3/17/93

DP Barcode : D185819
PC Code No : 109701
EEB Out :

To: Kathryn Davis
Product Manager 52
Special Review and Reregistration Division (H7508W)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 109701
Chemical Name : Permethrin, mixed cis,trans
Type Product : Insecticide
Product Name : Permethrin products
Company Name : ICI Americas Inc.
Purpose : Submission of data for reregistration in support of 72-1(b) and (d), 72-2(b), and 72-3(f).

Action Code : 627 Date Due : 03/17/93
Reviewer : C. Laird Date In : 12/22/92

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)	425840-02	Y	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)	425840-01	N	123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)	425840-04	Y	72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)	425840-03	Y				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

DP BARCODE: D185819 REREG CASE # 2510

CASE: 819432 DATA PACKAGE RECORD DATE: 12/17/92
SUBMISSION: S432185 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 109701 Permethrin, mixed cis,trans (ANSI) 100.00 %

ID#: 109701
COMPANY:
PRODUCT MANAGER: 52 KATHRYN DAVIS 703-308-8156 ROOM: CS1 3F3
PM TEAM REVIEWER: KATHRYN DAVIS 703-308-8156 ROOM: CS1 3F3
RECEIVED DATE: 12/10/92 DUE OUT DATE: 03/10/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 185819 EXPEDITE: N DATE SENT: 12/17/92 DATE RET.: / /
CHEMICAL: 109701 Permethrin, mixed cis,trans (ANSI)
DP TYPE: 999 Miscellaneous Data Package
ADMIN DUE DATE: 03/17/93 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	12/22/92	/ /
BRAN: EEB	12/22/92	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

PLEASE REVIEW
MRID 42584001 72-3(F)
4258402 72-2(B)
42584003 72-1(D)
42584004 72-1(B)

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

100.0 Pesticide Name: Permethrin (10% formulation)

100.3 Submission Purpose:

Submission of four aquatic studies both freshwater and esturine/marine.

101.0 Chemical and Physical Properties:

101.1 Common Name:

Permethrin

103.0 Toxicological Properties:

48-Hour LC_{50} for Daphnia magna; 425840-02
96-Hour Flow-Through LC_{50} for Mysid Shrimp; 425840-01
96-Hour Flow-Through for Bluegill Sunfish; 425840-04
96-Hout Flow-Through for Rainbow Trout; 425840-03.

105.0 Conclusions:

A. Daphnia magna (EC_{50})

This test is scientifically sound even though the measured concentrations of test material decreased significantly during the study. The 48-hour EC_{50} was established and verified as 9.9 ug formulation/l (mean measured concentration). Therefore, permethrin 10% EC formulation would be classified as very highly toxic to daphnids. The NOEC was 2.3 ug/l.

B. Mysid Shrimp (LC_{50})

This study is not scientifically sound. The test concentrations in this flow-through test were not measured. The actual concentrations to which the mysids were exposed are unknown. Under conditions of the test, the 96-hour LC_{50} was 0.47 ug formulation/l (nominal concentration). Therefore, permethrin 10% EC formulation would be classified as very highly toxic to mysids. The NOEC was 0.32 ug/l.

C. Bluegill Sunfish (LC_{50})

This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity test using bluegill sunfish. The 96-hour LC_{50} was 24 ug formulation/l (mean measured concentration). Therefore, permethrin 10% EC formulation is classified as very highly toxic to bluegill sunfish. The NOEC could not be determined since mortality was noted at all exposure levels.

D. Rainbow Trout (LC_{50})

This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity test using rainbow trout. The 96-hour LC_{50} was 73 ug formulation/l (mean measured concentration). Therefore, permethrin 10% EC formulation is classified as very highly toxic to rainbow trout. The NOEC was 0.48 ug/l.

Curtis E. Laird 3-3-93
Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Norman J. Cook 08.17.93
Norman J. Cook, Head-Section 2
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

for Douglas J. Urban 8/19/93
Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin.
Shaughnessey No. 109701.

2. **TEST MATERIAL:** Permethrin 10% EC formulation; (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS No. 52645-53-1; FNB92-1-26B, LS92-61, AR92-0080; 10.06% active ingredient; a clear yellow liquid.

3. **STUDY TYPE:** 72-3. Marine Shrimp Flow-Through Acute Toxicity Test. Species Tested: Mysid (*Mysidopsis bahia*).

4. **CITATION:** Kent, S.J., T.D. Williams, S.A. Sankey, and A.J. Grinell. 1992. Permethrin: Acute Toxicity to Mysid Shrimp (*Mysidopsis bahia*) of a 10% EC Formulation. Project No. BL4566/B. Prepared by Imperial Chemical Industries, PLC, Brixham, Devon, UK. Submitted by ICI Americas Inc., Wilmington, DE. EPA MRID No. 425840-01.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Louis M Rifici
Date: 2/4/93

6. **APPROVED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Rosemary Graham Mora
Date: 2/5/93

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: Curtis Laird 8-23-93 Henry T Craven
Date: 8/23/93

7. **CONCLUSIONS:** This study is not scientifically sound. The test concentrations in this flow through test were not measured. The actual concentrations to which the mysids were exposed are unknown. Under the conditions of the test, the 96-hour LC_{50} was 0.47 µg formulation/l (nominal concentration). Therefore, Permethrin 10% EC formulation would be classified as very highly toxic to mysids. The NOEC was 0.32 µg/l.

8. **RECOMMENDATIONS:** The registrant should conduct another flow-through and measure concentration every 24 hours. CEL 3-3-93

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Young mysids (<24 hours old) were obtained from in-house cultures. Brooding adults were cultured under test conditions (same dilution water, salinity, temperature, and photoperiod). Offspring were collected for testing over a 24-hour period immediately prior to test initiation.

B. **Test System:** A continuous-flow diluter was used to prepare and deliver the test solutions. The test chambers were covered glass tanks (30.5 x 20.5 x 15 cm) with a working volume of 8.5 l. Each tank contained two retention chambers constructed from glass beakers with a screen-covered hole on the side. The beakers had a working volume of 1 l. The tanks were randomly placed in the test system. The flow rate to the control and each test concentration from the diluter was 250 ml/minute. The flow rates from the diluter were checked daily.

The vessels were preconditioned with test solution for more than 24 hours prior to test initiation. Test temperature was maintained at 25 ±1°C by controlling dilution water temperature. The laboratory environment was maintained on a 16-hour daylight photoperiod with 15-minute gradual transitions.

Primary and secondary stock solutions were prepared in deionized water. The secondary stocks were delivered to the diluter mixing chambers using syringe infusion pumps. Natural seawater, collected from Tor Bay, Devon, was adjusted to a salinity of 20 ±2 parts per thousand (ppt) with dechlorinated freshwater and filtered (10 µm) before use as test dilution water.

C. **Dosage:** Ninety-six-hour, flow-through test. Seven nominal concentrations (0.056, 0.10, 0.18, 0.32, 0.56, 1.0, and 1.8 µg formulation/l) and a dilution water control were used.

D. **Design:** Twenty mysids were randomly allocated to each test level. Ten were placed in each retention chamber. The mysids were fed live brine shrimp nauplii (<24 hours old) daily during the test.

Observations of mortality were made at 0, 24, 48, 72, and 96 hours. Dead mysids were removed. The dissolved oxygen concentration (DO) and pH of each test solution were measured daily. The salinity of the dilution water control was measured daily. The temperature of the control chamber was recorded hourly and temperature in each vessel was measured daily.

Samples of freshly prepared stock solutions were taken at 0, 48, and 72 hours to confirm nominal concentrations. Samples of the stocks were also taken at 24, 72, and 96 hours to determine stability. The concentration of permethrin was measured using gas chromatography.

E. **Statistics:** The 96-hour median lethal concentration (LC_{50}) and confidence interval were calculated using the moving average method.

12. **REPORTED RESULTS:** "The concentrations of formulation in the test solutions were below the limit of detection for the analytical method available. Therefore, the individual stock solutions were analysed." The mean measured concentrations in the freshly prepared stock solutions ranged from 70 to 89% of nominal (Table 1, attached). After being in the syringe for at least 24 hours, mean measured concentrations in the stocks were 81-94% of nominal.

There was no mortality in the control or four lowest nominal concentrations (Table 2, attached). The 96-hour LC_{50} was 0.47 µg/l (95% C.I. = 0.39-0.59 µg/l). The no-observed-effect concentration (NOEC) was 0.32 µg/l.

During the test, the DO was 7.0-7.7 mg/l. The pH was 8.02-8.09 and the temperature ranged from 24.9 to 25.5°C. The salinity of the dilution water was 19.1-19.6 ppt.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors made no conclusions.

Good laboratory practice and quality assurance statements were included in the report stating compliance with OECD principles and, indirectly, with 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were generally in accordance with the SEP, except for the following:

7

The test concentrations in this flow through test were not measured. The actual concentrations to which the mysids were exposed are unknown.

The test material was a formulated product; control(s) containing the inert or carrier ingredients present in the formulation should have been included in the test design.

The test dilution water was seawater mixed with dechlorinated tap water (58:42 ratio). Dechlorinated tap water is not recommended. Free and/or total chlorine monitoring results for the tap water should have been included in the report.

The salinity of the dilution water in the study was approximately 20 ppt. The recommended salinity for estuarine shrimp is 10-17 ppt and for marine shrimp is 30-34 ppt.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to determine the 96-hour LC_{50} and obtained similar results (see attached printout) using the non-linear interpolation method.

C. **Discussion/Results:** The concentrations in this flow through test were not measured. The authors explain that the nominal concentrations were below the detection limit for the analytical method used. Measured concentrations of the stock solutions averaged 79-89% of nominal concentrations. Though the study was adequately performed and met the guideline requirements, the actual concentrations to which the mysids were exposed are unknown.

This study is not scientifically sound. Under the conditions of the test, the 96-hour LC_{50} was 0.47 μg formulation/l (nominal concentration). Therefore, Permethrin 10% EC formulation would be classified as very highly toxic to mysids. The NOEC was 0.32 μg/l.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** The test concentrations in this flow through test were not measured, therefore the actual concentrations to which the mysids were exposed are unknown.

8

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 01-28-93.

PERMETHRIN

Page_____ is not included in this copy.

Pages 10 through 11 are not included.

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 confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

RIFICI PERMETHRIN MYSIDOPSIS BAHIA 01-28-93

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
1.8	20	20	100	9.536742E-05
1	20	20	100	9.536742E-05
.56	20	18	90	2.012253E-02
.32	20	0	0	9.536742E-05
.18	20	0	0	9.536742E-05
.1	20	0	0	9.536742E-05
.056	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .32 AND .56 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 .4497935

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

1. **CHEMICAL:** Permethrin.
Shaughnessey No. 109701.

2. **TEST MATERIAL:** Permethrin 10% EC formulation; (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS No. 52645-53-1; FNB92-1-26B, LS92-61, AR92-0080; 10.06% active ingredient; a clear yellow liquid.

3. **STUDY TYPE:** 72-2. Freshwater Invertebrate Static Acute Toxicity Test. Species Tested: *Daphnia magna*.

4. **CITATION:** Kent, S.J., S.A. Sankey, and A.J. Grinell. 1992. Permethrin: Acute Toxicity to *Daphnia magna* of a 10% EC Formulation. Project No. BL4530/B. Prepared by Imperial Chemical Industries, PLC, Brixham, Devon, UK. Submitted by ICI Americas Inc., Wilmington, DE. EPA MRID No. 425840-02.

5. **REVIEWED BY:**

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: August 10, 1993

6. **APPROVED BY:**

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 08.17.93

7. **CONCLUSIONS:** This test is scientifically sound even though the measured concentrations of test material decreased significantly during the study. Under the conditions of the test, the 48-hour EC_{50} value was 9.9 µg formulation/l (mean measured concentration). Therefore, Permethrin 10% EC formulation would be classified as very highly toxic to daphnids. The NOEC was 2.3 µg/l.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:** Submission of data in support of reregistration.

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin.
Shaughnessey No. 109701.

2. **TEST MATERIAL:** Permethrin 10% EC formulation; (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS No. 52645-53-1; FNB92-1-26B, LS92-61, AR92-0080; 10.06% active ingredient; a clear yellow liquid.

3. **STUDY TYPE:** 72-2. Freshwater Invertebrate Static Acute Toxicity Test. Species Tested: *Daphnia magna*.

4. **CITATION:** Kent, S.J., S.A. Sankey, and A.J. Grinell. 1992. Permethrin: Acute Toxicity to *Daphnia magna* of a 10% EC Formulation. Project No. BL4530/B. Prepared by Imperial Chemical Industries, PLC, Brixham, Devon, UK. Submitted by ICI Americas Inc., Wilmington, DE. EPA MRID No. 425840-02.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Louis M Rifici
Date: 2/4/93

6. **APPROVED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Rosemary Graham Mora
Date: 2/5/93

Curtis E. Laird 8-23-93

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: Henry T. Craven
Date: 8/23/93

7. **CONCLUSIONS:** This test is not scientifically sound. Measured concentrations of test material decreased significantly during the study. Consequently, the actual concentrations to which the daphnids were exposed are unknown. Under the conditions of the test, the 48-hour EC_{50} value was 9.9 µg formulation/l (mean measured concentration). Therefore, Permethrin 10% EC formulation would be classified as very highly toxic to daphnids. The NOEC was 2.3 µg/l.

8. **RECOMMENDATIONS:** The registrant should conduct another daphnid study using a 24 hour renewal or flow-through test.

CEL 8-3-93

5.75

14

A. **Test Animals:** The *Daphnia magna* (<24 hours old) used in the test were taken from in-house cultures maintained at 20 ±2°C on a 16-hour light photoperiod. The cultures were fed a diet of yeast and *Chlorella vulgaris*, or a commercially-available microencapsulated food.

B. **Test System:** The test vessels were covered, 250-ml glass beakers containing 200 ml of solution. The test solution depth was 60 mm. The beakers were randomly arranged within the test area. The test temperature was 20 ±1°C. A 16-hour light photoperiod with 15-minute transition periods were provided.

The test dilution water was hard reconstituted water prepared by dissolving $NaHCO_3$ (192 mg/l), $CaSO_4.2H_2O$ (120 mg/l), $MgSO_4.7H_2O$ (245 mg/l), and KCl (8 mg/l) in glass-distilled water. Primary and working stock solutions of the test material were prepared in dilution water. The test solutions were prepared by adding appropriate volumes of the appropriate stock solution to the dilution water.

C. **Dosage:** Forty-eight-hour, static test. Seven nominal concentrations (1.8, 3.2, 5.6, 10, 18, 32, and 56 µg formulation/l) and a dilution water control were used.

D. **Design:** Five daphnids were added to each beaker, four beakers per concentration. The number of immobilized daphnids was determined after 24 and 48 hours.

The dissolved oxygen concentration (DO) of the dilution water was measured at test initiation. The DO of two replicates of each test level was measured at test termination. The pH of each test solution was determined at test initiation and termination. The temperature of the water in a vessel containing no daphnids was recorded hourly.

Water samples were removed at 0 and 48 hours for analysis. The concentration of permethrin was measured using gas chromatography.

E. **Statistics:** The 48-hour median effective concentration (EC_{50}) and confidence interval were calculated using the moving average angle method.

12. **REPORTED RESULTS:** All test solutions were clear and colorless. The mean measured concentrations were 1.2, 2.3, 3.9, 7.2, 9.8, 19, and 37 µg formulation/l (Table 1, attached). Measured concentrations at test initiation ranged from 78 to 93% of nominal concentrations. At test termination, measured values were 31-52% of nominal concentrations. "The reduction in concentration was probably due to the adsorbtion of permethrin onto surfaces with which it came into contact."

There was no immobility observed in the control and two lowest concentrations (Table 2, attached). The 48-hour EC_{50} value was 9.9 µg/l (95% C.I. = 8.0-12 µg/l). The no-observed-effect concentration (NOEC) was 2.3 µg/l.

During the test, the DO was 8.8-9.3 mg/l. The pH was 8.42-8.48 and the temperature ranged from 20.2 to 20.8°C. The dilution water had a hardness of 160 mg/l as $CaCO_3$, an alkalinity of 88.2 mg/l as $CaCO_3$ and a conductivity of 450 µS/cm.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** No conclusions were presented.

Good laboratory practice and quality assurance statements were included in the report stating compliance with OECD principles and, indirectly, with 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were generally in accordance with the SEP, except for the following:

The test material was a formulated product; control(s) containing the inert or carrier ingredients present in the formulation should have been included in the test design.

The report did not state whether the daphnids were randomly placed in the test beakers. Test daphnids must be randomly distributed to the test vessels.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to determine the 48-hour EC_{50} value and obtained similar results (see attached printout). The slope of the probit line was 3.6.

C. **Discussion/Results:** This test is scientifically sound even though the measured concentrations of test material decreased significantly during the study. Under the conditions of the test, the 48-hour EC_{50} value was 9.9 µg formulation/l (mean measured concentration). Therefore, Permethrin 10% EC formulation would be classified as very highly toxic to daphnids. The NOEC was 2.3 µg/l.

D. **Adequacy of the Study:**

(1) **Classification:** Core

(2) **Rationale:** N/A

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 01-28-93.

PERMETHRIN

Page_____ is not included in this copy.

Pages 18 through 19 are not included.

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 confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

RIFICI PERMETHRIN DAPHNIA MAGNA 01-27-93

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
37	20	19	95	2.002716E-03
19	20	17	85	.1288414
9.8	20	12	60.00001	25.17223
7.2	20	6	30	5.765915
3.9	20	1	5	2.002716E-03
2.3	20	0	0	9.536742E-05
1.2	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 3.9 AND 19 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 8.854784

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.0935181	9.817078	7.994661	12.14023

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.0894361	1	.8113841

SLOPE = 3.599107
95 PERCENT CONFIDENCE LIMITS = 2.522763 AND 4.675452

LC50 = 9.874653
95 PERCENT CONFIDENCE LIMITS = 8.120555 AND 12.16832

LC10 = 4.381839
95 PERCENT CONFIDENCE LIMITS = 2.967443 AND 5.589669

****

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin.
Shaughnessey No. 109701.

2. **TEST MATERIAL:** Permethrin 10% EC formulation; (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS No. 52645-53-1; FNB92-1-26B, LS92-61, AR92-0080; 10.06% active ingredient; a clear yellow liquid.

3. **STUDY TYPE:** 72-1. Freshwater Fish Acute Flow-Through Toxicity Test. Species Tested: Rainbow Trout (*Oncorhynchus mykiss*).

4. **CITATION:** Sankey, S.A., D.S. Morris, J.E. Caunter, and R.D. Stanley. 1992. Permethrin: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) of a 10% EC Formulation. Project No. BL4529/B. Prepared by Imperial Chemical Industries, PLC, Brixham, Devon, UK. Submitted by ICI Americas Inc., Wilmington, DE. EPA MRID No. 425840-03.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Louis M Rifici
Date: 2/4/93

6. **APPROVED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Rosemary Graham Mora
Date: 2/5/93

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature:
Date:

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity test using rainbow trout. The 96-hour LC_{50} was 73 µg formulation/l (mean measured concentration). Therefore, Permethrin 10% EC formulation is classified as very highly toxic to rainbow trout. The NOEC was 0.48 µg/l.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Rainbow trout (*Oncorhynchus mykiss*) were obtained from a commercial supplier in Zeals, Wiltshire, UK. The fish were acclimated to the test temperature (12 ±1°C) for 20 days prior to testing. Feeding was discontinued 48 hours before the test. Mean weight and length of the fish were 1.8 g (range 0.8-3.0 g) and 51 mm (38-60 mm), respectively. Biomass loading rate in the control was 0.8 g/l.

B. **Test System:** A continuous flow diluter, constructed of glass and silicone rubber, was used. The test containers were glass vessels measuring 610 x 305 x 310 mm. The test solution volume was 45 l. The flow rate to each vessel was 250 ml/minute, sufficient to replace 95% of the solution every 9 hours. The test stock solutions were prepared every 48 hours by diluting an appropriate volume of test material concentrated stock in distilled water. The test was performed in a temperature-controlled room (12 ±1°C) under a 16-hour light photoperiod with 10-minute transitions between light and dark.

The test dilution water was tap water which had been filtered and dechlorinated using sodium thiosulfate. During the test, the water had a hardness of 27.0-31.7 mg/l as $CaCO_3$, an alkalinity of 15.6-24.6 mg/l as $CaCO_3$ and a conductivity of 180.5-193.6 µS/cm.

C. **Dosage:** Ninety-six-hour, flow-through test. Seven nominal concentrations (1.0, 10, 18, 32, 56, 100, and 180 µg formulation/l) and a dilution water control were used.

D. **Design:** Twenty rainbow trout were randomly placed in each vessel and one test vessel was used for each concentration. The fish were not fed during the test. Observations and mortality counts were made every 24 hours. "Measurements were undertaken throughout the 96-hour period for pH, dissolved oxygen and temperature within the test vessels." Water hardness, conductivity, and chlorine content of the dilution water were determined daily. The temperature of the dilution water control was measured continuously.

Water samples were removed daily for analysis. The concentration of permethrin was measured using gas chromatography.

E. **Statistics:** The 96-hour median lethal concentration (LC_{50}) and confidence interval were calculated using the moving average angle method.

12. **REPORTED RESULTS:** The mean measured concentrations were 0.48, 7.1, 13, 24, 36, 67, and 130 µg formulation/l (Table 1, attached). These values were 48-75% of nominal concentrations. The stock solutions were cloudy white emulsions, however the test solutions were clear and colorless.

There was no mortality in the control or concentrations ≤24 µg/l (Table 2, attached). Sublethal effects were observed at all but the lowest level (Table 3, attached). The 96-hour LC_{50} value was 73 µg/l (95% C.I. = 59-91 µg/l). The no-observed-effect concentration (NOEC) was 0.48 µg/l.

During the test, the DO was 9.6-10.6 mg/l. The pH was 7.45-7.67 and the temperature ranged from 12.1 to 12.4°C.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** No conclusions were presented.

Good laboratory practice and quality assurance statements were included in the report stating compliance with OECD principles and, indirectly, with 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were generally in accordance with the SEP, except for the following:

The test material was a formulated product; control(s) containing the inert or carrier ingredients present in the formulation should have been included in the test design.

The test dilution water was dechlorinated tap water. Dechlorinated tap water is not recommended. However, free and total chlorine were monitored in the dilution water and remained <4 µg Cl_2/l.

A 15 to 30-minute transition period between light and dark is recommended in the SEP. A transition period of 10 minutes was used in the study.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to determine the 96-hour LC_{50} and obtained similar results (see attached printout). The slope from the probit calculation was 4.9.

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for a flow-through acute test using rainbow trout. The 96-hour LC_{50} was 73 µg formulation/l (mean measured concentration). Therefore, Permethrin 10% EC formulation is classified as very highly toxic to rainbow trout. The NOEC was 0.48 µg/l.

D. **Adequacy of the Study:**

(1) **Classification:** Core for a formulated product.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 01-26-93.

PERMETHRIN

Page_____ is not included in this copy.

Pages 25 through 27 are not included.

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.

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RIFICI PERMETHRIN RAINBOW TROUT 01-26-93

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
130	20	18	90	2.012253E-02
67	20	8	40	25.17223
36	20	2	10	2.012253E-02
24	20	0	0	9.536742E-05
13	20	0	0	9.536742E-05
7.1	20	0	0	9.536742E-05
.48	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 36 AND 130 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 75.52958

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	.1239417	72.67145	59.43682	90.65196

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.1251725	1	.9881939

SLOPE = 4.864204
95 PERCENT CONFIDENCE LIMITS = 3.143262 AND 6.585145

LC50 = 72.54042
95 PERCENT CONFIDENCE LIMITS = 60.4311 AND 89.24561

LC10 = 39.7639
95 PERCENT CONFIDENCE LIMITS = 27.82794 AND 49.03082

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DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin.
Shaughnessey No. 109701.

2. **TEST MATERIAL:** Permethrin 10% EC formulation; (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; CAS No. 52645-53-1; FNB92-1-26B, LS92-61, AR92-0080; 10.06% active ingredient; a clear yellow liquid.

3. **STUDY TYPE:** 72-1. Freshwater Fish Acute Flow-Through Toxicity Test. Species Tested: Bluegill Sunfish (*Lepomis macrochirus*).

4. **CITATION:** Sankey, S.A., D.S. Morris, J.E. Caunter, and R.D. Stanley. 1992. Permethrin: Acute Toxicity to Bluegill (*Lepomis macrochirus*) of a 10% EC Formulation. Project No. BL4570/B. Prepared by Imperial Chemical Industries, PLC, Brixham, Devon, UK. Submitted by ICI Americas Inc., Wilmington, DE. EPA MRID No. 425840-04.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
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KBN Engineering and
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Signature: Louis M Rifici
Date: 2/4/93

6. **APPROVED BY:**

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Date: 2/5/93

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: Curtis E. Jones 8-23-93
Date: Henry T. Craven 8/23/93

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity test using bluegill sunfish. The 96-hour LC_{50} was 24 µg formulation/l (mean measured concentration). Therefore, Permethrin 10% EC formulation is classified as very highly toxic to bluegill sunfish. The NOEC could not be determined since mortality was noted at all exposure levels.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bluegill sunfish (*Lepomis macrochirus*) were obtained from a commercial supplier in Salem, MA. The fish were acclimated to the test temperature (22 ±1°C) for 19 days prior to testing. Feeding was discontinued 72 hours before the test and <1% mortality occurred during the 48 hours prior to testing. Mean weight and length of the fish were 0.69 g (range 0.44-1.01 g) and 33 mm (30-37 mm), respectively. Biomass loading rate in the control was 0.31 g/l.

B. **Test System:** A continuous flow diluter, constructed of glass and silic ne rubber, was used. The test containers were glass vessels measuring 610 x 305 x 310 mm. The test solution volume was 45 l. The flow rate to each vessel was 250 ml/minute, sufficient to replace 95% of the solution every 9 hours. The test stock solutions were prepared every 48 hours by diluting an appropriate volume of test material concentrated stock in distilled water. The test was performed in a temperature-controlled room (22.0 ±1.0°C) under a 16-hour light photoperiod with 10-minute low light transitions.

The test dilution water was tap water which had been filtered and dechlorinated using sodium thiosulfate. During the test, the water had a hardness of 49.0-58.6 mg/l as $CaCO_3$, an alkalinity of 24.4-25.4 mg/l as $CaCO_3$ and a conductivity of 268-283 µS/cm.

C. **Dosage:** Ninety-six-hour flow-through test. Seven nominal concentrations (1.0, 10, 18, 32, 56, 100, and 180 µg formulation/l) and a dilution water control were used.

D. **Design:** Twenty bluegill were randomly placed in each vessel and one test vessel was used for each concentration. The fish were not fed during the test. Observations and mortality counts were made every 24 hours. "Measurements were undertaken throughout the 96-hour period for pH, dissolved oxygen and temperature within the test vessels." Water hardness, conductivity, and chlorine content of the dilution water were determined daily. The temperature of the dilution water control was measured continuously.

Water samples were removed daily for analysis. The concentration of permethrin was measured using gas chromatography.

E. **Statistics:** The 96-hour median lethal concentration (LC_{50}) and confidence interval were calculated using the probit method.

12. **REPORTED RESULTS:** The mean measured concentrations were 0.62, 8.8, 15, 29, 47, 86, and 170 µg formulation/l (Table 1, attached). These values were 62-94% of nominal concentrations. The stock solutions were white cloudy suspensions, however the authors did not note any undissolved material in the test solutions.

There was no mortality in the control (Table 2, attached). The mortality observed in the three lowest concentrations was considered incidental (similar to that observed in the remaining population) and not treatment related. Sublethal effects were observed at all but these three levels (Table 3, attached). The 96-hour LC_{50} value was 24 µg/l (95% C.I. = 17-31 µg/l). The no-observed-effect concentration (NOEC) was 15 µg/l.

During the test, the DO was 8.0-8.6 mg/l. The pH was 7.81-7.90 and the temperature ranged from 21.9 to 22.1°C. Total ammonia was <0.01 mg/l.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** No conclusions were presented.

Good laboratory practice and quality assurance statements were included in the report stating compliance with OECD principles and, indirectly, with 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were generally in accordance with the SEP, except for the following:

The test material was a formulated product; control(s) containing the inert or carrier ingredients present in the formulation should have been included in the test design.

The test dilution water was dechlorinated tap water. Dechlorinated tap water is not recommended. However, free and total chlorine were monitored in the dilution water and remained <4 µg Cl_2/l.

The slope of the probit line was not reported.

A 15 to 30-minute transition period between light and dark is recommended in the SEP. A transition period of 10 minutes was used in the study.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to determine the 96-hour LC_{50} and obtained similar results using the moving average method (see attached printout). It is difficult to determine the source of mortality observed in the three lowest concentrations and separate it from mortality observed in the test population when no mortality occurred in the control. Therefore, the NOEC for this test could not be determined since mortality was observed at all exposure levels.

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for a flow-through acute test using bluegill sunfish. The 96-hour LC_{50} was 24 µg formulation/l (mean measured concentration). Therefore, Permethrin 10% EC formulation is classified as very highly toxic to bluegill sunfish. The NOEC could not be determined.

D. **Adequacy of the Study:**

(1) **Classification:** Core for a formulated product.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 01-26-93.

PERMETHRIN

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Pages 33 through 35 are not included.

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RIFICI PERMETHRIN BLUEGILL SUNFISH 01-26-93

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
170	20	20	100	9.536742E-05
86	20	20	100	9.536742E-05
47	20	16	80	.5908966
29	20	11	55	41.19014
15	20	2	10	2.012253E-02
8.8	20	2	10	2.012253E-02
.62	20	1	5	2.002716E-03

THE BINOMIAL TEST SHOWS THAT 15 AND 47 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 27.16848

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	8.940982E-02	24.8582	18.34388	34.07821

~~34.07821~~

LR 1/26/93

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	11.88496	67.10346	0

A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001.

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED
USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 2.28309
95 PERCENT CONFIDENCE LIMITS =-5.587764 AND 10.15394

LC50 = 23.68575
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

LC10 = 6.579964
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

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