DATA EVALUATION RECORD
ALGAE OR DIATOM EC_{50} TEST
GUIDELINE 123-2 (TIER II)

1. **CHEMICAL:** S-dimethenamid **PC Code No.:** 120051

2. **TEST MATERIAL:** SAN 1289H Technical
91.1% as S-dimethenamid

3. **CITATION:**

Authors:	James R. Hoberg
Title:	SAN 1289H Technical - Toxicity to the Freshwater Diatom, *Navicula pelliculosa*
Study Completion Date:	January 20, 1997
Laboratory:	Springborn Laboratories, Inc., Wareham, MA
Sponsor:	Sandoz Agro, Inc., Des Plaines, IL
Laboratory Report ID:	96-11-6782
DP Barcode:	D238350, D238356
MRID No.:	443322-54

4. **REVIEWED BY:** Karl Bullock, M.S., Associate Scientist,
Golder Associates Inc.

Signature: Karl Bullock **Date:** 10/24/97

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
Golder Associates Inc.

Signature: P. Kosalwat **Date:** 10/24/97

5. **APPROVED BY:**

Signature: Joanne S. Edwards for Jim Bailey **Date:** 12/3/97
11/4/98

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 a freshwater diatom toxicity test. The 5-day EC_{50} and NOEC for *N. pelliculosa* exposed to SAN 1289H Technical were 0.33 and 0.056 ppm ai, respectively.

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8. **ADEQUACY OF THE STUDY:**

A. Classification: Core.

B. Rationale: N/A.

C. Repairability: N/A.

9. **GUIDELINE DEVIATIONS:** None.

10. **SUBMISSION PURPOSE:**

11. **MATERIALS AND METHODS:**

A. Test Organisms

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

B. Test System

Guideline Criteria	Reported Information
Solvent	None
Temperature Skeletonema: 20°C Others: 24-25°C	25°C
Light Intensity Anabaena: 2.0 KLux (±15%) Others: 4.0-5.0 KLux (±15%)	4.5-4.7 KLux
Photoperiod Skeletonema: 14 h light, 10 h dark or 16 h light, 8 h dark Others: Continuous	Continuous

Guideline Criteria	Reported Information
pH Skeletonema: approx. 8.0 Others: approx. 7.5	Initial: 7.2-7.5 Final: 7.9-8.5

C. Test Design

Guideline Criteria	Reported Information
Dose range 2X or 3X progression	2X
Doses at least 5	0.031, 0.063, 0.13, 0.25, 0.50, and 1.0 mg ai/L
Controls negative and/or solvent	Negative control
Replicates per dose 3 or more	3
Duration of test 120 hours	120 hours
Daily observations were made?	Yes
Method of Observations	Cellular counts
Maximum Labeled Rate	1.25 lb ai/A (0.92 ppm ai)

12. REPORTED RESULTS:

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

Dose Response

Mean measured concentration (mg ai/L)	Avg. Cell Density (x 10^4 cells/mL)	Inhibition (%)	Final pH
Control	94	-	8.5
0.028	94	0 (-0.44)	8.5
0.056	92	1.3	8.4
0.10	80	15	8.4
0.21	60	36	8.2
0.41	40	58	8.1
0.89	24	75	7.9

Other Significant Results: None.

Statistical Results for Cell Density:

Statistical Method: Linear regression analysis for EC_{50} and Williams' test for NOEC

EC_{50}: 0.34 ppm ai 95% C.I.: 0.17-0.71 ppm ai
Probit Slope: N/A NOEC: 0.056 ppm ai

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Non-linear regression analysis for EC_{50} and Williams' test for NOEC.

EC_{50}: 0.33 ppm ai 95% C.I.: 0.27-0.40 ppm ai
Probit Slope: N/A NOEC: 0.056 ppm ai

14. REVIEWER'S COMMENTS: This study is scientifically sound and fulfills the guideline requirements for a toxicity test with a freshwater diatom. The 5-day EC_{50} and NOEC for *N. pelliculosa* exposed to SAN 1289H Technical were 0.33 and 0.056 ppm ai, respectively. This study can be categorized as **Core.**

KARL BULLOCK SAN 1289H NAVICULA PELLICULOSA 10-22-97

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.89	100	75	75	0
.41	100	58	58	0
.21	100	36	36	0
.1	100	15	15	0
.056	100	1	1	0
.028	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 .3219039

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	4.638855E-02	.3392244	.2845818	.4098846

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	2.178125E-02	1	.105948

SLOPE = 2.14012

95 PERCENT CONFIDENCE LIMITS = 1.824271 AND 2.455969

LC50 = .3572128

95 PERCENT CONFIDENCE LIMITS = .310309 AND .4174747

LC10 = 9.109664E-02

95 PERCENT CONFIDENCE LIMITS = 7.229926E-02 AND .1096515

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S-dimethenamid - Navicula pelliculosa
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WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	3	94.000	94.000	94.000
2	0.028	3	94.000	94.000	94.000
3	0.056	3	92.667	92.667	92.667
4	0.10	3	80.000	80.000	80.000
5	0.21	3	60.000	60.000	60.000
6	0.41	3	40.000	40.000	40.000
7	0.89	3	23.667	23.667	23.667

S-dimethenamid - Navicula pelliculosa
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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	94.000				
0.028	94.000	0.000		1.76	k= 1, v=14
0.056	92.667	0.315		1.85	k= 2, v=14
0.10	80.000	3.303	*	1.88	k= 3, v=14
0.21	60.000	8.021	*	1.89	k= 4, v=14
0.41	40.000	12.739	*	1.90	k= 5, v=14
0.89	23.667	16.592	*	1.91	k= 6, v=14

s = 5.192
Note: df used for table values are approximate when v > 20.

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OBS	CONC	LOG_CONC	Y1	Y2	Y3	Y4	Y5	Y6
1	0.000	.	92	98	92	.	.	.
2	0.028	-1.55284	95	93	94	.	.	.
3	0.056	-1.25181	90	93	95	.	.	.
4	0.100	-1.00000	78	79	83	.	.	.
5	0.210	-0.67778	60	69	51	.	.	.
6	0.410	-0.38722	30	43	47	.	.	.
7	0.890	-0.05061	22	25	24	.	.	.

S-dimethenamid - Navicula 11
MODEL: COUNT = C0 * PROBNORM ((LOG_EC50 - LOG_CONC) / SIGMA)
WEIGHTED REGRESSION
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Non-Linear Least Squares Iterative Phase
Dependent Variable COUNT Method: Gauss-Newton

Iter	LOG_EC50	SIGMA	C0	Weighted SS
0	-0.447000	0.467000	94.000000	13.175308
1	-0.482466	0.583223	97.104012	8.960191
2	-0.479782	0.578707	97.017952	8.935859
3	-0.480320	0.579606	97.059292	8.937288
4	-0.480216	0.579430	97.051265	8.936990
5	-0.480237	0.579465	97.052843	8.937048
6	-0.480233	0.579458	97.052534	8.937037
7	-0.480233	0.579459	97.052595	8.937039
8	-0.480233	0.579459	97.052583	8.937038
9	-0.480233	0.579459	97.052585	8.937038

NOTE: Convergence criterion met.

Non-Linear Least Squares Summary Statistics Dependent Variable COUNT

Source	DF	Weighted SS	Weighted MS
Regression	3	1453.0000000	484.3333333
Residual	18	8.9370384	0.4965021
Uncorrected Total	21	1461.9370384	
(Corrected Total)	20	323.9500581	

Parameter	Estimate	Asymptotic Std. Error	Asymptotic 95 % Confidence Interval Lower	Upper
LOG_EC50	-0.48023335	0.0390203047	-0.562211422	-0.39825527
SIGMA	0.57945890	0.0506010512	0.473150736	0.68576706
C0	97.05258529	3.1431660396	90.449082110	103.65608846

Asymptotic Correlation Matrix

Corr	LOG_EC50	SIGMA	C0
LOG_EC50	1	-0.614645641	-0.800218274
SIGMA	-0.614645641	1	0.6370048944
C0	-0.800218274	0.6370048944	1

S-dimethenamid - Navicula 12
MODEL: COUNT = C0 * PROBNORM ((LOG_EC50 - LOG_CONC) / SIGMA)
SUMMARY OF NONLINEAR REGRESSION
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OBS	CONC	LOG_EC50	SIGMA	C0	RESID_SS	EC50
1	0	-0.48023	0.57946	97.0526	8.93704	0.33095

S-dimethenamid - Navicula 13
MODEL: COUNT = C0 * PROBNORM ((LOG_EC50 - LOG_CONC) / SIGMA)

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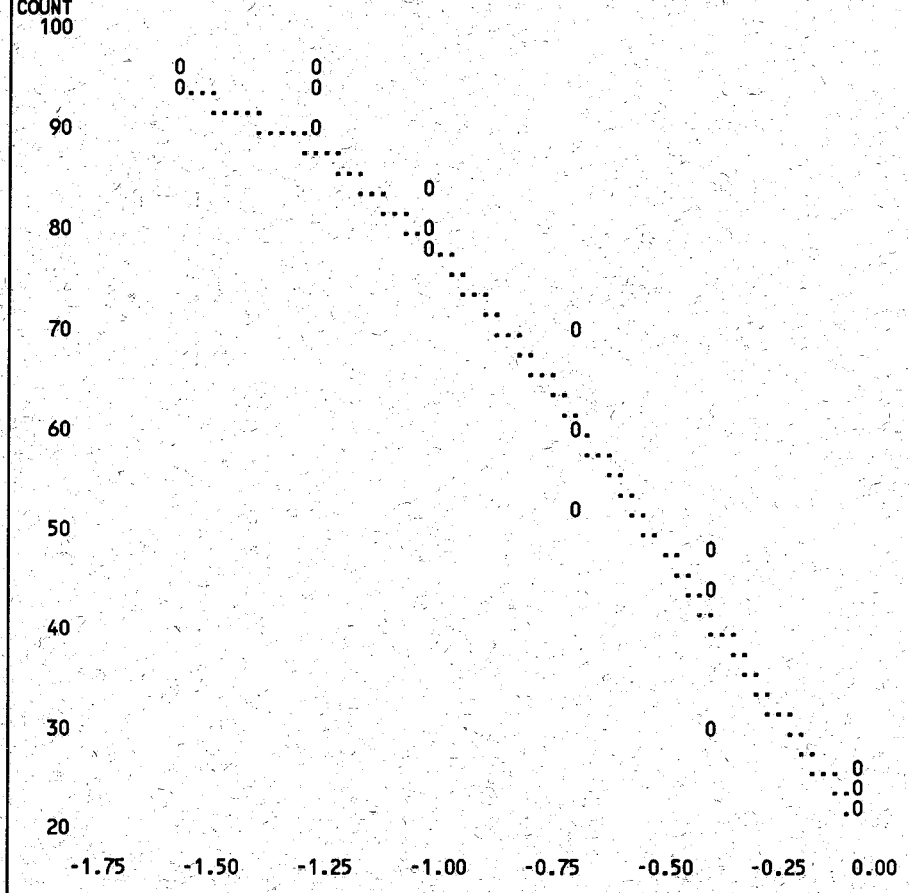
Plot of COUNT*LOG_CONC. Symbol used is '0'.
Plot of PRED*LOG_CONC. Symbol used is '.'.



NOTE: 1533 obs had missing values. 1449 obs hidden.
S-dimethenamid - Navicula 14
COMPARISON OF MEANS FOR NOEL DETERMINATION
TEST IF TREATMENT IS LESS THAN CONTROL
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General Linear Models Procedure
Class Level Information

Class	Levels	Values
DOSE	7	0 0.1 0.21 0.41 0.89 0.028 0.056

Number of observations in data set = 42

NOTE: Due to missing values, only 21 observations can be used in this analysis.

S-dimethenamid - Navicula 15
COMPARISON OF MEANS FOR NOEL DETERMINATION
TEST IF TREATMENT IS LESS THAN CONTROL
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General Linear Models Procedure

Dependent Variable: RESPONSE

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	6	14723.90476	2453.98413	91.05	0.0001
Error	14	377.33333	26.95238		
Corrected Total	20	15101.23810			

R-Square	C.V.	Root MSE	RESPONSE Mean
0.975013	7.503299	5.191568	69.19048

Source	DF	Type I SS	Mean Square	F Value	Pr > F
DOSE	6	14723.90476	2453.98413	91.05	0.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
DOSE	6	14723.90476	2453.98413	91.05	0.0001

S-dimethenamid - Navicula 16
COMPARISON OF MEANS FOR NOEL DETERMINATION
TEST IF TREATMENT IS LESS THAN CONTROL
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General Linear Models Procedure

Level of DOSE	N	RESPONSE Mean	RESPONSE SD
0	3	94.0000000	3.46410162
0.1	3	80.0000000	2.64575131
0.21	3	60.0000000	9.00000000
0.41	3	40.0000000	8.88819442
0.89	3	23.6666667	1.52752523
0.028	3	94.0000000	1.00000000
0.056	3	92.6666667	2.51661148

S-dimethenamid - Navicula 17
COMPARISON OF MEANS FOR NOEL DETERMINATION
TEST IF TREATMENT IS LESS THAN CONTROL
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General Linear Models Procedure

Dunnett's One-tailed T tests for variable: RESPONSE

NOTE: This tests controls the type I experimentwise error for comparisons of all treatments against a control.

Alpha= 0.05 Confidence= 0.95 df= 14 MSE= 26.95238
Critical Value of Dunnett's T= 2.532
Minimum Significant Difference= 10.734

Comparisons significant at the 0.05 level are indicated by '***'.

DOSE Comparison	Simultaneous Lower Confidence Limit	Difference Between Means	Simultaneous Upper Confidence Limit	
0.028 - 0	-10.734	0.000	10.734	
0.056 - 0	-12.067	-1.333	9.400	
0.1 - 0	-24.734	-14.000	-3.266	***
0.21 - 0	-44.734	-34.000	-23.266	***
0.41 - 0	-64.734	-54.000	-43.266	***
0.89 - 0	-81.067	-70.333	-59.600	***