Active Ingredient Name Checked in OPPIN 2/14/05 BJM

MRID No. 439773-13

DATA EVALUATION RECORD

§ 72-1 - ACUTE LC_{50} TEST WITH A COLDWATER FISH

1. **CHEMICAL:** ~~Tebufenozide~~ Cyhalothrin — PC Code No.: ~~129026~~ 129013

2. **TEST MATERIAL:** S-1668 — Purity: 96.3%

3. **CITATION:** 103

Authors: Jane Bowman and John Bucksath
Title: Acute Flow-Through Toxicity of S-1668 to Rainbow Trout (*Oncorhynchus mykiss*)
Study Completion Date: October 9, 1995
Laboratory: ABC Laboratories, Inc., Columbia, MO
Sponsor: Sumitomo Chemical Company, Ltd., Osaka 541, Japan
Laboratory Report ID: 42279
MRID No.: 439773-13
DP Barcode: D237130; D237151; D237155

4. **REVIEWED BY:** Thomas M. Steeger, Ph.D., Fishery Biologist, ERB IV, EFED, U.S. EPA

Signature: Thomas M Steeger **Date:** 8/25/98

5. **APPROVED BY:** Mike Rexrode, Fishery Biologist, ERB IV, EFED, U.S. EPA

Signature: M Rexrode **Date:** 9-8-98

6. **STUDY PARAMETERS:**

Age or Size of Test Organism: 46 ±4 mm
Definitive Test Duration: 96 hours
Study Method: Flow-through
Type of Concentrations: Mean measured

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for an acute toxicity test with a coldwater fish. The 96-hour LC_{50} was determined to be 0.37 ppb ai, which classifies S-1668 as very highly toxic to the rainbow trout. The NOEC was determined to be 0.24 ppb ai. The study is classified as supplemental but upgradeable to core provided the registrant demonstrates that neither water hardness nor pH affect the solubility or toxicity of S-1668.

Results Synopsis

LC_{50}: 0.37 ppb ai
NOEC: 0.24 ppb ai

95% C.I.: 0.24 - 0.56 ppb ai
Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:**

A. **Classification:** Supplemental

B. **Rationale:** pH and hardness exceeded the recommended range

C. **Repairability:** Upgradeable to core provided the registrant demonstrate that neither pH nor hardness affect solubility or toxicity of S-1668

9. **GUIDELINE DEVIATIONS:**

1. The acclimation period (72 hours) was less than recommended (14 days).

2. The pH (8.0-8.2) was higher than recommended (7.2-7.6).

3. Water hardness (150 - 152 mg/l as CaCO3) exceeded recommended range of 40 - 48 mg/L.

10. **SUBMISSION PURPOSE:**

11. **MATERIALS AND METHODS:**

A. **Test Organisms**

Guideline Criteria	Reported Information
Species Preferred species is the rainbow trout (*Oncorhynchus mykiss*)	*Oncorhynchus mykiss*
Mean Weight 0.1-5 g	Mean: 1.25 g SD: 0.34 g
Mean Standard Length Longest not > 2x shortest	Mean: 46 mm SD: 4 mm
Supplier	Mt. Lassen Trout Farm, Red Bluff, CA
All fish from same source?	Yes

Guideline Criteria	Reported Information
All fish from the same year class?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 14 days	72 hours
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	Fish were not fed during the acclimation and testing periods.
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	Naturally hard well water blended with demineralized well water.
Does water support test animals without observable signs of stress?	Yes

Guideline Criteria	Reported Information
Water Temperature 12°C	12.0-12.5°C
pH Prefer 7.2 to 7.6	8.0-8.2
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%	≥83% of saturation during the test
Total Hardness Prefer 40 to 200 mg/L as $CaCO_3$	150-152 mg/L as $CaCO_3$
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	Glass 51.5 x 28.7 x 30.4 cm (45 L) 30 L
Type of Dilution System Must provide reproducible supply of toxicant	Intermittent flow proportional diluter
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	8.6 vol/24 hours
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day	0.097 g/L/day
Photoperiod 16 hours light, 8 hours dark	16 h light, 8 h dark
Solvents Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: DMF Maximum conc.: 0.1 mL/L

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L with 30 fish, then no definitive test is required.	Yes; static range-finding test with nominal concentrations of 0.1, 0.5, 2.0, and 4.0 µg/L yielded 0, 0, 100, and 100% mortality. Three preliminary flow-through tests were conducted, but no results were reported due to either poor analytical recovery, lack of an adequate dose-response, or temperature deviations.
Nominal Concentrations of Definitive Test Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series	Control, solvent control, 0.13, 0.25, 0.50, 1.0, and 2.0 µg/L
Number of Test Organisms Minimum 10/level, may be divided among containers	20 fish per treatment level or control
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1°C 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	1. Temperature measured at 0, 48, and 96 hours in each test chamber and continuously in one centrally located test aquaria. 2. DO and pH measured at 0, 48, and 96 hours in each test chamber.

Guideline Criteria	Reported Information
Chemical Analysis 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	Yes, solutions collected at 0, 48, and 96 hours and analyzed by GLC.

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 50 to 65% of the nominal values.
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0% mortality in both dilution water and solvent control groups after 96 hours.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes, signs observed at the two highest concentrations.

Mortality

Concentration (µg/L)		Number of Fish	Cumulative Number Dead			
			Hour of Study			
Nominal	Mean Measured		24	48	72	96
Control	ND	20	0	0	0	0
Solvent Control	ND	20	0	0	0	0

DATA EVALUATION RECORD
§ 72-1 - ACUTE LC_{50} TEST WITH A COLDWATER FISH

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1. **CHEMICAL:** ~~Tebufenozide~~ PC Code No.: ~~129026~~

2. **TEST MATERIAL:** S-1668 Purity: 96.3%

3. **CITATION:**

Authors: Jane Bowman and John Bucksath
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Laboratory Report ID: 42279
MRID No.: 439773-13
DP Barcode: D237130; D237151; D237155

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

Signature: Karl Bullock **Date:** 2/19/98

APPROVED BY: Max Feken, M.S., Environmental Toxicologist, Golder Associates Inc.

Signature: [signature] **Date:** 2/19/98

5. **APPROVED BY:** See changes

Signature: Thomas M Steeger **Date:** 3/25/98

6. **STUDY PARAMETERS:**

Age or Size of Test Organism: 46 ±4 mm
Definitive Test Duration: 96 hours
Study Method: Flow-through
Type of Concentrations: Mean measured

7. **CONCLUSIONS:** This study is scientifically sound ~~and~~ but does not meets the guideline requirements for an acute toxicity test with a coldwater fish. The 96-hour LC_{50} was determined to be 0.37 ppb ai, which classifies S-1668 as very highly toxic to the rainbow trout. The NOEC was determined to be 0.24 ppb ai. The study is classified as Supplemental (see EFED reviewer's comments)

Results Synopsis

LC_{50}: 0.37 ppb ai 95% C.I.: 0.24 - 0.56 ppb ai
NOEC: 0.24 ppb ai Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:**

   A. Classification: ~~Core~~ Supplemental TMS 3/23/96

   B. Rationale: N/A Hardness and pH were outside of recommended ranges

   C. Repairability: N/A Registrant must demonstrate that neither pH or hardness affect the solubility or toxicity of S1668

9. **GUIDELINE DEVIATIONS:**
   1. The acclimation period (72 hours) was less than recommended (14 days).
   2. The pH (8.0-8.2) was higher than recommended (7.2-7.6). Hardness was roughly 3.3 x the recommended ranged (40-48 ppm)

10. **SUBMISSION PURPOSE:**

11. **MATERIALS AND METHODS:**

    A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the rainbow trout (*Oncorhynchus mykiss*)	*Oncorhynchus mykiss*
Mean Weight 0.1-5 g	Mean: 1.25 g SD: 0.34 g
Mean Standard Length Longest not > 2x shortest	Mean: 46 mm SD: 4 mm
Supplier	Mt. Lassen Trout Farm, Red Bluff, CA
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	72 hours
Wild caught organisms were quarantined for 7 days?	N/A

Guideline Criteria	Reported Information
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	Fish were not fed during the acclimation and testing periods.
Pretest Mortality < 3% mortality 48 hours prior to testing	Pretest mortality not reported

C. Test System

Guideline Criteria	Reported Information
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Does water support test animals without observable signs of stress?	Yes
Water Temperature 12°C	12.0-12.5°C
pH Prefer 7.2 to 7.6	8.0-8.2 out of range
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%	≥83% of saturation during the test
Total Hardness Prefer 40 to 200 mg/L as $CaCO_3$	150-152 mg/L as $CaCO_3$

40-48 mg/L as $CaCO_3$

hardness over 3x recommended range

Guideline Criteria	Reported Information
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	Glass 51.5 x 28.7 x 30.4 cm (45 L) 30 L
Type of Dilution System Must provide reproducible supply of toxicant	Intermittent flow proportional diluter
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	8.6 vol/24 hours
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day	0.097 g/L/day
Photoperiod 16 hours light, 8 hours dark	16 h light, 8 h dark
Solvents Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: DMF Maximum conc.: 0.1 mL/L

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L with 30 fish, then no definitive test is required.	Yes; static range-finding test with nominal concentrations of 0.1, 0.5, 2.0, and 4.0 µg/L yielded 0, 0, 100, and 100% mortality. Three preliminary flow-through tests were conducted, but no results were reported due to either poor analytical recovery, lack of an adequate dose-response, or temperature deviations.

Guideline Criteria	Reported Information
Nominal Concentrations of Definitive Test Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series	Control, solvent control, 0.13, 0.25, 0.50, 1.0, and 2.0 µg/L
Number of Test Organisms Minimum 10/level, may be divided among containers	20 fish per treatment level or control
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1°C 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	1. Temperature measured at 0, 48, and 96 hours in each test chamber and continuously in one centrally located test aquaria. 2. DO and pH measured at 0, 48, and 96 hours in each test chamber.
Chemical Analysis 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	Yes, solutions collected at 0, 48, and 96 hours and analyzed by GLC.

12. REPORTED RESULTS:

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes

Guideline Criteria	Reported Information
Recovery of Chemical	Mean recoveries for each concentration ranged from 50 to 65% of the nominal values.
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0% mortality in both dilution water and solvent control groups after 96 hours.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes, signs observed at the two highest concentrations.

Mortality

Concentration (µg/L)		Number of Fish	Cumulative Number Dead			
			Hour of Study			
Nominal	Mean Measured		24	48	72	96
Control	ND	20	0	0	0	0
Solvent Control	ND	20	0	0	0	0
0.13	0.081	20	0	0	0	0
0.25	0.16	20	0	0	0	0
0.50	0.25	20	0	0	0	0
1.0	0.58	20	0	10	20	20
2.0	1.3	20	14	20	20	20

Other Significant Results: Signs of test material toxicity including erratic swimming, loss of equilibrium, lying at the bottom of the test chamber, and labored respiration were observed in the two highest test concentrations.

Mean measured concentrations in the test chambers during the rainbow trout toxicity test were 0.081, 0.16, 0.25, 0.58, and 1.3 µg/L and represented 62, 64, 50, 58 and 65% of the nominal test concentrations.

Sealed containers with S-1668 had 18 and 29% recovery at 48 and 96 hours. The open container had 0% recovery at both 48 and 96 hours suggesting that the test material may be volatilizing from the water.

B. Statistical Results

Statistical method: Binomial

96-hr LC_{50}: 0.38 µg/L (0.37 µg ai/L) 95% C.I.: 0.25-0.58 µg/L (0.24-0.56 µg ai/L)

Probit Slope: N/A NOEC: 0.25 µg/L (0.24 µg ai/L)

13. VERIFICATION OF STATISTICAL RESULTS:

Parameter	Result
Binomial Test LC_{50} (C.I.)	0.37 ppb ai (0.24-0.56 ppb ai)
Moving Average Angle LC_{50} (95% C.I.)	0.38 (0.25 - 0.58 ppb ai) N/A
Probit LC_{50} (95% C.I.)	N/A
Probit Slope	N/A
NOEC	0.24 ppb ai

14. REVIEWER'S COMMENTS: This study is scientifically sound and meets the guidelines for an acute toxicity test with a coldwater fish. The 96-hour LC_{50} of 0.37 ppb ai classifies S-1668 as very highly toxic to the rainbow trout. The NOEC was determined to be 0.24 ppb ai. This study is classified as **Core.** 0.25

Secondary review by EFED resulted in a classification of supplemental. Both pH and hardness exceeded the recommended ranges: pH 7.2 - 7.6 and hardness 40 - 46 ppm. The study is upgradeable to core provided the registrant demonstrates that neither pH nor hardness affect the solubility or toxicity of S-1668.

It is also noteworthy that S-1668 appears to be highly unstable in the freshwater environment (based on low recovery) but despite this instability the compound is very highly toxic

KARL BULLOCK TEBUFENOZIDE RAINBOW TROUT 1-28-98

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1.25	20	20	100	9.536742E-05
.56	20	20	100	9.536742E-05
.24	20	0	0	9.536742E-05
.15	20	0	0	9.536742E-05
.078	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .24 AND .56 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 .3666061

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.

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