



2-14-96

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Data review for Isoxaflutole (D219144, Chemical #123000, Case 286745)

FROM: Renée Costello *Renée Costello 2/14/96*
Environmental Risk Characterization Branch
Environmental Fate and Effects Division (7507C)

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

TO: Joanne Miller, PM 23
Registration Division (7505C) *[Signature]*

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 - Toxicity to the Freshwater Green Alga, *Selenastrum capricornutum* DP Barcode: D219144 MRID No: 435732-43

Conclusions: This study is scientifically sound and fulfills the guideline requirement for acute toxicity testing with the freshwater green alga *Selenastrum capricornutum*. Based on initial measured concentrations, the 120 hour EC₅₀ of Isoxaflutole is 0.14 mg ai/L, the NOEC is 0.016 mg ai/L.

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

Peer reviewer: *Mike Davy 2/14/96*

Mike Davy, Agronomist

DATA EVALUATION RECORD
ALGAE OR DIATOM EC₅₀ TEST
GUIDELINE 122-2 OR 123-2 (TIER I OR II)

1. CHEMICAL: Isoxaflutole PC Code No.: 123000

2. TEST MATERIAL: Isoxaflutole technical Purity: 98.7%

3. CITATION

Authors: James R. Hoberg
Title: RPA 201772 - Toxicity to the Freshwater
Green Alga, *Selenastrum capricornutum*

Study Completion Date: June 21, 1993

Laboratory: Springborn

Sponsor: Rhone-Poulenc

Laboratory Report ID: 93-7-4877

DP Barcode: D219144

MRID No.: 435732-43

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

Signature: *Renée Costello*

Date: 2/12/96

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

Signature: *Michael Davy*

Date: 2/13/96

6. STUDY PARAMETERS

Definitive Test Duration: 120 hours

Type of Concentrations: Nominal and initial measured

7. CONCLUSIONS:

Results Synopsis

EC₅₀: 0.14 ppm ai

NOEL: 0.016 ppm ai

95% C.I.: 0.11 - 0.17 ppm ai

Slope: 1.98

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. GUIDELINE DEVIATIONS: The study was generally in accordance with the protocol.

10. SUBMISSION PURPOSE: 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>Selenastrum capricornutum</i>
<u>Initial Number of Cells</u> 3,000 - 10,000 cells/mL	3,000 cells/mL
<u>Nutrients</u> Standard formula, e.g. 20XAAP	Standard AAP medium

B. Test System

Guideline Criteria	Reported Information
<u>Solvent</u>	Acetone
<u>Temperature</u> <i>Skeletonema</i> : 20°C Others: 24-25°C	25 °C
<u>Light Intensity</u> <i>Anabaena</i> : 2.0 KLux (±15%) Others: 4.0-5.0 KLux (±15%)	3800 - 5100 Lux
<u>Photoperiod</u> <i>Skeletonema</i> : 14 h light, 10 h dark or 16 h light, 8 h dark Others: Continuous	Continuous
<u>pH</u> <i>Skeletonema</i> : approx. 8.0 Others: approx. 7.5	7.2 - 8.0

C. Test Design

Guideline Criteria	Reported Information
<u>Dose range</u> 2X or 3X progression	2x
<u>Doses</u> at least 5	0.50, 0.25, 0.13, 0.063, 0.031, and 0.016
<u>Controls</u> negative and/or solvent	solvent and negative
<u>Replicates per dose</u> 3 or more	3

Guideline Criteria	Reported Information
<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>	0 hour cell density not reported only 24, 48, 72 & 120
<u>Control cell count at 120 hr >2X initial count?</u>	>2x from 24 hours
<u>Initial chemical concentrations measured?</u> (Optional)	Yes
<u>Raw data included?</u>	No

Dose Response

Dose (mg ai/L)	Cell Density (x 10 ⁴ cells/mL)	% Inhibition	120-Hour pH
Control	121	N/A	8.0
Solvent Control	114	N/A	7.8
0.016	112	4	7.4
0.028	97	17	7.2
0.065	85	27	7.4
0.12	61	48	8.0
0.23	46	61	7.3
0.38	17	85	7.2

DP Barcode: D219144

MRID No.: 435732-43

Statistical Results

Statistical Method: William's Test and Linear regression

EC₅₀: 0.12 mg ai/L 95% C.I.: 0.065 - 0.23 mg ai/L

NOEC: 0.016 mg ai/L

13. Verification of Statistical Results

Statistical Method: William's Test

EC₅₀: 0.14 ppm 95% C.I.: 0.11 - 0.17 ppm

Slope: 1.98 NOEC: 0.016 ppm

Program: Nuthatch

Date: 2/12/96

Toxicity measurement for continuous endpoints, using weighted
nonlinear regression, weighting proportional to predicted means.

Reference

R.D. Bruce and D.J. Versteeg. 1992. A statistical procedure for
modeling continuous toxicity data. Env. Tox. and Chem.
11:1485-1494.

SEL.DAT : selenastrum 120-hr cell densities

Williams Test

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

Dose	Isotone Means	T-bar	P-value	Significance
0	117	.		
0.016	112	1.094	N.S.	
0.028	97.7	4.304	<0.005	*
0.065	85	7.076	<0.005	*
0.12	61.3	12.25	<0.005	*
0.23	46.3	15.54	<0.005	*
0.38	17	21.96	<0.005	*

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

Estimates of EC%

Parameter	Estimate	95% Bounds		Std.Err.	Lower Bound /Estimate
		Lower	Upper		
EC5	0.020	0.012	0.035	0.11	0.58
EC10	0.031	0.020	0.049	0.095	0.64
EC25	0.063	0.046	0.086	0.066	0.73
EC50	0.14	0.11	0.17	0.040	0.83

Slope = 1.98 Std.Err. = 0.198

!!!Poor fit: p = 0.012 based on DF= 4.0 17.

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SEL.DAT : selenastrum 120-hr cell densities

