10/16/92 EEB files

MRID No. 416041-04

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: Bluegill Sunfish (Lepomis macrochirus).

4. **CITATION:** Sousa, J.V. 1990. Iprodione Technical - Acute Toxicity To Bluegill Sunfish (Lepomis macrochirus) Under Flow-Through Conditions. SLI Report # 90-5-3329. Prepared by Springborn Laboratories, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-04.

5. **REVIEWED BY:**

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

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

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
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Signature: P. Kosalwat
Date: 5/1/91

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

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

Dennis J. McLane 9-21-92

7. **CONCLUSIONS:** This study is not scientifically sound. The actual concentrations the bluegill were exposed to are unknown. Under the conditions of the test, the 96-hour LC_{50} value of Iprodione Technical for bluegill sunfish was 3.7 mg/L mean measured concentration. Therefore, Iprodione is classified as moderately toxic to bluegill sunfish. The NOEC, based on the lack of sublethal effects, was 2.3 mg/L mean measured concentration.

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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:** Bluegill sunfish (Lepomis macrochirus) were obtained from a commercial supplier in Connecticut. The fish were maintained in flowing well water (9.4-12 tank volume replacements/day) and fed a commercially available pelleted fish food, ad libitum, daily. Water quality characteristics of the well water were: a total hardness of 24-28 mg/L as $CaCO_3$, an alkalinity of 24-26 mg/L as $CaCO_3$, a conductivity of 140 µmhos/cm, a pH of 7.0-7.2, a dissolved oxygen (D.O.) concentration of 88-107% of saturation, and a temperature of 21°-23°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 0.91 (0.18-1.5) g and 41 (32-47) mm, respectively. There was 0.3% 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 test aquaria were impartially placed in a circulating water bath set to maintain 22°±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 30-90 ft-candles at the solution surface were used.

A 212.5 mg a.i./L diluter stock solution was prepared by diluting 55.22 g of Iprodione Technical to 250 mL with acetone. The stock was delivered to the diluter using a syringe pump.

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C. **Dosage:** Ninety-six-hour flow-through test. Based on a preliminary test, five nominal concentrations (2.6, 4.3, 7.2, 12, and 20 mg/L), a dilution water control and a solvent control (0.094 mL acetone/L) were used. The test concentrations were based on the percent active ingredient in the product.

D. **Design:** Ten bluegill were impartially selected and distributed to each aquarium (20 per treatment level). The biomass loading was 0.093 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 amount of precipitate decreased with decreasing test concentration.

The mean measured concentrations were 2.3, 2.6, 3.9, 5.4, and 7.9 mg a.i./L. These values represent 39.5 to 88.5% of nominal concentrations (Table 3, attached). Measured concentrations between sampling days decreased except in the lowest level, 2.3 mg a.i./L. The magnitude of change was greater in higher levels than in lower levels.

The responses of bluegill sunfish are given in Table 4 (attached). The 96-hour LC_{50} was determined as 3.7 mg a.i./L with a 95% confidence interval of 3.3-4.0 mg a.i./L.

The no-observed-effect concentration (NOEC) was determined to be 2.3 mg a.i./L.

Dissolved oxygen ranged from 4.0 to 8.0 mg/L or 46 to 91% of saturation. In test solutions containing live fish, the D.O. remained above 60% of saturation. The pH values ranged from 6.7 to 7.3. The temperature was 22.3°-22.8°C throughout 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:

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 LC_{50} value and obtained similar results (see attached printout).

C. **Discussion/Results:** 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. Under the conditions of the test, the 96-hour LC_{50} value of Iprodione Technical for bluegill sunfish was 3.7 mg

a.i./L. Therefore, Iprodione is classified as moderately toxic to bluegill sunfish. The NOEC, based on the lack of sublethal effects, was 2.3 mg a.i./L.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** The measured concentrations were not consistent throughout the exposure period. The actual concentrations the bluegill were exposed to are unknown.

(3) **Repairability:** No.

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

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.

X 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.

LOUIS M. RIFICI IPRODIONE TECHNICAL LEPOMIS MACROCHIRUS 3-13-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
7.9	20	20	100	9.536742E-05
5.4	20	18	90	2.012253E-02
3.9	20	19	95	2.002716E-03
2.6	20	0	0	9.536742E-05
2.3	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 2.6 AND 3.9 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 3.270293

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	5.135009E-02	3.668323	3.32062	4.02469

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	1.941912	6.388526	0

A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001.

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

SLOPE = 11.85111
95 PERCENT CONFIDENCE LIMITS =-4.663711 AND 28.36594

LC50 = 3.501382
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 2.735751
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

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Shaughnessey No. 109801 Chemical Name Iprodione Chemical Class ____ Page 1 of ____

Study/Species/Lab/ Accession	Chemical % a.i.	Results	Reviewer/ Date	Validatic Status
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg (95% C.L.) Contr. Mort.(%)=		
Species ____		Slope= # Animals/Level= Age(Days)= Sex =	____	____
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L) Contr. Mort.(%)=		
Species ____		Slope= # Animals/Level= Age(Days)= Sex =	____	____
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =	____	____
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =	____	____
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
48-Hour LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Temperature =	____	____
Lab ____		48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = 3.7 pp M (95% C.L. 3.3 – 4.0) Con. Mor(%)=0 Sol. Con. Mor.(%)= 0	LE 03/14/91	INVALID
Species Lepomis macrochirus		Slope= N/A # Animals/Level= 20 Temp.=		
Lab Springborn Labs, Inc. 96.2		96-Hour Dose Level pp M/(%Mortality) 2.3 (0), 2.6 (0), 3.9 (95), 5.4 (90), 7.9 (100)		
Acc. MRID 416 041-03		Comments: Mean measured concentrations		
96-Hour LC_{50}		LC50 = pp__ (95% C.L) Con. Mort.(%)= Sol. Con. Mort.(%)=		
Species		Slope= # Animals/Level= Temp.=	____	____
Lab ____		96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		