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

1. **CHEMICAL:** Lambda-Cyhalothrin PC Code No.:128867

2. **TEST MATERIAL:** 25 CS Formulation (WF2289); white liquid
Purity: 23.7%

3. **CITATION**
Authors: S.J. Kent, S.A. Sankey, J.E. Caunter and S.E. Magor
Title: Lambda-Cyhalothrin: Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) of a 25CS Formulation
Study Completion Date: 1995
Laboratory: Brixham Environmental Laboratory, Brixham, Devon, UK
Sponsor: Zeneca Agrochemicals
Laboratory Report ID: AA1091/C
MRID No.: 4308812
DP Barcode: D223935

4. **REVIEWED BY:** Joanne S. Edwards, Entomologist, EEB, EFED
Signature: Joanne S Edwards **Date:** 5/13/96

5. **APPROVED BY:** Leslie Touart, Head of Section 1, EEB, EFED
Signature: L Touart **Date:** 6·11·96

6. **STUDY PARAMETERS**
Scientific Name of Test Organism: bluegill sunfish
Age or Size of Test Organism: 41.8 mm mean length
Definitive Test Duration: 96 hours
Study Method: Flow-through
Type of Concentrations: final measured concentrations

7. **CONCLUSIONS:**

Results Synopsis

LC_{50}: (Probit method)

1.2 ppb (1.0 -1.5 ppb C.I.) (technical lambda-cyhalothrin)
4.9 ppb (4.4 -6.3 ppb C.I.) (25 CS Formulation)

8. **ADEQUACY OF THE STUDY**

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. **GUIDELINE DEVIATIONS**

See under Item 14. Reviewer's Comments

10. **SUBMISSION PURPOSE:**

11. **MATERIALS AND METHODS**

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the bluegill sunfish (*Lepomis macrochirus*)	Bluegill sunfish
Mean Weight 0.5-5 g	1.94 g
Mean Standard Length Longest not > 2x shortest	Mean: 41.8 mm Range: 32.6 - 55.0 mm
Supplier	Sea Plantations Inc., Salem, MA
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	23 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 (last treated with amoxicillin >100 days prior to test)
Feeding No feeding during the study	No feeding during the test or for 72 hours prior to the test

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Guideline Criteria	Reported Information
Pretest Mortality No more than 3% mortality 48 hours prior to testing	0% mortality

C. **Test System**

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Dechlorinated tap water that had been passed through activated carbon, coarsely filtered to remove particulate material and dechlorinated with sodium thisulphate; held in a secondary reservoir, then passed through an ultra violet sterilizer to a second set of filters, then to a third storage tank
Does water support test animals without observable signs of stress?	Yes
Water Temperature 17°C or 22°C	21.5 to 21.7 °C
pH Prefer 7.2 to 7.6	7.62 - 7.79
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%	8.6 to 9.2 mg/L
Total Hardness Prefer 40 to 48 mg/L as $CaCO_3$	47.3 to 51.3 mg/l as $CaCO_3$
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 19 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	Borosilicate glass vessels (610 mm length X 305 mm width X 310 mm height 54 L 45 L
Type of Dilution System Must provide reproducible supply of toxicant	Continuous flow-through

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	Approx. 95% exchange of water every 9 hrs
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day	0.86 g/L
Photoperiod 16 hours light, 8 hours dark	16 hours light, 8 hours dark
Solvents Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests	No solvent employed

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.	Not reported
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	1.8, 3.2, 5.6, 10, 18 and 32 ug formulation/L.
Number of Test Organisms Minimum 10/level, may be divided among containers	20 per level
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes

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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 every 48 h in the high, medium, and low doses and in the control	All criteria met
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; however 0 hr analyses could not be used due to a flask contamination

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	37-72% (the low measured concentrations were due to adsorption of the material onto surfaces that the stock and test solutions were in contact with)
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0%
Raw data included?	Excerpted
Signs of toxicity (if any) were described?	Yes

Mortality

Concentration (ppb) Formulation/Technical		Number of Fish	Cumulative % Mortality			
			Hour of Study			
Nominal	Final Measured (96 hr)		24	48	72	96
Control		20	0	0	0	0
1.8/0.43	0.46/0.11	20	0	0	0	0
3.2/0.76	1.35/0.32	20	0	0	0	0
5.6/1.3	3.54/0.84	20	0	0	5	10
10/2.4	4.64/1.1	20	0	15	20	40
18/4.3	9.7/2.3	20	55	95	100	100
32/7.6	Terminated	20	100	100	100	100

Other Significant Results:

Symptoms of toxicity were observed down to dose level 5.6 ppb (Table 3, attached). At both the 5.6 and 10 ppb dose levels, more than 30% of the population were either dead or exhibited signs of toxicity (sounding, loss of balance).

B. Statistical Results

Method: Stefan's- moving angle

technical lambda-cyhalothrin:

96-hr LC_{50}: 1.3 ppb 95% C.I.: 1.1 -1.6 ppb

25 CS Formulation:

96-hr LC_{50}: 5.3 ppb 95% C.I.: 4.4 -6.4 ppb

13. VERIFICATION OF STATISTICAL RESULTS

25 CS Formulation

Parameter	Result (ppb)
Binomial Test LC_{50} (C.I.)	5.1 (0.464 -9.7 C.I.)
Moving Average Angle LC_{50} (95% C.I.)	5.2 (4.5 -5.8 C.I.)
Probit LC_{50} (95% C.I.)	4.9 (4.4 -6.3 C.I.)

Probit Slope	9.6
NOEC	none established

technical Lambda- Cyhalothrin

Parameter	Result (ppb)
Binomial Test LC_{50} (C.I.)	1.2 (0.11-2.3 C.I.)
Moving Average Angle LC_{50} (95% C.I.)	1.2 (1.1-1.4 C.I.)
Probit LC_{50} (95% C.I.)	1.2 (1.0-1.5 C.I.)
Probit Slope	9.6
NOEC	none established

Because of the low recovery of the material, we based the results on measured concentrations at 96 hours. Slightly more conservative results were obtained.

14. REVIEWER'S COMMENTS:

The following deviations were noted. These deviations were not found to affect the overall quality of the study:

o The measured concentrations were lower than 70% for 6 out of the 7 levels. Recovery ranged from 37 to 72% of the measured concentrations. As adsorption of the material to surfaces is expected with this type of material (i.e. a pyrethroid), the low recovery does not invalidate the study. We believe a more accurate LC50 is based on final measured concentrations, thus our findingins are slightly more conservative than that of the study authors (4.9 ppb vs 5.3 ppb for the 25 CS formulation).

o 5-10 volume additions per 24 hr period are recommended; turnover rate in this study was lower, approx. 95% every 9 hours.

This study is scientifically sound and satisfies the guideline requirement (72-1b) for testing with a formulated product. The 72-hour acute LC50 for bluegill exposed to a 25 CS formulation containing lambda-cyhalothrin is 4.9 ppb based on final measured concentrations.

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MRID# 43908812 & 43908813

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_____ Identity of the source of product ingredients.

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_____ A draft product label.

_____ The product confidential statement of formula.

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SLOPE = 7.585421
95 PERCENT CONFIDENCE LIMITS = 4.276113 AND 10.89473

LC50 = 6.090032
95 PERCENT CONFIDENCE LIMITS = 5.322956 AND 7.24979

LC10 = 4.141839
95 PERCENT CONFIDENCE LIMITS = 3.098812 AND 4.805232
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jedwards Karate bluegill
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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
4.3	20	20	100	9.536742E-05
2.8	20	20	100	9.536742E-05
1.4	20	8	40	25.17223
.93	20	2	10	2.012253E-02
.46	20	0	0	9.536742E-05
.16	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .93 AND 2.8 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 1.526053

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	3.170479E-02	1.272997	1.052523	1.555834

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	.1898638	1	.9356841

SLOPE = 7.709325
95 PERCENT CONFIDENCE LIMITS = 4.350113 AND 11.06854

LC50 = 1.443111
95 PERCENT CONFIDENCE LIMITS = 1.26404 AND 1.711834

LC10 = .9875612
95 PERCENT CONFIDENCE LIMITS = .7420353 AND 1.143172
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jedwards karate bluegill

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
2.3	20	20	100	2.012253E-02
1.1	20	8	40	9.536742E-05
.84	20	2	10	5.765915
.32	20	0	0	5.765915
.11	20	0	0	2.069473

THE BINOMIAL TEST SHOWS THAT .11 AND 2.3 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.

jedwards Karate bluegill

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
18	20	20	100	9.536742E-05
12	20	20	100	9.536742E-05
5.9	20	8	40	25.17223
3.9	20	2	10	2.012253E-02
1.9	20	0	0	9.536742E-05
.68	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.9 AND 12 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 6.44468

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	3.021811E-02	6.447624	5.301318	4.400111

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	.1903334	1	.9395024

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 1.205689

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	7.602794E-02	1.222902	1.078056	1.384684

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
9	.372139	1	.9937404

SLOPE = 9.5904
95 PERCENT CONFIDENCE LIMITS = 3.739949 AND 15.44085

LC50 = 1.15775
95 PERCENT CONFIDENCE LIMITS = 1.039922 AND 1.494708

LC10 = .8534748
95 PERCENT CONFIDENCE LIMITS = .6151581 AND .9566306

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jedwards karate bluegill

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
9.7	20	20	100	2.012253E-02
4.64	20	8	40	9.536742E-05
3.544	20	2	10	5.765915
1.35	20	0	0	5.765915
.464	20	0	0	2.069473

THE BINOMIAL TEST SHOWS THAT .464 AND 9.7 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 5.085696

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	7.602794E-02	5.158466	4.5477	5.840615

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
10	.3725167	1	.993772

SLOPE = 9.595953
95 PERCENT CONFIDENCE LIMITS = 3.739145 AND 15.45276

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LC50 = 4.883559
95 PERCENT CONFIDENCE LIMITS = 4.386797 AND 6.305879

LC10 = 3.600716
95 PERCENT CONFIDENCE LIMITS = 2.595041 AND 4.035645
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DATA EVALUATION RECORD
§ 72-1(C) -- ACUTE LC_{50} TEST WITH A COLDWATER FISH

1. **CHEMICAL:** Lambda-Cyhalothrin PC Code No.:128867

2. **TEST MATERIAL:** 25 CS Formulation (WF2289); white liquid
Purity: 23.7%

3. CITATION
Authors: S.J. Kent, S.A. Sankey, J.E. Caunter and P.A. Johnson
Title: Lambda-Cyhalothrin: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) of a 25CS Formulation
Study Completion Date: 1995
Laboratory: Brixham Environmental Laboratory, Brixham, Devon, UK
Sponsor: Zeneca Ag Products
Laboratory Report ID: AA1091/B
MRID No.: 430813
DP Barcode: D223935

4. **REVIEWED BY:** Joanne S. Edwards, Entomologist, EEB, EFED
Signature: Joann S Edwards **Date:** 5/13/96

5. **APPROVED BY:** Leslie Touart, Head of Section 1, EEB, EFED
Signature: LWT **Date:** 6.11.96

6. STUDY PARAMETERS
Scientific Name of Test Organism: rainbow trout
Age or Size of Test Organism: 44 mm mean length
Definitive Test Duration: 96 hour
Study Method: Flow-through
Type of Concentrations: Mean measured concentrations

7. CONCLUSIONS:

Results Synopsis

LC50: (Stefan's probit method)

2.7 ppb (2.3 - 3.1 C.I.) (technical lambda-cyhalothrin)
11.2 ppb (9.8-13.0 C.I.) (25 CS Formulation)

8. ADEQUACY OF THE STUDY

A. **Classification:** Core

B. **Rationale:** N/A

C. **Repairability:** N/A

9. GUIDELINE DEVIATIONS

See under Item 14. Reviewer's Comments

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the rainbow trout (*Oncorhynchus mykiss*)	Rainbow trout
Mean Weight 0.5-5 g	1.13 g
Mean Standard Length Longest not > 2x shortest	Mean: 44 mm Range: 33 - 53 mm
Supplier	Sea Plantations Inc., Salem, MA
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	31 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
Feeding No feeding during the study	No feeding during the test or for 72 hours prior to the test
Pretest Mortality No more than 3% mortality 48 hours prior to testing	0 % mortality

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Dechlorinated tap water that had been passed through activated carbon, coarsely filtered to remove particulate material and dechlorinated with sodium thisulphate; held in a secondary reservoir, then passed through an ultra violet sterilizer to a second set of filters, then to a third storage tank
Does water support test animals without observable signs of stress?	Yes
Water Temperature 12°C	12 ± 1°C
pH Prefer 7.2 to 7.6	7.67 - 7.84
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%	10 -10.6 mg/L
Total Hardness Prefer 40 to 48 mg/L as $CaCO_3$	40.6 to 44.6 mg/l as $CaCO_3$
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 19 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	Borosilicate glass vessels (610 mm length X 305 mm width X 310 mm height (a minimum of silicone rubber tubing was used) 54 L 45 L
Type of Dilution System Must provide reproducible supply of toxicant	Continuous flow-through
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	Approx. 95% exchange of water every 9 hrs

Guideline Criteria	Reported Information
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day	0.5 g/L
Photoperiod 16 hours light, 8 hours dark	16 hours light, 8 hours dark
Solvents Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests	No solvent employed

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.	Not reported
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	1.8, 3.2, 5.6, 10, 18 and 32 ug formulation/L.
Number of Test Organisms Minimum 10/level, may be divided among containers	20 per level
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 every 48 h in the high, medium, and low doses and in the control	All criteria met

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; concentrations were measured at 0, 5, 24, 48, 52, 72 and 96 hrs

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	70-103 %
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0%
Raw data included?	Excerpted
Signs of toxicity (if any) were described?	Yes

Mortality

Concentration (ppb) Formulation/Technical		Number of Fish	Cumulative % Mortality			
			Hour of Study			
Nominal	Mean Measured		24	48	72	96
Control		20	0	0	0	0
1.8/0.43	1.27/0.31	20	0	0	0	0
3.2/0.76	3.0/0.71	20	0	0	0	0
5.6/1.3	5.49/1.3	20	0	0	0	0
10/2.4	8.86/2.1	20	0	0	10	20
18/4.3	16.03/3.8	20	0	40	85	90

Concentration (ppb) Formulation/Technical		Number of Fish	Cumulative % Mortality			
			Hour of Study			
Nominal	Mean Measured		24	48	72	96
32/7.6	32.91/7.8	20	65	100	100	100

Other Significant Results:

Symptoms of toxicity were observed in all dose levels (Table 3, attached). At all levels, more than 30% of the population were either dead or exhibited signs of toxicity (sounding, loss of balance).

B. Statistical Results

Method: Stefan's moving angle

Results are based on nominal concentrations (authors reported that in spite of the slight variations in the measured concentrations the values obtained were maintained within expected limits for this type of substance):

technical lambda-cyhalothrin:

96-hr LC_{50}: 3.0 ppb 95% C.I.: 2.5 -3.6 ppb

25 CS Formulation:

96-hr LC_{50}: 13 ppb 95% C.I.: 11 - 15 ppb

13. VERIFICATION OF STATISTICAL RESULTS

25 CS Formulation (based on mean measured concentrations)

Parameter	Result (ppb)
Binomial Test LC_{50} (C.I.)	11.3 (8.9 - 16)
Moving Average Angle LC_{50} (95% C.I.)	11.8 (10.1 - 13.7)
Probit LC_{50} (95% C.I.)	11.2 (9.8 - 13)
Probit Slope	8.5
NOEC	none established

Technical Lambda-Cyhalothrin (based on mean measured concentrations)

Parameter	Result (ppb)
Binomial Test LC_{50} (C.I.)	2.7 (2.1 - 3.8)
Moving Average Angle LC_{50} (95% C.I.)	2.8 (2.4 - 3.3)
Probit LC_{50} (95% C.I.)	2.7 (2.3 - 3.1)
Probit Slope	8.5
NOEC	none established

We based the results on the probit analysis using mean measured concentrations. Slightly more conservative results were obtained.

14. REVIEWER'S COMMENTS:

The following deviations were noted. None of these were found to affect the overall quality of the study:

- o 5-10 volume additions per 24 hr period are recommended; turnover rate in this study was lower, approx. 95% every 9 hours.
- o one fish was below the recommended weight (0.48 g).
- o dechlorinated water was used in this study; its use is not recommended.

This study is scientifically sound and satisfies the guideline requirement (72-1d) for testing with a formulated product. The 72-hour acute LC50 for rainbow trout exposed to a 25 CS formulation containing lambda-cyhalothrin is 11.3 ppb based on mean measured concentrations.