

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 12, 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Acute Fish Toxicity Studies Submitted to
Support the Registration of Etofenprox
(SHA#128965, DPCode:D214718, ID#099657-A)

FROM: *for* Anthony F. Maciorowski, Chief *Amw Staveland*
Ecological Effects Branch *4/15/96*
Environmental Fate and Effects Division (7507C)

TO: Adam Heyward (PM 13)
Insecticide/Rodenticide Branch
Registration Division (7505C)

EEB has received and reviewed the two fish acute toxicity studies submitted by Mitsui Toatsu Chemicals, Inc.. The studies were submitted to fill a data gap in support of the registration of Etofenprox. The following is a brief summary of the reviews:

CITATION: Machado, Mark W., 1995, Etofenprox Technical - Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions, performed by Springborn Laboratories, Inc., Wareham, MA, submitted by Mitsui Toatsu Chemicals, Inc., New York, NY, Laboratory Report ID: 94-12-5625, MRID No.: 436213-01.

CONCLUSIONS: This study is scientifically sound and fulfills the guideline requirements (72-1(c)). The 96-hour LC₅₀ for rainbow trout exposed to etofenprox was determined to be 2.7 ppb ai, which classifies this compound as very highly toxic to the rainbow trout.

Results Synopsis

LC₅₀: 2.7 ppb ai
NOEL: 0.7 ppb ai

95% C.I.: 2.2 - 3.6 ppb ai
Probit Slope: 5.1

CITATION Machado, Mark W., 1995, Etofenprox Technical - Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-Through Conditions, performed by Springborn Laboratories, Inc., Wareham, MA, submitted by Mitsui Toatsu Chemicals, Inc., New York, NY, Laboratory Report ID: 95-1-5653, MRID No.: 436213-02.

CONCLUSIONS: This study is scientifically sound and fulfills the guideline requirements (72-1(a)). The 96-hour LC₅₀ for bluegill sunfish exposed to etofenprox was determined to be 13 ppb ai,

which classifies this compound as very highly toxic to the bluegill sunfish.

Results Synopsis

LC₅₀: 13 ppb ai
NOEC: 7 ppb ai

95% C.I.: 11 - 18 ppb ai
Probit Slope: N/A

If you have any questions regarding this submission, please contact Harry Winnik, Biologist, 305-7089.

DP Barcode: D214718

MRID No.: 436213-01

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

1. **CHEMICAL:** Etofenprox **PC Code No.:** 128965

2. **TEST MATERIAL:** Etofenprox **Purity:** 95.6%

3. **CITATION**

Author: Mark W. Machado
Title: Etofenprox Technical - Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions.

Study Completion Date: March 7, 1995

Laboratory: Springborn Laboratories, Inc., Wareham, MA

Sponsor: Mitsui Toatsu Chemicals, Inc., New York, NY

Laboratory Report ID: 94-12-5625

MRID No.: 436213-01

DP Barcode: D214718

4. **REVIEWED BY:** Mark Mossler, M.S., Toxicologist,
KBN Engineering and Applied Sciences, Inc.,

Signature: 

Date: 9/19/95

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
KBN Engineering and Applied Sciences, Inc.,

Signature: 

Date: 9/19/95

5. **APPROVED BY:** ^{HARRY A. WINNIK}
~~Daniel Balluff~~, Section 4, EFED

Signature: 

Date: 4/12/96

6. **STUDY PARAMETERS**

Age or Size of Test Organism: 35-48 mm
Definitive Test Duration: 96 hours
Study Method: Flow-Through
Type of Concentrations: Mean measured

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements. The 96-hour LC₅₀ for rainbow trout exposed to etofenprox was determined to be 2.7 ppb ai, which classifies this compound as very highly toxic to the rainbow trout.

Results Synopsis

LC₅₀: 2.7 ppb ai

NOEL: 0.7 ppb ai

95% C.I.: 2.2 - 3.6 ppb ai
Probit Slope: 5.1

8. ADEQUACY OF THE STUDY**A. Classification:** Core**B. Rationale:** N/A**C. Repairability:** N/A**9. GUIDELINE DEVIATIONS**

1. The size and volume of the test chambers were less than recommended.
2. The hardness of the dilution water was slightly less than recommended.

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> 0.5-5 g	0.69 g
<u>Mean Standard Length</u> Longest not > 2x shortest	Mean: 41 mm Range: 35-48 mm
<u>Supplier</u>	Mount Lassen Trout Farm, Red Bluff, CA
All fish from same source?	Yes
All fish from the same year class?	Not reported

B. Source/Acclimation

Guideline Criteria	Reported Information
<u>Acclimation Period</u> Minimum 14 days	14 days

Guideline Criteria	Reported Information
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
<u>Feeding</u> No feeding during the study	Last fed 48 hours prior to testing
<u>Pretest Mortality</u> < 3% mortality 48 hours prior to testing	0% mortality prior to testing.

C. Test System

Guideline Criteria	Reported Information
<u>Source of dilution water</u> Soft reconstituted water or water from a natural source, not dechlorinated tap water	Well water
Does water support test animals without observable signs of stress?	Yes
<u>Water Temperature</u> 12°C	9-11°C
<u>pH</u> Prefer 7.2 to 7.6	6.9-7.3
<u>Dissolved Oxygen</u> Static: ≥ 60% during 1 st 48 hrs and ≥ 40% during 2 nd 48 hrs, flow-through: ≥ 60%	80-93% saturation during the test
<u>Total Hardness</u> Prefer 40 to 48 mg/L as CaCO ₃	32-36 mg/L

Guideline Criteria	Reported Information
<u>Test Aquaria</u> 1. <u>Material:</u> Glass or stainless steel 2. <u>Size:</u> Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. <u>Fill volume:</u> 15-30 L of solution	Glass 39 x 20 x 25 cm 11 L
<u>Type of Dilution System</u> Must provide reproducible supply of toxicant	Intermittent-flow proportional diluter
<u>Flow Rate</u> Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	6.7 volume replacements every 24 hours
<u>Biomass Loading Rate</u> 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	0.093 g/L/day
<u>Photoperiod</u> 16 hours light, 8 hours dark	16 hours light, 8 hours dark
<u>Solvents</u> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: acetone Maximum conc.: 0.091 mL/L

D. Test Design

Guideline Criteria	Reported Information
<u>Range Finding Test</u> If $\text{LC}_{50} > 100$ mg/L with 30 fish, then no definitive test is required.	Yes, 3.2, 5.4, 9.0, 15, and 25 $\mu\text{g ai/L}$. Complete mortality at four highest concentrations by 96 hours

Guideline Criteria	Reported Information
<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	0.78, 1.3, 2.2, 3.6, and 6.0 $\mu\text{g ai/L}$.
<u>Number of Test Organisms</u> Minimum 10/level, may be divided among containers	20, 10 per replicate
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
<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	Yes Yes
<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	Yes

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

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

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Guideline Criteria	Reported Information
Recovery of Chemical	46-64%
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0%
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes, signs observed at the 3 highest concentrations

Mortality

Concentration (ppb)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Control	<0.21	20	0	0	0	0
Solvent Control	<0.21	20	0	0	0	0
0.78	0.50	20	0	0	0	0
1.3	0.66	20	0	0	0	0
2.2	1.1	20	0	0	1	1
3.6	1.7	20	0	0	0	2
6.0	3.1	20	0	4	9	13

Other Significant Results: Fish exposed at the three highest-concentration treatment levels demonstrated partial loss of equilibrium, lethargy, erratic swimming, and darkened pigmentation.

B. Statistical Results

Method: probit

96-hr LC₅₀: 2.7 ppb ai

95% C.I.: 2.2 - 3.6 ppb ai

Probit Slope: Not reported

NOEC: 0.66 ppb ai

13. VERIFICATION OF STATISTICAL RESULTS

Parameter	Result
Binomial Test LC ₅₀ (C.I.)	2.67 (0 - infinity) ppb ai
Moving Average Angle LC ₅₀ (95% C.I.)	2.67 (2.28 - 3.51) ppb ai
Probit LC ₅₀ (95% C.I.)	2.68 (2.24 - 3.60) ppb ai
Probit Slope	5.1
NOEC	0.66 ppb ai

14. REVIEWER'S COMMENTS: This study is scientifically sound, fulfills the guideline requirements, and can be classified as CORE. The 96-hour LC₅₀ for rainbow trout exposed to etofenprox was determined to be 2.7 ppb ai, which classifies this compound as very highly toxic to the rainbow trout. The NOEC was 0.7 ppb ai.

DP Barcode: D214718

MRID No.: 436213-02

DATA EVALUATION RECORD
§ 72-1(A) -- ACUTE LC₅₀ TEST WITH A WARMWATER FISH

1. **CHEMICAL:** Etofenprox **PC Code No.:** 128965

2. **TEST MATERIAL:** Etofenprox **Purity:** 95.6%

3. **CITATION**

Author: Mark W. Machado
Title: Etofenprox Technical - Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-Through Conditions.

Study Completion Date: March 7, 1995

Laboratory: Springborn Laboratories, Inc., Wareham, MA

Sponsor: Mitsui Toatsu Chemicals, Inc., New York, NY

Laboratory Report ID: 95-1-5653


MRID No.: 436213-02

DP Barcode: D214718

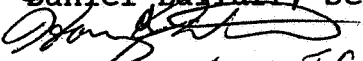
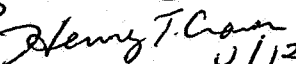
4. **REVIEWED BY:** Mark Mossler, M.S., Toxicologist,
KBN Engineering and Applied Sciences, Inc.,

Signature:  **Date:** 9/19/95

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
KBN Engineering and Applied Sciences, Inc.,

Signature:  **Date:** 9/19/95

5. **APPROVED BY:** ^{HARRY A. VINNIK}
~~Daniel Balluff~~, Section 4, EFED

Signature:  **Date:** 4/12/96
 4/12/96

6. **STUDY PARAMETERS**

Age or Size of Test Organism: 39-52 mm
Definitive Test Duration: 96 hours
Study Method: Flow-Through
Type of Concentrations: Mean measured

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements. The 96-hour LC₅₀ for bluegill sunfish exposed to etofenprox was determined to be 13 ppb ai, which classifies this compound as very highly toxic to the bluegill sunfish.

Results Synopsis

LC₅₀: 13 ppb ai

NOEC: 7 ppb ai

95% C.I.: 11 - 18 ppb ai

Probit Slope: N/A

8. ADEQUACY OF THE STUDY**A. Classification:** Core**B. Rationale:** N/A**C. Repairability:** N/A**9. GUIDELINE DEVIATIONS**

1. The size and volume of the test chambers were less than recommended.
2. The hardness of the dilution water was slightly less than recommended.

10. SUBMISSION PURPOSE:**11. MATERIALS AND METHODS****A. Test Organisms**

Guideline Criteria	Reported Information
<u>Species</u> Preferred species is the bluegill sunfish (<i>Lepomis macrochirus</i>)	<i>Lepomis macrochirus</i>
<u>Mean Weight</u> 0.5-5 g	1.4 g
<u>Mean Standard Length</u> Longest not > 2x shortest	Mean: 46 mm Range: 39-52 mm
<u>Supplier</u>	Osage Catfisheries, Osage Beach, MO
All fish from same source?	Yes
All fish from the same year class?	Not reported

B. Source/Acclimation

Guideline Criteria	Reported Information
<u>Acclimation Period</u> Minimum 14 days	14 days

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Guideline Criteria	Reported Information
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
<u>Feeding</u> No feeding during the study	Last fed 48 hours prior to testing
<u>Pretest Mortality</u> < 3% mortality 48 hours prior to testing	0% mortality 48 hours prior to testing.

C. Test System

Guideline Criteria	Reported Information
<u>Source of dilution water</u> Soft reconstituted water or water from a natural source, not dechlorinated tap water	Well water
Does water support test animals without observable signs of stress?	Yes
<u>Water Temperature</u> 17°C or 22°C	21-23°C
<u>pH</u> Prefer 7.2 to 7.6	7.0-7.4
<u>Dissolved Oxygen</u> Static: ≥ 60% during 1 st 48 hrs and ≥ 40% during 2 nd 48 hrs, flow-through: ≥ 60%	74-105% of saturation during the test
<u>Total Hardness</u> Prefer 40 to 48 mg/L as CaCO ₃	36 mg/L

Guideline Criteria	Reported Information
<u>Test Aquaria</u> 1. <u>Material:</u> Glass or stainless steel 2. <u>Size:</u> Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. <u>Fill volume:</u> 15-30 L of solution	Glass 39 x 20 x 25 cm 11 L
<u>Type of Dilution System</u> Must provide reproducible supply of toxicant	Intermittent-flow proportional diluter
<u>Flow Rate</u> Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	7 volume replacements every 24 hours
<u>Biomass Loading Rate</u> 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	0.18 g/L/day
<u>Photoperiod</u> 16 hours light, 8 hours dark	16 hours light, 8 hours dark
<u>Solvents</u> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: acetone Maximum conc.: 0.091 mL/L

D. Test Design

Guideline Criteria	Reported Information
<u>Range Finding Test</u> If $\text{LC}_{50} > 100$ mg/L with 30 fish, then no definitive test is required.	Yes, 3.2, 5.4, 9.0, 15, and 25 $\mu\text{g ai/L}$. Complete mortality at the highest concentration by 72 hours

Guideline Criteria	Reported Information
<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	5.2, 8.6, 14, 24, and 40 µg ai/L.
<u>Number of Test Organisms</u> Minimum 10/level, may be divided among containers	20, 10 per replicate
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
<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	Yes Yes
<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	Yes

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	44-49%
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0%
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes, signs observed at the 2 highest concentrations

Mortality

Concentration (ppb)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Control	<0.50	20	0	0	0	0
Solvent Control	<0.50	20	0	0	0	0
5.2	2.5	20	0	0	0	0
8.6	4.2	20	0	0	0	0
14	6.9	20	0	0	0	0
24	11	20	0	0	3	5
40	18	20	0	14	19	20

Other Significant Results: Fish exposed at the two highest-concentration treatment levels demonstrated partial loss of equilibrium, lethargy, erratic swimming, and darkened pigmentation.

B. Statistical Results

Method: nonlinear interpolation and binomial probability

96-hr LC₅₀: 13 ppb ai

95% C.I.: 11 - 18 ppb ai

Probit Slope: N/A

NOEC: 6.9 ppb ai

13. VERIFICATION OF STATISTICAL RESULTS

Parameter	Result
Binomial Test LC_{50} (C.I.)	13 (11 - 18) ppb ai
Moving Average Angle LC_{50} (95% C.I.)	N/A
Probit LC_{50} (95% C.I.)	N/A
Probit Slope	N/A
NOEC	7 ppb ai

14. REVIEWER'S COMMENTS: This study is scientifically sound, fulfills the guideline requirements, and can be classified as CORE. The 96-hour LC_{50} for bluegill sunfish exposed to etofenprox was determined to be 13 ppb ai, which classifies this compound as very highly toxic to the bluegill sunfish. The NOEC was 7 ppb ai.

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