MRID No. 440796-01

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

1. **CHEMICAL**: Tebuconazole

PC Code No.: 128997

2. TEST MATERIAL:

Folicur Technical

Purity: 96.7%

3. <u>CITATION</u>:

Author:

L.M. Bowers

Toxicity of Folicur Technical to the Green Alga Selenastrum Title:

capricornutum

Study Completion Date:

June 24, 1996

Laboratory:

Bayer Corporation, Environmental Research Section, Stilwell,

Sponsor:

Bayer Corporation, Kansas City, MO

<u>Laboratory Report ID</u>:

107341

DP Barcode:

D230858

MRID No.:

440796-01

4. REVIEWED BY: Max Feken, M.S., Environmental Toxicologist,

KBN Engineering and Applied Sciences, Inc.

Signature:

Date: 12/4/96

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,

KBN Engineering and Applied Sciences, Inc.

Signature:

Date:

5. APPROVED BY: Brian Montague, Fisheries Biologist

Environmental Risk Branch I

Environmental Fate and Effects Division

Signature:

Date: 4/2000

6. STUDY PARAMETERS:

Definitive Test Duration:

120 hours

Type of Concentrations:

Mean measured

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an aquatic plant toxicity test with green algae species.

Results Synopsis

EC₅₀: 2.83 ppm ai

95% C.I.: 2.41 - 3.02 ppm ai

NOEC: 1.19 ppm ai

Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. Classification: Core



B. Rationale: N/AC. Repairability: N/A

9. **GUIDELINE DEVIATIONS**: None

10. <u>SUBMISSION PURPOSE</u>: Submitted to support registration of tebuconazole for outdoor crop uses.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species Selenastrum capricornutum	Selenastrum capricornutum
Initial Number of Cells 3,000 - 10,000 cells/mL	10,000 cells/mL
Nutrients Standard formula, e.g. 20XAAP	Sterile Freshwater Media (ASTM, 1990)

B. Test System

Guideline Criteria	Reported Information
Solvent	Acetone (0.5 mL/L)
Temperature Skeletonema: 20°C Others: 24-25°C	23.7 - 24.5°C
Light Intensity Anabaena: 2.0 Klux (±15%) Others: 4.0-5.0 Klux (±15%)	Approximately 4.3 Klux
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	Initial: 6.7 - 7.0 Final: 6.5 - 8.2

C. Test Design

Guideline Criteria	Reported Information
Dose range 2X or 3X progression	2X
Doses at least 5	0.63, 1.25, 2.5, 5.0, and 10 mg/L
Controls negative and/or solvent	Negative and solvent control
Replicates per dose 3 or more	3
Duration of test 120 hours	120 hours
Daily observations were made?	Observations were made daily.
Method of Observations	Cellular counts
Maximum Labeled Rate	Not reported

12. <u>REPORTED RESULTS</u>:

Guideline Criteria	Reported Information
Initial and 120 h cell densities were measured?	Yes
Control cell count at 120 hr ≥2X initial count?	Yes
Initial chemical concentrations measured? (Optional)	Yes
Raw data included?	Yes

<u>Dose Response - Day 4</u>

li .	ntration ai/L Mean Measured	Avg. Cell Density (x 10 ⁴ cells/ml)	% reduction ^a	120-Hour pH
Control	< 0.05	176	-71	8.2
Solvent Control	<0.05	103		8.1
0.63	0.68	123	-19	8.2
1.25	1.19	118	-14	NR ^b
2.5	2.46	67	45	8.2
5.0	4.94	0.5	100	NR
10.0	10.9	0.2	100	6.5

^aCompared to the solvent control ^bNR - Not Reported

<u>Dose Response - Day 5</u>

Concentration mg ai/L Mean Nominal Measured		Avg. Cell Density (x 10 ⁴ cells/ml)	% reduction ^a	120-Hour pH
Control	< 0.05	177	-13	8.2
Solvent Control	<0.05	156		8.1
0.63	0.68	116	25	8.2
1.25	1.19	119	23	NR ^b
2.5	2.46	121	22	8.2
5.0	4.94	1.4	100	NR
10.0	10.9	0.9	100	6.5

^aCompared to the solvent control ^bNR - Not Reported

Other Significant Results: The authors stated that "because the results on Day 5 did not follow a clear dose-response these data were considered unreliable for calculation of the EC_{50} ." The reviewer agrees with this observation and has chosen to calculate the EC_{50} and NOEC based on the results from Day 4.

Statistical Results

Statistical Method: EC₅₀ was calculated using the linear interpolation (ICp) method

and mean comparisons were made using the Dunnett's test.

Results based on mean measured concentrations.

EC₅₀: 2.83 mg ai/L 95% C.I.: 2.41 - 3.02 mg ai/L

Probit Slope: N/A NOEC: 2.46 mg/L

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Binomial method for EC₅₀ and Williams' test for mean

comparisons. Results based on the mean measured

concentrations.

EC₅₀: 2.57 ppm ai 95% C.I.: Not determined

Probit Slope: N/A NOEC: 1.19 ppm ai

14. **REVIEWER'S COMMENTS:** This study is scientifically sound and fulfills the guideline requirements for an aquatic plant toxicity test. Based on mean measured concentrations, the 120-hour EC₅₀ for *Selenastrum capricornutum* exposed to Folicur Technical was 2.83 ppm ai. The NOEC was determined to be 1.19 ppm ai. This study is categorized as **Core**.

MAX FEKEN FOLICUR SELENASTRUM 11-26-96

CONC.	NUMBER	NUMBER	PERCENT	BINOMIAL		
	EXPOSED	DEAD	DEAD	PROB. (PERCENT)		
4.94	100	100	100	0		
2.46	100	45	45	0		
1.19	100	0	0	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 2.570743

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

FOLICUR - SELENASTRUM (DAY 4)

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WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	SOLVENT	3	103.000	103.000	139.375
2	CONTROL	3	175.750	175.750	139.375
3	0.68	3	123.000	123.000	123.000
4	1.19	3	117.583	117.583	117.583
5	2.46	3	67.250	67.250	67.250
6	4.94	3	0.470	0.470	0.470
7	10.9	3	0.220	0.220	0.220

FOLICUR - SELENASTRUM (DAY 4)

File: 44079601 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	139.375				.
CONTROL	139.375	2.152	*	1.76	k = 1, v = 14
0.68	123.000	1.183		1.85	k = 2, v = 14
1.19	117.583	0.863		1.88	k = 3, v = 14
2.46	67.250	2.115	*	1.89	k = 4, v = 14
4.94	0.470	6.066	*	1.90	k = 5, v = 14
10.9	0.220	6.081	*	1.91	k = 6, v = 14

s = 20.702

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

FOLICUR - SELENASTRUM (DAY 5)

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WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	SOLVENT	3	155.500	155.500	166.438
2	CONTROL	3	177.377	177.377	166.438
3	0.68	3	116.127	116.127	118.834
4	1.19	3	119.127	119.127	118.834
5	2.46	3	121.250	121.250	118.834
6	4.94	3	1.443	1.443	1.443
7	10.9	3	0.907	0.907	0.907

FOLICUR - SELENASTRUM (DAY 5)

File: 44079601 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	166.438				
CONTROL	166.438	0.628		1.76	k = 1, v = 14
0.68	118.834	2.106	*	1.85	k = 2, v = 14
1.19	118.834	2.106	*	1.88	k = 3, v = 14
2.46	118.834	2.106	*	1.89	k = 4, v = 14
4.94	1.443	8.848	*	1.90	k = 5, v = 14
10.9	0.907	8.879	*	1.91	k = 6, v = 14

s = 21.324

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

5 Day 7. 46 ppm value higher have than in 4 Day cell count there 4 Day count wood in determiny EC 30 Levels. DP BARCODE: D230858

CASE: 192680

DATA PACKAGE RECORD

SUBMISSION: S510527 BEAN SHEET DATE: 12/01/97

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* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 400 DATA-MISC DATA-NOT REQUES

RANKING : 0 POINTS ()

CHEMICALS: 128997 Tebuconazole

0.0000%

Folicur Technical ID#: 003125-00383

COMPANY: 003125 BAYER CORP

247 703-308-9354 ROOM: CM2 PRODUCT MANAGER: 21 MARY WALLER MARY WALLER 703-308-9354 ROOM: CM2 247 PM TEAM REVIEWER:

RECEIVED DATE: 08/05/96 DUE OUT DATE: 12/03/96

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 230858 EXPEDITE: N DATE SENT: 10/23/96 DATE RET.: / /

CHEMICAL: 128997 Tebuconazole

DP TYPE: 001 Submission Related Data Package

LABEL: N CSF: N ADMIN DUE DATE: 11/17/96 DATE IN DATE OUT ASSIGNED TO NEGOT DATE: / / 04/20/00 10/24/96 DIV : EFED PROJ DATE: 10/25/96 04/20/04 BRAN: ERB1 04/25/00 10/25/96 CONTR: ODENKIRCH 12/01/97 SECT: IO 04/20/10 / /

* * * DATA REVIEW INSTRUCTIONS * * *

6(a)(2) committee has determined that this is not adverse effects data and should be reviewed normally.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

INS CSF LABEL DP BC BRANCH/SECTION DATE OUT DUE BACK

* KBN Disk attached Elf