

4-6-98

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

1. CHEMICAL: SAN 1269H (Diflufenzopyr+Dicamba) PC Code No:005107

2. TEST MATERIAL: The test substance, SAN 1269H, is a formulated product consisting of the active ingredients Dicamba sodium salt and SAN 836H (Diflufenzopyr sodium salt).
Purity: 50% (wt. as acid equivalents) as Dicamba; 20% (wt. as acid equivalents) as Diflufenzopyr.

3. CITATION

Author: Hoberg, James
Title: SAN 1269H- Toxicity to the Freshwater Blue-Green, Alga, *Anabaena flos-aquae*
Study Completion Date: May 14, 1996
Laboratory: Springborn Laboratories, Inc.
Sponsor: Sandoz Agro, Inc.
Laboratory Report ID: 96-6-6553
DP Barcode: D238406
MRID No.: 443074-50

4. REVIEWED BY: Fred Jenkins, Aquatic Biologist, ERBII, EFED

Signature: *Fred Jenkins* Date: *4/6/98*

5. APPROVED BY: Mike Davy, Agronomist, ERBII, EFED

Signature: *Michael Davy* Date: *4-6-98*

6. STUDY PARAMETERS

Scientific Name of Test Organism: *Anabaena flos-aquae*
Definitive Test Duration: 5 Days
Type of Concentrations: Mean measured

7. CONCLUSIONS:

Results Synopsis

EC₅₀: > 0.26 ppm A.E. (acid equivalents) 95% C.I.: N/A
NOEL: 0.0059 ppm A.E. Slope: N/A

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale: The study met guideline criteria.

C. Repairability: N/A

9. GUIDELINE DEVIATIONS

The light intensity range for the test conditions reported (1.076-3.228 K lux) in the study fall outside of The Hazard Evaluation Division Standard Evaluation Procedure for Non-Target Plants: Growth and Reproduction of Aquatic Plants-Tiers 1 and 2 (SEP) recommended light intensity of 2 K lux.

10. SUBMISSION PURPOSE:

Registration under Section 3

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>Anabaena flos-aquae</i>
<u>Initial Number of Cells</u> 3,000 - 10,000 cells/ml	10000 cells/ml
<u>Nutrients</u> Standard formula, e.g. 20XAAP	AAP Medium

2

B. Test System

Guideline Criteria	Reported Information
<u>Solvent</u>	N/A
<u>Temperature</u> Skeletonema: 20°C Others: 24-25°C	24°C
<u>Light Intensity</u> Anabaena: 2.2 K lux (±15%) Others: 4.3 K lux (±15%)	1.076-3.228 K Lux
<u>Photoperiod</u> Skeletonema: 14 h light, 10 h dark or 16 h light, 8 h dark Others: Continuous	Continuous
<u>pH</u> Skeletonema: approx. 8.0 Others: approx. 7.5	Ranged from 7.2 to 8.4

C. Test Design

Guideline Criteria	Reported Information
<u>Dose range</u> 2X or 3X progression	2X progression
<u>Doses</u> at least 5	6 doses
<u>Controls</u> negative and/or solvent	negative control
<u>Replicates per dose</u> 3 or more (4 or more for Navicula)	3
<u>Duration of test</u> 120 hours	120 hours
<u>Daily observations were made?</u>	Yes

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Guideline Criteria	Reported Information
<u>Method of Observations</u>	Cellular counts
<u>Maximum Labeled Rate</u>	0.35 lb A.E./Acre

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Initial and 120 h cell densities were measured?	Yes
Control cell count at 120 hr $\geq 2X$ initial count?	Yes
Initial chemical concentrations measured? (Optional)	Yes
Raw data included?	Yes

Dose Response

Dose (Mean Measured) (ppm A.E.) ¹	Cell Density (x 10 ⁴ cells/ml)	% Inhibition	120-Hour pH
Control	181	N/A	8.4
0.0059	172	4.7	8.4
0.011	165	8.7	8.4
0.025	162	11	8.4
0.046	146	19	8.4
0.12	141	22	8.4
0.26	139	23	8.3

1 The nominal concentrations used in the study were 0.0095, 0.019, 0.038, 0.075, 0.15 and 0.30 ppm A.E.. The mean measured concentrations of SAN 836h were ranged from 84% to 93% of the nominal concentrations. The mean measured concentrations for Dicamba ranged from 44 to 87% of the nominal fortified levels.

Statistical Results

Statistical Method: Williams Test (NOEC) and Observation (EC₅₀)

EC₅₀: > 0.26 ppm A.E. 95% C.I.: N/A

Slope: N/A NOEC: 0.0059 mg A.E./L

13. Verification of Statistical Results

Statistical Method: Observation (EC₅₀) and Williams Test (NOEC)

EC₅₀: > 0.26 ppm A.E. 95% C.I.: N/A

Slope: N/A NOEC: 0.0059 ppm A.E.

14. REVIEWER'S COMMENTS:

The study was scientifically sound and met guideline requirements. There was a deviation from the guidelines (See Guideline Deviations), but this deviation did not significantly impair the results of the study.

Table 4. Cell density ($\times 10^4$ cells/mL) of *Anabaena flos-aquae* after 1, 2, 3, 4 and 5 days of exposure to SAN 1269H.

Mean Measured Concentration (mg A.E./L)	OBSERVATION INTERVAL (DAYS)					Percent Reduction
	Day 1	Day 2	Day 3	Day 4	Day 5	
Control A	2	4	45	120	160	
B	3	7	25	121	182	
C	4	7	46	120	200	
Mean(SD) ^a	3(1)	6(2)	39(12)	120(1)	181(20)	NA ^b
0.0059 A	4	7	48	115	171	
B	2	4	47	106	169	
C	3	5	43	120	176	
Mean(SD) ^a	3(1)	5(2)	46(3)	114(7)	172(4)	4.7
0.011 A	2	3	45	107	162	
B	2	4	43	109	167	
C	3	4	46	103	166	
Mean(SD) ^a	2(1)	4(1)	44(2)	107(3)	165(2) ^c	8.7
0.025 A	2	3	42	91	167	
B	3	5	43	102	158	
C	1	3	44	98	160	
Mean(SD) ^a	2(1)	3(1)	43(1)	97(6)	162(5) ^c	11
0.046 A	2	2	43	80	144	
B	1	2	41	79	148	
C	1	3	38	87	146	
Mean(SD) ^a	1(<1)	2(1)	40(2)	82(4)	146(2) ^c	19
0.12 A	2	0	34	68	142	
B	0	0	32	73	138	
C	1	2	39	65	143	
Mean(SD) ^a	1(1)	1(1)	35(4)	69(4)	141(3) ^c	22
0.26 A	0	0	36	64	140	
B	1	3	33	58	137	
C	0	0	35	62	141	
Mean(SD) ^a	<1(1)	1(1)	35(1)	61(3)	139(2) ^c	23

- ^a Mean and standard deviation (SD) were calculated from original raw data (Appendix V), not from the rounded values presented in this table.
- ^b NA = not applicable
- ^c Statistically reduced as compared to the control based on Williams' Test.

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WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION		ORIGINAL N	MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	control	3	180.667	180.667	180.667	
2	0.0059	3	172.000	172.000	172.000	
3	0.011	3	165.000	165.000	165.000	
4	0.025	3	161.667	161.667	161.667	
5	0.046	3	146.000	146.000	146.000	
6	0.12	3	141.000	141.000	141.000	
7	0.26	3	139.333	139.333	139.333	

Anabaena 1269h tox

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WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. MEAN	SIG WILLIAMS	TABLE P=.05	DEGREES OF WILLIAMS	FREEDOM
control	180.667					
0.0059	172.000	1.311		1.76	k= 1, v=14	
0.011	165.000	2.370	*	1.85	k= 2, v=14	
0.025	161.667	2.874	*	1.88	k= 3, v=14	
0.046	146.000	5.243	*	1.89	k= 4, v=14	
0.12	141.000	5.999	*	1.90	k= 5, v=14	
0.26	139.333	6.252	*	1.91	k= 6, v=14	

s = 8.098

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

Anabaena 1269h tox

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