DP Barcode : D177151
PC Code No : 109701
EEB Out : AUG 3 1993

To: Linda Deluise
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
Company Name : ICI Americas Inc.
Purpose : Submission of data summaries in support of reregistration.

Action Code : 627 Date Due : 07/19/92
Reviewer : C. Laird Date In : 04/22/92

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)	422770-04 422770-05	N N	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)	422770-01 422770-02	Y N	72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)	422770-03	N				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

B

Dan

DP BARCODE: D177151 REREG CASE # 2510

CASE: 819432 DATA PACKAGE RECORD DATE: 04/20/92
SUBMISSION: S416352 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 109701 Cyclopropanecarboxylic acid, 3-(2,2-dichloroetheny 100.00 %

ID#: 109701
COMPANY:
PRODUCT MANAGER: 52 CHRISTINE RICE 703-308-8177 ROOM: CS1 3F3
PM TEAM REVIEWER: LINDA DELUISE 703-308-8065 ROOM: CS1 3N3
RECEIVED DATE: 04/10/92 DUE OUT DATE: 07/09/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 177151 EXPEDITE: N DATE SENT: 04/20/92 DATE RET.: / /
CHEMICAL: 109701 Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-di
DP TYPE: 999 Miscellaneous Data Package
ADMIN DUE DATE: 07/19/92 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	04/22/92	08/03/93
BRAN: EEB	04/22/92	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

PLEASE REVIEW

GUIDELINE 72-1(B) MRID 42277001,02 Fish Toxicity bluegill - TEP
GUIDELINE 72-1(D) MRID 42277003 ✓ Fish Toxicity rainbow trout - TEP
GUIDELINE 72-2(B) MRID 42277004,05 Invertebrate toxicity

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

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

2 49

DATA EVALUATION RECORD

100.0 Pesticide Name: Permethrin

100.3 Submission Purpose:

Submission of five aquatic studies in support of registration.

101.0 Chemical and Physical Properties:

101.1 Common Name:

Permethrin

103.0 Toxoicological Properties:

96-Hour LC_{50} for bluegill sunfish and rainbow trout (Summary MRID No. 73687; MRID No. 422770-02 and rainbow trout Summary MRID No. 73687; MRID No. 422770-03);
96-Hour LC_{50} for bluegill sunfish (Summary MRID No. 110705; MRID No. 422770-01);
48-Hour LC_{50} for Daphnia magna (Summary MRID No. 110659; MRID No. 422770-05), and
48-Hour LC_{50} for Daphnia magna (Summary MRID No. 42139; MRID No. 422770-04).

105.0 Conclusions:

EEB has validated the five aquatic studies and have the following comments:

A. Bluegill Sunfish (LC_{50}; MRID No. 110705)

This study is scientifically sound and meets the guideline requirements for an acute toxicity study using bluegill. Based on mean measured concentrations, the 96-hour LC_{50} for Lepomis macrochirus exposed to JFU 5054 was 0.013 mg/l which classifies JFU 5054 as very highly toxic to Lepomis macrochirus. The NOEC could not be determined due to mortality at all test levels in test Series I.

B. Rainbow Trout and Bluegill Sunfish (LC_{50}; MRID No. 73687)

These studies are not scientifically sound and do not meet the guideline requirements for an acute static toxicity study using freshwater fish. Water quality was not monitored during the tests. Also, materials and methods used were not fully described (e.g., percentage active ingredient of the test

material was not reported). Based on the nominal concentrations, the 96-hour LC_{50} was 20.9 ug/l for rainbow trout and 32.6 ug/l for bluegill sunfish which classifies the test material as very highly toxic to these species. The NOEC was 8.4 ug/l for rainbow trout and 20 ug/l for bluegill sunfish.

C. Daphnia magna (LC_{50}; MRTID No. 110659)

This study is not scientifically sound and does not meet the guideline requirements for an acute toxicity study using freshwater invertebrates. Water quality was not monitored during the test. Also, materials and methods used in the test were not fully described (e.g., percentage of active ingredient of the test material was not reported). Based on nominal concentrations, the 48-hour EC_{50} was 0.151 ug/l which classifies FMC-33297 3.2 EC as very highly toxic to Daphnia magana. The 48-hour NOEC was 0.084 ug ai/l.

D. Daphnia magna (LC_{50}; MRID No. 42139)

This test is scientifically sound but does not meet the guideline requirements for an acute toxicity study using freshwater invertebrates. Several pertinent details of the tests were not reported (see Section 14A). Materials and methods were not fully described. The 48-hour EC_{50} for Daphnia magna exposed to PP557 (a formulated product) was 1.31 ug/l nominal which classifies PP557 as very highly toxic to Daphnia magna. The NOEC was 0.5 ug ai/l nominal.

Curtis E. Laird 6-21-93
Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Environmental Fate and effects Division (H7507C)

Norman J. Cook 07.30.93
Norman J. Cook, Head-Section 2
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Anthony F. Maciorowski, Chief A.F. Maciorowski 8/03/93
Ecological Efffects Branch
Environmental Fate and Effects Division (H7507C)

422770-01
MRID No. 110705

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin. Shaughnessey Number: 109701.

2. **TEST MATERIAL:** Formulation JFU 5054; 24% emulsifiable concentrate of PP557; purity of 27.3% w/w; an amber liquid.

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

4. **CITATION:** Hill, R.W., B.G. Maddock, B. Hart, and S.K. Cornish. 1977. Acute Toxicity of JFU 5054 to Bluegill Sunfish (*Lepomis macrochirus*). Report No. BL/B/1832. Study performed by Imperial Chemical Industries, Brixham Laboratory. Submitted by Imperial Chemical Industries Limited, Plant Protection Division. EPA MRID No. 110705.

5. **REVIEWED BY:**

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

Signature: 422770-01 Rosemary Graham Mora
Date: 5/18/93

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 5/18/93

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

Signature: C.E.T. 6-17-93
Date: Henry T. Craven 7/16/93

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute toxicity study using bluegill. Based on mean measured concentrations, the 96-hour LC_{50} for *Lepomis macrochirus* exposed to JFU 5054 was 0.013 mg/l which classifies JFU 5054 as very highly toxic to *Lepomis macrochirus*. The NOEC could not be determined due to mortality at all test levels in test Series I.

8. **RECOMMENDATIONS:**

9. **BACKGROUND:**

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

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11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bluegill sunfish (*Lepomis macrochirus*) were obtained from Dutchland Laboratory Animals Inc., Denver, PA. Prior to test initiation, the fish were held in stock tanks for 13 days at 23°C and for an additional 2 days in test vessels at 22 ±0.5°C.

The fish had a mean weight of 1.69 g (range of 1.19-2.49 g) and a mean length of 50 mm (range of 42-55 mm).

B. **Test System:** The test was conducted using a continuous flow-through system at a temperature of 22 ±0.5°C. The glass test vessels had a holding capacity of 20 l. The flow rate was 200 ml/minute which provided a theoretical replacement rate of 95% in 4.5 hours.

The dilution water was supplied from a 20,000-gallon reservoir. During the test, the dilution water had a total hardness of 51-52.5 mg/l as $CaCO_3$.

"Concentrated stock solutions were prepared by diluting a known weight of the formulation with test water. The formulation formed a stable cream coloured emulsion with water in all proportions tested." The stock solutions and freshwater were fed to the test system (via peristaltic pumps) and were mixed prior to introduction to the test vessels.

C. **Dosage:** Ninety-six-hour, flow-through test. Two series of test concentrations were selected for this study. Series I included the nominal test concentrations of 0.018, 0.024, 0.032, and 0.075 mg/l. Series II included the nominal test concentrations of 0.0075, 0.0135, and 0.0155 mg/l. A dilution water control was also included in each series.

D. **Design:** Twenty fish were exposed to each test treatment. Mortality was noted at 24, 48, 72, and 96 hours during the study.

Dissolved oxygen concentration, pH, and temperature were measured twice daily. Chemical analysis of each treatment was performed, using gas chromatography, on samples collected at 0, 48, 72, or 96 hours.

E. **Statistics:** The LC_{50} values and their 95% confidence intervals (C.I.) were determined using the probit method (Finney, 1971).

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12. **REPORTED RESULTS:** Mean measured concentrations of Series I were 0.010, 0.0225, 0.024, and 0.066 mg/l which represent 56-94% of nominal concentrations. Mean measured concentrations of Series II were 0.0005, 0.0022, and 0.0034 mg/l which represent 7-22% of nominal (Table 7, attached).

No mortality was observed in the controls or the three lowest test concentrations (Series II) (Table 1, attached). Mortality in the remaining exposure concentrations ranged from 20 to 100%. The 96-hour LC_{50} (95% C.I.) for bluegill was 0.0205 (0.0192-0.0219) mg/l. The no effect level was 0.0075 mg/l, based on the lack of sublethal effects and mortality at this concentration.

During the study, the test solutions had a pH of 7.65-7.80, a temperature of 22 ±0.5°C, and a dissolved oxygen concentration of 89-94% of saturation.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** No conclusions, other than those presented above, were included in the report.

No GLP compliance or quality assurance statements were included in the report.

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 deviations:

Inert control was not included in the study design.

The source of the dilution water was not reported and its characteristics were not fully described.

The age of the test fish was not given.

The report does not indicate whether food was withheld from the fish during testing as recommended.

The recommended photoperiod for a freshwater fish acute toxicity study is 16-hour light/8-hour dark with 15- to 30-minute transitions. The photoperiod was not reported.

The system used to maintain the test temperature was not reported. The temperature monitoring results were not reported.

Temperature was measured twice daily; temperature should be measured every six hours or continuously (hourly) for tests where solution temperature is maintained using a waterbath or room temperature, respectively.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to determine the 96-hour LC_{50} using mean measured concentrations from Series I. The 96-hour LC_{50} (C.I.) was 0.013 (0.011-0.016) mg/l. The slope of the dose-response curve was 6.9.

C. **Discussion/Results:** Analytical results from Series II are not valid since the test material was not detected in the majority of the samples (Table 7, attached). Consequently, Series II test is invalid. The measured concentrations in Series I were generally consistent over the test period and were used to calculate the LC_{50}.

This study is scientifically sound and meets the guideline requirements for an acute toxicity study using bluegill. Based on mean measured concentrations, the 96-hour LC_{50} for *Lepomis macrochirus* exposed to JFU 5054 was 0.013 mg/l which classifies JFU 5054 as very highly toxic to *Lepomis macrochirus*. The NOEC could not be determined due to mortality in all test concentrations in Series I.

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; 5 May 1993.

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PERMETHRIN

Page _____ is not included in this copy.

Pages 9 through 10 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 confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

4-22-96-01

Rosemary Graham Mora JFU 5054 Bluegill

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.066	20	20	100	9.536742E-05
.024	20	20	100	9.536742E-05
.0225	20	18	90	2.012253E-02
.01	20	4	20	.5908966

THE BINOMIAL TEST SHOWS THAT .01 AND .0225 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 1.396778E-02

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	.1713618	1.396778E-02	1.140686E-02	1.660666E-02

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.1321281	1	.4751488

SLOPE = 6.924568

95 PERCENT CONFIDENCE LIMITS = 4.407527 AND 9.441608

LC50 = 1.329086E-02

95 PERCENT CONFIDENCE LIMITS = .0110302 AND .0154921

LC10 = 8.712606E-03

95 PERCENT CONFIDENCE LIMITS = 6.096376E-03 AND 1.059175E-02

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AB

422770-02,-03
MRID No. 73687

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin. Shaughnessey Number: 109701.

2. **TEST MATERIAL:** FMC-33297 3.2 EC; Lot No. Me R105; C6501-38-C; tested as 100% active; a clear liquid.

3. **STUDY TYPE:** 72-1. Freshwater Fish Toxicity Tests. Species Tested: Rainbow Trout (*Salmo gairdneri*) and Bluegill (*Lepomis macrochirus*).

4. **CITATION:** Bentley, R.E. 1975. Acute Toxicity of FMC-33297 3.2 EC to Bluegill (*Lepomis macrochirus*) and Rainbow Trout (*Salmo gairdneri*). Study performed by E G & G, Bionomics, Wareham, MA. Submitted by FMC Corporation, Middleport, NY. EPA MRID No. 73687.
(422770-02,-03)

5. **REVIEWED BY:**

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

Signature: Rosemary Graham Mora
Date: 5/18/93

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 5/18/93

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

Signature: C.E.L 6-17-93
Date: Henry T. Craven 7/16/93

7. **CONCLUSIONS:** These tests are not scientifically sound and do not meet the guideline requirements for an acute static toxicity study using freshwater fish. Water quality was not monitored during the tests. Also, materials and methods used were not fully described (e.g., percentage active ingredient of the test material was not reported). Based on nominal concentrations, the 96-hour LC_{50} was 20.9 µg/l for rainbow trout and 32.6 µg/l for bluegill which classifies the test material as very highly toxic to these species. The NOEC was 8.4 µg/l for rainbow trout and 20 µg/l for bluegill.

8. **RECOMMENDATIONS:**

9. **BACKGROUND:**

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2 spp

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** *Lepomis macrochirus* and *Salmo gairdneri* were obtained from commercial suppliers in Nebraska and Washington, respectively. The mean wet weight for the bluegill and rainbow trout was 1.1 and 1.3 g, respectively; the mean standard length was 37 and 39 mm, respectively.

The fish were held for at least 30 days under flow-through conditions in well water with a hardness of 35 mg/l as $CaCO_3$, and a pH of 7.1. The holding temperature was 21 ±1°C for the bluegill and 14 ±1°C for the rainbow trout. The fish were acclimated to test conditions (water quality and temperature) for 48 hours prior to test initiation. During this 48-hour period, the fish were not fed and no mortality was observed.

B. **Test System:** For both tests, the test chambers were 19.6-l glass vessels. The test temperatures (21 ±1°C for bluegill; 12 ±1°C for rainbow trout) were maintained by waterbaths. Test solutions were not aerated during the tests.

"The FMC-33297 3.2 EC was introduced to each jar in a solution of water."

C. **Dosage:** Ninety-six-hour static tests. Nine nominal test concentrations (20, 26, 37, 47, 63, 84, 109, 150, and 200 µg/l) were selected for the bluegill test. Ten nominal test concentrations (8.4, 11, 15, 20, 26, 37, 47, 63, 84, and 109 µg/l) for the rainbow trout test. In addition, a dilution water control was included in each test.

D. **Design:** Ten fish were randomly added to each vessel (one vessel/treatment) within 30 minutes of the introduction of the test material. Mortality was assessed at 24, 48, and 96 hours during the tests.

E. **Statistics:** "The LC_{50} values and their 95% confidence intervals were calculated by converting the test concentrations and the corresponding observed percentage mortalities to logs and probits, respectively. There values were then utilized in a least squares regression analysis, and the LC_{50} values

were estimated from the calculated regression equation."

12. **REPORTED RESULTS:** By test termination, no mortality had occurred in the control or the lowest test concentration in either study. Mortality in the remaining test concentrations ranged from 50 to 100% in the bluegill test and from 20 to 100% in the rainbow trout study (Table 2, attached).

The 96-hour LC_{50} (95% confidence interval) was 38.4 (26.6-41.5) µg/l for bluegill (Table 1, attached). The 96-hour LC_{50} for rainbow trout was illegible (Table 1, attached). The NOECs were 20 and 8.4 µg/l for bluegill and rainbow trout, respectively.

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

No GLP compliance statement or quality assurance statement was included in the report.

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 deviations:

The actual percentage active ingredient was not reported. The report states that the test material was "tested as 100% active." According to its code name (FMC-33297 3.2 EC), the test material appears to be an emulsifiable concentrate with a very low percentage active ingredient.

No inert control was included in the study design.

The dilution water used in the tests was not described. The water used during the holding period was described but it is not clear whether the same water was used as dilution water during the tests.

The test temperature should have been monitored every six hours; the report does not indicate whether temperature was measured during the tests.

No water quality parameters were reported as being monitored during the tests. The dissolved oxygen concentration and pH should be measured in the control,

14 K6

low, middle, and high concentrations at 0, 48, and 96 hours and at 0 and 96 hours, respectively.

The recommended photoperiod for an acute toxicity study using freshwater fish is 16-hour light/8-hour dark with 15- to 30-minute transitions. The photoperiod was not reported.

The report states that the fish were not fed during the 48-hour period prior to test initiation, but it is not clear whether food was withheld during the tests.

B. **Statistical Analysis:** The EC_{50} values and 95% confidence intervals were calculated for each test using EPA's Toxanal computer program. The results for the bluegill test were more conservative than those of the author (printouts, attached). The author's LC_{50} results for the rainbow trout study were illegible. Based on the reviewer's analyses, the 96-hour LC_{50} (95% confidence interval) was 20.9 (16.7-25.7) µg/l for rainbow trout and 32.6 (26.9-38.3) µg/l for bluegill. The slopes were 6.0 and 3.7 for rainbow trout and bluegill tests, respectively.

C. **Discussion/Results:** These tests are not scientifically sound and do not meet the guideline requirements for an acute static toxicity study using freshwater fish. Water quality was not monitored during the tests and materials and methods used were not fully described. Based on nominal concentrations, the 96-hour LC_{50} was 20.9 µg/l for rainbow trout and 32.6 µg/l for bluegill which classifies the test material as very highly toxic to these species. The NOEC was 8.4 µg/l for rainbow trout and 20 µg/l for bluegill.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** Water quality was not monitored during the tests and materials and methods used were not fully described (e.g., percentage active ingredient of the test material was not reported).

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes; 4 May 1993.

PERMETHRIN

Page _____ is not included in this copy.

Pages 16 through 17 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.

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_____ 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.

42740-02, -0

Rosemary Graham Mora FMC-33297 3.2 EC Rainbow Trout

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
109	10	10	100	9.765625E-02
84	10	10	100	9.765625E-02
63	10	10	100	9.765625E-02
47	10	8	80	5.46875
37	10	7	70	17.1875
26	10	9	90	1.074219
20	10	4	40	37.69531
15	10	2	20	5.46875
11	10	3	30	17.1875
8.399999		10	0	0

9.765625E-02

THE BINOMIAL TEST SHOWS THAT 8.399999 AND 63 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 20.97949

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
6	.1420486	21.22551	16.95943	27.1221

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.1110573	1	.3553039

SLOPE = 3.674852

95 PERCENT CONFIDENCE LIMITS = 2.450198 AND 4.899506

LC50 = 20.92536

95 PERCENT CONFIDENCE LIMITS = 16.65051 AND 25.74072

LC10 = 9.442366

95 PERCENT CONFIDENCE LIMITS = 5.700889 AND 12.54787

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90

422770-02, -03

Rosemary Graham Mora FMC-33297 3.2 EC Bluegill

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
200	10	10	100	9.765625E-02
150	10	10	100	9.765625E-02
109	10	10	100	9.765625E-02
84	10	10	100	9.765625E-02
63	10	10	100	9.765625E-02
47	10	7	70	17.1875
37	10	6	60.00001	37.69531
26	10	5	50	62.30469
20	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 20 AND 63 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 25.99999

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
4	.131072	33.61009	28.7556	38.20126

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.1751383	1	.6127652

SLOPE = 6.040668
95 PERCENT CONFIDENCE LIMITS = 3.512677 AND 8.568659

LC50 = 32.55081
95 PERCENT CONFIDENCE LIMITS = 26.89322 AND 38.34512

LC10 = 20.0595
95 PERCENT CONFIDENCE LIMITS = 12.861 AND 24.79224

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(422770-04)
MRID No. 42139

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin. Shaughnessey Number: 109701.

2. **TEST MATERIAL:** Emulsifiable concentrate (EC) JFU 5054 with technical PP557; formulated PP557; Sample No. 4214/172; 24% active ingredient w/v.

3. **STUDY TYPE:** Freshwater Invertebrate Toxicity Tests. Species Tested: *Daphnia magna*.

4. **CITATION:** Evered, P. and S. Doma. 1977. PP 557: Acute Toxicity of Emulsifiable Concentrate (JFU 5054) to First Instar *Daphnia magna*. Report No. TMJ 1504 B. Study performed and submitted by ICI Plant Protection Division, Research & Development Dept. EPA MRID No. 42139.

(422770-04)

5. **REVIEWED BY:**

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6. **APPROVED BY:**

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7. **CONCLUSIONS:** These tests are scientifically sound but does not meet the guideline requirements for an acute toxicity study using freshwater invertebrates. Several pertinent details of the tests were not reported (see Section 14A). Materials and methods were not fully described. The 48-hour EC_{50} for *Daphnia magna* exposed to PP557 (a formulated product) was 1.31 µg ai/l nominal which classifies PP557 as very highly toxic to *Daphnia magna*. The NOEC was 0.5 µg ai/l nominal.

8. **RECOMMENDATIONS:**

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** *Daphnia magna* (12 ±12 hours old) were used in this study.

B. **Test System:** The tests were conducted in beakers. The test beakers were held at 18 ±2°C under fluorescent lighting (3500 lux). No aeration was used. The dilution water was hard reconstituted water.

"The EC was diluted to 100 mg/l by dispersing 41.7 µl of concentrate in 100 ml of water and then further diluted (1 ml made up to 100 ml with distilled water) to give a 1 mg/l stock." Appropriate amounts of this stock were added to 200 ml of dilution water.

C. **Dosage:** Forty-eight-hour static tests. Three tests (Tests I, II, and III) were performed using nine concentrations of the test material, ranging from 0.05 to 20 µg ai/l. In addition, a dilution water control was included in each test.

D. **Design:** Three tests were performed during this study. For each test, three replicate test vessels (beakers) were used in each treatment. Ten daphnids were added to each test vessel of each treatment. The daphnids were not fed during the tests.

The effect (immobilization) of the test material on the daphnids was assessed at 24 and 48 hours during the study. Test I was monitored for an additional 48 hours.

Dissolved oxygen concentration (DO) and pH were measured at 0, 24, and 48 hours in the control and the 20 µg/l test solution.

E. **Statistics:** "The EC_{50} values and their 95% confidence limits were calculated statistically using linear regression on log concentration plotted against a logit transformation of the *Daphnia* response."

12. **REPORTED RESULTS:** For Tests I, II, and III, no immobility was observed in the controls or the four lowest test concentrations by test termination. By the end of Test I, 40-100% immobility was observed in the five highest test concentrations. By the end of Test II, 43-100% immobility was observed in the five highest test concentrations. By the end of Test III, immobility was 53-100% in the five highest test concentrations (Table 1, attached).

During these tests, the pH and DO were maintained at 8.2 and 95% of saturation, respectively.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The 48-hour EC_{50} (95% confidence interval) for *Daphnia magna* exposed to formulated PP557 was 1.31 (1.17-1.48) µg ai/l nominal concentration (Table 2, attached). "PP557 is toxic to *Daphnia*...There was no significant increase in toxicity in the 48 to 96 hour period."

No GLP compliance statement or quality assurance statement was included in the report.

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 deviations:

A physical description of the test material was not given in the report.

During this study, each test concentration was approximately 50% of the next highest concentration; each test concentration should be at least 60% of the next highest.

The length of time between solution preparation and test initiation was not reported.

No inert control was included in the study design.

The dimension and construction material of the test vessels were not described in the report.

The test temperature should have been monitored continuously in at least one test vessel or every six hours in a system controlled by a waterbath. The report does not describe the system used to maintain the test temperature and whether the temperature was monitored during the tests.

The pH and DO was measured only in the control and the highest test concentration; these parameters should have been measured in the control, low, middle, and high concentrations.

The recommended photoperiod for a freshwater invertebrates acute toxicity study is 16-hour light/8-

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hour dark with 15- to 30-minute transitions. The photoperiod was not reported.

Test organisms should be from the fourth or later broods of a given parent. The author did not indicate which brood was the source of the test animals.

The report did not indicate whether the daphnids were randomly assigned to the test chambers.

B. **Statistical Analysis:** The EC_{50} values and 95% confidence intervals were calculated for each test using EPA's Toxanal computer program. In addition, the reviewer used the mean percentage mortality of all replicates of all tests to determine an overall EC_{50}. The results were similar to those of the authors (printouts attached).

C. **Discussion/Results:** These tests are scientifically sound but does not meet the guideline requirements for an acute toxicity study using freshwater invertebrates. Several pertinent details of the tests were not reported (see Section 14A). Materials and methods must be fully described. The 48-hour EC_{50} for *Daphnia magna* exposed to PP557 (a formulated product) was 1.31 µg ai/l nominal which classifies PP557 as very highly toxic to *Daphnia magna*. The NOEC was 0.5 µg ai/l nominal.

D. **Adequacy of the Study:**

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

(2) **Rationale:** Several pertinent details of the tests were not presented in the report (see Section 14A).

(3) **Repairability:** Yes, study may be upgraded to core upon submittal and satisfactory review of the study details described in Section 14A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes; 3 May 1993.

Page _____ is not included in this copy.

Pages 24 through 25 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 confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

4227710

RGMora PP557 Daphnia magna TEST I

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
20	30	30	100	9.313227E-08
10	30	30	100	9.313227E-08
5	30	30	100	9.313227E-08
2.5	30	20	66.66667	4.936858
1.3	30	12	40	18.07973
.5	30	0	0	9.313227E-08
.2	30	0	0	9.313227E-08
.1	30	0	0	9.313227E-08
.05	30	0	0	9.313227E-08

THE BINOMIAL TEST SHOWS THAT .5 AND 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 1.658287

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
8	4.004971E-02	1.392642	1.063784	1.83089

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	9.054438E-02	1	.8108973

SLOPE = 4.24901
95 PERCENT CONFIDENCE LIMITS = 2.970458 AND 5.527562

LC50 = 1.691573
95 PERCENT CONFIDENCE LIMITS = 1.404949 AND 2.005808

LC10 = .849958
95 PERCENT CONFIDENCE LIMITS = .5786235 AND 1.072142

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422770-C-

RGMora PP557 -Daphnia magna TEST II

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
20	30	30	100	9.313227E-08
10	30	30	100	9.313227E-08
5	30	30	100	9.313227E-08
2.5	30	19	63.33333	10.02442
1.3	30	13	43.33333	29.23324
.5	30	0	0	9.313227E-08
.2	30	0	0	9.313227E-08
.1	30	0	0	9.313227E-08
.05	30	0	0	9.313227E-08

THE BINOMIAL TEST SHOWS THAT .5 AND 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 1.614601

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
8	4.001348E-02	1.394503	1.065387	1.833221

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	8.539737E-02	1	.6037438

SLOPE = 4.046099
95 PERCENT CONFIDENCE LIMITS = 2.863715 AND 5.228484

LC50 = 1.68654
95 PERCENT CONFIDENCE LIMITS = 1.394858 AND 2.008845

LC10 = .8186796
95 PERCENT CONFIDENCE LIMITS = .5549862 AND 1.039475

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42270-c

RGMora PP557 Daphnia magna TEST III

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
20	30	30	100	9.313227E-08
10	30	30	100	9.313227E-08
5	30	30	100	9.313227E-08
2.5	30	20	66.66667	4.936858
1.3	30	16	53.33334	42.77678
.5	30	0	0	9.313227E-08
.2	30	0	0	9.313227E-08
.1	30	0	0	9.313227E-08
.05	30	0	0	9.313227E-08

THE BINOMIAL TEST SHOWS THAT .5 AND 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 1.246

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
8	4.050471E-02	1.296342	.9858459	1.701614

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	8.140038E-02	1	.3979042

SLOPE = 3.900292
95 PERCENT CONFIDENCE LIMITS = 2.78751 AND 5.013075

LC50 = 1.537033
95 PERCENT CONFIDENCE LIMITS = 1.263747 AND 1.839356

LC10 = .7262171
95 PERCENT CONFIDENCE LIMITS = .4892488 AND .9286558

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43-PP0-

Rosemary Graham Mora PP557 Daphnia magna TEST 1-3 Based on mean affected

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
20	10	10	100	9.765625E-02
10	10	10	100	9.765625E-02
5	10	10	100	9.765625E-02
2.5	10	7	70	17.1875
1.25	10	5	50	62.30469
.5	10	0	0	9.765625E-02
.2	10	0	0	9.765625E-02
.1	10	0	0	9.765625E-02
.05	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT .5 AND 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 1.25

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
8	.1424634	1.282191	.7426076	2.194095

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
8	.244189	1	.9624239

SLOPE = 3.983043
95 PERCENT CONFIDENCE LIMITS = 2.014803 AND 5.951283

LC50 = 1.510541
95 PERCENT CONFIDENCE LIMITS = 1.032895 AND 2.10325

LC10 = .7249043
95 PERCENT CONFIDENCE LIMITS = .2953848 AND 1.053962

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(422770-05)
MRID No. 110659

DATA EVALUATION RECORD

1. **CHEMICAL:** Permethrin. Shaughnessey Number: 109701.

2. **TEST MATERIAL:** FMC-33297 3.2 EC; Lot No. Me R105; C6501-38-C; tested as 100% active; a clear liquid.

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

4. **CITATION:** Bentley, R.E. 1975. Acute Toxicity of FMC-33297 3.2 EC to Water Flea (*Daphnia magna*). Study performed by E G & G, Bionomics, Wareham, MA. Submitted by FMC Corporation, Middleport, NY. EPA MRID No. 110659. (422770-05) (SUMMARY)

5. **REVIEWED BY:**

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Date: Henry T. Craven 7/16/93

7. **CONCLUSIONS:** This study is not scientifically sound and does not meet the guideline requirements for an acute toxicity study using freshwater invertebrates. Water quality was not monitored during the test. Also, materials and methods used in the test were not fully described (e.g., percentage active ingredient of the test material was not reported). Based on nominal concentrations, the 48-hour EC_{50} was 0.151 µg ai/l which classifies FMC-33297 3.2 EC as very highly toxic to *Daphnia magna*. The 48-hour NOEC was 0.084 µg ai/l.

8. **RECOMMENDATIONS:**

9. **BACKGROUND:**

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

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11. **MATERIALS AND METHODS:**

A. **Test Animals:** *Daphnia magna* were obtained from laboratory cultures.

B. **Test System:** The test chambers were 250-ml beakers containing 200 ml of test solution. The dilution water was well water which had been aged for 24 hours and had a pH of 7.1 and a hardness of 35 mg/l as $CaCO_3$. The test temperature was 21 ±1°C. Test solutions were not aerated during the test.

"The FMC-33297 3.2 EC was introduced to each beaker in a solution of water."

C. **Dosage:** Ninety-six-hour static test. Six nominal test concentrations (0.084, 0.109, 0.146, 0.196, 0.261, 0.365 µg/l) were selected for this test. In addition, a dilution water control was included.

D. **Design:** Five daphnids (≤12 hours old) were randomly added to each replicate beaker within 30 minutes of introduction of the test material. Each treatment level and control consisted of 3 replicates. After 48 hours of exposure, the daphnids were fed a 1:2 combination of starter trout feed and cerophyll. Immobility was assessed at 24, 48, and 96 hours during the test.

E. **Statistics:** "The EC_{50} values and their 95% confidence intervals were calculated by converting the test concentrations and the corresponding observed percentage immobilization to logs and probits, respectively. There values were then utilized in a least squares regression analysis, and the EC_{50} values were estimated from the calculated regression equation."

12. **REPORTED RESULTS:** By 48 hours, no immobility was observed in the control or the lowest test concentration and immobility in the remaining concentrations ranged from 7 to 100%. By test termination (96 hours), no immobility was observed in the control and immobility in the test concentrations ranged from 7 to 100% (Table 2, attached).

Based on nominal concentrations, the 48-hour EC_{50} (95% confidence interval [C.I.]) was 0.151 (0.120-0.188) µg ai/l and the 96-hour EC_{50} (C.I.) was 0.112 (0.076-0.164) µg ai/l. The 96-hour no-discernible effect level was <0.084 µg ai/l.

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

No GLP compliance statement or quality assurance statement was included in the report.

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 deviations:

The actual percentage active ingredient was not reported. The report states that the test material was "tested as 100% active." According to its code name (FMC-33297 3.2 EC), the test material appears to be an emulsifiable concentrate with a very low percentage active ingredient.

No inert control was included in the study design.

The construction material of the test vessels was not reported.

The system used to maintain the test temperature was not reported and it is not known whether the temperature was monitored during the test.

No water quality parameters were reported as being monitored during the test. The dissolved oxygen concentration and pH should be measured in the control, low, middle, and high concentrations at 0, 48, and 96 hours and at 0 and 96 hours, respectively.

The recommended photoperiod for an acute toxicity study using freshwater invertebrates is 16-hour light/8-hour dark with 15- to 30-minute transitions. The photoperiod was not reported.

Since the test was conducted for 96 hours, food for the daphnids was introduced into the test solutions after 48 hours of exposure. No justification was given for conducting the test for 96 hours. The SEP states, if possible, feeding should be limited to just prior to testing. Feeding would not have been necessary if the study had been conducted for 48 hours.

B. **Statistical Analysis:** The 48-hour EC_{50} and its 95% confidence interval were calculated using EPA's Toxanal computer program. The reviewer obtained less

conservative results than those of the author (printout, attached).

C. **Discussion/Results:** Since daphnids were fed after 48 hours of exposure and the guidelines only require 48-hour testing, only data from this first period were used in this evaluation.

This study is not scientifically sound and does not meet the guideline requirements for an acute toxicity study using freshwater invertebrates. Water quality was not monitored during the test. Also, materials and methods used in the conduct of the test were not fully described. Based on nominal concentrations, the 48-hour EC_{50} was 0.151 µg ai/l which classifies FMC-33297 3.2 EC as very highly toxic to *Daphnia magna*. The 48-hour NOEC was 0.084 µg ai/l.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** Water quality was not monitored during the test and materials and methods were not fully described (e.g., percentage active ingredient of the test material was not reported).

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes; 4 May 1993.

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Rosemary Graham Mora FMC-33297 3.2 EC Daphnia magna 48-hours

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.365	15	14	93.33334	4.882813E-02
.261	15	15	100	3.051758E-03
.196	15	10	66.66667	15.08789
.146	15	3	20	1.757813
.109	15	1	6.666667	4.882813E-02
.084	15	0	0	3.051758E-03

THE BINOMIAL TEST SHOWS THAT .146 AND .261 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 .176958

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
5	9.578543E-02	.1723493	.1495127	.1992191

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.1181608	1	.1111256

SLOPE = 7.475058

95 PERCENT CONFIDENCE LIMITS = 4.905543 AND 10.04457

LC50 = .1772308

95 PERCENT CONFIDENCE LIMITS = .1572817 AND .2003345

LC10 = .1198508

95 PERCENT CONFIDENCE LIMITS = 9.409717E-02 AND .1378892

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Table 2 -- Concentrations tested and corresponding observed percent immobilization for water flea (Daphnia magna) exposed to FMC-33297 3.2 EC after 24, 48 and 96 hours. Each immobilization value represents the mean of 3 replicates.

Concentration (ug/L)	% immobilization observed		
	24 hour	48 hour	96 hour
0.365	27	93	100
0.261	80	100	100
0.196	0	70	80
0.146	0	20	33
0.109	0	7	47
0.084	0	0	7
control	0	0	0

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