1-6-93

DATA EVALUATION RECORD

1. **CHEMICAL**: Iprodione.
Shaughnessey No. 109801.

2. **TEST MATERIAL**: Rovral 50 WP; 50% active ingredient (iprodione); a tan powder.

3. **STUDY TYPE**: 72-1. Freshwater Fish Acute Flow-Through Toxicity Test. Species Tested: Bluegill sunfish (*Lepomis macrochirus*).

4. **CITATION**: Surprenant, D.C. 1987. Acute Toxicity of Rovral 50 WP to Bluegill (*Lepomis macrochirus*) Under Flow-Through Conditions. SLS Report No. 87-12-2578. Prepared by Springborn Life Sciences, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 404892-03.

5. **REVIEWED BY**:

Mark A. Mossler, M.S.   **Signature**:
Associate Scientist
KBN Engineering and   **Date**:   12/22/92
Applied Sciences, Inc.

6. **APPROVED BY**:

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

Henry T. Craven, M.S.   **Signature**: Henry T. Craven
Supervisor, EEB/EFED
USEPA   **Date**:   1/6/93
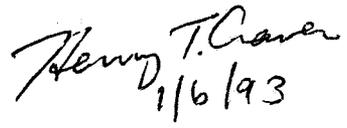
1-6-93

7. **CONCLUSIONS**: This study is scientifically sound but does not meet the requirements for an acute toxicity study using freshwater fish. Undissolved test material was present in all test chambers and it was not stated whether the solution samples were filtered. A 96-hour LC_{50} value of 7.8 mg ai/l classifies Rovral 50 WP as moderately toxic to bluegill sunfish. A precise NOEC could not be determined.

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

b

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 Nebraska. The fish were maintained in flowing well water (5.1-5.6 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 30-32 mg/l as $CaCO_3$, an alkalinity of 26-30 mg/l as $CaCO_3$, a conductivity of 100-110 μmhos/cm, a pH of 6.9-7.0, a dissolved oxygen (DO) concentration of 93-95% of saturation, and a temperature of 20-22°C. The laboratory was maintained on a 16-hour light photoperiod.

   The fish were acclimated to the laboratory for a minimum of twelve days. Feeding was discontinued 48 hours before the test. Mean weight and length of a representative group were 1.5 (range of 1.03-2.68) g and 49 (range of 44-56) 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) containing approximately 15 l of test solution for a depth of 19.5 cm. A constant-flow serial diluter with a 65% dilution factor 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 22 ±1°C.

   The dilution water was from the same source as that used in holding/culturing (hardness of 30-32 mg/l as $CaCO_3$, alkalinity of 30-33 mg/l as $CaCO_3$, conductivity of 100-110 μmhos/cm, pH of 7.1-7.2). A 16-hour light/8-hour dark photoperiod was provided with a light intensity of 20-46 footcandles at the solution surface.

   A 9.6 mg active ingredient (ai)/ml diluter stock solution was prepared daily by diluting 38.4 g of Rovral 50 WP to 2 l with deionized water. The stock was delivered to the diluter using a peristaltic pump.

C. **Dosage:** Ninety-six-hour flow-through test. Based on preliminary tests, six nominal concentrations (2.9, 4.5, 6.9, 11, 16, and 25 mg ai/l) and a dilution water control were selected for the definitive test.

D. **Design:** Ten bluegill were impartially distributed to each treatment and control aquarium (two aquaria per concentration). The loading rate was 0.15 g/l of flowing test solution per day. Observations of mortality and test solution characteristics were made every 24 hours. Dead fish were removed at each observation period.

The temperature, dissolved oxygen, and pH were measured once daily in each of the exposure concentrations and the controls.

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 by 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 52 to 91% of nominal (Table 1, attached). The concentrations were determined to be 2.3, 4.1, 5.3, 6.7, 12, and 13 mg ai/l. The two highest concentration solutions were cloudy and all test solutions contained undissolved material in suspension which accumulated on the bottom of each chamber.

The responses of the bluegill sunfish are presented in Table 2 (attached). The 96-hour LC_{50} was determined to be 8.6 mg ai/l with a 95% confidence interval of 7.7-9.7 mg ai/l. The NOEC was determined to be <2.3 mg ai/l, the lowest concentration tested.

Dissolved oxygen ranged from 8.5 to 9.4 mg/l or 97 to 107% of saturation. The pH values ranged from 7.3 to 7.5. The temperature was 22-23°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:

Lot and batch numbers of the test material were not identified.

The hardness of the dilution water (30-32 mg/l) was less than recommended (40-200 mg/l).

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 DO was occasionally above 100% saturation during the study.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC_{50} value and obtained the same results using probit analysis. However, using the moving average angle method, a slightly more conservative estimate of the LC_{50} was determined (see attached printout). The 96-hour LC_{50} for bluegill sunfish exposed to Rovral 50 WP was 7.8 mg ai/l (95% C.I.= 6.9-8.9 mg ai//l).

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 all test solutions, it is crucial that the samples be filtered to obtain the

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actual exposure concentrations. If the samples were not filtered, the toxicity of the test material would be underestimated (i.e., appears as having a higher LC_{50}).

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 freshwater fish. A 96-hour LC_{50} value of 7.8 mg ai/l classifies Rovral 50 WP as moderately toxic to bluegill sunfish. The NOEC could not be determined due to sublethal effects at all test concentrations.

D. **Adequacy of the Study:**

    (1) **Classification:** Supplemental.

    (2) **Rationale:** Undissolved test material was present in all test chambers and it was not stated whether the solution samples were filtered.

    (3) **Repairability:** Yes, this study can be upgraded to "core for a formulated product" pending satisfactory submission of the sampling methodology.

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

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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.

MOSSLER   ROVRAL 50   LEPOMIS MACROCHIRUS   12-15-92
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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
13	20	19	95	2.002716E-03
12	20	16	80	.5908966
6.7	20	6	30	5.765915
5.3	20	0	0	9.536742E-05
4.1	20	0	0	9.536742E-05
2.3	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 5.3 AND 12 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 8.415019

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	3.569209E-02	7.796804	6.939031	8.932631

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	8.167861E-02	1	.4529299

SLOPE   =   7.840109
95 PERCENT CONFIDENCE LIMITS = 5.599448   AND   10.08077

LC50 =   8.633572
95 PERCENT CONFIDENCE LIMITS = 7.726105 AND 9.657531

LC10 =   5.945701
95 PERCENT CONFIDENCE LIMITS = 4.905238 AND 6.751125
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Ecological Effects Branch One-Liner Data Entry Form

Chemical __Iprodione__   Shaughnessy No. __109401__   Pesticide Use __Fungicide__

AQUATIC VERTEBRATE TOX.	% AI	LC_{50} (95%CL) SLOPE	HRS/ TYPE	NOEC	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1. Bluegill Sunfish _Lepomis macrochirus_	50%	7.8 mg ai/l (6.9-8.9 mg ai/l) n/a	96 hr/ Flow-Through	Could not be determined	1987/1992	404892-03 supplemental	SLI	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: __SLI = Springborn Life Sciences, Inc.__

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