US EPA ARCHIVE DOCUMENT

2/13/97

DP Barcode : D228125
PC Code No : 004006
EEB Out :

To: George LaRocca
Product Manager 13
Registration Division (7505C)

From: Norman J. Cook, Acting Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # :
Chemical Name : Imiprothrin MEP/S-41311
Type Product : Insecticide (synthetic pyrethroid)
Product Name : Pralle®
Company Name : Sumitomo Chemical Company, Ltd.
Purpose : Sec. 3 full registration
Action Code : Date Due: 1/30/97
Reviewer : Richard Lee Date In :

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

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

MEMORANDUM

To: George T. LaRocca, PM 13
Registration Division (7505C)

From: Norman J. Cook, Acting Chief for David Rose 2/13/97
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Subject: Proposed full registration of Imiprothrin, a New Synthetic Pyrethroid, as a Manufacturing Use Product (D228125) Sh# 004006

Ecological Effects Branch has reviewed fish and wildlife toxicity data submitted by Sumitomo Chemical Company, Ltd. to support registration of Imiprothrin or S-41311 (Pralle® MUP), a new synthetic pyrethroid, as a manufacturing use product. The chemical is specifically intended for formulation of an insecticide to control indoor crawling insects by crack or crevice spot treatment. The registrant has submitted two avian dietary , and three fresh-water aquatic acute toxicity studies to support the proposed end-use. For a manufacturing product use, the submitted toxicity studies appear adequate for satisfaction of basic ecological toxicity data requirements except for a data gap of an avian acute oral toxicity study. However, the study will be waived due to unlikeliness of exposure and the low toxicity to birds. The chemical is practically non-toxic to birds based on the subacute dietary basis. The LC50 values for mallards and bobwhite quails are both >5620 ppm (MRID 437507-13 and MRID 437507-14, respectively).

Based on the results of aquatic acute toxicity tests, Imiprothrin is very highly toxic to aquatic organisms. However, little exposure is anticipated from the proposed end-use. All aquatic toxicity studies are listed as follows:

Species (MRID)	LC50/EC50 (ppm)
Daphnia (437507-17)	0.051
Rainbow trout (437507-16)	0.038
Bluegill (437507-15)	0.07

2

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EEB has completed a full risk assessment (3(c)(5) finding) of proposed registration of imiprothrin as manufacturing end-use insecticide. Based upon tha available data and use information EEB concludes that the proposed uses provide for minimal risks to non-target organisms.

If you have any questions please contact Richard Lee (305-5577) or Ann Stavola (305-5354).

DP Barcode: D228125 MRID No.: 437507-13

DATA EVALUATION RECORD
§ 71-2(B) -- WATERFOWL DIETARY LC_{50} TEST

1. **CHEMICAL:** Imiprothrin (Pralle) PC Code No.: 004006

2. **TEST MATERIAL:** S-41311 T.G. Purity: 92.9 %

3. **CITATION**

Authors: Campbell S. & J. Beavers
Title: S-41311: A Dietary LC50 Study with the Mallard
Study Completion Date: 7/20/94
Laboratory: Wildlife International Ltd.
Sponsor: Smitomo Chemical Co.
Laboratory Report ID: S.G.W-41-0006 (Proj. # 166-158)
MRID No.: 437507-13
DP Barcode: 228125

4. **REVIEWED BY:** Richard M. Lee, Entomologist, EEB, EFED

Signature: **Date:**

5. **APPROVED BY:** Ann Stavola, Head of Section (5), EEB, EFED

Signature: Richard M. Lee **Date:** 1/29/97
Ann Stavola 2/5/97

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Anas platyrhynchos*

Age of Test Organisms at Test Initiation: 10 days old
Definitive Study Duration: 8 days (5 d. trt., 3 d. observ.)

7. **CONCLUSIONS:**

Results Synopsis
LC_{50}: >5620 ppm ai 95% C.I.: ____-____ ppm ai
NOEL: 1780 ppm ai Probit Slope: ____

8. **ADEQUACY OF THE STUDY**

A. **Classification:** Core

B. **Rationale:**

C. **Repairability:**

9. **GUIDELINE DEVIATIONS**

1. Brooder temperature was slightly lower.

2. (etc.)

10. **SUBMISSION PURPOSE:** Sec. 3 full registration

11. **MATERIALS AND METHODS**

A. Test Organisms

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the Mallard duck (*Anas platyrhynchos*).	Mallard duck (*Anas platyrhynchos*)
Age at beginning of test: 10-14 days old.	10 days old
Supplier	Whistling Wings, Hanover, Ill
Chicks appeared healthy and did not have excessive mortality before the test?	Yes, they are in good health prior to test.
Acclimation period: As long as possible.	9 days

B. Test System

Guideline Criteria	Reported Information
Pen size: about 70 x 100 x 24 cm	72 x 90 x 25.5 cm (H)
Brooder temperature: about 35°C (95°F)	31°C ± 2°C (SD)
Room temperature: 22-27°C (71-81°F)	25.8°C ± 1.2°C (SD)
Relative humidity: 30-80%	69% ± 12% (SD)
Adequate ventilation?	Not reported
Photoperiod Minimum of 14 h of light.	16 hrs light
Diet: A commercial diet for game birds.	Game bird ration formulated by W.I.L. (form. info. reported)

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Not reported
Definitive Test **Nominal concentrations:** Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless LC_{50} > 5000 ppm.	Six nominal conc. plus 4 positive controls: 0, 316, 562, 1000, 1780, 3160, 5620 ppm (LC50 > 5620 ppm)
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets?	Yes, 4 control groups with the maximum amount of vehicle used.
Number of birds per group: 10 (strongly recommended)	10 ducklings
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	2 % corn oil (test substance was dissolved in acetone first, and acetone was let evaporated)
Vehicle amount (% of diet by weight): Not more than 2%	2 %
Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed.	8 days (5 d. exp + 3 d. observ.)
No mortality during last 72 hr of observations?	no mortality

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Body weights measured at **beginning and end of study?**	At day 0, 5, and 8

Guideline Criteria	Reported Information
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Yes
Control Mortality: Not more than 10%	No control mortality.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Conc. (ppm)		No. of Birds	Cumulative Number of Dead							
			Day of Study							
Nominal	Mean Measured		1	2	3	4	5	6	7	8
Control		10	0	0	0	0	0	0	0	0
316	305	10	0	0	0	0	0	0	0	0
562	555	10	0	0	0	0	0	0	0	0
1000	946	10	0	0	0	0	0	0	0	0
1780	1730	10	0	0	0	0	0	0	0	0
3160	3210	10	0	0	0	0	1	1	1	1
5620	5860	10	0	0	0	0	0	0	0	0

Other Significant Results: Slight reduction in body weight gain and feeding consumption at 3160 and 5620 ppm.

Statistical Results

Statistical Method: Visual inspection because LC50 > 5620 ppm (highest dosage tested).

LC_{50}: >5620 ppm (nominal) 95% C.I.: _____-_____ ppm

NOEL: 1780 ppm Probit Slope: _____

13. Verification of Statistical Results

Statistical Method: Visual inspection

LC_{50}: >5620 ppm (nominal) 95% C.I.: _____-_____ ppm

NOEL: 1780 ppm Probit Slope: _____

Adjusted for active ingredient: (Optional if over 80% ai)

LC_{50}: _____ ppm ai 95% C.I.: _____-_____ ppm ai

NOEL: _____ ppm ai

14. REVIEWER'S COMMENTS:

DP Barcode: D228125 MRID No.: 437507-14

DATA EVALUATION RECORD
§ 71-2(A) -- UPLAND GAME BIRD DIETARY LC_{50} TEST

1. **CHEMICAL:** Imiprothrin (Pralle) PC Code No.: 004006

2. **TEST MATERIAL:** S-41311 T.G. Purity: 92.9 %

3. **CITATION**

Authors: Campbell S. & J. Beavers
Title: S-41311: A Dietary LC50 Study with the Northern Bobwhite
Study Completion Date: 7/20/94
Laboratory: Wildlife International Ltd.
Sponsor: Smitomo Chemical Co.
Laboratory Report ID: S.G.W-41-0007 (Proj. # 166-157)
MRID No.: 437507-14
DP Barcode: 228125

4. **REVIEWED BY:** Richard M. Lee, Entomologist, EEB, EFED

Signature: Richard M. Lee **Date:** 1/29/97

5. **APPROVED BY:** Ann Stavola, Head of Section (5), EEB, EFED

Signature: Ann Stavola **Date:** 2/5/97

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: (*Colinus virginianus*)

Age of Test Organisms at Test Initiation: 10 days old
Definitive Study Duration: 8 days (5 d. trt., 3 d. observ.)

7. **CONCLUSIONS:**

Results Synopsis
LC_{50}: >5620 ppm ai 95% C.I.: ____-____ ppm ai
NOEL: 1000 ppm ai Probit Slope: ____

8. **ADEQUACY OF THE STUDY**

A. Classification: Core

B. Rationale:

C. Repairability:

9. **GUIDELINE DEVIATIONS**

1. Brooder temperature was slightly higher.

2. (etc.)

10. SUBMISSION PURPOSE: Sec. 3 full registration

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species: An upland game bird species, preferably the bobwhite (*Colinus virginianus*).	Bobwhite quail (*Colinus virginianus*)
Age at beginning of test: 10-14 days old.	10 days old
Supplier	Wildlife International Ltd.
Chicks appeared healthy and did not have excessive mortality before the test?	Yes
Acclimation period: As long as possible.	10 days

B. Test System

Guideline Criteria	Reported Information
Pen size: about 35 x 100 x 24 cm	72 x 90 x 23 cm (H)
Brooder temperature: about 35°C (95°F)	37°C ± 1°C (SD)
Room temperature: 22-27°C (71-81°F)	27°C ± 1.4°C (SD)
Relative humidity: 30-80%	65% ± 10% (SD)
Adequate ventilation?	Not reported
Photoperiod Minimum of 14 h of light.	16 hrs light
Diet: A commercial diet for game birds.	Game bird ration formulated by W.I.L. (form. info. reported)

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Not reported
Definitive Test **Nominal concentrations:** Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless LC_{50} > 5000 ppm.	Six nominal conc. plus 4 positive controls: 0, 316, 562, 1000, 1780, 3160, 5620 ppm (LC50 > 5620 ppm)
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets?	Yes
Number of birds per group: 10 (strongly recommended)	10 chicks
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	corn oil (test substance was dissolved in acetone first, and acetone was let evaporated)
Vehicle amount (% of diet by weight): Not more than 2%	2 %
Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed.	8 days (5 d. exp + 3 d. observ.)
No mortality during last 72 hr of observations?	no mortality

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Body weights measured at beginning and end of study?	At day 0, 5, and 8

Guideline Criteria	Reported Information
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Yes
Control Mortality: Not more than 10%	No control mortality.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Conc. (ppm)		No. of Birds	Cumulative Number of Dead							
			Day of Study							
Nominal	Mean Measured		1	2	3	4	5	6	7	8
Control		10	0	0	0	0	0	0	0	0
316	305	10	0	0	0	0	0	0	0	0
562	555	10	0	0	0	0	0	0	0	0
1000	946	10	0	0	0	0	0	0	0	0
1780	1730	10	0	0	0	0	0	0	0	0
3160	3210	10	0	0	1	1	1	1	1	1
5620	5860	10	0	0	0	0	0	0	0	0

Other Significant Results:
Slight reduction in body weight gain at 1780 and 3160 ppm.

Statistical Results

Statistical Method: Visual inspection because LC50 > 5620 ppm (highest dosage tested).

LC_{50}: >5620 ppm (nominal) 95% C.I.: _____-_____ ppm

NOEL: 1000 ppm Probit Slope: _____

13. Verification of Statistical Results

DP Barcode: D228125 MRID No.: 437507-14

Statistical Method: Visual inspection

LC_{50}: >5620 ppm (nominal) 95% C.I.: _____-_____ ppm

NOEL: 1000 ppm Probit Slope: _____

Adjusted for active ingredient: (Optional if over 80% ai)

LC_{50}: _____ ppm ai 95% C.I.: _____-_____ ppm ai

NOEL: _____ ppm ai

14. REVIEWER'S COMMENTS:

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

1. **CHEMICAL:** Imiprothrin (Pralle®) PC Code No.: 004006

2. **TEST MATERIAL:** S-41311 T.G. Purity: 92.9%

3. **CITATION**

Authors: Bowman J. & L. Stuerman
Title: Acute Flow-through Toxicity of S-41311 to Bluegill sunfish (*Lepomis macrochirus*)
$Study Completion Date: 6/7/93
Laboratory: ABC Laboratory , Inc.
Sponsor: Sumitomo Chemical Co. Ltd.
Laboratory Report ID: SGW-31-0003
MRID No.: 437507-15
DP Barcode: D228125

4. **REVIEWED BY:** Richard Lee, Entomologist, EEB, EFED

Signature: Richard M Lee **Date:** 1/29/97

5. **APPROVED BY:** Ann Stavola, Head, Section 5, EEB, EFED

Signature: Ann Stavola **Date:** 2/5/97

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: (*Lepomis macrochirus*)
Age or Size of Test Organism: 1.11 ± 0.44, 35 ± 4 mm
Definitive Test Duration: 96 hrs
Study Method: A 96-h acute toxicity test
Type of Concentrations: flow-through/measured conc.

7. **CONCLUSIONS:**

Results Synopsis
LC_{50}: 0.070 ppm ai (measured) 95% C.I.: 0.063-0.079 ppm ai
NOEL: 0.033 ppm ai Probit Slope: 11

8. **ADEQUACY OF THE STUDY**

A. **Classification:** Core

B. **Rationale:**

C. **Repairability:**

9. **GUIDELINE DEVIATIONS**

1. The pH value was too high (8.1-8.2 instead of 7.2-7.6)

2. Total Hardness was too high (142-148 mg/L instead of 40-48 mg/L)

10. **SUBMISSION PURPOSE**: Sec.3 full registration

11. **MATERIALS AND METHODS**

A. **Test Organisms**

Guideline Criteria	Reported Information
Species Preferred species is the Bluegill sunfish (*Lepomis macrochirus*)	Bluegill sunfish (*Lepomis macrochirus*)
Mean Weight 0.5-5 g	1.11 ± 0.44 g
Mean Standard Length Longest not > 2x shortest	Mean: 35 mm Range: 31 - 39 mm
Supplier	Osage Catfisheries, Osage Beach, MO
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	48 hrs to test condition, but was held for 20 wks.
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported
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	No feeding during the acclimation and test period.

Guideline Criteria	Reported Information
Pretest Mortality < 3% mortality 48 hours prior to testing	No mortality prior to testing.

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, not dechlorinated tap water	Blended natural hard well water & demineralized hard well water.
Does water support test animals without observable signs of stress?	Yes
Water Temperature 12°C	22 ± 1°C
pH Prefer 7.2 to 7.6	8.1 - 8.2
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%	8.4 to 8.6 mg/L (or 100 - 102%) at 22°C
Total Hardness Prefer 40 to 48 mg/L as $CaCO_3$	142 - 148 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 45-L 56.6 cm(L) x 26.5 cm(W) x 30.8 cm(H) 30 L
Type of Dilution System Must provide reproducible supply of toxicant	A Half-L proportional diluter system (Mount & Brungs) w/ Hamilton Micro Lab 420 syringe dispenser

Guideline Criteria	Reported Information
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	15 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	0.051 g/L (or g/L/day)
Photoperiod 16 hours light, 8 hours dark	16 hrs daylight
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.	100 mg/L had 100% mortality; 0.01 ppm had no mortality.
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	0.012, 0.019, 0.032, 0.054, and 0.090 ppm nominal conc. plus negative and positive controls
Number of Test Organisms Minimum 10/level, may be divided among containers	20 fishes/level
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes

Guideline Criteria	Reported Information
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	22 ± 1°C measured at 0, 48, and 96 hrs Measured all test conc. at 0, 48, and 96 hrs.
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	The mean measured con. were 0.013, 0.022, 0.033, 0.050, and 0.085 ppm ai.

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	90 ± 11%
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	No control mortality.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Concentration (ppm)	Number of Fish	Cumulative Number Dead

Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Control		20	0	0	0	0
Solvent Control		20	0	0	0	0
0.012	0.013	20	0	0	0	0
0.019	0.022	20	0	0	0	0
0.032	0.033	20	9	0	0	0
0.054	0.050	20	0	0	1	1
0.090	0.085	20	9	14	15	16

Other Significant Results:

B. Statistical Results

Method: Moving average method

96-hr LC_{50}: 0.070 ppm ai 95% C.I.: 0.063 - 0.079 ppm

Probit Slope: 11 NOEC: 0.033 ppm ai

13. VERIFICATION OF STATISTICAL RESULTS

Parameter	Result
Binomial Test LC_{50} (C.I.)	0.070(0.053-0.085) ppm ai
Moving Average Angle LC_{50} (95% C.I.)	0.070(0.063-0.079) ppm ai
Probit LC_{50} (95% C.I.)	____ (____-____) ppm ai
Probit Slope	
NOEC	ppm ai

14. REVIEWER'S COMMENTS:

The pH value and total hardness measured were too high. However, the LC50 value obtained probably is valid because statistical analysis is based on measured concentrations.

RICHARD LEE PRALLE BLUEGILL LC50

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.085	20	16	80	.5908966
.05	20	1	5	2.002716E-03
.033	20	0	0	9.536742E-05
.022	20	0	0	9.536742E-05
.013	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .05 AND .085 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 6.984291E-02

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	.1382494	6.984291E-02	6.324115E-02	7.885836E-02

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
10	.1956855	1	.9999405

SLOPE = 10.81479
95 PERCENT CONFIDENCE LIMITS = 6.03072 AND 15.59885

LC50 = 7.104106E-02
95 PERCENT CONFIDENCE LIMITS = 6.263514E-02 AND 8.014375E-02

LC10 = 5.420978E-02
95 PERCENT CONFIDENCE LIMITS = 4.153875E-02 AND 6.169209E-02

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

1. CHEMICAL: Imiprothrin (Pralle®) PC Code No.: 004006

2. TEST MATERIAL: S-41311 T.G. Purity: 92.9%

3. CITATION

Authors: Bowman J. & L. Stuerman
Title: Acute Flow-through Toxicity of S-41311 to Rainbow trout *Oncorhynchus mykiss*
Study Completion Date: 6/14/93
Laboratory: ABC Laboratory , Inc.
Sponsor: Sumitomo Chemical Co. Ltd.
Laboratory Report ID: SGW-31-0002
MRID No.: 437507-16
DP Barcode: 228125

4. REVIEWED BY: Richard Lee, Entomologist, EEB, EFED

Signature: Richard A. Lee Date: 1/29/97

5. APPROVED BY: Ann Stavola, Head, Section 5, EEB, EFED

Signature: Ann Stavola Date: 2/3/97

6. STUDY PARAMETERS

Scientific Name of Test Organism: *Oncorhynchus mykiss*
Age or Size of Test Organism: 1.19 ± 0.3 g., 44 ± 4 mm
Definitive Test Duration: 96 hrs
Study Method: A 96-h acute toxicity test
Type of Concentrations: flow-through

7. CONCLUSIONS:

Results Synopsis
LC_{50}: 0.038 ppm ai 95% C.I.: 0.021-0.062 ppm ai
NOEL: 0.021 ppm ai Probit Slope: 9.8

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale:

C. Repairability:

9. GUIDELINE DEVIATIONS

1. The pH value was too high (8.0-8.2 instead of 7.2-7.6)

2. Total Hardness was too high (134-148 mg/L instead of 40-48 mg/L)

10. SUBMISSION PURPOSE: Sec.3 full registration

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the rainbow trout (*Onchorhynchus mykiss*)	*Rainbow trout* Oncorhynchus mykiss
Mean Weight 0.5-5 g	1.19 g ± 0.30 g
Mean Standard Length Longest not > 2x shortest	Mean: 44 mm Range: 40 - 48 mm
Supplier	Mt. Lassen Trout Farm Red Bluff, Calif.
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	48 hrs, but was hatched at WLI lab.
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported
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	No feeding during the acclimation and test period.

Guideline Criteria	Reported Information
Pretest Mortality < 3% mortality 48 hours prior to testing	No mortality prior to testing.

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Blended natural hard well water & demineralized hard well water.
Does water support test animals without observable signs of stress?	Yes
Water Temperature 12°C	12 °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%	8.8 to 9.3 mg/L (or 85 - 90%) at 12°C
Total Hardness Prefer 40 to 48 mg/L as $CaCO_3$	134 - 148 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 45-L 56.6 cm(L) x 26.5 cm(W) x 30.8 cm(H) 30 L
Type of Dilution System Must provide reproducible supply of toxicant	A Half-L proportional diluter system (Mount & Brungs) w/ Hamilton Micro Lab 420 syringe dispenser

3

Guideline Criteria	Reported Information
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	15 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	0.053 g/L (or g/L/day)
Photoperiod 16 hours light, 8 hours dark	16 hrs light
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.	LC20 was ca. 0.01 mg/L
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	0.012, 0.019, 0.032, 0.054, and 0.090 ppm nominal conc. plus negative and positive controls
Number of Test Organisms Minimum 10/level, may be divided among containers	20 fishes/level
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes

4

Guideline Criteria	Reported Information
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	12 °C measured at 0, 48, and 96 hrs Measured all test conc. at 0, 48, and 96 hrs.
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	The mean measured con. were 0.012, 0.021, 0.040, 0.062, and 0.1 ppm ai.

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	90 ± 11%
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	No control mortality.
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Concentration (ppm)	Number of Fish	Cumulative Number Dead

Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Control		20	0	0	0	0
Solvent Control		20	0	0	0	0
0.012	0.012	20	0	0	0	0
0.019	0.021	20	0	0	0	0
0.032	0.040	20	9	11	11	11
0.054	0.062	20	20	20	20	20
0.090	0.10	20	20	20	20	20

Other Significant Results:

B. Statistical Results

Method: Binomial Test

96-hr LC_{50}: 0.038 ppm ai (measured) 95% C.I.: 0.021-0.062 ppm

Probit Slope: 9.8 NOEC: 0.021 ppm ai

13. VERIFICATION OF STATISTICAL RESULTS

Parameter	Result
Binomial Test LC_{50} (C.I.)	0.038(0.021-0.062) ppm ai
Moving Average Angle LC_{50} (95% C.I.)	____ (____-____) ppm ai
Probit LC_{50} (95% C.I.)	____ (____-____) ppm ai
Probit Slope	
NOEC	ppm ai

14. REVIEWER'S COMMENTS:

The pH value and total hardness measured were too high. However, the LC50 value obtained probably is valid because statistical analysis is based on measured concentrations.

RICHARD LEE PRALLE RAINBOW TROUT LC50

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.1	20	20	100	9.536742E-05
.062	20	20	100	9.536742E-05
.04	20	11	55	41.19014
.021	20	0	0	9.536742E-05
.012	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .021 AND .062 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 3.833395E-02

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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DATA EVALUATION RECORD
§ 72-2(C) -- ACUTE LC_{50} TEST WITH A FRESHWATER INVERTEBRATE

1. **CHEMICAL:** Imiprothrin (Pralle®) PC Code No.: 004006

2. **TEST MATERIAL:** S-41311 T.G. Purity: 92.9%

3. **CITATION**

Authors: Bowman J. & L. Stuerman
Title: Acute Flow-through Toxicity of S-41311 to *Daphnia magna*
Study Completion Date: 7/30/93
Laboratory: ABC Laboratory , Inc.
Sponsor: Sumitomo Chemical Co. Ltd.
Laboratory Report ID: SGW -31-0004
MRID NO.: 437507-17
DP Barcode: 228125

4. **REVIEWED BY:** Richard Lee, Entomologist, EEB, EFED

Signature: Richard A. Lee **Date:** 1/29/97

5. **APPROVED BY:** Ann Stavola, Head, Section 5, EEB, EFED

Signature: Ann Stavola **Date:** 2/7/97

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Daphnia magna*
Age or Size of Test Organism: First inster (< 24 hrs old)
Definitive Test Duration: 48 hrs
Study Method: A 48-h acute toxicity test
Type of Concentrations: flow-through/measured

7. **CONCLUSIONS:**

Results Synopsis
EC_{50}: 0.051 ppm ai 95% C.I.: 0.03-0.082 ppm ai
NOEL: 0.03 ppm ai Probit Slope: 11

8. **ADEQUACY OF THE STUDY**

A. **Classification:** Core

B. **Rationale:**

C. **Repairability:**

9. **GUIDELINE DEVIATIONS**

1. The pH value was too high (8.1-8.2 instead of 7.2-7.6)

2. Total hardness was too high (162-170 mg/L instead of 40 -48 mg/L).
3. The DO decreased to 41-48% saturatioin by 48 hrs.

11. SUBMISSION PURPOSE: Sec. 3 Registration

12. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is *Daphnia magna*	*Daphnia magna*
All organisms are approximately the same size and weight?	Yes
Life Stage Daphnids: 1st instar (<24 h). Amphipods, stoneflies, and mayflies: 2nd instar. Midges: 2nd & 3th instar.	1st instar (<24 h) daphnids
Supplier	In-house culture/Columbia Natl. Fish. Res. Lab.
All organisms from the same source?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 7 days	16 days
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

Guideline Criteria	Reported Information
Feeding No feeding during the study.	Fed only during holding period.
Pretest Mortality No more than 3% mortality 48 hours prior to testing.	0 % mortality prior to testing

C. **Test System**

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water.	Blended natural hard well water and demineralized well water.
Does water support test animals without observable signs of stress?	Yes
Water Temperature Daphnia: 20°C Amphipods and mayflies: 17°C Midges and mayflies: 22°C Stoneflies: 12°C	20 ± 2 °C
pH 7.6 to 8.0 is recommended.	8.1 - 8.2
Dissolved Oxygen Static: ≥ 60% during 1st 48 h and ≥ 40% during 2nd 48 h, flow-through: ≥ 60%.	41 - 93% at 21°C /flow-through
Total Hardness 160 to 180 mg/L as $CaCO_3$ is recommended.	162 - 170 mg/L as $CaCO_3$
Test Aquaria 1. Material: Glass or stainless steel. 2. Size: 250 ml (daphnids and midges) or 3.9 L (1 gal). 3. Fill volume: 200 ml (daphnids and midges) or 2-3 L.	 Glass beaker One Litter One L.

Guideline Criteria	Reported Information
Type of Dilution System Must provide reproducible supply of toxicant.	A half-L proportional diluter system (Mount & Brungs) w/ Hamilton Micro Lab. 420 sylinge dispensere
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period.	7.6 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.	One daphnid per 100 ml of solution.
Photoperiod 16 hours light, 8 hours dark.	16 hrs daylight
Solvents Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests.	0.04 ml/0.4 L. or 0.1 ml/L. DMF

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L, then no definitive test is required.	In range finding test, LC50 was ca. 0.054 ppm (nominal)
Nominal Concentrations of Definitive Test Control & 5 treatment levels; a geometric series with each concentration being at least 60% of the next higher one.	0.020, 0.032, 0.054, 0.090, and 0.15 ppm plus positive and negative controls.
Number of Test Organisms Minimum 20/level, may be divided among containers.	20 / level

Guideline Criteria	Reported Information
Test organisms randomly or impartially assigned to test vessels?	Yes
Water Parameter Measurements 1. Temperature Measured continuously or, if water baths are used, every 6 h, 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.	20 ± 1 °C, measured continuously. At begining and end of the study.
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	Concentration were measured.

13. REPORTED RESULTS

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Control Mortality Static: ≤10% Flow-through: ≤5%	0 %
Recovery of Chemical	90 ± 11 %
Raw data included?	Yes

Mortality

Concentration (ppm)		Number of Organ-isms	Cumulative # Dead/Immobilized			
			Hour of Study			
Nominal	Mean Measured		24	48	72	96
Control		20	0	0	-	-
Solvent Control		20	0	0	-	-
0.020	0.013	20	0	0	-	-
0.032	0.030	20	0	0	-	-
0.054	0.049	20	0/0	5/4	-	-
0.090	0.082	20	4/6	20	-	-
0.15	0.16	20	2/13	20	-	-

Other Significant Results:

B. Statistical Results

Method: Binomial Test

48-hr EC_{50}: 0.051 ppm ai 95% C.I.: 0.03 - 0.082 ppm ai
48-hr LC_{50}: 0.056 ppm ai 95% C.I.: 0.049-0.082 ppm ai

Probit Slope: 11 NOEC: 0.03 ppm ai

14. VERIFICATION OF STATISTICAL RESULTS

Parameter	Result
Binomial Test LC_{50} (C.I.)	0.051 (0.03-0.082) ppm ai
Moving Average Angle LC_{50} (95% C.I.)	____ (____-____.) ppm ai
Probit LC_{50} (95% C.I.)	____ (____-____) ppm ai
Probit Slope	
NOEC	ppm ai

15. REVIEWER'S COMMENTS:

The D.O. was low (41-48& saturation) at 24 & 48 hrs, but did not negatively affect the results of the study.

Both pH and total hardness of dilutioin water were high, but the results are valid because statistical analysis was based on the measured concentrations.

RICHARD LEE PRALLE DAPHNIA EC50

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.16	20	20	100	9.536742E-05
.082	20	20	100	9.536742E-05
.049	20	9	45	41.19014
.03	20	0	0	9.536742E-05
.013	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .03 AND .082 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 5.069446E-02

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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RICHARD LEE PRALLE DAPHNIA LC50

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.16	20	20	100	9.536742E-05
.082	20	20	100	9.536742E-05
.049	20	5	25	2.069473
.03	20	0	0	9.536742E-05
.013	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .049 AND .082 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 5.627973E-02

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.