 0.24 mg a.i./l (95% C.I. = 0.20-0.31 mg a.i./l).

- C. Discussion/Results:** This study is not scientifically sound. Immobilization in the dilution water control and solvent control averaged 5 and 10%, respectively. The author did not attempt to explain the control results but it seems likely that some unidentified stress was present during the test (e.g., variable temperature) or during culturing. The 48-hour EC₅₀ was 0.24 mg a.i./l, therefore, Iprodione technical is classified as highly toxic to daphnids. Since sublethal effects were observed at all exposure levels, an NOEC value could not be estimated.

- D. Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** Immobilization in the dilution water control and solvent control averaged 5 and 10%, respectively.

(3) Repairability: No.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 06-08-92.

IPRODIONE

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.

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.

RIFICI IPRADIONE DAPHNIA MAGNA 6-8-92

| CONC. | NUMBER EXPOSED | NUMBER DEAD | PERCENT DEAD | BINOMIAL PROB. (PERCENT) |
|--------------|----------------|-------------|--------------|--------------------------|
| .43 | 18 | 18 | 100 | 3.814697E-04 |
| .3 | 18 | 6 | 33.3333 | 11.89423 |
| .14 | 18 | 1 | 5.5556 | 7.247925E-03 |
| .089 | 18 | 1 | 5.5556 | 7.247925E-03 |
| 6.800001E-02 | | 20 | 1 | 5 |
| 2.002716E-03 | | | | |

THE BINOMIAL TEST SHOWS THAT .14 AND .43 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 .3216694

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

| SPAN | G | LC50 | 95 PERCENT CONFIDENCE LIMITS |
|----------|--------------|------------|------------------------------|
| 4 | 6.419803E-02 | ← .2394388 | .1983833 - .3059668 |
| .3059668 | | | LMR 6/8/92 |

RESULTS CALCULATED USING THE PROBIT METHOD

| ITERATIONS | G | H | GOODNESS OF FIT PROBABILITY |
|------------|----------|----------|-----------------------------|
| 5 | 1.477027 | 4.568165 | 3.336549E-03 |

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

SLOPE = 3.903115
95 PERCENT CONFIDENCE LIMITS = -.8404579 AND 8.646689

LC50 = .2674083
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = .1264136
95 PERCENT CONFIDENCE LIMITS = 0 AND .2602768

Shaughnessey # 109801 Chemical Name Proprione Chemical Class _____ Page 1 of 1

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

48-Hour EC₅₀ 96.2 EC₅₀ - 0.24 * 95% C.L. MOVING AVERAGE ppm (0.20-0.31) Control Mortality (%) - 5
Immobility

Solvent Control Mortality (%) - 10

Species: Paphius marginatus Slope - N/A # Animals/Level - 20 Temperature - 19-23°C

Lab: Springborn Labs. Inc. 48-Hour Dose Level ppm (% Effect) LMR Invald
MRID # 4116920-01 0.068 (5), 0.089 (15), 0.14 (15), 0.30 (40), 0.43 (100) 6/8/92

Comments: * mean measured concentrations

96-Hour LC₅₀ _____ 95% C.L. _____ Control Mortality (%) - _____
pp (_____)

Solvent Control Mortality (%) - _____

Slope - _____ # Animals/Level - _____ Temperature - _____

Lab: _____
MRID # _____
96-Hour Dose Level pp / (% Mortality) _____
() , () , () , () , ()

Comments: _____