10/14/92

EEB files

MRID NO. 416041-08

DATA EVALUATION RECORD

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

2. **TEST MATERIAL:** Iprodione Technical; Lot No. 8906201; 96.2% active ingredient; an off-white granular powder.

3. **STUDY TYPE:** Growth and Reproduction of Aquatic Plants -- Tier 1. Species Tested: Duckweed (Lemna gibba).

4. **CITATION:** Giddings, J. M. 1990. Iprodione Technical - Toxicity to the Duckweed Lemna gibba G3. SLI Report No. 90-6-3351. Prepared by Springborn Laboratories, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-08.

5. **REVIEWED BY:**

Dennis J. McLane **Signature:** Dennis J. McLane
Wildlife Biologist
Ecological Effects Branch **Date:** 9-28-92
Environmental Fate and Effects Division

6. **APPROVED BY:**

Les Touart, Section Chief **Signature:**
Section 1
Ecological Effects Branch **Date:** 10-14-92
Environmental Fate and Effects Division

7. **CONCLUSIONS:** This study fulfills the guideline requirements. However, rather than use the nominal concentration, the measured concentrations from the 0-hour and the 72 hour of the study values were averaged to provide a mean concentration of 1.01 mg a.i./L. At this concentration minimal effects occurred. Based on these results, Tier II studies are not required.

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

Delete marked items

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4. **CITATION:** Giddings, J.M. 1990. Iprodione Technical - Toxicity to the Duckweed Lemna gibba G3. SLI Report No. 90-06-3351. Conducted by Springborn Laboratories, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-08.

5. **REVIEWED BY:**

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

Signature: Louis M. Rifici
Date: 4/30/91

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 4/30/91

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

Signature:
Date:

7. **CONCLUSIONS:** This study is not scientifically sound. The concentration of active ingredient in the exposure concentrations greatly decreased during the first three days and were not monitored thereafter. Therefore, the actual concentrations the duckweed were exposed to are unknown. Under the conditions of the test, the growth of Lemna gibba was not significantly affected by a 14-day exposure to an initial concentration of 1.5 mg a.i./L Iprodione Technical.

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

9. **BACKGROUND:**

6 lbs

2

9. **BACKGROUND:** Part of a package of data submitted for reregistration.

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

11. **MATERIALS AND METHODS:**

A. **Test Species:** Lemna gibba used in the test came from laboratory stock cultures originally obtained from C.F. Cleland, USDA, Washington, DC. Stock cultures were maintained in M-type Hoagland's medium (Hillman, 1961) under continuous 3000-4000 lux illumination, and a temperature of 25°±2°C for 5 days before testing. Lighting was provided by Vita-Lite fluorescent lights. The cultures were grown in 270-mL covered crystallizing dishes containing 100 mL of medium. Transfers were made into fresh medium to once or twice a week. The culture used as inoculum for the test had been transferred to five days before the test.

B. **Test System:** The test vessels and medium used were the same as those used in culturing. The test medium (excluding EDTA) was pH adjusted to 5.1 prior to test solution preparation. The test conditions were similar to those used in culturing. The temperature in the growth chamber was maintained at 25°-28°C. Light was provided continuously at an intensity of 1200-5000 lux.

A 15 mg/mL primary stock was prepared by diluting 0.156 g of Iprodione Technical to 10 mL with acetone. A 0.05 mL portion of this solution was diluted to 500 mL in sterile medium.

C. **Dosage:** Fourteen-day growth and reproduction test. Based on the results of a preliminary test, a single nominal concentration of 1.5 mg a.i./L was selected for the definitive test.

D. **Design:** Three replicate sterile 270-mL crystallizing dishes (3 per treatment level and the controls) were conditioned by rinsing with the appropriate test solution. One-hundred mL of the appropriate test solution were placed into each dish. Each dish was covered with an inverted sterile, glass petri dish.

An inoculum of Lemna gibba (5 plants with 3 fronds each) was aseptically introduced into each dish within 25 minutes of solution preparation. The dishes were placed in a growth chamber. At 3-day intervals, fronds

were counted and the plants transferred to fresh test solutions. After each renewal, the dishes were impartially repositioned in the growth chamber.

The pH was measured at test initiation, termination, and in the freshly prepared and discarded test solutions at each renewal. Temperature was recorded continuously with a minimum/maximum thermometer. The light intensity was measured at the beginning of the test and every 24-hour interval of the exposure period.

Samples were removed from each test solution and the controls at test initiation and at the first renewal for analysis by high-performance liquid chromatography (HPLC).

E. **Statistics:** T-tests (Sokal and Rohlf, 1981) were performed to compare control growth and solvent control growth. Mean frond counts of the pooled controls and the exposure concentration were compared to determine significant differences.

12. **REPORTED RESULTS:** The concentration of iprodione present in the exposure concentration at the beginning of the test was 1.5 mg a.i./L (Table 2, attached). In the three days, the concentration had decreased to 0.52 mg a.i./L or 35% of nominal. Because of the loss of active ingredient from the solution, the report results were based on the concentration present at initiation.

Frond counts for the controls and the exposure concentration after 14 days are given in Table 4, attached). Exposure to 1.5 mg a.i./L caused a 0.5% decrease in Lemna gibba growth in 14 days compared to the pooled control. This growth was not significantly different from growth in the pooled control. Several yellow fronds and chlorotic fronds were observed in each replicate of the exposure concentration beginning on day 9.

The pH in the controls and the exposure concentration were 5.0 to 5.8. The temperature ranged from 25° to 28°C.

4

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

Lemna gibba was tested for 14 days at the maximum label rate with no decrease in growth so follow-up Tier 2 testing was not performed.

Quality Assurance and GLP Compliance Statements were included in the report indicating adherence to USEPA GLP Regulations.

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

A. **Test Procedure:** The following test procedures deviated from guideline procedure:

The light intensity during the test (1.2-5.0 klux) was lower than recommended (5 klux).

The temperature during the test was 25°-28°C. The recommended test temperature for Lemna gibba is 25°C.

The concentration of active ingredient in the exposure concentration greatly decreased during the first three days of exposure. Because the test solutions were not monitored thereafter, the actual concentrations the duckweed exposed to are unknown.

B. **Statistical Analysis:** Statistical analysis should not be performed on the with pooled control. An ANOVA was performed with the solvent control and the treatment data and no statistical difference was found (see attached).

C. **Discussion/Results:** The study fulfills the guideline requirements. The items in 14.A. above are not expected to significantly effect the results of the study. However, rather than use the nominal concentration, the measured concentration of 1.01 mg a.i./L. At this concentration minimal effects occurred. Based on these results, Tier II studies are not required.

D. **Adequacy of the Study:**

(1) Classification: Core

(2) Rationale: N/A

(3) Repairability: N/A

15. **COMPLETION OF ONE-LINER FOR STUDY:** yes, 9-25-92

5

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.

Shaughnessey 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 LD_{50} Species Lab Acc.	____	LD50 = mg/kg (95% C.L.) Contr. Mort.(%)= Slope= # Animals/Level= Age(Days)= Sex = 14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
14-Day Single Dose Oral LD_{50} Species Lab Acc.	____	LD50 = mg/kg. (95% C.L.) Contr. Mort.(%)= Slope= # Animals/Level= Age(Days)= Sex = 14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
8-Day Dietary LC_{50} Species Lab Acc.	____	LC50 = ppm (95% C.L.) Contr. Mort.(%)= Slope= # Animals/Level= Age(Days)= Sex = 8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
8-Day Dietary LC_{50} Species Lab Acc.	____	LC50 = ppm (95% C.L.) Contr. Mort.(%)= Slope= # Animals/Level= Age(Days)= Sex = 8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
~~48-Hour LC_{50}~~ 14-day Tier I Species Lemna gibba G3 Lab Springborn Laboratories, Inc. ~~Acc.~~ MRID # 416041-08	96.2	LC50 = N/A pp__ (95% C.L. N/A) Contr. ~~Mort.~~ decrease (%)=0 Sol. Contr. ~~Mort.~~ (%)=0 Slope= N/A # Animals/Level= Temperature =25°C ~~48-Hour~~ Dose Level ppm*/(% ~~Mortality~~ decrease) 1.5 (0.5), ( ), ( ), ( ), ( ) Comments: *initial measured concentration	DJM ~~-LR~~ ~~3/15/91~~ 9-25-92	Core ~~[illegible]~~
96-Hour LC_{50} Species Lab Acc.	____	LC50 = pp__ (95% C.L.) Con. Mor.(%)= Sol. Con. Mor.(%)= Slope= # Animals/Level= Temp.= 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
96-Hour LC_{50} Species Lab Acc.	____	LC50 = pp__ (95% C.L.) Con. Mort.(%)= Sol. Con. Mort.(%)= Slope= # Animals/Level= Temp.= 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____

OUTPUT
Command ===>

SAS 1
7:55 Monday, September 28, 1992

OBS	TRT	RESP
1	a	617
2	a	602
3	a	561
4	b	646
5	b	601
6	b	576

ZOOM R

OUTPUT
Command ===>

SAS 2
7:55 Monday, September 28, 1992

General Linear Models Procedure
Class Level Information

Class	Levels	Values
TRT	2	a b

Number of observations in data set = 6

ZOOM R

OUTPUT
Command ===>

SAS 3
7:55 Monday, September 28, 1992

General Linear Models Procedure

Dependent Variable: RESP

Source	DF	Sum of Squares	F Value	Pr > F
Model	1	308.16666667	0.29	0.6166
Error	4	4197.33333333		
Corrected Total	5	4505.50000000		

R-Square	C.V.	RESP Mean
0.068398	5.394407	600.50000000

ZOOM R

OUTPUT
Command ===>

General Linear Models Procedure

Dependent Variable: RESP

Source	DF	Type I SS	F Value	Pr > F
TRT	1	308.16666667	0.29	0.6166

Source	DF	Type III SS	F Value	Pr > F
TRT	1	308.16666667	0.29	0.6166

ZOOM R

OUTPUT
Command ===>

General Linear Models Procedure

Duncan's Multiple Range Test for variable: RESP

NOTE: This test controls the type I comparisonwise error rate, not the experimentwise error rate

Alpha= 0.05 df= 4 MSE= 1049.333

Number of Means 2
Critical Range 73.57

Means with the same letter are not significantly different.

ZOOM R

OUTPUT
Command ===>

General Linear Models Procedure

Duncan Grouping	Mean	N	TRT
A	607.67	3	b
A			
A	593.33	3	a

ZOOM R