10/14/92 EEB files

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 2. Species Tested: Selenastrum capricornutum

4. **CITATION:** Giddings, J. M. 1990. Iprodione Technical - Toxicity to the Freshwater Green Alga Selenastrum capricornutum. SLI Report No. 90-6-3346. Prepared by Springborn Laboratories, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-07.

5. **REVIEWED BY:**

Dennis J. McLane **Signature:** Dennis J. McLane
Wildlife Biologist
Ecological Effects Branch **Date:** 10-5-92
Environmental Fate and Effects Division

6. **APPROVED BY:**

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

7. **CONCLUSIONS:** This study fulfills the guideline requirements if the EEB NOEC and the EC_{50} are used. The concentration levels were set as per the guidelines provided the application rates are the same reported in MRID No. 416041-10. If the applications rate is higher than 2 lbs/A then another study is needed. However, due to the type of data, the two of the EC_{50} methods could not provide an EC_{50}, The third method, the binomial did provide and EC_{50} of zero (see attached printout). In contrast to this the Dunnett's test shows that 0.13 mg/L was not different from the solvent control. Therefore, the EC_{50} is greater than the NOEC or >0.13 mg/L.

MRID No. 416041-0

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Dennis J. McLane
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Environmental Fate and Effects Division

Signature: Dennis J. McLane
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8. **RECOMMENDATIONS:** N/A.

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:** The alga used in the test, Selenastrum capricornutum, came from laboratory stock cultures originally obtained from Carolina Biological Supply Company, Burlington, NC. Test vessels used were sterile 125-mL Erlenmeyer flasks fitted with stainless steel caps which permitted gas exchange and containing 50 mL of medium. Stock cultures were maintained in Marine Biological Laboratory medium (MBL Medium; Nichols, 1973) under test conditions. Lighting was provided by Vita-Lite and Cool-White fluorescent lights. Test vessels were maintained on an orbital shaker (100 rpm) under continuous illumination (approximately 4-5 klux at the surface of the media). The temperature was maintained at 22°-27°C. Transfers to fresh medium were approximately once or twice a week. The culture used as inoculum was transferred 3 days before test initiation.

B. **Test System:** The test medium was the same as that used for culturing (excluding EDTA) with the pH adjusted to 7.5 ±0.1. The test conditions were similar to those used in culturing. The temperature in the growth chamber was maintained at 22°-27°C.

A 40 mg/mL primary stock was prepared by diluting 2.0792 g of Iprodione Technical diluted to 50 mL with acetone. Appropriate volumes of primary stock were diluted to 10 mL with acetone to create secondary stocks. Equal volumes (0.05 mL) of the secondary stocks were diluted to 500 mL in sterile MBL Medium. Solvent and media controls were also prepared. The solvent control contained 0.1 mL/L of acetone in medium. Three replicate 125-mL flasks (3 per treatment level and the controls) were conditioned by rinsing with the appropriate test solution. Fifty mL of the appropriate test solution were placed into each flask.

C. **Dosage:** Five-day growth reproduction test. Based on the results of preliminary tests , seven nominal Iprodione Technical concentrations of 0.06, 0.13, 0.26, 0.52, 1.0, 2.0, and 4.0 mg a.i./L were selected for the

definitive test.

D. **Design:** An inoculum of Selenastrum capricornutum cells calculated to provide 0.3 x 10^4 cell/mL was aseptically introduced into each flask. The inoculum volume was 690 µL per flask. The flasks were impartially placed on the shaker in the growth chamber. At each 24-hour interval, cell counts were conducted on each replicate vessel using a hemacytometer and compound microscope. One sample from each vessel was counted.

The (pH) and conductivity were measured at test initiation and termination. Temperature was recorded continuously with a minimum/maximum thermometer. The shaking rate of the orbit shaker was recorded daily. The light intensity was measured at the beginning of the test and every 24-hour interval of the exposure period.

At test initiation and termination, samples were removed form each test solution and the controls for analysis by high-performance liquid chromatography (HPLC).

E. **Statistics:** For each observation period (except 48 hours), the EC_{50} value and its 95% confidence limits were determined by linear regression of response (percent reduction of cell density as compared with controls) vs. mean measured exposure concentration over the range of test concentration excluding controls. Various mathematical manipulations (logarithm and probit transformations) were used on the concentration and response data to get the linear regression with the highest coefficient of determination (r^2).

The NOEC was determined using a multiple comparison procedure.

12. **REPORTED RESULTS:** Mean measured concentrations for the present test were 0.054, 0.13, 0.23. 0.37, 0.79, 1.1, 1.5 mg/L. Measured concentrations averaged 85% and 65% of nominal at test initiation and termination, respectively (Table 2, attached).

Cell densities determined at each observation time are presented in Table 3 (attached). Cell densities increased over time in all replicates. The percent decrease in cell growth compared to the control was linear and appeared to follow the concentration gradient. The data from the two

follow the concentration gradient. The data from the two sets of controls were pooled before subsequent statistical analysis. The 120-hour NOEC was 0.13 mg/L.

The 120-hour EC_{50} was calculated as 1.9 mg/L with a 95% confidence interval of 0.32-23 mg/L.

Conductivity ranged from 230 to 320 µmhos/cm. At initiation, the pH in all test solutions was 7.4. By the end of the test, the pH was 10.0-10.2. The temperature ranged from 24 to 25°C during the study.

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

No conclusions were made by the study author.

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 maximum label application rate was not given in the report. The rate used by the reviewer in this report was taken from another report using the same chemical and Anabaena flos-aquae (MRID # 416041-10); p.12).

The light intensity during the test (4-5 klux) was higher than recommended (4 klux).

The concentration of active ingredient in the exposure concentration greatly decreased during the exposure period. Because the test solutions were not monitored thereafter, the actual concentrations the alga was exposed to are unknown.

B. Statistical Analysis: The EEB's Toxanal failed to produce an EC_{50} value (see explanation in attached printout). The Toxstat program (Dunnett's Test) shows that 0.13 mg/L (mean measured concentration) is the NOEC.(see attached printout) Although the binomial estimated the EC_{50} at zero and the data did not meet the assumptions of the necessary to use the moving average or the probit methods the EC_{50} should be above the NOEC. Hence the EC_{50} is >0.13 mg/L.

S

C. **Discussion/Results:** The concentration levels were set as per the guidelines provided the application rates are the same reported in MRID No. 416041-10. If the applications rate is higher than 2 lbs/A then another study is needed. However, due to the type of data, the two of the EC_{50} methods could not provide an EC_{50}, The third method, the binomial did provide and EC_{50} of zero (see attached printout). In contrast to this the Dunnett's test shows that 0.13 mg/L was not different from the solvent control. Therefore, the EC_{50} is greater than the NOEC or >0.13 mg/L. This study fulfills the guideline requirements if the EEB NOEC and the EC_{50} are used.

D. **Adequacy of the Study:**

(1) **Classification:** Core

(2) **Rationale:** Provided the EEB NOEC and the EC_{50} are used for this study. Also, EEB's assumption that 2 lbs/A is the highest application rate for Iprodione products.

(3) **Repairability:** N/A

15. **COMPLETION OF ONE-LINER FOR STUDY:** yes, 10-2-92

IPRODIONE

Page_____ is not included in this copy.

Pages 7 through 9 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.

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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.

TITLE: TIER II SELENASTRUM COSTATUM
FILE: SELENAST.DAT
TRANSFORM: NO TRANSFORM NUMBER OF GROUPS: 8

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	SOLVENT CONTROL	1	120.5000	120.5000
1	SOLVENT CONTROL	2	130.2500	130.2500
1	SOLVENT CONTROL	3	127.5000	127.5000
2	.054	1	123.7500	123.7500
2	.054	2	114.5000	114.5000
2	.054	3	109.2500	109.2500
3	.13	1	122.2500	122.2500
3	.13	2	125.7500	125.7500
3	.13	3	107.5000	107.5000
4	.23	1	85.0000	85.0000
4	.23	2	101.2500	101.2500
4	.23	3	113.7500	113.7500
5	.37	1	94.2500	94.2500
5	.37	2	79.5000	79.5000
5	.37	3	68.5000	68.5000
6	.79	1	99.7500	99.7500
6	.79	2	81.5000	81.5000
6	.79	3	90.7500	90.7500
7	1.1	1	87.7500	87.7500
7	1.1	2	81.5000	81.5000
7	1.1	3	90.5000	90.5000
8	1.5	1	52.7500	52.7500
8	1.5	2	74.2500	74.2500
8	1.5	3	71.5000	71.5000

TIER II SELENASTRUM COSTATUM
File: SELENAST.DAT Transform: NO TRANSFORM

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 1 of 2

GRP	IDENTIFICATION	N	MIN	MAX	MEAN
1	SOLVENT CONTROL	3	120.500	130.250	126.083
2	.054	3	109.250	123.750	115.833
3	.13	3	107.500	125.750	118.500
4	.23	3	85.000	113.750	100.000
5	.37	3	68.500	94.250	80.750
6	.79	3	81.500	99.750	90.667
7	1.1	3	81.500	90.500	86.583
8	1.5	3	52.750	74.250	66.167

TIER II SELENASTRUM COSTATUM
File: SELENAST.DAT Transform: NO TRANSFORM

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 2 of 2

GRP	IDENTIFICATION	VARIANCE	SD	SEM
1	SOLVENT CONTROL	25.271	5.027	2.902
2	.054	53.896	7.341	4.239
3	.13	93.813	9.686	5.592
4	.23	207.813	14.416	8.323
5	.37	166.938	12.920	7.460
6	.79	83.271	9.125	5.268
7	1.1	21.271	4.612	2.663
8	1.5	136.896	11.700	6.755

TIER II SELENASTRUM COSTATUM
File: SELENAST.DAT Transform: NO TRANSFORM

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	7	9077.852	1296.836	13.146
Within (Error)	16	1578.333	98.646	
Total	23	10656.185		

Critical F value = 2.66 (0.05,7,16)
Since F > Critical F REJECT Ho:All groups equal

TIER II SELENASTRUM COSTATUM
File: SELENAST.DAT Transform: NO TRANSFORM

DUNNETTS TEST - TABLE 1 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	TRANSFORMED MEAN	MEAN CALCULATED IN ORIGINAL UNITS	T STAT	SIG
1	SOLVENT CONTROL	126.083	126.083		
2	.054	115.833	115.833	1.264	
3	.13	118.500	118.500	0.935	
4	.23	100.000	100.000	3.216	*
5	.37	80.750	80.750	5.590	*
6	.79	90.667	90.667	4.367	*
7	1.1	86.583	86.583	4.871	*
8	1.5	66.167	66.167	7.388	*

Dunnett table value = 2.56 (1 Tailed Value, P=0.05, df=16,7)

TIER II SELENASTRUM COSTATUM
File: SELENAST.DAT Transform: NO TRANSFORM

DUNNETTS TEST - TABLE 2 OF 2 Ho:Control<Treatment

GROUP	IDENTIFICATION	NUM OF REPS	Minimum Sig Diff (IN ORIG. UNITS)	% of CONTROL	DIFFERENCE FROM CONTROL
1	SOLVENT CONTROL	3			
2	.054	3	20.760	16.5	10.250
3	.13	3	20.760	16.5	7.583
4	.23	3	20.760	16.5	26.083
5	.37	3	20.760	16.5	45.333
6	.79	3	20.760	16.5	35.417
7	1.1	3	20.760	16.5	39.500
8	1.5	3	20.760	16.5	59.917

TIER II SELENASTRUM COSTATUM
File: SELENAST.DAT Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	SOLVENT CONTROL	3	126.083	126.083	126.083
2	.054	3	115.833	115.833	117.167
3	.13	3	118.500	118.500	117.167
4	.23	3	100.000	100.000	100.000
5	.37	3	80.750	80.750	86.000
6	.79	3	90.667	90.667	86.000
7	1.1	3	86.583	86.583	86.000
8	1.5	3	66.167	66.167	66.167

TIER II SELENASTRUM COSTATUM
File: SELENAST.DAT Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
SOLVENT CONTROL	126.083				
.054	117.167	1.100		1.75	k= 1, v=16
.13	117.167	1.100		1.83	k= 2, v=16
.23	100.000	3.216	*	1.86	k= 3, v=16
.37	86.000	4.943	*	1.87	k= 4, v=16
.79	86.000	4.943	*	1.88	k= 5, v=16
1.1	86.000	4.943	*	1.89	k= 6, v=16
1.5	66.167	7.388	*	1.89	k= 7, v=16

s = 9.932
Note: df used for table values are approximate when v > 20.

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MCALNE IPRODIONE
GROWTH AND REPRODUCTION OF AQUATIC PLANTS TIER II SELENASTRUM CAPRICORNUTUM

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1.5	100	48	48	0
1.1	100	31	31	0
.79	100	28	28	0
.37	100	36	36	0
.23	100	21	21	0
.13	100	6	6	0
.054	100	8	8	0

BECAUSE THE NUMBER OF ORGANISMS USED WAS SO LARGE, THE 95 PERCENT CONFIDENCE INTERVALS CALCULATED FROM THE BINOMIAL PROBABILITY ARE UNRELIABLE. USE THE INTERVALS CALCULATED BY THE OTHER TESTS.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 0

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
3	.4320533	3.610169	2.883315E-03

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

SLOPE = .8874289
95 PERCENT CONFIDENCE LIMITS = .3041151 AND 1.470743

LC50 = 2.358444
95 PERCENT CONFIDENCE LIMITS = 1.012872 AND 64.59485

LC10 = 8.740276E-02
95 PERCENT CONFIDENCE LIMITS = 2.888962E-03 AND .206753

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}		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~~ 120-Hour LC_{50}		LC50 = >1.5 ppm* (95% C.L. N/A) Contr. Mort.(%)=0 inhibition Sol. Contr. Mort.(%)=0	DJM 10-5-92 Core	
Species Selenastrum Capricornutum		Slope= N/A # Animals/Level= 0.3×10^4 cells/mL Temperature = 24°C	~~FINAL~~	~~FINAL~~
Lab Springborn Laboratories 96.2		120-hour ~~48-Hour~~ Dose Level ppm/(% ~~Mortality~~ inhibition) 0.057 (~~0~~ 0) 0.13 (~~0~~ 0) 0.23 (~~0~~ 21) 0.37 (~~0~~ 36) 0.79 (~~0~~ 28), 1.1 (~~0~~ 31), 1.5 (~~0~~ 48)	3/15/94	
Acc. MRID 416641-07		Comments: *Measured concentrations		
96-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mor(%)= Sol. Con. Mor.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
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:		