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 (D219141, 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)

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 - Toxicity to Duckweeed, *Lemna gibba*
DP Barcode: D219141 MRID No.: 435732-46

Conclusions: This study is scientifically sound and fulfills the guideline requirement for acute toxicity testing with the Duckweeed *Lemna gibba*.

Results Synopsis
Frond count:
EC_{50}: 0.0049 mg ai/L 95% C.I.: 0.0036 - 0.0066 mg ai/L
NOEC: 0.0011 mg ai/L Slope: 1.55

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

Peer reviewer: Michael Davy 2/14/96

Mike Davy, Agronomist

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DATA EVALUATION RECORD
EC_{50} TEST WITH *LEMNA GIBBA*
GUIDELINE 122-2 OR 123-2 (TIER II)

1. **CHEMICAL:** Isoxaflutole PC Code No.: 123000

2. **TEST MATERIAL:** Isoxaflutole Purity: 96.8%

3. **CITATION**

Authors: James R. Hoberg
Title: RPA 201772 - Toxicity to Duckweeed, *Lemna gibba*
Study Completion Date: May 26, 1994
Laboratory: Springborn
Sponsor: Rhone-Poulenc
Laboratory Report ID: 94-6-5319
DP Barcode: D219141
MRID No.: 435732-46

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

Signature: Renée Costello **Date:** 2/14/96

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

Signature: Michael Davy **Date:** 2/14/96

6. **STUDY PARAMETERS**

Definitive Test Duration: 14 days
Type of Concentrations: Mean measured and Nominal

7. **CONCLUSIONS:**

Results Synopsis
Frond density:
EC_{50}: 0.0049 mg ai/L 95% C.I.: 0.0036 - 0.0066 mg ai/L
NOEC: 0.0011 mg ai/L Slope: 1.55

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 acceptable protocols.

10. **SUBMISSION PURPOSE:** Registration

11. **MATERIALS AND METHODS**

A. Test Organisms

Guideline Criteria	Reported Information
Species *Lemna gibba*	*Lemna gibba*
Number of Plants/Fronds 5 plants, 3 fronds per plant.	5 plants, 3 fronds per plant
Nutrients Standard formula, e.g. 20XAAP	Hoagland's medium - similar to AAP

B. Test System

Guideline Criteria	Reported Information
Solvent	acetone
Temperature 25°C	24 to 25 °C
Light Intensity 5.0 Lux (±15%)	3200 to 4300 Lux
Photoperiod Continuous	Continuous
pH Approximately 5.0	5.0 to 6.2
Test System Static or renewal	Renewal

C. Test Design

Guideline Criteria	Reported Information
Dose range 2X or 3X progression	2x
Doses at least 5	0.00063, 0.0013, 0.0025, 0.0050, 0.010, and 0.020
Controls negative and/or solvent	negative and solvent
Replicates per dose 3 or more	3

Guideline Criteria	Reported Information
Duration of test 14 days	14 days
Daily observations were made?	every 3 days and at test termination
Method of Observations	fronds counted
Maximum Labeled Rate	0.18 lb ai/acre

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Initial and 14 day frond count?	3, 6, 9, 12, and 14
Control frond count at 14 day ≥2X initial count?	>2x 3 day count
Initial chemical concentrations measured? (Optional)	Yes -- mean measured
Raw data included?	Yes

Dose Response

Dose (mg ai/L)	Mean Frond Biomass (g)	% Inhibition	14-Day pH
Control	0.11	N/A	6.2
Solvent Control	0.12	N/A	6.2
0.00056	0.12	-2.7	6.1
0.0011	0.11	7	6.1
0.0024	0.056	52	6.0
0.0047	0.030	74	6.0
0.0093	0.017	86	5.7
0.017	0.016	86	5.7

Dose (mg ai/L)	Mean Fronds/ Replicate	% Inhibition	14-Day pH
Control	598	N/A	6.2
Solvent Control	597	N/A	6.2
0.00056	570	4.4	6.1
0.0011	625	-4.8	6.1
0.0024	443	26	6.0
0.0047	223	63	6.0
0.0093	197	67	5.7
0.017	155	74	5.7

Statistical Results

Statistical Method: Linear regression
Frond density:
EC_{50}: 0.0054 mg ai/L 95% C.I.: 0.0024 - 0.013 mg ai/L

NOEC: 0.0011 mg ai/L

Frond biomass:
EC_{50}: 0.0032 mg ai/L 95% C.I.: 0.0013 - 0.0076 mg ai/L

NOEC: 0.0011 mg ai/L

13. Verification of Statistical Results

Statistical Method: Williams test
Frond density:
EC_{50}: 0.0049 mg ai/L 95% C.I.: 0.0036 - 0.0066 mg ai/L
EC_{25}: 0.0018 mg ai/L 95% C.I.: 0.0011 - 0.0030 mg ai/L
NOEC: 0.0011 mg ai/L Slope: 1.55

Frond biomass:
EC_{50}: 0.0051 mg ai/L 95% C.I.: 0.0024 - 0.011 mg ai/L
EC_{25}: 0.0023 mg ai/L 95% C.I.: 0.00068 - 0.0078 mg ai/L
NOEC: 0.0011 mg ai/L Slope: 1.97

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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.

LEM.DAT : lemna 14-day frond production

Williams Test

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

Dose	Isotone Means	T-bar	P-value	Significance
0	597	.		
0.00056	597	-0.04239	N.S.	
0.0011	597	-0.04239	N.S.	
0.0024	443	9.739	<0.005	*
0.0047	223	23.77	<0.005	*
0.0093	197	25.38	<0.005	*
0.017	155	28.09	<0.005	*

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

Estimates of EC%

Parameter	Estimate	95% Bounds Lower	95% Bounds Upper	Std.Err.	Lower Bound /Estimate
EC5	0.00043	0.00018	0.0010	0.18	0.43
EC10	0.00073	0.00036	0.0015	0.15	0.49
EC25	0.0018	0.0011	0.0030	0.11	0.60
EC50	0.0049	0.0036	0.0066	0.064	0.74

Slope = 1.55 Std.Err. = 0.195

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

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.

LEM2.DAT : lemna biomass

Williams Test

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

Dose	Isotone Means	T-bar	P-value	Significance
0	0.115	.		
0.0011	0.107	1.186	N.S.	
0.0024	0.0679	6.725	<0.005	*
0.0047	0.0679	6.725	<0.005	*
0.0056	0.0679	6.725	<0.005	*
0.0093	0.0165	14.01	<0.005	*
0.017	0.0157	14.13	<0.005	*

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

Estimates of EC%

Parameter	Estimate	95% Bounds Lower	95% Bounds Upper	Std.Err.	Lower Bound /Estimate
EC5	0.00074	9.8E-05	0.0056	0.42	0.13
EC10	0.0011	0.00020	0.0063	0.36	0.18
EC25	0.0023	0.00068	0.0078	0.25	0.30
EC50	0.0051	0.0024	0.011	0.16	0.48

Slope = 1.97 Std.Err. = 0.724

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

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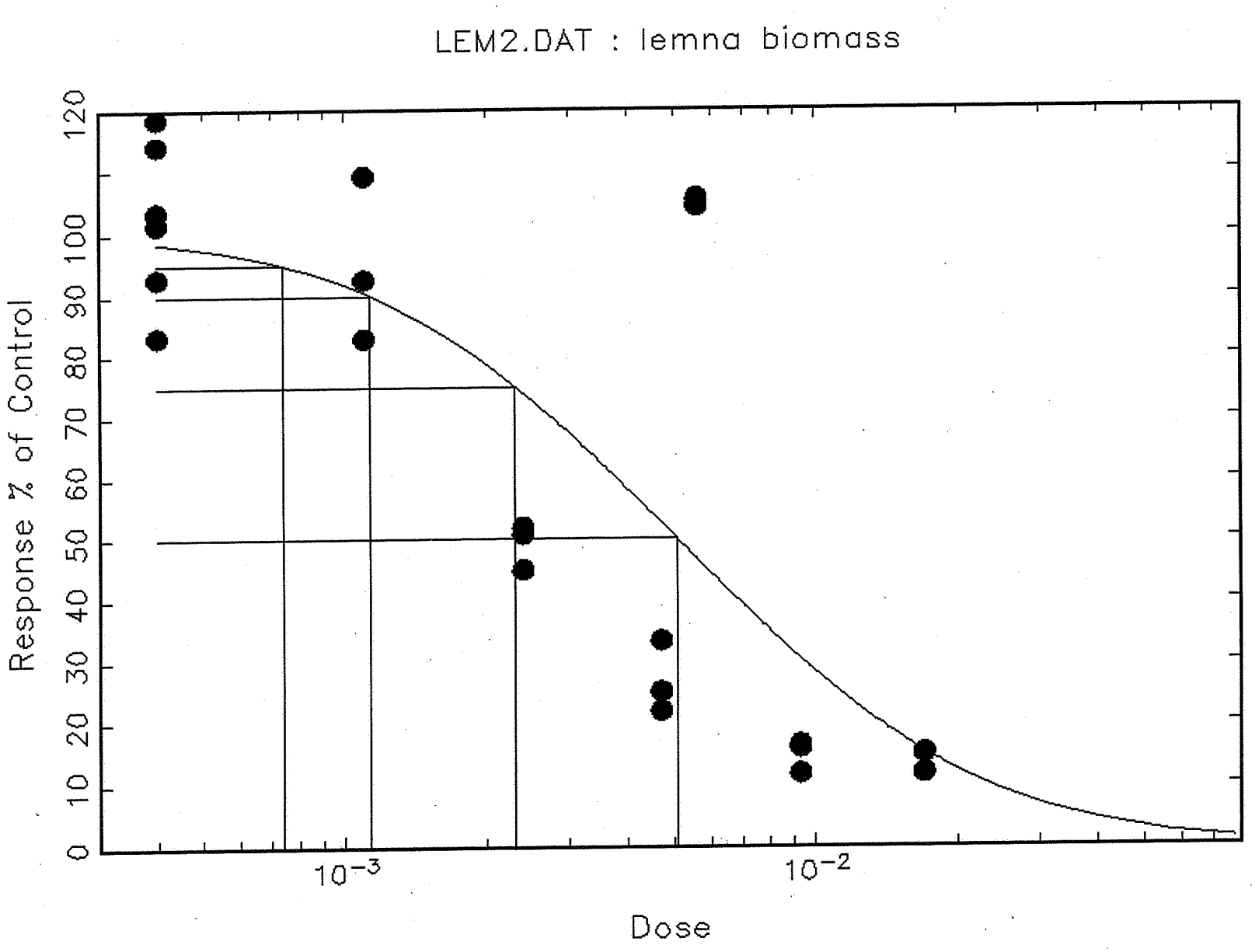
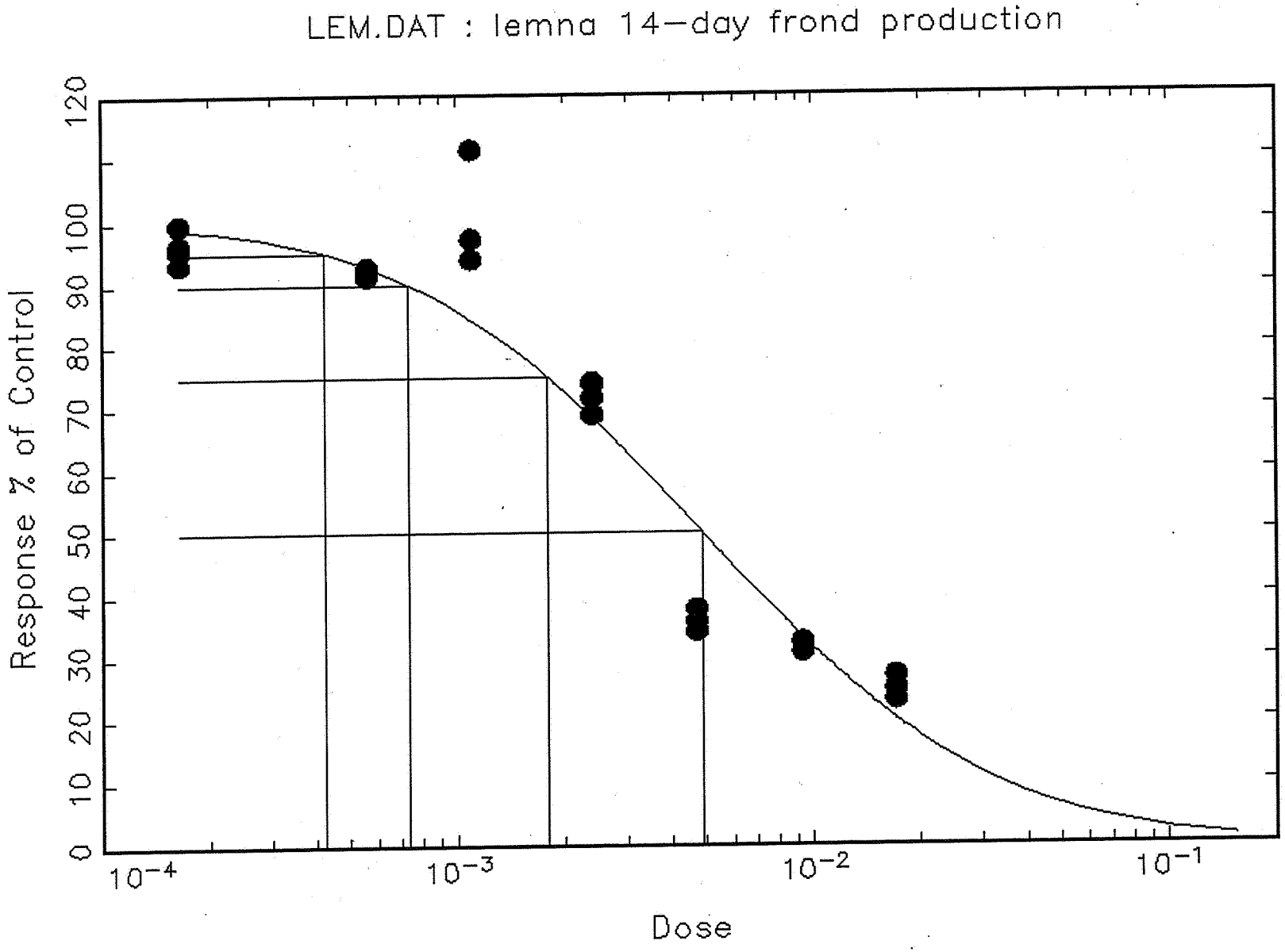

LEM2.DAT : lemna biomass
Response % of Control
0
10
20
30
40
50
60
70
80
90
100
120
10^{-3}
10^{-2}
Dose

4


LEM.DAT : lemna 14-day frond production
Response % of Control
0
10
20
30
40
50
60
70
80
90
100
120
10^{-4}
10^{-3}
10^{-2}
10^{-1}
Dose

b