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

JAN 11 1995

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Data review for Isoxaflutole (D219142, Chemical #123000,
Case 286745, ID# 286745)

FROM: Renée Costello, Biologist *Renée Costello* 12/18/95
Environmental Risk Characterization Branch
Environmental Fate and Effects Division (7507C)

THRU: Elizabeth M. Leovey, Chief *Elizabeth M. Leovey*
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 Technical - Acute Toxicity to the Freshwater Blue-green Alga, *Anabaena flos-aquae*. EPA MRID No. 435732-45

Conclusions: This study is scientifically sound and meets the guideline requirements for an algae acute toxicity test. Based on mean measured concentrations, the 120 hour EC₅₀ of isoxaflutole technical is 0.18 mg ai/L. The NOEC is 0.0086 mg ai/L

Peer review: Mike Davy, Agronomist, ERCB *Michael Davy* 1/11/96

DATA EVALUATION RECORD
ALGAE OR DIATOM EC₅₀ 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 Freshwater Blue-green Alga, *Anabaena*
flos-aquae

Study Completion Date: March 21, 1994

Laboratory: Springborn

Sponsor: Rhone-Poulenc

Laboratory Report ID: 94-3-5207

DP Barcode: D219142

MRID No.: 435732-45

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

Signature: *Renée Costello*

Date: 12/18/95

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

Signature: *Michael Davy*

Date: 1-11-96

6. STUDY PARAMETERS

Definitive Test Duration: 120 hours

Type of Concentrations: Nominal and initial measured

7. CONCLUSIONS:

Results Synopsis

EC₅₀: 0.18 mg ai/L

95% C.I.: 0.14 - 0.24 mg ai/L

Probit Slope: 1.19

NOEC: 0.0086 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 EC₅₀ and an NOEC.

This deviation did not effect the results of the study.

10. **SUBMISSION PURPOSE:** Product registration.

11. **MATERIALS AND METHODS**

A. Test Organisms

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

B. Test System

| Guideline Criteria | Reported Information |
|--------------------------------------------------------------------------------------------------------------|----------------------|
| Solvent | Acetone |
| Temperature Skeletonema: 20°C Others: 24-25°C | 25 °C |
| Light Intensity Anabaena: 2.0 KLux (±15%) Others: 4.0-5.0 KLux (±15%) | 1100 - 3300 Lux |
| Photoperiod Skeletonema: 14 h light, 10 h dark or 16 h light, 8 h dark Others: Continuous | Continuous |
| pH Skeletonema: approx. 8.0 Others: approx. 7.5 | 7.4 - 8.5 |

C. Test Design

| Guideline Criteria | Reported Information |
|-------------------------------------------|------------------------------------------------------|
| Dose range 2X or 3X progression | 30% in order to achieve an NOEC and EC ₅₀ |
| Doses at least 5 | 0.0024, 0.0081, 0.027, 0.090, 0.30, and 1.0 |

| Guideline Criteria | Reported Information |
|--------------------------------------------|----------------------|
| Controls negative and/or solvent | solvent and negative |
| Replicates per dose 3 or more | 3 |
| Duration of test 120 hours | 120 hours |
| Daily observations were made? | Yes every 24 hours |
| Method of Observations | Cellular counts |
| Maximum Labeled Rate | 0.18 lb ai/acre |

12. REPORTED RESULTS

| Guideline Criteria | Reported Information |
|------------------------------------------------------------------------|----------------------|
| Initial and 120 h cell densities were measured? | Yes |
| Control cell count at 120 hr \geq2X initial count? | >2x from 24 hours |
| Initial chemical concentrations measured? | Yes |
| Raw data included? | Yes |

Dose Response

| Dose (mg ai/L) | Cell Density ($\times 10^4$ cells/mL) | % Inhibition | 120-Hour pH |
|-------------------|-------------------------------------------|--------------|-------------|
| Control | 89 | N/A | 8.5 |
| Solvent Control | 94 | N/A | 8.4 |
| 0.0020 | 92 | -0.64 | 8.0 |
| 0.0086 | 85 | 6.8 | 7.9 |
| 0.028 | 73 | 20 | 7.8 |
| 0.087 | 62 | 32 | 7.9 |
| 0.23 | 49 | 46 | 7.9 |
| 0.99 | 12 | 87 | 7.7 |

DP Barcode: D219142

MRID No.: 435732-45

Statistical Results

Statistical Method: William's test

EC₅₀: 0.17 mg ai/L 95% C.I.: 0.031 - 1.1 mg ai/L

NOEC: 0.0086 mg ai/L

13. Verification of Statistical Results

Statistical Method: Toxanal

EC₅₀: 0.18 mg ai/L 95% C.I.: 0.14 - 0.24 mg ai/L

Probit Slope: 1.19 NOEC: 0.0086 mg ai/L

costello isoxaflutole anabaena

| CONC. | NUMBER EXPOSED | NUMBER DEAD | PERCENT DEAD | BINOMIAL PROB. (PERCENT) |
|-------|----------------|-------------|--------------|--------------------------|
| .99 | 100 | 87 | 87 | 0 |
| .23 | 100 | 46 | 46 | 0 |
| .087 | 100 | 32 | 32 | 0 |
| .028 | 100 | 20 | 20 | 0 |
| .0086 | 100 | 7 | 7 | 0 |
| .002 | 100 | 1 | 1 | 0 |

THE BINOMIAL TEST SHOWS THAT .23 AND .99 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .2615028

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

| SPAN | G | LC50 | 95 PERCENT CONFIDENCE LIMITS | |
|----------|--------------|------|------------------------------|----------|
| 3 | 4.185487E-02 | | .2055365 | .1575311 |
| .2775972 | | | | |

RESULTS CALCULATED USING THE PROBIT METHOD

| ITERATIONS | G | H |
|------------|--------------|---|
| 3 | 2.302101E-02 | 1 |
| .1337676 | | |

SLOPE = 1.186771
95 PERCENT CONFIDENCE LIMITS = 1.006706 AND 1.366836

LC50 = .1820007
95 PERCENT CONFIDENCE LIMITS = .1423098 AND .2390341

LC10 = 1.548611E-02
95 PERCENT CONFIDENCE LIMITS = 1.009744E-02 AND .0217165

Anabaena cell densities
 File: a:isoxaflutole\ana.dat

Transform: NO TRANSFORM

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 1 of 2

| GRP | IDENTIFICATION | N | MIN | MAX | MEAN |
|-----|-----------------|---|--------|---------|--------|
| 1 | control | 3 | 84.000 | 95.000 | 89.167 |
| 2 | solvent control | 3 | 88.250 | 100.750 | 93.833 |
| 3 | 0.0020 | 3 | 85.000 | 98.000 | 92.083 |
| 4 | 0.0086 | 3 | 80.750 | 90.000 | 85.250 |
| 5 | 0.028 | 3 | 64.500 | 84.500 | 72.833 |
| 6 | 0.087 | 3 | 53.000 | 68.250 | 62.083 |
| 7 | 0.23 | 3 | 43.500 | 53.750 | 49.417 |
| 8 | 0.99 | 3 | 10.250 | 14.250 | 11.750 |

Anabaena cell densities
 File: a:isoxaflutole\ana.dat

Transform: NO TRANSFORM

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 2 of 2

| GRP | IDENTIFICATION | VARIANCE | SD | SEM |
|-----|-----------------|----------|--------|-------|
| 1 | control | 30.583 | 5.530 | 3.193 |
| 2 | solvent control | 40.396 | 6.356 | 3.670 |
| 3 | 0.0020 | 43.271 | 6.578 | 3.798 |
| 4 | 0.0086 | 21.438 | 4.630 | 2.673 |
| 5 | 0.028 | 108.333 | 10.408 | 6.009 |
| 6 | 0.087 | 64.521 | 8.032 | 4.638 |
| 7 | 0.23 | 28.146 | 5.305 | 3.063 |
| 8 | 0.99 | 4.750 | 2.179 | 1.258 |

Anabaena cell densities
 File: a:isoxaflutole\ana.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 | 89.167 | 89.167 | 91.694 |
| 2 | solvent control | 3 | 93.833 | 93.833 | 91.694 |
| 3 | 0.0020 | 3 | 92.083 | 92.083 | 91.694 |
| 4 | 0.0086 | 3 | 85.250 | 85.250 | 85.250 |
| 5 | 0.028 | 3 | 72.833 | 72.833 | 72.833 |
| 6 | 0.087 | 3 | 62.083 | 62.083 | 62.083 |
| 7 | 0.23 | 3 | 49.417 | 49.417 | 49.417 |
| 8 | 0.99 | 3 | 11.750 | 11.750 | 11.750 |

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WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

| IDENTIFICATION | ISOTONIZED MEAN | CALC. WILLIAMS | SIG P=.05 | TABLE WILLIAMS | DEGREES OF FREEDOM |
|-----------------|-----------------|----------------|-----------|----------------|--------------------|
| control | 91.694 | | | | |
| solvent control | 91.694 | 0.474 | | 1.75 | k= 1, v=16 |
| 0.0020 | 91.694 | 0.474 | | 1.83 | k= 2, v=16 |
| 0.0086 | 85.250 | 0.734 | | 1.86 | k= 3, v=16 |
| 0.028 | 72.833 | 3.062 | * | 1.87 | k= 4, v=16 |
| 0.087 | 62.083 | 5.077 | * | 1.88 | k= 5, v=16 |
| 0.23 | 49.417 | 7.452 | * | 1.89 | k= 6, v=16 |
| 0.99 | 11.750 | 14.513 | * | 1.89 | k= 7, v=16 |

s = 6.533

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