

US EPA ARCHIVE DOCUMENT

70-16-92

EEB.105

MRID No. 416041-05

DATA EVALUATION RECORD

- 1. **CHEMICAL:** Iprodione.  
Shaughnessey No. 109801.
- 2. **TEST MATERIAL:** Iprodione Technical; Lot # 89062 01; CAS 36734-19-7; 96.2% active ingredient; an off white granular solid.
- 3. **STUDY TYPE:** Freshwater Fish Acute Flow-Through Toxicity Test. Species Tested: Rainbow Trout (Oncorhynchus mykiss).
- 4. **CITATION:** Sousa, J.V. 1990. Iprodione Technical - Acute Toxicity To Rainbow Trout (Oncorhynchus mykiss) Under Flow-Through Conditions. SLI Report No. 90-5-3331. Prepared by Springborn Laboratories, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-05.

5. **REVIEWED BY:**

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

Signature: *Louis M. Rifici*  
Date: 5/1/91

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.  
Senior Scientist  
KBN Engineering and  
Applied Sciences, Inc.

Signature: *P. Kosalwat*  
Date: 5/1/91

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

Signature: *Henry T. Craven*  
Date: 5/16/92

7. **CONCLUSIONS:** This study is not scientifically sound. The concentration of the test material was not consistent between sampling times indicating the concentrations the fish were exposed to were unknown. Under the conditions of the test, the 96-hour LC<sub>50</sub> value of Iprodione Technical for rainbow trout was 4.1 mg/L (mean measured). Therefore, Iprodione is classified as moderately toxic to rainbow trout. Sublethal or lethal effects were observed at all test levels except the controls. The NOEC, therefore, was less than the lowest concentration tested, 1.0 mg/L (mean measured).

Signature: *James P. McA...* 9-21-92  
Date:

6 hrs

8. **RECOMMENDATIONS:** Repeat the test and, if precipitates are present in the test chambers, filter the water samples before extraction and chemical analysis.

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Rainbow trout (*Oncorhynchus mykiss*) were obtained from a commercial supplier in California. The fish were maintained in flowing well water (7.4-8.2 tank volume replacements/day) and fed a commercially available pelleted fish food, ad libitum, daily. Water quality characteristics of the well water and holding tank were a total hardness of 24-35 mg/L as CaCO<sub>3</sub>, a conductivity of 110-140  $\mu$ mhos/cm, a pH of 7.1-7.2, a dissolved oxygen (D.O.) concentration of 76-82% of saturation, an alkalinity of 24-35 mg/L as CaCO<sub>3</sub>, and a temperature of 11°-14°C. The laboratory was maintained on a 16-hour daylight photoperiod. A record of daily observations was kept.

The fish were acclimated to the laboratory for a minimum of two weeks. Feeding was discontinued 48 hours before the test. Mean weight and length of a representative group were 0.64 (0.36-0.97) g and 39 (35-43) mm, respectively. There was no mortality in the population in the 48 hours before test initiation.

B. **Test System:** The system consisted of 14 glass aquaria (39 x 20 x 25 cm), each containing approximately 15 L of test solution. A serial diluter delivered 68 mL/minute (or 6.5 volume replacements per day) of test solution or control water to the individual aquaria over the course of the study. The aquaria were impartially placed in a circulating water bath set to maintain 12°±1°C. The dilution water was the same as that used in holding/culturing. A 16-hour light/8-hour dark photoperiod and a light intensity of 40-100 ft-candles at the solution surface were used.

A 106 mg a.i./L diluter stock solution was prepared by diluting 27.61 g of Iprodione Technical to 250 mL with acetone. The stock was delivered to the diluter using a syringe pump.

C. **Dosage:** Ninety-six-hour flow-through test. Based on a preliminary test, five nominal concentrations (1.3, 2.2, 3.6, 6.0, and 10 mg/L), a dilution water control, and a solvent control (0.1 mg acetone/L) were used. The test concentrations were based on the percent active ingredient in the product.

D. **Design:** Ten rainbow trout were impartially selected and distributed to each aquarium. The biomass loading was 0.065 g/L/day. Observations of mortality and test solution characteristics were made every 24 hours. Dead fish were removed from the containers at each observation.

The temperature, dissolved oxygen (D.O.), and pH were measured once daily in each replicate of the exposure concentrations and the controls. The temperature was also monitored continuously in replicate B of the dilution water control. Alkalinity, hardness, and conductivity of one replicate of each test level were determined at test initiation.

Iprodione concentrations from each replicate aquarium were measured by high-pressure liquid chromatography from samples taken at test initiation and termination.

The fish were not fed during the test.

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. (1982).

12. **REPORTED RESULTS:** A precipitate was observed in the delivery system of the diluter and in all exposed aquaria.

The mean measured concentrations were 1.0, 1.9, 2.9, 3.9, and 7.0 mg/L. These values represent 65 to 86.4% of nominal concentrations (Table 3, attached). Measured concentrations between sampling days were fairly consistent.

The responses of rainbow trout are given in Table 4 (attached). The 96-hour  $LC_{50}$  was determined as 4.1 mg a.i./L with a 95% C. I. of 2.9-7.0 mg a.i./L. The no-observed-effect concentration (NOEC) was less than 1.0 mg a.i./L.

Dissolved oxygen ranged from 6.3 to 8.9 mg/L or 60 to 80% of saturation. The pH values ranged from 6.8 to 7.4. The temperature was 12.4°-13.9°C the test.

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

The author presented no conclusions.

Quality Assurance and Good Laboratory Practice Regulation Statements were included in the report, indicating that the study was conducted in accordance with all pertinent EPA Good Laboratory Practice Regulations.

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 as follows:

The recommended test temperature for rainbow trout is  $12^{\circ}\pm 1^{\circ}\text{C}$ . The temperature in this test was as high as  $13.9^{\circ}\text{C}$ .

A 30-minute dawn and dusk simulation is recommended in the SEP, but was not used in the study.

- B. Statistical Analysis: The reviewer used EPA's Toxanal program to calculate the  $\text{LC}_{50}$  value and obtained the same results (see attached printout).

- C. Discussion/Results: The two highest test levels exhibited the greatest variability in measured concentrations between sampling days. Additionally, measured concentrations between the two replicates of a given test level differed by as much as 30%. Average concentrations for a given exposure level increased or decreased between sampling days suggesting no pattern to the observed changes.

Precipitates were present in the test chambers, however, a filtration step in the sample preparation procedure which would have excluded solid material from the final solution to be analyzed, was not included. The author reports that the samples are taken from the approximate midpoint of the test chamber with a pipette. It should not be assumed that precipitated material does not float or is not stirred up by the fish when a technician takes the water sample thereby including solid material in the water sample. It is the opinion of the reviewer that precipitates contaminated the water samples and, since they were not

filtered away, led to the variation in measured concentrations found in the two highest test levels.

This study is not scientifically sound. The concentration of the test material was not consistent between sampling times indicating the concentrations the fish were exposed to are unknown. Under the conditions of the test, the 96-hour  $LC_{50}$  value of Iprodione Technical for rainbow trout was 4.1 mg/L (mean measured). Therefore, Iprodione is classified as moderately toxic to rainbow trout. Sublethal or lethal effects were observed at all test levels except the controls. The NOEC, therefore, was less than the lowest concentration tested, 1.0 mg/L (mean measured).

**D. Adequacy of the Study:**

- (1) **Classification:** Invalid.
- (2) **Rationale:** The concentration of the test material was not consistent between sampling times.
- (3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 03-14-91.

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I PRODIONE

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Page \_\_\_ is not included in this copy.

Pages 6 through 7 are not included.

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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.

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LOUIS M. RIFICI IPRODIONE ONCORHYNCHUS MYKISS 3-14-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
7	20	20	100	9.536742E-05
3.9	20	9	45	41.19014
2.9	20	0	0	9.536742E-05
1.9	20	1	5	2.002716E-03
1	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 2.9 AND 7 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 4.053566

THE MOVING AVERAGE METHOD CANNOT BE USED WITH THIS DATA SET BECAUSE NO SPAN WHICH PRODUCES MOVING AVERAGE ANGLES THAT BRACKET 45 DEGREES ALSO USES TWO PERCENT DEAD BETWEEN 0 AND 100 PERCENT.

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	2.229997	5.374005	1.070678E-03

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

SLOPE = 8.203845  
95 PERCENT CONFIDENCE LIMITS = -4.047099 AND 20.45479

LC50 = 4.065628  
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = 2.846573  
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

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Shughnessy No. 109801

Chemical Name Iprodione

Chemical Class \_\_\_\_\_

Page 1 of 1

Study/Species/Lab/  
Accession \_\_\_\_\_

Chemical  
# a.i.

Results

Reviewer/  
Date \_\_\_\_\_  
Validation  
Status \_\_\_\_\_

14-Day Single Dose Oral LD50

LD50 = mg/kg ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

14-Day Dose Level mg/kg/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

14-Day Single Dose Oral LD50

LD50 = mg/kg. ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

14-Day Dose Level mg/kg/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

8-Day Dietary LC50

LC50 = ppm ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

8-Day Dose Level ppm/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

8-Day Dietary LC50

LC50 = ppm ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = # Animals/Level = \_\_\_\_\_ Age (Days) = \_\_\_\_\_  
Sex = \_\_\_\_\_

Lab \_\_\_\_\_

8-Day Dose Level ppm/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

48-Hour LC50

LC50 = pp ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_  
Sol. Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = # Animals/Level = \_\_\_\_\_ Temperature = \_\_\_\_\_

Lab \_\_\_\_\_

48-Hour Dose Level pp/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_

96-Hour LC50

LC50 = 4.1 # 95% C.L. non-linear interpolation  
ppm ( 2.9 - 7.0 ) Contr. Mort. (X) = 0  
Sol. Contr. Mort. (X) = 0

Species Oncorhynchus mykiss

Slope = N/A # Animals/Level = 20 Temp. = 13°C

Lab Springborn Laboratories 96.2%

96-Hour Dose Level ppm/(X Mortality)  
1.0 (0) , 1.9 (5) , 2.9 (0) , 3.9 (45) , 7.0 (100)

LR  
3/14/91 Invalid

Acc. MRID 416041-05

Comments: \* Mean measured concentrations

96-Hour LC50

LC50 = pp ( 95% C.L. ) Contr. Mort. (X) = \_\_\_\_\_  
Sol. Contr. Mort. (X) = \_\_\_\_\_

Species \_\_\_\_\_

Slope = # Animals/Level = \_\_\_\_\_ Temperature = \_\_\_\_\_

Lab \_\_\_\_\_

96-Hour Dose Level pp/(X Mortality)  
( ) , ( ) , ( ) , ( ) , ( )

Acc. \_\_\_\_\_

Comments: \_\_\_\_\_