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.: 4308813
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: Date: 6.11.96

6. **STUDY PARAMETERS**
Scientific Name of Test Organism: rainbow trout
Age or Size of Test Organism: 44 mm mean length 1.1g
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

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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.

SLOPE = 8.524493
95 PERCENT CONFIDENCE LIMITS = 5.102014 AND 11.94697

LC50 = 2.667319
95 PERCENT CONFIDENCE LIMITS = 2.326849 AND 3.086118

LC10 = 1.892747
95 PERCENT CONFIDENCE LIMITS = 1.446487 AND 2.190997
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jedwards karate rainbow trout
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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
32.91	20	20	100	9.536742E-05
16.03	20	18	90	2.012253E-02
8.859999		20	4	20
.5908966				
5.49	20	0	0	9.536742E-05
3	20	0	0	9.536742E-05
1.27	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 8.859999 AND 16.03 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 11.31213

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	5.055477E-02	11.79471	10.13118	13.71537

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.1610533	1	.9986849

SLOPE = 8.52818
95 PERCENT CONFIDENCE LIMITS = 5.105698 AND 11.95066

LC50 = 11.25317
95 PERCENT CONFIDENCE LIMITS = 9.817731 AND 13.01945

LC10 = 7.986509
95 PERCENT CONFIDENCE LIMITS = 6.105648 AND 9.244001
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jedwards karate rainbow trout
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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)

7.8	20	20	100	9.536742E-05
3.8	20	18	90	2.012253E-02
2.1	20	4	20	.5908966
1.3	20	0	0	9.536742E-05
.71	20	0	0	9.536742E-05
.31	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 2.1 AND 3.8 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 2.681368

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	5.057121E-02	2.795044	2.400502	3.250556

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.1611924	1	.9987039

SLOPE = 8.524493
95 PERCENT CONFIDENCE LIMITS = 5.102014 AND 11.94697

LC50 = 2.667319
95 PERCENT CONFIDENCE LIMITS = 2.326849 AND 3.086118

LC10 = 1.892747
95 PERCENT CONFIDENCE LIMITS = 1.446487 AND 2.190997

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jedwards karate rainbow trout

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
32	20	20	100	9.536742E-05
18	20	18	90	2.012253E-02
10	20	4	20	.5908966
5.6	20	0	0	9.536742E-05
3.2	20	0	0	9.536742E-05
1.8	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 10 AND 18 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 12.74068

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

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_____ Identity of the source of product ingredients.

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