

MRID No. 443322-27

DATA EVALUATION RECORD
§ 72-1 - ACUTE LC₅₀ TEST WITH A COLDWATER FISH

1. **CHEMICAL:** S-Dimethenamid PC Code No.: 120051
2. **TEST MATERIAL:** SAN 1289H Purity:
 Technical 91.1% (S-dimethenamid)
96.3% (tot.dimethenamid)
3. **CITATION:**
Author: William C. Graves and James P. Swigert
Title: SAN 1289H Technical: A 96-hour Flow-Through Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*)
Study Completion Date: June 4, 1996
Laboratory: Wildlife International Ltd., Easton, MD
Sponsor: Sandoz Agro, Inc., Des Plaines, IL
Laboratory Report ID: 131A-163
MRID No.: 443322-27
DP Barcode: D238350, D238356

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

Signature: *Karl Bullock* **Date:** 10/21/97

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

Signature: *P. Kosalwat* **Date:** 10/21/97

5. **APPROVED BY:**

Signature: *James D. Edwards* **Date:** 11/18/97
Jim A. Bailey 11/4/98

6. **STUDY PARAMETERS:**

Age or Size of Test Organism: 42-60 mm
Definitive Test Duration: 96 hours
Study Method: Flow-through
Type of Concentrations: Mean measured as total dimethenamid

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute toxicity test with the rainbow trout. The 96-hour LC₅₀ was determined to be 6.3 ppm, which classifies SAN 1289H technical as moderately toxic to the rainbow trout. The NOEC was determined to be 3.7 ppm.



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Results Synopsis

LC₅₀: 6.3 ppm
 NOEC: 3.7 ppm

95% C.I.: 3.7-11 ppm
 Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. **Classification:** Core.

B. **Rationale:** N/A.

C. **Repairability:** N/A.

9. **GUIDELINE DEVIATIONS:** The reported pH was higher and the acclimation period was shorter than recommended. These deviations are not believed to detract from the study's validity.

10. SUBMISSION PURPOSE:**11. MATERIALS AND METHODS:**

A. **Test Organisms**

Guideline Criteria	Reported Information
<u>Species</u> Preferred species is the rainbow trout (<i>Oncorhynchus mykiss</i>)	<i>Oncorhynchus mykiss</i>
<u>Mean Weight</u> 0.1-5 g	1.9 g
<u>Mean Standard Length</u> Longest not > 2x shortest	Mean: 51 mm Range: 42-60 mm
<u>Supplier</u>	Troutlodge Inc., Sumner, WA
All fish from same source?	Yes
All fish from the same year class?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 14 days	113-day holding period, 52-hour acclimation period
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No sickness or injury within the 7 days prior to testing
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
Feeding No feeding during the study	Last fed 52 hours prior to testing
Pretest Mortality < 3% mortality 48 hours prior to testing	Pretest mortality not reported

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, not dechlorinated tap water	Well water, filtered and aerated before use.
Does water support test animals without observable signs of stress?	Yes
Water Temperature 12°C	11.8-12.5°C
pH Prefer 7.2 to 7.6	8.2-8.3
Dissolved Oxygen Static: ≥ 60% during 1 st 48 hrs and ≥ 40% during 2 nd 48 hrs, flow-through: ≥ 60%	≥81% of saturation during the test
Total Hardness Prefer 40 to 200 mg/L as CaCO ₃	Mean: 124 mg/L as CaCO ₃

Guideline Criteria	Reported Information
<p>Test Aquaria</p> <p>1. Material: Glass or stainless steel</p> <p>2. Size: Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm</p> <p>3. Fill volume: 15-30 L of solution</p>	<p>Teflon-lined polyethylene</p> <p>25-L</p> <p>15 L</p>
<p>Type of Dilution System Must provide reproducible supply of toxicant</p>	<p>Continuous-flow diluter.</p>
<p>Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period</p>	<p>Approximately 6 vol/24 hours, meter systems checked twice daily</p>
<p>Biomass Loading Rate Static: ≤ 0.8 g/L at $\leq 17^\circ\text{C}$, ≤ 0.5 g/L at $> 17^\circ\text{C}$; flow-through: ≤ 1 g/L/day</p>	<p>0.22 g/L/day</p>
<p>Photoperiod 16 hours light, 8 hours dark</p>	<p>16 h light, 8 h dark</p>
<p>Solvents Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests</p>	<p>Solvent: dimethylformamide Maximum conc.: 0.1 mL/L</p>

D. Test Design

Guideline Criteria	Reported Information
<p><u>Range Finding Test</u> If LC₅₀ >100 mg/L with 30 fish, then no definitive test is required.</p>	<p>Nominal concentrations based upon results of one exploratory range finding toxicity test.</p>
<p><u>Nominal Concentrations of Definitive Test</u> Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series</p>	<p>Negative control, solvent control, 1.3, 2.2, 3.6, 6.0, and 10 mg/L, not corrected for purity.</p>
<p><u>Number of Test Organisms</u> Minimum 10/level, may be divided among containers</p>	<p>20 fish per treatment level or control</p>
<p>Test organisms randomly or impartially assigned to test vessels?</p>	<p>Yes</p>
<p>Biological observations made every 24 hours?</p>	<p>Yes</p>
<p><u>Water Parameter Measurements</u> 1. <u>Temperature</u> Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1°C 2. <u>DO and pH</u> Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control</p>	<p>Temperature measured in each chamber at test initiation and termination, and also monitored continuously in one negative control replicate. DO and pH measured every 24 hours in alternate replicates from each control and treatment group.</p>
<p><u>Chemical Analysis</u> Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used</p>	<p>Solutions collected at 0, 48, and 96 hours were analyzed by GC-ECD</p>

12. REPORTED RESULTS:**A. General Results**

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Recovery of Chemical	Mean recoveries for each concentration ranged from 103 to 110% of the nominal values.
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0% mortality in both negative control and solvent control groups
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes, signs observed at the two highest concentrations

Mortality

Concentration (ppm)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured*		Hour of Study			
			24	48	72	96
Negative Control	ND	20	0	0	0	0
Solvent Control	ND	20	0	0	0	0
1.3	1.4	20	0	0	0	0
2.2	2.3	20	0	0	0	0
3.6	3.7	20	0	0	0	0
6.0	6.5	20	0	0	0	11
10.0	11.0	20	0	2	20	20

* as total dimethenamid

Other Significant Results: Signs of toxicity were limited to surfacing and lying on the bottom with little motion other than gill movement. These signs were noted in the 6.5 ppm group at 72 hours, and in the 11 ppm group at 48 hours.

B. Statistical Results

Statistical method: binomial method

96-hr LC₅₀: 6.3 ppm
Probit Slope: N/A

95% C.I.: 3.7-11 ppm
NOEC: 3.7 ppm

13. VERIFICATION OF STATISTICAL RESULTS:

Parameter	Result
Binomial Test LC ₅₀ (C.I.)	6.3 (3.7-11) ppm
Moving Average Angle LC ₅₀ (95% C.I.)	N/A
Probit LC ₅₀ (95% C.I.)	N/A
Probit Slope	N/A
NOEC	3.7 ppm

14. REVIEWER'S COMMENTS: This study is scientifically sound and fulfills the guideline requirements for an acute toxicity test with the rainbow trout. The 96-hour LC₅₀ was determined to be 6.3 ppm, which classifies SAN 1289H Technical as moderately toxic to the rainbow trout. The NOEC was determined to be 3.7 ppm. This study is classified as **Core**.

Karl Bullock SAN 1289H RAINBOW TROUT 10-13-97

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
11	20	20	100	9.536742E-05
6.5	20	11	55	41.19014
3.7	20	0	0	9.536742E-05
2.3	20	0	0	9.536742E-05
1.4	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.7 AND 11 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 6.262622

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.
