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

1. CHEMICAL: Lamda-Cyhalothrin PC Code No.: 128~~867~~ 897

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 *Daphnia magna* Of a 25 CS Formulation
Study Completion Date: 1995
Laboratory: Brixham Environmental Laboratory, Brixham, Devon, UK
Sponsor: Zeneca Ag Products
Laboratory Report ID: AA1091/B
MRID No.: 43908811
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.W.T. Date: 6-11-96

6. STUDY PARAMETERS

Scientific Name of Test Organism:	*Daphnia magna*
Age of Test Organism:	<24 hrs
Definitive Test Duration:	48 hours
Study Method:	Static
Type of Concentrations:	Final measured

7. CONCLUSIONS:

Results Synopsis (Stefan's moving angle method)

technical lambda cyhalothrin:
48-hr EC50: 0.18 ppb 95% C.I.: 0.14 -0.23 ppb

25 CS Formulation:
48-hr EC50: 0.76 ppb 95% C.I.: 0.61 -0.98 ppb

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 *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; less than 24 hrs old
Supplier	In house lab cultures
All organisms from the same source?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 7 days	Parental stock were 18 ± 1 day old
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No evidence of disease
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.	Daphnids were not fed during the study
Pretest Mortality No more than 3% mortality 48 hours prior to testing.	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.	Reconstituted 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 ± 1°C
pH Prefer 7.2 to 7.6.	8.06 to 8.14
Dissolved Oxygen Static: ≥ 60% during 1st 48 h and ≥ 40% during 2nd 48 h, flow-through: ≥ 60%.	8.6 to 9.0 mg/l
Total Hardness Prefer 40 to 48 mg/L as $CaCO_3$.	238 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.	Borosilicate glass beakers 250 ml capacity; each vessel contained 200 ml test solution
Type of Dilution System Must provide reproducible supply of toxicant.	Static; no aeration during study

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.	N/A
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day.	Not reported
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.	None employed

D. Test Design:

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L, then no definitive test is required.	Not reported
Nominal Concentrations of Definitive Test Control & 5 treatment levels; a geometric series with each concentration being at least 60% of the next higher one.	0.32, 0.56, 1.0, 1.8, 3.2, 5.6, 10, and 18 ppb formulation concentrations
Number of Test Organisms Minimum 20/level, may be divided among containers.	20/level; four replicates per level (5 daphnids in each)
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.	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	Chemical analyses were performed

12. REPORTED 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%
Percent Recovery of Chemical	51 to 63% of nominal; low recovery due to adsorption of material onto surfaces the material came in contact with
Raw data included?	Excerpted

Mortality

Concentration (ppb)	Number of Organisms	% Immobil-ized

Nominal conc. of ~~Formulation~~	Final Measured Technical/ ~~Formulation~~		48 hrs
Control		20	0
0.32	0.017/ 0.072	20	0
0.56	0.029/ 0.122	20	0
1	0.058/ 0.245	20	15
1.8	0.097/ 0.409	20	25
3.2	0.18/ 0.759	20	30
5.6	0.30/ 1.27	20	70
10	0.87/ 3.67	20	90
18	0.84/ 3.54	20	100

Other Significant Results:

B. Statistical Results

Method: Stefan's Method - Moving-angle (mean measured concentrations)

technical lambda cyhalothrin:
48-hr EC_{50}: 0.44 ppb 95% C.I.: 0.35 -0.56 ppb

NOEC: 0.075 ppb based on immobility

25 CS Formulation:
48-hr EC_{50}: 1.8 ppb 95% C.I.: 1.5 -2.3 ppb

NOEC: 0.32 ppb based on immobility

13. VERIFICATION OF STATISTICAL RESULTS

Technical Lambda-Cyhalothrin

Parameter	Result (ppb)

Binomial Test EC_{50} (C.I.)	0.23 (0.097-0.84)
Moving Average Angle EC_{50} (95% C.I.)	0.18 (0.14-0.23)
Probit EC_{50} (95% C.I.)	0.2 (0.16- 0.26)
Probit Slope	2.5
NOEC	0.56 (nominal level)

25 CS Formulation

Parameter	Result (ppb)
Binomial Test EC_{50} (C.I.)	0.98 (0.41- 3.54)
Moving Average Angle EC_{50} (95% C.I.)	0.76 (0.61 -0.98)
Probit EC_{50} (95% C.I.)	0.86 (0.67 -1.11)
Probit Slope	2.5
NOEC	0.56 (nominal level)

Because of the low recovery of the material, we based the results on the final measured concentrations at 48 hours. Slightly more conservative results were obtained.

14. REVIEWER'S COMMENTS:

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

- o Pretest mortality was not reported.
- o The total hardness (238 mg/L as $CaCO_3$) was higher than the recommended (40 to 48 mg/L as $CaCO_3$).
- o Biomass loading was not reported.
- 0. Recovery was only 51-63% of the nominal. As adsorption of the material to surfaces is expected with this type of material (i.e. a pyrethroid), the low recovery does not invalidate this study. We believe a more accurate EC50 is based on the final measured concentrations, thus our findings are more conservative than that of the study authors (0.76 ppb vs 1.8 ppb for the 25 CS formulation).

This study is scientifically sound and satisfies the guideline requirement (72-2b) for testing with a formulated product. The 48-hr EC50 for daphnids exposed to a 25 CS

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formulation containing lambda-cyhalothrin is 0.76 ppb based on final measured concentrations.

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Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

X FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confi by product registrants. If you have any questions, please the individual who prepared the response to your request.

.7	20	14	70	5.765915
.43	20	6	30	5.765915
.22	20	5	25	2.069473
.13	20	3	15	.1288414
.075	20	0	0	9.536742E-05
.046	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .22 AND 1.5 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 .5486346

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
7	.028451	.4364235	.3496743	.555062

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	6.432716E-02	1	.4914616

SLOPE = 2.60885
95 PERCENT CONFIDENCE LIMITS = 1.947172 AND 3.270527

LC50 = .4617129
95 PERCENT CONFIDENCE LIMITS = .3626849 AND .5930913

LC10 = .1505107
95 PERCENT CONFIDENCE LIMITS = 9.602669E-02 AND .2040396

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jedwards Karate daphnid

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
9.7	20	20	100	9.536742E-05
6.3	20	18	90	2.012253E-02
3	20	14	70	5.765915
1.8	20	6	30	5.765915
.93	20	5	25	2.069473
.55	20	3	15	.1288414
.32	20	0	0	9.536742E-05
.19	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .93 AND 6.3 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.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 2.32379

jedwards karate acute daphnid

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.87	20	18	90	2.012253E-02
.84	20	20	100	9.536742E-05
.3	20	14	70	5.765915
.18	20	6	30	5.765915
.097	20	5	25	2.069473
.058	20	3	15	.1288414
.029	20	0	0	9.536742E-05
.017	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .097 AND .84 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 .232379

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
7	2.795558E-02	.180557	.1434347	.2317155

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.0653914	1	.4795555

SLOPE = 2.505684
95 PERCENT CONFIDENCE LIMITS = 1.864937 AND 3.146431

LC50 = .2030734
95 PERCENT CONFIDENCE LIMITS = .1580813 AND .2633227

LC10 = 6.321285E-02
95 PERCENT CONFIDENCE LIMITS = 3.946256E-02 AND .0868088

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RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
7	2.851291E-02	1.845791	1.478488	2.34827

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	6.430383E-02	1	.5072152

SLOPE = 2.611196

95 PERCENT CONFIDENCE LIMITS = 1.949044 AND 3.273349

LC50 = 1.951487

95 PERCENT CONFIDENCE LIMITS = 1.532988 AND 2.506154

LC10 = .6367933

95 PERCENT CONFIDENCE LIMITS = .4062809 AND .8632499

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jedwards Karate Daphnid

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
2.3	20	20	100	9.536742E-05
1.5	20	18	90	2.012253E-02

jedwards karate dapphnid

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
3.67	20	18	90	2.012253E-02
3.54	20	20	100	9.536742E-05
1.27	20	14	70	5.765915
.759	20	6	30	5.765915
.409	20	5	25	2.069473
.245	20	3	15	.1288414
.122	20	0	0	9.536742E-05
.072	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .409 AND 3.54 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 .9817992

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
7	2.796425E-02	.7622845	.6056547	.9781175

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	6.533972E-02	1	.4820826

SLOPE = 2.505571

95 PERCENT CONFIDENCE LIMITS = 1.865106 AND 3.146036

LC50 = .8571961

95 PERCENT CONFIDENCE LIMITS = .6672476 AND 1.11148

LC10 = .2668146

95 PERCENT CONFIDENCE LIMITS = .166567 AND .3664295

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