

DATA EVALUATION RECORD

1. **CHEMICAL:** Iprodione.
Shaughnessey No. 109801.
2. **TEST MATERIAL:** Iprodione technical; an off-white powder.
3. **STUDY TYPE:** 72-3. Marine Fish Acute Flow-Through Toxicity Test. Species Tested: Sheepshead minnow (*Cyprinodon variegatus*).
4. **CITATION:** Surprenant, D.C. 1988. Acute Toxicity of Iprodione Technical to Sheepshead Minnow (*Cyprinodon variegatus*) Under Flow-Through Conditions. SLS Report No. 87-11-2583. Prepared by Springborn Life Sciences, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 404892-05.
5. **REVIEWED BY:**

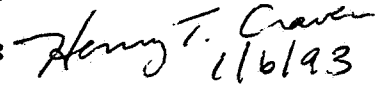
Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: 
Date: 12/22/92
6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
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Signature: P. Kosalwat
Date: 12/22/92

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

Signature: 
Date: 1/6/93
7. **CONCLUSIONS:** This study is scientifically sound but does not meet the requirements for an acute toxicity study using marine fish. The two highest test concentration solutions contained precipitates and it was not stated whether the solution samples were filtered. Additionally, the percent active ingredient of the test material was not reported. A 96-hour LC₅₀ value of 7.7 mg/l classifies iprodione as moderately toxic to the sheepshead minnow. A precise NOEC could not be determined.
8. **RECOMMENDATIONS:** N/A.

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

- A. Test Animals: Sheepshead minnows (*Cyprinodon variegatus*) were obtained from a commercial supplier in Massachusetts. The fish were maintained in recirculating seawater and fed a commercially available pelleted fish food, *ad libitum*, daily. Water quality characteristics of the seawater were: a salinity of 33-35 parts per thousand (ppt), a pH of 7.4-7.5, a dissolved oxygen (DO) concentration of 84-88% of saturation, and a temperature of 20-21°C. The culture area was maintained on a 16-hour daylight photoperiod.

The fish were acclimated to the laboratory conditions for a minimum of two weeks. Feeding was discontinued 48 hours before the test. Mean weight and length of a representative group were 0.20 (range of 0.05-0.44) g and 24 (range of 20-29) mm, respectively. There was no mortality in the population during the 48 hours before test initiation.

- B. Test System: The system consisted of 14 glass aquaria (39 x 20 x 25 cm) with 19.5-cm standpipes, each containing approximately 15 l of test solution. An intermittent-flow proportional diluter with a 65% dilution factor delivered 500 ml/cycle (or 6 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 22 ±1°C.

The dilution water was from the same source as that used in holding/culturing, which had been collected from Cape Cod Canal, Bourne, MA. The seawater was passed through 5- and 20-micron filters as well as an activated carbon filter. A 16-hour light/8-hour dark photoperiod was provided with a light intensity of 22-100 footcandles at the solution surface.

A 42.6 mg active ingredient (ai)/ml diluter stock solution was prepared by diluting 42.6 g of test material to 1 l with acetone. The stock was delivered to the diluter using a peristaltic pump.

- C. Dosage: Ninety-six-hour flow-through acute toxicity test. Based on preliminary tests, five nominal

concentrations (3.6, 5.5, 8.4, 13, and 20 mg/l), a solvent control (0.47 ml acetone/l of solution), and a dilution water control were selected for the definitive test.

- D. **Design:** Ten minnows were impartially distributed to each replicate treatment and control aquarium (for a total of 20 fish per test group). The loading rate was 0.022 g/l of flowing test solution per day. Observations of mortality, biological effects, and test solution characteristics were made every 24 hours. Dead fish were removed when observed.

The temperature, dissolved oxygen, and pH were measured once daily in each replicate of the exposure concentrations and the controls. Salinity of the dilution water was measured at initiation.

Water samples were taken from the approximate mid-point of each treatment and control aquarium at test initiation and termination and analyzed for the test material using high pressure liquid chromatography.

- 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 that employed three methods of analysis. The probit, moving average angle, and binomial probability methods were examined to determine the best-fitting model. The no-observed-effect concentration (NOEC) was defined as the highest concentration tested at and below which there were no toxicant-related mortalities or sublethal effects.

12. **REPORTED RESULTS:** Mean measured concentrations ranged from 50 to 64% of nominal (Table 1, attached). The concentrations were determined to be 2.2, 3.5, 5.1, 7.0, and 10 mg/l. The two highest concentration solutions contained precipitates.

The responses of the sheepshead minnows are presented in Table 2 (attached). The 96-hour LC_{50} was determined to be 7.7 mg/l with a 95% confidence interval of 7.1-8.4 mg/l. The NOEC was determined to be <2.2 mg ai/l, the lowest concentration tested, due to lethargy among all surviving fish.

Dissolved oxygen ranged from 7.0 to 8.5 mg/l or 72 to 93% of saturation. The pH was 7.9 and salinity was 31 ppt. The temperature was 21-22°C during the test.

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

The author presented no conclusions.

Quality Assurance and Good Laboratory Practice Statements were included in the report, indicating that the study was conducted in accordance with all pertinent EPA Good Laboratory Practice Regulations. However, the stability, characterization, and verification of the test substance is the responsibility of the study sponsor.

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

- A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the SEP, but deviated as follows:

The test material was not described. The purity, batch, and lot number should be reported. The author only stated that the test material was tested as 100% active ingredient.

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

Temperature was not monitored every six hours as recommended.

The salinity during the test was 31 ppt. The recommended salinity for euryhaline fish is 10-17 ppt.

- B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC₅₀ value and obtained the same results using the moving average angle method (see attached printout).

- C. **Discussion/Results:** It was not stated in the methods section whether the solution samples taken at test initiation and termination were filtered. Since there was undissolved test material in the two highest concentration test solutions, it is crucial that the samples be filtered to obtain the actual exposure concentrations.

After review of the sublethal effects observed, the reviewer concurs that the NOEC could not be determined

in this study due to effects observed at all test levels.

This study is scientifically sound but does not meet the requirements for an acute toxicity study using marine fish. A 96-hour LC_{50} value of 7.7 mg ai/l classifies iprodione as moderately toxic to the sheepshead minnow. The NOEC could not be determined due to sublethal effects at all test concentrations.

D. Adequacy of the Study:

- (1) **Classification:** Supplemental.
- (2) **Rationale:** The highest two test concentration solutions contained precipitates and it was not stated whether the solution samples were filtered. The purity of the test material was not reported.
- (3) **Repairability:** Yes, this study can be upgraded to "core" pending satisfactory submission of the sampling methodology and test material purity.

15. COMPLETION OF ONE-LINER FOR STUDY: Yes, 12-16-92.

I PRODIONE

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.
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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.

MOSSLER IPRODIONE CYPRINODON VARIEGATUS 12-16-92

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
10	20	20	100	9.536742E-05
7	20	3	15	.1288414
5.1	20	1	5	2.002716E-03
3.5	20	0	0	9.536742E-05
2.2	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 7 AND 10 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 7.934457

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
2	6.572952E-02	7.667109	7.114758 8.357081

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
10	1.411952	3.027311	2.822119E-02

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

SLOPE = 14.12951
95 PERCENT CONFIDENCE LIMITS = -2.659962 AND 30.91898

LC50 = 7.657971
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = 6.226313
95 PERCENT CONFIDENCE LIMITS = 0 AND 7.775314

Ecological Effects Branch One-Linear Data Entry Form

Chemical Iprodione Shaughnessy No. 108801 Pesticide Use Fungicide

AQUATIC VERTEBRATE TOX.	% AI	LC ₅₀ (95%CL) SLOPE	HRS/ TYPE	NOEC	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1. <i>Sheepshead minnow</i> <i>Cyprinodon variegatus</i>	NR	7.7mg / (1.1-8.4mg / 11) N/A	96 hr / Flow-Through	could not be determined	1988 / 1992	404/092-05 / Supplemental	SLF	MM
2.								
3.								
4.								
5.								
6.								
7.								
CHRONIC TOX.	% AI	MATC LC ₅₀	DAYS	AFFECTED PARA.	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1.								
2.								
3.								

COMMENTS: % active ingredient not reported (NR)
SLI = Springborn High Sciences, Inc.