

US EPA ARCHIVE DOCUMENT

10/14/92

EEB files

MRID NO. 416041-09

**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: Skeletonema costatum
4. **CITATION:** Giddings, J. M. 1990. Iprodione Technical - Toxicity to the Marine Diatom Skeletonema costatum. SLI Report No. 90-06-3347. Prepared by Springborn Laboratories, Inc., Wareham, MA. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-09.
5. **REVIEWED BY:**  
Dennis J. McLane  
Wildlife Biologist  
Ecological Effects Branch  
Environmental Fate and Effects Division  
Signature: *Dennis J. McLane*  
Date: 10-5-92
6. **APPROVED BY:**  
Les Touart, Section Chief  
Section 1  
Ecological Effects Branch  
Environmental Fate and Effects Division  
Signature: *LT*  
Date: 10-14-92
7. **CONCLUSIONS:** The study fulfills the guideline requirements. The items mentioned in 14. A. below are not expected to significantly effect the results of the study. Provided the EEB calculated 120-hour EC<sub>50</sub> of 0.226 mg a.i./L. and the EEB calculated 120-hour NOEC of 0.0145 mg a.i./L is used rather than the SLI values.
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:**

*add highlighted areas*

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5. **REVIEWED BY:**  

Dennis J. McLane Wildlife Biologist Ecological Effects Branch Environmental Fate and Effects Division	Signature: <i>Dennis J. McLane</i> Date: 10-5-92
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6. **APPROVED BY:**  

Les Touart, Section Chief Section 1 Ecological Effects Branch Environmental Fate and Effects Division	Signature: Date:
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9. **BACKGROUND:** Part of a package of data submitted for reregistration.
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11. **MATERIALS AND METHODS:**

2

- A. **Test Species:** The alga used in the test, Skeletonema costatum, came from laboratory stock cultures originally obtained from Bigelow Laboratory, Boothbay Harbor, ME. Stock cultures were maintained in Marine Algal Medium (USEPA, 1978) under test conditions. Transfers to fresh medium were made approximately once or twice a week. The culture used as inoculum had been transferred three days before test initiation.
- B. **Test System:** Test vessels used were sterile 125-mL Erlenmeyer flasks fitted with stainless steel caps which permitted gas exchange. The test medium was the same as that used for culturing (excluding EDTA) with the pH adjusted to 8.1. Test vessels were maintained on an orbital shaker (60 rpm). Lighting was provided by Vita-Lite fluorescent lights on a 16-hour light:8-hour dark photoperiod with an intensity of 3.5-5.0 klux at the surface of the media. The temperature in the growth chamber was maintained at 19°-22°C.

A 20-mg/mL stock was prepared by diluting 1.0393 g of Iprodione Technical to 50 mL with acetone. Appropriate volumes of primary stock were diluted to 10 mL with acetone to create secondary stocks. Appropriate volumes of the secondary stocks were diluted to 500 mL in sterile medium. Solvent and medium controls were also prepared. The solvent control contained 0.1 mL/L of acetone in medium.

- C. **Dosage:** Five-day growth and reproduction test. Based on the results of preliminary tests, seven nominal concentrations of 0.03, 0.064, 0.13, 0.26, 0.50, 1.0, and 2.0 mg a.i./L were selected for the definitive test.
- D. **Design:** Three replicates 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.

An inoculum of Skeletonema costatum cells calculated to provide  $1 \times 10^4$  cells/mL was aseptically introduced into each flask. The inoculum volume was 810  $\mu$ L 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 from each test solution and the controls for analysis by high-performance liquid chromatography (HPLC).

- E. **Statistics:** Measured concentrations from Day 0 were used in the statistical analysis. For each observation period, 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 concentrations 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:** After 120-hours, Iprodione was not detected in any exposure level except the highest, 2.0 mg a.i./L, where the concentration was 9% of nominal. The measured concentrations at the beginning of the test were 0.029, 0.070, 0.12, 0.23, 0.45, 0.68, and 1.1 mg a.i./L. Measured concentrations averaged 55% and 109% of nominal at test initiation (Table 2, attached).

Cell densities determined at each observation time are presented in Table 3 (attached). Cell density increased over time except in the highest level. In general, cell growth decreased with increasing Iprodione concentration. There was no significant difference between control and solvent control cell density so the data from the two groups were pooled before subsequent statistical analysis. The NOEC, established at 120 hours, was 0.12 mg a.i./L. Because of the loss of Iprodione during the test, toxicity test endpoints are reported based on initial measured concentrations.

The 120-hour  $EC_{50}$  was calculated to be 0.59 mg a.i./L with a

95% confidence interval of 0.17-1.0 mg a.i./L.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**  
No conclusions were made by the author.

Good laboratory practice and Quality Assurance Unit statements were included in the report indicating compliance with EPA Good Laboratory Practice Standards under the Federal Insecticide, Fungicide, and Rodenticide Act Test Guidelines & 122-2 and & 123-2 (USEPA, 1982).

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 (3.5-5.0 klux) was lower than recommended (4 klux).

The temperature during the test was 19°-22°C. The recommended test temperature for Skeletonema costatum is 20°C.

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 duckweed exposed to are unknown.

B. **Statistical Analysis:** Statistical analysis should not be performed on the with pooled control. Using the solvent control, the Toxanal program indicated that, the Probit cannot be used, "Since the probability is less than 0.05, results calculated using the probit method should not be used." Similarly, the binomial test results cannot be used, "Because the number of organisms used was so large, the 95 percent confidence intervals calculated from the binomial probability are unreliable." Therefore the moving average method used. An approximate EC<sub>50</sub> for this set of data is 0.226 mg a.i./L." (see attached printout). Also notice it is EEB's policy when measured results are available, as in this case, for 0 hour and hour 120 is to determine an

average value for the two to calculate the EC<sub>50</sub>. With the exception of the highest level 120-hour level, these concentrations were not measurable. Hence, one half of the 0-hour measured concentration was used except for the highest concentration which had a measure amount for 120-hour period.

To determine the 120-hour NOEC this reviewer ANOVA, William's Test and solvent control. The results (see attached print out) show the 120-hour NOEC is 0.0145 mg a.i./L and not the 0.12 mg a.i./L reported by SLI.

C. **Discussion/Results:** The study fulfills the guideline requirements. The items mentioned in A. above are not expected to significantly effect the results of the study. Provided the EEB calculated 120-hour EC<sub>50</sub> of 0.226 mg a.i./L. and the EEB calculated 120-hour NOEC of 0.0145 mg a.i./L is used rather than the SLI values.

D. **Adequacy of the Study:**

(1) **Classification:** Core

(2) **Rationale:** This study is "Core" based on these two assumptions:

1) 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).

2) Provided the EEB calculated 120-hour EC<sub>50</sub> of 0.226 mg a.i./L. and the EEB calculated 120-hour NOEC of 0.0145 mg a.i./L is used rather than the SLI values.

(3) **Repairability:** None required provided the above two assumptions are acceptable to the sponsor.

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

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I PRODIONE

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Page      is not included in this copy.

Pages   7   through  10  are not included.

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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.
- 

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.

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MCLANE IPRODIONE PLANT AQUATIC TIER II SKELETONEMA COSTATUM

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.645	100	100	100	0
.34	100	47	47	0
.225	100	32	32	0
.115	100	41	41	0
.06	100	17	17	0
.035	100	27	27	0
.0145	100	11	11	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 .3485611

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	1.967235E-02		.2255739	.2094605
.2432603				

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H
4	.692884	14.87011

GOODNESS OF FIT PROBABILITY  
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 = 1.268326  
95 PERCENT CONFIDENCE LIMITS = .2125759 AND 2.324077

LC50 = .1963957  
95 PERCENT CONFIDENCE LIMITS = 6.470655E-02 AND 3.47384

LC10 = 1.957998E-02  
95 PERCENT CONFIDENCE LIMITS = 1.109945E-06 AND 6.104748E-02

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TITLE: PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 FILE: B:MARITOM.ZZZ  
 TRANSFORM: NO TRANSFORM NUMBER OF GROUPS: 8

GRP	IDENTIFICATION	REP	VALUE	TRANS VALUE
1	SOLVENT CONTROL	1	163.3300	163.3300
1	SOLVENT CONTROL	2	228.5000	228.5000
1	SOLVENT CONTROL	3	216.0000	216.0000
2	.0145	1	208.0000	208.0000
2	.0145	2	179.6700	179.6700
2	.0145	3	153.6700	153.6700
3	.035	1	166.3300	166.3300
3	.035	2	155.6700	155.6700
3	.035	3	123.7500	123.7500
4	.06	1	140.6700	140.6700
4	.06	2	158.0000	158.0000
4	.06	3	206.5000	206.5000
5	.115	1	124.2500	124.2500
5	.115	2	99.0000	99.0000
5	.115	3	135.0000	135.0000
6	.225	1	128.0000	128.0000
6	.225	2	134.0000	134.0000
6	.225	3	152.0000	152.0000
7	.34	1	96.7500	96.7500
7	.34	2	102.5000	102.5000
7	.34	3	122.0000	122.0000
8	.645	1	0.0000	0.0000
8	.645	2	0.0000	0.0000
8	.645	3	0.0000	0.0000

PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 File: B:MARITOM.ZZZ Transform: NO TRANSFORM

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 1 of 2

GRP	IDENTIFICATION	N	MIN	MAX	MEAN
1	SOLVENT CONTROL	3	163.330	228.500	202.610
2	.0145	3	153.670	208.000	180.447
3	.035	3	123.750	166.330	148.583
4	.06	3	140.670	206.500	168.390
5	.115	3	99.000	135.000	119.417
6	.225	3	128.000	152.000	138.000
7	.34	3	96.750	122.000	107.083
8	.645	3	0.000	0.000	0.000

PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 File: B:MARITOM.ZZZ Transform: NO TRANSFORM

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 2 of 2

GRP	IDENTIFICATION	VARIANCE	SD	SEM
1	SOLVENT CONTROL	1196.251	34.587	19.969
2	.0145	738.390	27.173	15.689
3	.035	490.930	22.157	12.792
4	.06	1164.361	34.123	19.701
5	.115	341.521	18.480	10.670
6	.225	156.000	12.490	7.211
7	.34	175.146	13.234	7.641
8	.645	0.000	0.000	0.000

PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 File: B:MARITOM.ZZZ Transform: NO TRANSFORM

ANOVA TABLE

SOURCE	DF	SS	MS	F
Between	7	81486.528	11640.933	21.848
Within (Error)	16	8525.197	532.825	
Total	23	90011.726		

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

PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 File: B:MARITOM.ZZZ 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	202.610	202.610		
2	.0145	180.447	180.447	1.176	
3	.035	148.583	148.583	2.867	*
4	.06	168.390	168.390	1.816	
5	.115	119.417	119.417	4.414	*
6	.225	138.000	138.000	3.428	*
7	.34	107.083	107.083	5.068	*
8	.645	0.000	0.000	10.750	*

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

PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 File: B:MARITOM.ZZZ 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	.0145	3	48.249	23.8	22.163
3	.035	3	48.249	23.8	54.027
4	.06	3	48.249	23.8	34.220
5	.115	3	48.249	23.8	83.193
6	.225	3	48.249	23.8	64.610
7	.34	3	48.249	23.8	95.527
8	.645	3	48.249	23.8	202.610

PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 File: B:MARITOM.ZZZ 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	202.610	202.610	202.610
2	.0145	3	180.447	180.447	180.447
3	.035	3	148.583	148.583	158.487
4	.06	3	168.390	168.390	158.487
5	.115	3	119.417	119.417	128.708
6	.225	3	138.000	138.000	128.708
7	.34	3	107.083	107.083	107.083
8	.645	3	0.000	0.000	0.000

PLANT AQUATIC TIER II SKELETONEMA COSTATUM  
 File: B:MARITOM.ZZZ 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	202.610				
.0145	180.447	1.176		1.75	k= 1, v=16
.035	158.487	2.341	*	1.83	k= 2, v=16
.06	158.487	2.341	*	1.86	k= 3, v=16
.115	128.708	3.921	*	1.87	k= 4, v=16
.225	128.708	3.921	*	1.88	k= 5, v=16
.34	107.083	5.068	*	1.89	k= 6, v=16
.645	0.000	10.750	*	1.89	k= 7, v=16

s = 23.083

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

Shaphnessy No. 109801

Chemical Name IFRODIONE Chemical Class \_\_\_\_\_ Page 1 of 1

Study/Species/Lab/ Accession 14-Day Single Dose Oral LD50 Chemical 2 a.i. Results  
 Reviewer/ Validation Date Status  
 LD50 = mg/kg ( 95% C.L. ) Contr. Mort. (X) =  
 Species Slope = # Animals/Level = Age (Days) = Sex =  
 Lab 14-Day Dose Level mg/kg/(X Mortality)  
 ( , , , , )  
 Acc. Comments:

14-Day Single Dose Oral LD50 LD50 = mg/kg. ( 95% C.L. ) Contr. Mort. (X) =  
 Species Slope = # Animals/Level = Age (Days) = Sex =  
 Lab 14-Day Dose Level mg/kg/(X Mortality)  
 ( , , , , )  
 Acc. Comments:

8-Day Dietary LC50 LC50 = ppm ( 95% C.L. ) Contr. Mort. (X) =  
 Species Slope = # Animals/Level = Age (Days) = Sex =  
 Lab 8-Day Dose Level ppm/(X Mortality)  
 ( , , , , )  
 Acc. Comments:

8-Day Dietary LC50 LC50 = ppm ( 95% C.L. ) Contr. Mort. (X) =  
 Species Slope = # Animals/Level = Age (Days) = Sex =  
 Lab 8-Day Dose Level ppm/(X Mortality)  
 ( , , , , )  
 Acc. Comments:

~~48~~-Hour LC50 120 LC50 = 0.43 <sup>ppm</sup> ( 95% C.L. moving average inhibition ) Contr. Mort. (X) = 0  
 Species Skeletonema costatum <sup>cells ml Sol. Contr. Mort. (X) = 0</sup>  
 Lab Springborn Laboratories <sup>96.2%</sup> Slope = N/A # Animals/Level =  
<sup>120-hour 90% inhibition Temperature = 20°C</sup>  
<sup>48-hour Dose Level ppm/(X Mortality)</sup> 0.045 (100), 0.07 (20.2), 0.12 (9.5), 0.23 (35.8), 0.45 (25.8) <sup>LR N/A</sup>  
 Acc. MRID 416041-09 <sup>0.0149</sup> Comments: <sup>0.68 (42.5), 1.1 (100)</sup> \* Initial Inorganic Concentration

96-Hour LC50 120 LC50 = 0.226 <sup>ppm</sup> ( 95% C.L. ) Con. Mort. (X) = 0  
 Species Skeletonema costatum <sup>cell ml Sol. Con. Mort. (X) = 0</sup>  
 Lab Springborn Laboratories <sup>96.2%</sup> Slope = N/A # Animals/Level =  
<sup>120</sup> 96-Hour Dose Level pp / (X Mortality) <sup>Temp. = 20°C</sup> 0.645 (100), 0.34 (47), 0.225 (32), 0.115 (41), 0.06 (17), 0.035 (27), 0.015 (11) <sup>DSM cone</sup>  
 Acc. MRID 416041-09 <sup>9-30-92</sup> Comments:

96-Hour LC50 LC50 = ppm ( 95% C.L. ) Con. Mort. (X) =  
 Species Slope = # Animals/Level = Sol. Con. Mort. (X) =  
 Lab 96-Hour Dose Level pp / (X Mortality) Temp. =  
 ( , , , , )  
 Acc. Comments: