

US EPA ARCHIVE DOCUMENT

2-20-96



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Data review for Isoxaflutole (D219140, Chemical #123000, Case 286745)

FROM: Renée Costello *Renée Costello 2/20/96*  
Environmental Risk Characterization Branch  
Environmental Fate and Effects Division (7507C)

THRU: Elizabeth M.K. Leovey, Chief *Elizabeth Leovey*  
Environmental Risk Characterization Branch  
Environmental Fate and Effects Division (7507C) *Elizabeth Leovey*

TO: Joanne Miller, PM 23  
Registration Division (7505C)

The Environmental Risk Characterization Branch (ERCB) has completed the review of the data submitted in support of registration of Isoxaflutole, chemical number 123000. The following is a brief summary of the data reviewed:

**Citation:** RPA 201772 Technical - Acute Toxicity to the marine diatom, *Skeletonema costatum*. EPA MRID #435732-47

**Conclusions:** This study is scientifically sound and fulfills the guideline requirement for acute toxicity testing on the marine diatom *Skeletonema costatum*. Based on initial measured concentrations, the 120 hour EC<sub>50</sub> of Isoxaflutole is 0.11 mg ai/L and the NOEC is 0.0022 mg ai/L.

If there are any questions regarding this data review contact Renée Costello at 305-5294.

Peer reviewer:

Mike Davy, Agronomist *Mike Davy*

DATA EVALUATION RECORD  
DIATOM EC<sub>50</sub> TEST  
GUIDELINE 122-2 OR 123-2 (TIER II)

1. CHEMICAL: Isoxaflutole PC Code No.: 123000

2. TEST MATERIAL: Isoxaflutole technical Purity: 96.8%

3. CITATION

Authors: James R. Hoberg

Title: RPA 201772 Technical - Acute Toxicity to the marine diatom, *Skeletonema costatum*.

Study Completion Date: April 11, 1994

Laboratory: Springborn

Sponsor: Rhone-Poulenc

Laboratory Report ID: 94-6-5302

DP Barcode: D219140

MRID No.: 435732-47

4. REVIEWED BY: Renée Costello, Biologist, ERCB, EFED

Signature: *Renée Costello*

Date: 2/20/96

5. REVIEWED BY: Mike Davy, Agronomist, ERCB, EFED

Signature: *Michael Davy*

Date: 2-26-96

6. STUDY PARAMETERS

Definitive Test Duration: 120 hours

Type of Concentrations: Nominal and initial measured

7. CONCLUSIONS:

Results Synopsis

EC<sub>50</sub>: 0.11 mg ai/L

95% C.I.: 0.05 - 0.33 mg ai/L

NOEC: 0.0022 mg ai/L

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. GUIDELINE DEVIATIONS: 1. Dose range progression was 30% in order to achieve an EC<sub>50</sub> and an NOEC. 2. Continuous lighting was used. This species should have a 14-16 hour light followed by a 8-10 hour dark period. These deviations did not effect the results of the study.

10. SUBMISSION PURPOSE: Product registration.

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
<u>Species</u> <i>Skeletonema costatum</i> <i>Anabaena flos-aquae</i> <i>Selenastrum capricornutum</i> <i>Navicula pelliculosa</i>	<i>Skeletonema costatum</i>
<u>Initial Number of Cells</u> 3,000 - 10,000 cells/mL	10,000 cells/mL
<u>Nutrients</u> Standard formula, e.g. 20XAAP	Artificially Enriched Seawater (AES) medium

B. Test System

Guideline Criteria	Reported Information
<u>Solvent</u>	Acetone
<u>Temperature</u> Skeletonema: 20°C Others: 24-25°C	19 - 20°C
<u>Light Intensity</u> Anabaena: 2.0 KLux (±15%) Others: 4.0-5.0 KLux (±15%)	3200 - 4800 Lux
<u>Photoperiod</u> Skeletonema: 14 h light, 10 h dark or 16 h light, 8 h dark Others: Continuous	Continuous
<u>pH</u> Skeletonema: approx. 8.0 Others: approx. 7.5	7.9 - 8.7

C. Test Design

Guideline Criteria	Reported Information
<u>Dose range</u> 2X or 3X progression	30% in order to achieve an NOEC and EC <sub>50</sub>
<u>Doses</u> at least 5	0.0024, 0.0081, 0.027, 0.090, 0.30, and 1.0
<u>Controls</u> negative and/or solvent	solvent and negative

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Guideline Criteria	Reported Information
<u>Replicates per dose</u> 3 or more	3
<u>Duration of test</u> 120 hours	120 hours
<u>Daily observations were made?</u>	Yes every 24 hours
<u>Method of Observations</u>	Cellular counts
<u>Maximum Labeled Rate</u>	0.18 lb ai/acre

12. REPORTED RESULTS

Guideline Criteria	Reported Information
<u>Initial and 120 h cell densities were measured?</u>	Yes
<u>Control cell count at 120 hr &gt;2X initial count?</u>	> 2x from 24 hours
<u>Initial chemical concentrations measured?</u>	Yes
<u>Raw data included?</u>	Yes

Dose Response

Initial measured concentration (mg ai/L)	Mean Cell Density (x 10 <sup>4</sup> cells/mL)	% Inhibition	120-Hour pH
Control	106	N/A	8.7
Solvent Control	105	N/A	8.7
0.0022	108	-2.1	8.6
0.0074	94	11	8.6
0.024	87	17	8.7
0.074	64	39	8.6
0.24	52	51	8.7
0.75	4	97	7.9

DP Barcode: D219140

MRID No.: 435732-47

Statistical Results

Statistical Method: William's test

EC<sub>50</sub>: 0.11 mg ai/L                      95% C.I.: 0.022 - 0.55 mg ai/L

NOEC: 0.0022 mg ai/L

**13. Verification of Statistical Results**

Statistical Method: Nuthatch

EC<sub>50</sub>: 0.19 mg ai/L                      95% C.I.: 0.14 - 0.25 mg ai/L

EC<sub>25</sub>: 0.10 mg ai/L                      95% C.I.: 0.067 - 0.15 mg ai/L

NOEC: 0.0022 mg ai/L

SKEL.DAT : skeletonema cell counts 120-hour

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Williams Test

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[One-Sided Test for Decrease, alpha = 0.050000 ]

Dose	Isotone Means	T-bar	P-value	Significance
0	106	.		
0.0022	106	-0.1932	N.S.	
0.0074	93.7	3.846	<0.005	*
0.024	87.7	5.743	<0.005	*
0.074	64.3	13.12	<0.005	*
0.24	52.3	16.91	<0.005	*
0.75	4	32.19	<0.005	*

"\*"=Significant; "N.S."=Not Significant.

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Estimates of EC%

Parameter	Estimate	95% Bounds		Std.Err.	Lower Bound /Estimate
		Lower	Upper		
EC5	0.040	0.021	0.076	0.13	0.52
EC10	0.057	0.032	0.099	0.12	0.57
EC25	0.10	0.067	0.15	0.086	0.66
EC50	0.19	0.14	0.25	0.057	0.76

Slope = 2.43 Std.Err. = 0.325

!!!Poor fit: p < 0.001 based on DF= 4.00 17.0

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SKEL.DAT : skeletonema cell counts 120-hour

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Observed vs. Predicted Treatment Group Means

Dose	#Reps.	Obs. Mean	Pred. Mean	Obs. -Pred.	Pred. %Control
0.00	6.00	106.	98.6	7.28	100.
0.00220	3.00	108.	98.6	9.11	100.

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0.000126					
0.00740	3.00	93.7	98.5	-4.86	100.
0.0305					
0.0240	3.00	87.7	97.1	-9.47	98.6
1.44					
0.0740	3.00	64.3	82.9	-18.5	84.1
15.9					
0.240	3.00	52.3	39.8	12.5	40.4
59.6					
0.750	3.00	4.00	7.32	-3.32	7.43
92.6					



skeletonema cell counts 120-hour  
 File: a:skel.dat Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	3	106.667	106.667	106.667
2	solvent control	3	105.000	105.000	106.333
3	0.0022	3	107.667	107.667	106.333
4	0.0074	3	93.667	93.667	93.667
5	0.024	3	87.667	87.667	87.667
6	0.074	3	64.333	64.333	64.333
7	0.24	3	52.333	52.333	52.333
8	0.75	3	4.000	4.000	4.000

skeletonema cell counts 120-hour  
 File: a:skel.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
control	106.667				
solvent control	106.333	0.089		1.75	k= 1, v=16
0.0022	106.333	0.089		1.83	k= 2, v=16
0.0074	93.667	3.474	*	1.86	k= 3, v=16
0.024	87.667	5.078	*	1.87	k= 4, v=16
0.074	64.333	11.314	*	1.88	k= 5, v=16
0.24	52.333	14.521	*	1.89	k= 6, v=16
0.75	4.000	27.439	*	1.89	k= 7, v=16

S = 4.583

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

