D167570
DPBARCODE/ (RECORD)
129064 109702
SHAUGHNESSY NO

REVIEW NO.

EEB REVIEW

DATE IN: 12-18-91 OUT: APR 6 1992
ASSIGNED: 1-2-92
CASE # :S400902 REREG CASE #:
SUB. # :S400902 LIST A, B, C, D
ID # :279-GREU

DATE OF SUBMISSION 6-1-91

DATE RECEIVED BY EFED 12-17-91

SRRD/RD REQUESTED COMPLETION DATE 12-12-91

EEB ESTIMATED COMPLETION DATE

SRRD/RD **ACTION** CODE/TYPE OF REVIEW NEW CHEMICAL 115

MRID #(S) 41968208 Rainbow Trout Acute Tox Test
41968209 RAINBOW TROUT ACUTE TOX TEST
41968210 DAPHNIA MAGNA ACUTE TOX TEST
41968211 SHEEPSHEAD MINNOW ACUTE TOX TEST
41968212 SHEEPSHEAD MINNOW ACUTE TOX TEST
41968213 MYSID SHRIMP ACUTE TOX TEST

DP TYPE 001

PRODUCT MANAGER, NO. GEORGE LAROCCA 13 ADAM HEYWARD

PRODUCT NAME(S) CYPERMETHRIN Mixes

TYPE PRODUCT INSECTICIDE

COMPANY NAME FMC CORP

SUBMISSION PURPOSE REVIEW TOXICITY DATA

COMMON CHEMICAL NAME CYPERMETHRIN Mixes

REVIEWER: Linda Carls

1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 6 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Subject: Data review for Cypermethrin minus (129064) and Cypermethrin (109702)

From: Doug Urban, Acting Branch Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) 4/6/92

To: George LaRocca, PM 13
Registration Division (H7505C)

The Ecological Effects Branch (EEB) has completed its review of the studies submitted by FMC Corporation for Cypermethrin (109702) and Cypermethrin minus (129064). The studies were submitted in order to compare cypermethrin minus with cypermethrin. The following is a summary of the data reviewed:

1. **CITATION:** Overman, M.A., M.G. Barron, and D.D. Vaishnav. 1990. Cypermethrin-S (FMC 56701): Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Test Conditions. Laboratory Project ID 3903026-0700-3140. FMC Study No. A89-2935-01. Prepared by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-08.

   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} of 0.69 µg/l (mean measured concentration) classifies cypermethrin-S as very highly toxic to rainbow trout. The NOEC could not be determined due to mortality at all concentrations.

2. **CITATION:** Vaishnav, D.D. and J.J. Yurk. 1990. Cypermethrin (FMC 45806): Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Test Conditions. ESE Project ID No. 3903026-0750-3140. Prepared by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-09.

   CONCLUSIONS: This study is scientifically sound and meets the guideline requirements for an acute, flow-through,

2

freshwater fish toxicity study. The 96-hour LC_{50} of 0.90 µg/l (based on mean measured concentrations) classifies cypermethrin as very highly toxic to rainbow trout. The NOEC was 0.37 µg/l.

3. **CITATION:** Ward, T.J. and R.L. Boeri. 1991. Acute Toxicity of FMC 56701 Technical and Cypermethrin Technical to the Daphnid, *Daphnia magna*. EnviroSystems Study Number 90186-FMC. FMC Study No. A90-3310. Prepared by EnviroSystems Division, Resource Analysts, Inc., Hampton, NH. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-10.

CONCLUSIONS: This study is not scientifically sound. Contamination of the controls in both tests was significant. No valid controls exist for these tests. The 48-hour EC_{50} value of FMC 56701 was 0.148 µg/l mean measured concentration. The 48-hour EC_{50} value of cypermethrin technical was 0.10 µg/l mean measured concentration. Therefore, both FMC 56701 and cypermethrin technical are considered very highly toxic to daphnids. The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be <0.149 µg/l and 0.067 µg/l, respectively.

4. **CITATION:** Chandler, A.B. 1990. FMC 45806: Acute Toxicity to Sheepshead Minnow (*Cyprinodon variegatus*) Under Flow-Through Test Conditions. Laboratory Project No. 3903026-0350-3140. Study performed by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-12.

CONCLUSIONS: This study is not scientifically sound and does not meet the guideline requirements for a flow-through acute toxicity study using estuarine fish. Measured concentrations varied greatly from test initiation to test termination, therefore, the actual concentrations to which the organisms were exposed are unknown. In addition, there were several inconsistencies within the report which cast doubt on the validity of the study. The 96-hour lc_{50} of fmc 45806 for *cyprinodon variegatus* was 3.43 µg a.i./l measured concentration which classifies Fmc 45806 as very highly toxic to *cyprinodon variegatus*. According to the author's report, the noec was 2.14 µg/l.

5. **CITATION:** Overman, M.A., M.G. Barron, and D.D. Vaishnav. 1990. Cypermethrin-S (FMC 56701): Acute Toxicity to Sheepshead Minnow (*Cyprinodon variegatus*) Under Flow-Through Test Conditions. Laboratory Project No. 3903026-0600-3140. Study performed by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-11.

CONCLUSIONS: This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity study using estuarine fish. The 96-hour LC_{50} for *Cyprinodon variegatus* was 2.39 µg/l measured concentration which classifies Cypermethrin-S as very highly toxic to *Cyprinodon variegatus*. According to the authors' report, the NOEC was 1.79 µg/l.

6. **CITATION:** Ward, T.J. and R.L. Boeri. 1991. Acute Toxicity of FMC 56701 Technical and Cypermethrin Technical to the Mysid, *Mysidopsis bahia*. EnviroSystems Study No. 90187-FMC. FMC Study Number A90-3309. Prepared by EnviroSystems Division, Resource Analysts, Inc., Hampton, NH. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-13.

CONCLUSIONS: This study is not scientifically sound. Contamination of the controls in both tests was significant. No valid controls exist for these tests. The 96-hour LC_{50} value of FMC 56701 was 2.2 ng/l mean measured concentration and the 96-hour LC_{50} value of cypermethrin technical was 5.0 ng/l mean measured concentration. Therefore, both FMC 56701 and cypermethrin technical are classified as very highly toxic to mysids. The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be 1.0 ng/l and 3.4 ng/l, respectively.

The registrant has not fulfilled the Ecological Effects data requirements. However, the rainbow trout studies are valid and provide useful information on the toxicity of the chemical to cold water fish, and will not need to be redone. Therefore, the comparison between the currently registered cypermethrin and cypermethrin minus or cypermethrin-S, a new technical grade, can not be completed until acceptable studies for the three remaining species (Daphnia, sheepshead minnow, and mysid shrimp) are submitted and reviewed by EEB.

If there are any questions, contact Renee Lamb at 305-5294.

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin-S (Fury Technical). Shaughnessey No. 129064.

2. **TEST MATERIAL:** Cypermethrin-S (FMC 56701); Lot No. E6278-103; 88.2% active ingredient; a viscous brown liquid.

3. **STUDY TYPE:** Freshwater Fish Flow-Through Acute Toxicity Test. Species Tested: rainbow trout (*Oncorhynchus mykiss*).

4. **CITATION:** Overman, M.A., M.G. Barron, and D.D. Vaishnav. 1990. Cypermethrin-S (FMC 56701): Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Test Conditions. Laboratory Project ID 3903026-0700-3140. FMC Study No. A89-2935-01. Prepared by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-08.

5. **REVIEWED BY:**

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

Signature: Louis M. Rifici
Date: 3/9/92

Renee Lamb 3/31/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 3/9/92

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

Signature: Henry T. Craven
Date: 4/7/92

Anu Stavola 4/12/92

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} of 0.69 µg/l (mean measured concentration) classifies cypermethrin-S as very highly toxic to rainbow trout. The NOEC could not be determined due to mortality at all concentrations.

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Juvenile rainbow trout (*Oncorhynchus mykiss*) were obtained from a commercial supplier in Hampton, NH. The fish were acclimated to the dilution water and maintained at 12 ±2°C for 20 days prior to test initiation. During holding, they were fed a mixture of trout chow and commercial flake food twice daily. At test initiation, the fish were 69 days old.

B. **Test System:** A diluter system with a dilution factor of 60% was used to mix and deliver the test concentrations to the test vessels. Vessels used in the test were covered, 11-l glass chambers (28 x 25 x 15.5 cm high) containing approximately 6 l of test solution.

The test material was dissolved in N,N dimethylformamide (DMF) to give a final stock concentration of 200 mg/l. A volume of the stock was delivered to the diluter mixing chamber with each cycle and diluted accordingly to give the test concentrations. The solution for the highest test concentration came directly from the mixing chamber.

The dilution water was well water obtained on-site and had a hardness of 269 mg/l as $CaCO_3$, an alkalinity of 254 mg/l as $CaCO_3$, a conductivity of 430 µmhos/cm, and a pH of 7.9 at test initiation.

The test was conducted at 12 ±2°C. The photoperiod was 16-hour light/8-hour dark with 30-minute dawn and dusk simulation periods. The trout were not fed during the test.

C. **Dosage:** Ninety-six-hour flow-through test. Five nominal concentrations (0.70, 1.17, 1.94, 3.24, and 5.40 µg/l), a solvent control (30 µl DMF/l), and a dilution water control were used.

D. **Design:** Ten fish were impartially added to each test chamber, two chambers per concentration. Nineteen fish were used for the solvent control exposure. All chambers were observed once every 24 hours for mortality and sublethal responses.

The dissolved oxygen concentration (DO), pH, and temperature of each test solution were determined

daily. The temperature of the water bath was determined hourly using a data logging device.

Water samples were removed from each chamber at test initiation and termination. Replicate solutions were combined. The concentration of cypermethrin-S in the samples was determined using HPLC.

E. **Statistics:** The 96-hour median lethal concentration (LC_{50}) and associated 95% confidence interval (C.I.) were calculated using probit analysis.

12. **REPORTED RESULTS:** The mean measured concentrations were 0.47, 0.82, 1.65, 2.77, and 5.27 µg/l (Table 1, attached). These values represent 67-98% of nominal concentrations.

The mortality responses of the rainbow trout are given in Table 6 (attached). The 96-hour LC_{50}, based on mean measured concentrations, was 0.69 µg/l (95% C.I. = 0.60-0.82 µg/l). The 96-hour no-observed-effect concentration (NOEC) could not be determined due to mortality at all test levels.

The temperature, pH, and DO during the test were 12-13°C, 7.8-8.1, and 8.6-10.4 mg/l, respectively.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors made no conclusions other than those previously mentioned.

Quality Assurance and Good Laboratory Practice statements were included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards set forth in 40 CFR Part 160.

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

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

The hardness of the dilution water used (269 mg/l as $CaCO_3$) was greater than recommended (40 to 200 mg/l as $CaCO_3$).

The results of continuous temperature monitoring were not presented in the report.

The diluter system was not fully described. The number of volume replacements in the test system and the biomass loading rate were not given in the report. In

7 3

addition, the length and weight of the test fish were not reported.

The results of preliminary tests, if any, were not given in the report.

The slope of the probit line (from the LC_{50} determination) was not given in the report.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program and mean measured concentrations to calculate the LC_{50} value and obtained the same results (see attached printout). The slope of the probit line was 7.7.

C. **Discussion/Results:** One weakness of this study is the lack of documentation of several important parameters. The biomass loading, length and weight of the test fish, and volume replacements in the diluter system were not reported. The laboratory's protocol states the ranges which could be encountered during testing, but it appears that these parameters were not determined for this study. Judging from the response of the control fish, the analytical measurements, and the water quality measurements, the above parameters were probably adequate for testing.

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} of 0.69 µg/l (mean measured concentration) classifies cypermethrin-S as very highly toxic to rainbow trout. The NOEC could not be determined due to mortality at all concentrations.

D. **Adequacy of the Study:**

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 03-09-92.

Cypermethrin Review

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.

RIFICI CYPERMETHRIN-S ONCORHYCHUS MYKISS 3-9-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
5.27	20	20	100	9.536742E-05
2.77	20	20	100	9.536742E-05
1.65	20	20	100	9.536742E-05
.82	20	14	70	5.765915
.47	20	2	10	2.012253E-02

THE BINOMIAL TEST SHOWS THAT .47 AND 1.65 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 .6898963

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	7.602793E-02	.7106821	.5938736	.8258135

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.2124433	1	.9969819

SLOPE = 7.671963

95 PERCENT CONFIDENCE LIMITS = 4.135835 AND 11.20809

LC50 = .6953561

95 PERCENT CONFIDENCE LIMITS = .5991101 AND .8162923

LC10 = .4749736

95 PERCENT CONFIDENCE LIMITS = .3319585 AND .5596098

****

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin.
Shaughnessey No. ~~129064~~. 109702

2. **TEST MATERIAL:** Cypermethrin (FMC 45806); Lot No. PL89-63; 91.5% active ingredient; a brown viscous liquid.

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

4. **CITATION:** Vaishnav, D.D. and J.J. Yurk. 1990. Cypermethrin (FMC 45806): Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Test Conditions. ESE Project ID No. 3903026-0750-3140. Prepared by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-09.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Mark A. Mossler
Date: 3/9/92
Renée Lamb 3/31/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 3/9/92

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

Signature: Henry Craven 4/7/92
Date: Arm Stavola 4/29/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute, flow-through, freshwater fish toxicity study. The 96-hour LC_{50} of 0.90 µg/l (based on mean measured concentrations) classifies cypermethrin as very highly toxic to rainbow trout. The NOEC was 0.37 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 and maintained in the laboratory for two weeks prior to testing. The fish were 83 days old at time of test initiation and were held in the dilution water at 12 ±2°C during acclimation. The fish were fed a mixture of trout chow and commercial flake food twice daily.

B. **Test System:** The test system was reported as being a flow-through system but a full description was not provided. The test was conducted in 10.5-l glass aquaria (28 x 25 x 15 cm). Each aquarium contained approximately 5 l of test solution or control water. The aquaria were covered except during observation and water quality measurement.

Well water with a hardness (as $CaCO_3$), alkalinity (as $CaCO_3$), conductivity, and pH of 269 mg/l, 253 mg/l, 390 µmhos/cm, and 8.0, respectively, was used as dilution water in the test. The laboratory was maintained on a 16-hour light/8-hour dark cycle with 30-minute dawn/dusk simulations. The dilution water was chilled to 12 ±2°C before delivery to the diluter headbox.

The stock solution was prepared in dimethylformamide (DMF) at a concentration of 100,000 µg/l.

C. **Dosage:** Ninety-six-hour flow-through test. Based on a preliminary test, five nominal concentrations (0.39, 0.65, 1.08, 1.80, and 3.00 µg/l), a solvent control (0.03 ml DMF/l), and a dilution water control were used for the definitive test.

D. **Design:** Ten fish were impartially distributed to each aquarium; two aquaria per concentration. The fish were not fed during the test.

Observations of mortality and sublethal effects were made every 24 hours. The dissolved oxygen (D.O.), pH, and temperature were measured in all test vessels every 24 hours until the end of the test or until all fish died.

The test material concentrations were measured by high-performance liquid chromatography (HPLC) on samples

taken at test initiation and termination (or where 100% mortality occurred).

E. **Statistics:** Results are calculated based on mean measured concentrations. The median lethal concentration (LC_{50}) and associated 95% confidence interval (C.I.) for each 24-hour interval were calculated using a computer program which employed three methods of analysis. The methods included probit analysis, moving average angle analysis, and binomial probability.

12. **REPORTED RESULTS:** The mean measured concentrations were 0.219, 0.366, 0.719, 1.35, and 2.24 µg/l (Table 1, attached). Measured concentrations at initiation were generally greater than those measured at test termination.

The responses of trout to cypermethrin are given in Table 6 (attached). The 96-hour LC_{50} based on mean measured concentrations was 0.90 µg/l (95% C.I. = 0.72-1.35 µg/l). The no-observed-effect concentration (NOEC) was determined to be 0.366 µg/l, based on lack of mortality.

During the test, the pH ranged from 7.9 to 8.1., D.O. from 8.4 to 10.6 mg/l (78-98% of saturation at 12°C), and temperature from 11.0 to 12.2°C.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors presented no conclusions other than those stated.

Quality Assurance and GLP Compliance Statements were included in the report, indicating that the study was conducted in accordance with FIFRA Good Laboratory Practice Standards (40 CFR Part 160) with the exception that the analysis of purity for the test material determined by the sponsor was not conducted according to GLPs.

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

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

Pretest mortality and the overall fish health were not reported.

No weight or length measurements were given in the report.

The loading rate was not reported.

The test was reported as being conducted in a flow-through system; however, the number of volume replacements, flow rate, and diluter description was not included.

It was not reported if the diluter was calibrated before test initiation and checked twice daily.

It was not stated whether the stock solution was corrected for the percent active ingredient.

The hardness of the dilution water (269 mg/l as $CaCO_3$) was higher than recommended (200 mg/l as $CaCO_3$).

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the LC_{50} value and obtained the same results (see attached printout).

C. **Discussion/Results:** Although the loading rate, weight, and length of the test fish were not reported; the results of the D.O. measurements, coupled with mortality data, indicated that oxygen stress was not a problem in the test chambers.

This study is scientifically sound and meets the guideline requirements for an acute, flow-through, freshwater fish toxicity study. The 96-hour LC_{50} of 0.90 µg/l (based on mean measured concentrations) classifies cypermethrin as very highly toxic to rainbow trout. The NOEC was determined to be 0.37 µg/l.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

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

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

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 3-6-92.

Cypermethrin Review

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.

_____ 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.

MOSSLER CYPERMETHRIN-S ONCORHYNCHUS MYKISS 3-6-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
2.24	20	20	100	9.536742E-05
1.35	20	20	100	9.536742E-05
.719	20	3	15	.1288414
.366	20	0	0	9.536742E-05
.219	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .719 AND 1.35 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 .8971188

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.

****

MRID No. 419682-10

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin-S (Fury Technical). Shaughnessey No. 129064. / Cypermethrin Tech. #109702

2. **TEST MATERIAL:** 1. FMC 56701 Technical (Cypermethrin-S); E6278-103; 88.2% active ingredient; a viscous brown liquid. 2. Cypermethrin Technical (FMC 45806); Code 3765; 92.3% active ingredient; a viscous amber liquid.

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

4. **CITATION:** Ward, T.J. and R.L. Boeri. 1991. Acute Toxicity of FMC 56701 Technical and Cypermethrin Technical to the Daphnid, *Daphnia magna*. EnviroSystems Study Number 90186-FMC. FMC Study No. A90-3310. Prepared by EnviroSystems Division, Resource Analysts, Inc., Hampton, NH. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-10.

5. **REVIEWED BY:**

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

Signature: Louis M Rifici
Date: 3/9/92 Renée Lamb 3/31/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 3/10/92

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

Signature: Henry T. Craven 4/7/92
Date: Anne Stavola 4/2/92

7. **CONCLUSIONS:** This study is not scientifically sound. Contamination of the controls in both tests was significant. No valid controls exist for these tests. The 48-hour EC_{50} value of FMC 56701 was 0.148 µg/l mean measured concentration. The 48-hour EC_{50} value of cypermethrin technical was 0.10 µg/l mean measured concentration. Therefore, both FMC 56701 and cypermethrin technical are considered very highly toxic to daphnids. The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be <0.149 µg/l and 0.067 µg/l, respectively.

191

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Juvenile *Daphnia magna* (<24 hours old) were obtained from in-house cultures. The cultures were maintained in dilution water and were acclimated to the test conditions. During acclimation, the temperature was 19-20.0°C and the dissolved oxygen concentration (DO) was maintained above 6.9 mg/l. The daphnids were fed yeast and trout chow, and *Selenastrum capricornutum* daily before the test.

B. **Test System:** The test chambers were 250-ml glass beakers containing 200 ml of test solution (depth of 6-6.5 cm). The beakers were randomly positioned in an incubator set to 20 ±1°C. A 16-hour daylight photoperiod with a light intensity of 25 $\mu Es^{-1}m^{-2}$ was maintained using cool-white fluorescent tubes.

Well water, collected on site, was adjusted to a hardness of 180 mg/l and aerated before use as dilution water. The pH was 6.8-7.7.

Stock solutions were prepared in acetone. "Appropriate amounts of stock solution were added directly to the dilution water in the morning of the first day of exposure."

C. **Dosage:** Forty-eight-hour static-renewal test. Based on the results of preliminary tests, five or six nominal concentrations, a dilution water control, and a solvent control were used in each test. The concentrations for the test using FMC 56701 were 0.150, 0.250, 0.400, 0.600, and 1.000 µg a.i./l and using cypermethrin technical were 0.025, 0.040, 0.060, 0.150, 0.250, and 0.400 µg a.i./l.

D. **Design:** Ten daphnids were distributed to each beaker, two beakers per concentration, for a total of 20 individuals per concentration. The daphnids were not fed during the test. The test solutions were renewed at the end of the first day of exposure and at the beginning and end of the second day of exposure.

Observations of mortality, immobilization, and sublethal responses were made initially and every 24 hours. Dead daphnids were removed when first observed. The DO, pH, conductivity, and temperature were recorded in each test chamber containing live daphnids daily. The temperature of a single beaker was recorded continuously.

Water samples from each test vessel were collected at test initiation and termination, and before and after each renewal in each test. Samples were stored in the refrigerator and shipped to the sponsor on ice via overnight carrier. The concentration of cypermethrin-S (from FMC 56701) or cypermethrin in the samples were determined using gas chromatography.

E. **Statistics:** The 48-hour LC_{50} values and associated 95% confidence intervals (C.I.) were determined using a computer program developed by Stephan (1983).

12. **REPORTED RESULTS:** No insoluble material was observed at any concentration. The control solutions were contaminated with the test material in both tests (Tables 1 and 2, attached). Measured levels of FMC 56701 in the controls ranged from not detected (<0.002 µg/l) to 0.152 µg/l and levels of cypermethrin technical ranged from 0.003 to 0.033 µg/l. The mean measured concentrations for the FMC 56701 test were 0.149, 0.260, 0.471, 0.634, and 1.057 µg/l or 99-118% of nominal concentrations and for the cypermethrin technical test were 0.040, 0.061, 0.067, 0.148, 0.249, and 0.386 µg/l or 96-160% of nominals.

The responses of the daphnids in the two tests are presented in Tables 4 and 5 (attached). The 48-hour LC_{50} value of FMC 56701 was 0.148 µg/l mean measured concentration (95% C.I. = 0.034-0.237 µg/l). The 48-hour LC_{50} value of cypermethrin technical was 0.134 µg/l mean measured concentration (95% C.I. = 0.114-0.157 µg/l). The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be <0.149 µg/l and 0.067 µg/l, respectively.

The water quality in the two tests were as follows: 1.) FMC 56701 test, a DO of 8.3-9.3 mg/l, a conductivity of 800 µmhos/cm, a temperature of 19.8-20.5°C, and a pH of 7.7-7.9; 2.) cypermethrin technical test, a DO of 8.6-9.5 mg/l, a conductivity of 800 µmhos/cm, a temperature of 19.3-20.1°C, and a pH of 6.8-7.9.

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

Quality Assurance and Good Laboratory Practice Statements were included in the report, indicating that the study was conducted in accordance with FIFRA Good Laboratory Practice Standards set forth in 40 CFR Part 160.

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

A. Test Procedure: The test procedures were generally in accordance with protocols recommended by the SEP, except for the following deviations:

Contamination of the control solutions was significant and fairly consistent in both tests. No valid controls exist for these tests.

The concentration of acetone used in the solvent controls was not reported.

No transitional period between light and dark was used in the test.

The authors did not state whether the daphnids were randomly assigned to the test chambers.

The results of continuous temperature monitoring were not presented in the report.

First instar *Daphnia magna* used in tests should be from the fourth or later broods of a given parent. The authors did not indicate which brood was the source of the test animals.

B. Statistical Analysis: The reviewer used EPA's Toxanal program to calculate the 48-hour EC_{50} values and obtained the same or similar results (see attached printouts). However, the reviewer's results for cypermethrin technical (96-hour EC_{50} of 0.10 µg/l [95% C.I. = 0.067-0.148 µg/l]) were more conservative and will therefore be reported as the EC_{50} value for this test

C. Discussion/Results: No explanations concerning the contamination of the controls were given by the authors. Contamination was significant (concentrations ranged from not detected (<0.002 µg/l) to 0.152 µg/l and fairly consistent in both tests. No valid controls exist for these tests.

The initial pH in the test with FMC 56701 was 7.7 (Table B., attached). However, the initial pH in the

cypermethrin technical test was 6.8 (Table B.2, attached). The dilution water in the two tests was from the same source and had exactly the same conductivity. The authors did not attempt to explain this difference between the two tests.

This study is not scientifically sound. The 48-hour EC_{50} value of FMC 56701 was 0.148 µg/l mean measured concentration. The 48-hour EC_{50} value of cypermethrin technical was 0.10 µg/l mean measured concentration. Therefore, both FMC 56701 and cypermethrin technical are considered very highly toxic to daphnids. The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be <0.149 µg/l and 0.067 µg/l, respectively.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** Contamination of the controls in both tests was significant. No valid controls exist for these tests.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 03-05-92.

Cypermethrin Review

Page _____ is not included in this copy.

Pages 24 through 29 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.

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE
OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY,
THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

(FMC 57701)

RIFICI CYPERMETHRIN-S DAPHNIA MAGNA 3-9-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
1.057	19	19	100	1.907348E-04
.634	19	19	100	1.907348E-04
.471	19	19	100	1.907348E-04
.26	19	19	100	1.907348E-04
.149	19	7	36.8421	17.96417

THE BINOMIAL TEST SHOWS THAT 0 AND .26 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 .1627283

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.

****

(FMC 45806)

RIFICI CYPERMETHRIN-F DAPHNIA MAGNA 3-9-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.386	20	20	100	9.536742E-05
.249	20	20	100	9.536742E-05
.148	20	20	100	9.536742E-05
.067	20	0	0	9.536742E-05
.061	20	0	0	9.536742E-05
.04	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .067 AND .148 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 9.957911E-02

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.

****

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin-S (Fury Technical).
Shaughnessey Number: 129064.

2. **TEST MATERIAL:** Cypermethrin-S (FMC 56701); Lot No. E6278-103; 88.2% active ingredient; a brown, viscous liquid.

3. **STUDY TYPE:** Estuarine Fish Static Acute Toxicity Test.
Species Tested: Sheepshead Minnow (*Cyprinodon variegatus*).

4. **CITATION:** Overman, M.A., M.G. Barron, and D.D. Vaishnav. 1990. Cypermethrin-S (FMC 56701): Acute Toxicity to Sheepshead Minnow (*Cyprinodon variegatus*) Under Flow-Through Test Conditions. Laboratory Project No. 3903026-0600-3140. Study performed by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-11.

5. **REVIEWED BY:**

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

Signature: Rosemary Graham Mora
Date: 3/10/92

Renée Lamb 3/31/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 3/10/92

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

Signature: Henry T Craven 4/7/92
Date: Arvindra Stavola 4/2/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a flow-through acute toxicity study using estuarine fish. The 96-hour LC_{50} for *Cyprinodon variegatus* was 2.39 µg/l measured concentration which classifies Cypermethrin-S as very highly toxic to *Cyprinodon variegatus*. According to the authors' report, the NOEC was 1.79 µg/l.

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

9. **BACKGROUND:**

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

6.5 32 1

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Sheepshead minnow (*Cyprinodon variegatus*) were obtained from SP Engineering, Salem, MA, and held for 91 days in the laboratory in dilution water (21 ±1°C). The fish were fed brine shrimp at least once daily during the holding period. At the time of test initiation, the fish were at least 91 days old.

B. **Test System:** The test was conducted under flow-through conditions using a proportional diluter with a 0.6 dilution factor. The test chambers were covered, rectangular glass vessels (28 x 25 x 15 cm) which maintained a solution volume of 5 l.

The test chambers were exposed to a photoperiod of 16 hours of light and 8 hours of darkness. A 30-minute transition period from light to dark and dark to light was provided. The water temperature was maintained at 22 ±2°C.

The dilution water was natural filtered saltwater which was aerated in a header tank prior to use. Well water was added to obtain a salinity of 20 parts per thousand (ppt). At test initiation, the dilution water had a pH of 8.2-8.3, a dissolved oxygen (DO) concentration 8.0-8.1 mg/l, and a salinity of 22 ppt.

A primary stock solution (200,000 µg/l) was prepared by dissolving the test material in dimethyl formamide (DMF). This primary stock solution was diluted in the chemical mixing chamber to provide the highest test concentration. Dilutions of this concentration in the diluter system provided the four lowest nominal test concentrations.

C. **Dosage:** Ninety-six-hour flow-through acute test. The five nominal concentrations of Cypermethrin-S chosen for this study were 0.7, 1.17, 1.94, 3.24, and 5.4 µg/l. In addition, a dilution water control and a solvent control (30 µl DMF/l) were included.

D. **Design:** Ten fish were impartially distributed to each of two replicates of the treatments and controls. The fish were not fed during the test.

Survival and behavioral abnormalities were noted daily during the study.

Dissolved oxygen concentrations, temperature, and pH were measured daily in all test solutions. Salinity was measured daily in the dilution water control. Temperature in the dilution water control chamber was measured hourly throughout the test.

The concentration of test material in all test levels was determined for samples collected on days 0 and 4 using high performance liquid chromatography. For each concentration, duplicate samples were combined.

E. **Statistics:** The LC_{50} values were determined using the binomial method (Stephan, 1982).

12. **REPORTED RESULTS:** Mean measured concentrations of Cypermethrin-S were reported as 0.28, 0.62, 0.91, 1.79, and 3.0 µg/l in the test concentrations (Table 1, attached). These measured concentrations represent 40-56% of nominal concentrations.

No mortality was observed in the controls or the three lowest test concentrations (0.28-0.91 µg/l mean measured concentrations) (Table 6, attached). Five percent mortality was observed at 1.79 µg/l mean measured concentration and 90% mortality at 3.0 µg/l. Based on mean measured concentrations, the 96-hour LC_{50} value and 95% confidence interval for sheepshead minnow exposed to Cypermethrin-S were 2.37 and 1.79-3.0 µg/l, respectively. The NOEC was reported as 1.79 µg/l mean measured concentration.

During the study, the pH was 8.1-8.3, the test temperature was 21-22°C, and the dissolved oxygen concentration was ≥4.4 mg/l. The salinity of the control was 22-23 ppt.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors made no conclusions other than those presented above.

A Certification of GLP Compliance, signed by the study director and representatives of the sponsor company, was included in the report indicating that this study was conducted in accordance with U.S. EPA GLP Regulations (40 CFR Part 160). A Statement of Quality Assurance was included in the report and was signed by a representative of the quality assurance unit of the performing laboratory.

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

A. **Test Procedure:** The test procedures were generally in accordance with the protocols recommended by the guidelines, except for the following deviations:

The concentration of the lowest test solution varied greatly from test initiation (0.28 µg/l) to test termination (less than detection limit).

Pretest mortality and condition of the test organisms was not presented in the report.

The authors did not report the size and age of the test organisms. In addition, the biomass loading rate was not reported.

The authors did not report observations of sublethal effects.

The report did not mention whether food was withheld from the test organism for at least 24 hours prior to test initiation.

The report did not mention whether dead fish were removed from the test vessels at the time of observation.

The method used to maintain the test temperature (i.e., air or water bath) was not reported.

The test salinity and pH were 22-23 ppt and 8.1-8.3, respectively; the SEP recommends a salinity of 10-17 ppt and a pH of 7.7-8.0 for estuarine fish.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to determine the 96-hour LC_{50} value and 95% confidence interval and obtained results similar to those of the authors (printout attached).

C. **Discussion/Results:** The variation of the lowest test concentration did not affect the results of this study since this concentration did not bracket the LC_{50} value established by this study. The deviations listed above probably did not affect the results of this test.

This study is scientifically sound and meets the guideline requirements for a flow-through toxicity study using estuarine fish. The 96-hour LC_{50} of Cypermethrin-S to *Cyprinodon variegatus* was 2.39 µg/l, mean measured concentration. According to the authors' report, the NOEC was 1.79 µg/l.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

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

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

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, March 6, 1992.

Cypermethrin Review

Page _____ is not included in this copy.

Pages 37 through 38 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.

MARY GRAHAM MORA CYPERMETHRIN-S C.VARIEGATUS 03-05-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
3	20	18	90	2.012253E-02
1.79	20	1	5	2.002716E-03
.91	20	0	0	9.536742E-05
.62	20	0	0	9.536742E-05
.28	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 1.79 AND 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 2.370528

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	.1031077	2.370528	2.176681	2.595147

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
7	.1656964	1	1

SLOPE = 13.04867
95 PERCENT CONFIDENCE LIMITS = 7.7371 AND 18.36024

LC50 = 2.39281
95 PERCENT CONFIDENCE LIMITS = 2.127798 AND 2.667535

LC10 = 1.912407
95 PERCENT CONFIDENCE LIMITS = 1.544939 AND 2.146909

****

MRID No. 419682-12

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin ~~S (Fury Technical)~~.
Shaughnessey Number: ~~129064~~. 109702

2. **TEST MATERIAL:** FMC 45806; Lot No. PL89-63; 91.5% active ingredient; a thick, brown liquid. KL 1/15/92

3. **STUDY TYPE:** Estuarine Fish ~~Static~~ Flow-through Acute Toxicity Test.
Species Tested: Sheepshead Minnow (*Cyprinodon variegatus*).

4. **CITATION:** Chandler, A.B. 1990. FMC 45806: Acute Toxicity to Sheepshead Minnow (*Cyprinodon variegatus*) Under Flow-Through Test Conditions. Laboratory Project No. 3903026-0350-3140. Study performed by Environmental Science and Engineering, Inc., Gainesville, FL. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-12.

5. **REVIEWED BY:**

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

Signature: Rosemary Graham Mora
Date: 3/10/92
Renée Lamb 3/31/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 3/10/92

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

Signature: Henry T. Craven 4/1/92
Date: Ann Stavola 4/2/92

7. **CONCLUSIONS:** This study is not scientifically sound and does ~~not~~ meet the guideline requirements for a flow-through acute toxicity study using estuarine fish. * Measured concentrations varied greatly from test initiation to test termination, therefore, the actual concentrations to which the organisms were exposed are unknown. In addition, there were several inconsistencies within the report which cast doubt on the validity of the study. The 96-hour LC_{50} of FMC 45806 for *Cyprinodon variegatus* was ~~3.43~~ 3.42 µg a.i./l measured concentration which classifies FMC 45806 as very highly toxic to *Cyprinodon variegatus*. ~~According to the author's report,~~ the NOEC was ~~2.14~~ 1.89 µg/l. 4/0 1

Rosemary Graham Mora 9/28/92

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

* Although there were discrepancies from protocol, this study will be upgraded to core. The study is being used as a comparison between the toxicity of cypermethrin and beta-cypermethrin + analysis of the dose response data indicates the LC_{50} value is unlikely to change significantly in a new [illegible] New LC_{50} → 3.42 µg/L (1.89 to 4.07 µg/L). Ann Stavola 9/29/92

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Two groups of sheepshead minnow, (*Cyprinodon variegatus*) ages 30 and 59 days old, were obtained from Aquatic BioSystems, Fort Collins, CO, 74 and 28 days before test initiation, respectively. The fish were acclimated to 20-24 parts per thousand (ppt) of filtered seawater and maintained at 18-22°C. At test termination, the minnows had an average standard length of 20.5 mm (17-25 mm) and average wet weight of 0.29 g (0.1481-0.7239 g). The fish were fed brine shrimp at least once daily during the holding period.

B. **Test System:** The test was conducted under flow-through conditions using a diluter with a 0.6 dilution factor. The test chambers were glass aquaria designed to maintain a solution volume of 9 l. The flow rate during the study was adequate to provide 6.3 volume additions per day. The diluter was equilibrated for 1 day prior to test initiation.

The test chambers were exposed to a photoperiod of 16 hours of light and 8 hours of darkness. The water temperature was maintained at 20-22°C.

The dilution water was natural filtered saltwater to which well water was added to obtain a salinity of 20 ppt. At test initiation, the dilution water control had a pH of 8.2 and a dissolved oxygen (DO) concentration of 7.7 mg/l.

A primary stock solution (77 µg a.i./l) was prepared by dissolving the 0.0084 mg test material in "100 ml of dimethyl formamide (DMF) filtered natural seawater." Proportional dilutions of this concentration in the diluter system provided all nominal test concentrations.

C. **Dosage:** Ninety-six-hour flow-through acute test. The five nominal concentrations of FMC 45806 chosen for this study were 0.71, 1.19, 1.98, 3.29, and 5.49 µg a.i./l. In addition, a dilution water control and a solvent control were included. The solvent control contained "the same amount of solvent as the test concentration."

41 2

D. **Design:** "The test was initiated when 20 fish were impartially distributed to each test chamber." The fish were not fed during the test. The organism biomass loading rate was 0.05 g/l/day.

Survival was noted daily during the study and behavioral abnormalities were noted.

Dissolved oxygen concentrations and pH were measured daily in all test solutions. Salinity and temperature was measured daily at all test levels. Temperature was monitored using a min/max thermometer.

The concentration of test material in all test levels was determined for samples collected on days 0 and 4 using high performance liquid chromatography.

E. **Statistics:** The LC_{50} values were determined using non-linear interpolation (Stephan, 1977 and 1982).

12. **REPORTED RESULTS:** Mean measured concentrations of FMC 45806 were reported as 0.393, 0.531, 0.675, 1.89, and 4.07 µg a.i./l in the test concentrations (Table 3-1, attached). Measured concentrations measured at test termination were 92-415% of initial concentrations.

No mortality was observed in the controls or the four lowest test concentrations (0.393-1.89 µg a.i./l mean measured concentrations) (Table 3-3, attached). Seventy percent mortality was observed at 4.07 µg a.i./l mean measured concentration. The 96-hour LC_{50} value and 95% confidence interval for sheepshead minnow exposed to FMC 45806 were 3.42 and 1.87-4.07 µg a.i./l, respectively. The NOEC was reported as 2.14 µg a.i./l.

During the study, the pH was 7.9-8.3, the test temperature was 20-22°C, and the dissolved oxygen concentration was $\geq$6.0 mg/l. The salinity of the control was 20 ppt.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors made no conclusions other than those presented above.

A Certification of GLP Compliance, signed by the study director and representatives of the sponsor company, was included in the report indicating that this study was conducted in accordance with U.S. EPA GLP Regulations (40 CFR Part 160). Two statements of Quality Assurance were included in the report and signed by a representative of the

sponsor and quality assurance unit of the performing laboratory.

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

A. Test Procedure: The test procedures were generally in accordance with the protocols recommended by the SEP, except for the following deviations:

The concentrations of the test solutions varied greatly; final measured concentrations were 92-415% of initial measured concentrations.

Pretest mortality and condition of the test organisms was not presented in the report.

The test organism were fed 24 hours prior to test initiation. The SEP recommends that food be withheld at least 24 hours prior to test initiation.

The report did not mention whether dead fish were removed from the test vessels at the time of observation.

The dimensions of the test vessel were not reported.

The method used to maintain the test temperature (i.e., air or water bath) was not reported.

The report did not mention the use of dawn/dusk simulation periods. The SEP recommends the use 15-30 transition periods.

The test salinity and pH were 20 ppt and 7.9-8.3, respectively; the SEP recommends a salinity of 10-17 ppt and a pH of 7.7-8.0 for estuarine fish.

The study report also contains several inconsistencies as noted below:

The NOEC is reported as 2.14 µg a.i./l; this is not a mean measured concentration according to Table 3-1 (page 13, attached).

The 96-hour LC_{50} value presented in Table 3-4 (page 16 of the report, attached) is not the same as that presented in the "Results and Discussion" section of the report (page 12, attached).

Mean measured concentrations presented in Table 3-3, 3-6, and 3-7 (pages 15, 18, and 19, attached) of the report are not consistent with those presented in Table 3-1 (page 13, attached).

On pages 10 and 11, the author reports that 14 test aquaria were used in the test system and 20 fish were distributed to each test chamber. This would lead the reader to believe that 40 fish were used at each test concentration. However, the cumulative number of fish dead and the percent mortality data indicate that only 20 organisms were used per concentration level.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to determine the 96-hour LC_{50} value and 95% confidence interval using the mean measured concentrations (Table 3-1, attached) with mortality data reported in the text (page 12, attached) (printout attached). The 96-hour LC_{50} (confidence interval) was 3.43 µg a.i./l (0 to infinity). Since there were several inconsistencies noted in the report, the reviewer's results are used.

C. **Discussion/Results:** This study is not scientifically sound and does not meet the guideline requirements for a flow-through toxicity study using estuarine fish. The measured test concentrations varied greatly from test initiation to test termination, therefore, the actual concentrations to which the test organisms were exposed are unknown. In addition, there were many inconsistencies within the report which cast doubt on the validity of the test. The 96-hour LC_{50} of FMC 45806 to *Cyprinodon variegatus* was 3.43 µg a.i./l, based on mean measured concentrations. According to the author's report, the NOEC was 2.14 µg/l.

D. **Adequacy of the Study:**

(1) **Classification:** ~~Invalid.~~ Core 9/29/92

(2) **Rationale:** 1) The measured concentrations varied greatly from test initiation to test termination. 2) There were several inconsistencies within the report which cast doubt on the validity of the test.

(3) **Repairability:** ~~No.~~ N/A

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, March 9, 1992.

44 5

r lamb fmc 45806 sheep

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
4.07	20	14	70	5.765915
1.89	20	0	0	9.536742E-05
.675	20	0	0	9.536742E-05
.531	20	0	0	9.536742E-05
.393	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 1.89 AND +INFINITY 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 3.425765

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.

****

45 6

Cypermethrin Review

Page _____ is not included in this copy.

Pages 46 through 51 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.

ROSEMARY GRAHAM MORA FMC 45806 C.VARIEGATUS

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
4.07	20	14	70	5.765915
1.89	20	0	0	9.536742E-05
.675	20	0	0	9.536742E-05
.531	20	0	0	9.536742E-05
.393	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 0 AND +INFINITY 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 3.425765

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.

****

DATA EVALUATION RECORD

1. **CHEMICAL:** Cypermethrin-S (Fury Technical) / Cypermethrin Tech # 109702
Shaughnessey No. 129064.

2. **TEST MATERIAL:** 1. FMC 56701 Technical (Cypermethrin-S); E6278-103; 88.2% active ingredient; a viscous brown liquid. 2. Cypermethrin Technical (FMC 45806); Code 3765; 92.3% active ingredient; a viscous amber liquid.

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

4. **CITATION:** Ward, T.J. and R.L. Boeri. 1991. Acute Toxicity of FMC 56701 Technical and Cypermethrin Technical to the Mysid, *Mysidopsis bahia*. EnviroSystems Study No. 90187-FMC. FMC Study Number A90-3309. Prepared by EnviroSystems Division, Resource Analysts, Inc., Hampton, NH. Submitted by FMC Corporation, Philadelphia, PA. EPA MRID No. 419682-13.

5. **REVIEWED BY:**

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

Signature: Louis M Rifici
Date: 3/1/92
Renée Lamb
3/3/92

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 3/9/92

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

Signature: Henry T. Craven 4/7/92
Ann Stavola
Date: 4/2/92

7. **CONCLUSIONS:** This study is not scientifically sound. Contamination of the controls in both tests was significant. No valid controls exist for these tests. The 96-hour LC_{50} value of FMC 56701 was 2.2 ng/l mean measured concentration and the 96-hour LC_{50} value of cypermethrin technical was 5.0 ng/l mean measured concentration. Therefore, both FMC 56701 and cypermethrin technical are classified as very highly toxic to mysids. The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be 1.0 ng/l and 3.4 ng/l, respectively.

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

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Juvenile mysids (*Mysidopsis bahia*) were obtained from in-house cultures. Adult mysids used in culture were fed newly-hatched brine shrimp nauplii once or twice daily and acclimated to the test conditions and dilution water for at least 14 days. During the final 24 hours of acclimation, the temperature was 22.7-22.9°C and the dissolved oxygen concentration (DO) was greater than 7.7 mg/l.

The average weight of the control mysids at the end of the test was 3-7 mg, resulting in a biomass loading rate of 0.002 g/l.

B. **Test System:** An intermittent-flow proportional diluter was used to prepare and deliver the test solutions. The diluter was calibrated before and after the tests. The test chambers were 19.6-l glass aquaria filled with 15 l of test solution. The test solution depth was approximately 18 cm. The number of volume replacements/day during the tests with FMC 56701 and cypermethrin technical were 4.3 and 3.9, respectively. The aquaria were randomly positioned in a water bath and held at 22 ±1°C. The laboratory environment was maintained on a 16-hour daylight photoperiod with a light intensity of 16 $\mu Es^{-1}m^{-2}$ using cool-white fluorescent tubes.

Natural filtered seawater (collected from the Atlantic Ocean in Hampton, NH) was adjusted to a salinity of 17 parts per thousand (ppt) and aerated before use as dilution water. The pH was 7.8-8.0.

Stock solutions were prepared in acetone. Appropriate amounts of stock were pumped directly to the dilution water in the toxicant mixing cell.

C. **Dosage:** Ninety-six-hour flow-through test. Based on the results of preliminary tests, five nominal concentrations, a dilution water control, and a solvent control were used in each test. The concentrations for the test using FMC 56701 were 0.7, 1.3, 2.5, 5.0, and

10.0 ng a.i./l and using cypermethrin technical were 1.4, 2.6, 5.0, 10.0, and 20.0 ng a.i./l.

D. **Design:** Mysids (<24 hours old) were randomly and equally distributed to each aquarium, two aquaria per concentration, for a total of 20 mysids per concentration. The mysids were fed newly hatched brine shrimp daily during the test.

Observations of mortality and sublethal responses were made at test initiation and every 24 hours thereafter. Dead mysids were removed when observed. The DO, pH, salinity, and temperature were recorded in each test chamber containing live mysids twice daily. The temperature of one aquarium was recorded continuously.

Water samples from each test vessel were collected at test initiation, after 48 hours, and termination in each test. Samples were stored in the refrigerator and shipped to the sponsor on ice via overnight carrier. The concentration of cypermethrin-S (from FMC 56701) or cypermethrin in the samples were determined using gas chromatography.

E. **Statistics:** The 96-hour LC_{50} values and associated 95% confidence intervals (C.I.) were determined using a computer program developed by Stephan (1983).

12. **REPORTED RESULTS:** No insoluble material was observed at any concentration. The control solutions were contaminated with the test material in both tests (Table 1, attached). Measured levels of FMC 56701 in the controls ranged from not detected (<0.2 ng/l) to 3.1 ng/l and levels of cypermethrin technical ranged from 1.0 to 5.5 ng/l. The mean measured concentrations for the FMC 56701 test were 1.0, 1.5, 1.8, 3.3, and 6.2 ng/l or 62-143% of nominal concentrations and for the cypermethrin technical test were 3.7, 3.4, 3.9, 5.4, and 7.9 ng/l or 40-264% of nominals.

The responses of the mysid shrimp in the two tests are presented in Tables 4 and 5 (attached). The 96-hour LC_{50} value for FMC 56701 was 2.1 ng/l (95% C.I. = 1.8-2.4 ng/l) mean measured concentration. The 96-hour LC_{50} value for cypermethrin technical was 4.9 ng/l (95% C.I. = 4.5-5.4 ng/l) mean measured concentration. The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be 1.5 ng/l and 3.4 ng/l, respectively.

The water quality in the two tests were as follows: 1.) FMC 56701 test, a DO of 7.8 to 8.6 mg/l, a salinity of 17 ppt, a temperature of 21.9-22.9°C, and a pH of 7.9-8.2; 2.) cypermethrin technical test, a DO of 6.2-8.1 mg/l, a salinity of 17 ppt, a temperature of 21.3-23.0°C, and a pH of 7.1-8.3.

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

Quality Assurance and Good Laboratory Practice Statements were included in the report, indicating that the study was conducted in accordance with FIFRA Good Laboratory Practice Regulations set forth in 40 CFR Part 160.

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

A. **Test Procedure:** The test procedures were generally in accordance with protocols recommended by the SEP except for the following deviations:

Contamination of the control solutions was significant (concentrations ranged from not detected [<0.2 ng/l] to 5.5 ng/l) and fairly consistent in both tests. No valid controls exist for these tests.

The concentrations of acetone used in the solvent controls were not reported.

The concentrations used represented a 50% progression. The SEP recommends at least a 60% progression be used.

The flow rates used resulted in 3.9 and 4.3 volume replacements per day. The SEP recommends 5 to 10 volume replacements per day.

The results of continuous temperature monitoring of a test aquarium were not given in the report.

The report did not state whether the mysids were randomly assigned to the test chambers. Random assignment is required.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal program to calculate the 96-hour LC_{50} values and obtained similar results (see attached printouts). The slope of the concentration-response curves in the FMC 56701 and cypermethrin technical tests were 7.7 and 10.8, respectively.

C. **Discussion/Results:** No explanations concerning the contamination of the controls were given by the authors. Contamination was significant (concentrations ranged from not detected [<0.2 ng/l] to 5.5 ng/l) and fairly consistent in both tests. No valid controls exist for these tests.

The NOEC for FMC 56701 was reported as 1.5 ng/l by the authors. Since 2 deaths occurred at this level while only a single mortality was observed at the next lowest level (1.0 ng/l) and in the solvent control, the NOEC for the test was probably 1.0 ng/l.

The pH in the test of FMC 56701 was 7.9-8.2. However, the pH in the cypermethrin technical test was 7.1-8.3 with a reduction from an average of 7.7 down to 7.1 occurring on day 2 (Table B.2, attached). The authors did not attempt to explain this difference between the two tests.

This study is not scientifically sound. The 96-hour LC_{50} value of FMC 56701 was 2.2 ng/l mean measured concentration. The 96-hour LC_{50} value of cypermethrin technical was 5.0 ng/l mean measured concentration. Therefore, both FMC 56701 and cypermethrin technical are considered very highly toxic to mysids. The no observed effect concentration (NOEC) for FMC 56701 and cypermethrin technical were estimated to be 1.0 ng/l and 3.4 ng/l, respectively.

D. **Adequacy of the Study:**

(1) **Classification:** Invalid.

(2) **Rationale:** Contamination of the controls in both tests was significant. No valid controls exist for these tests.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 03-05-92.

Cypermethrin Review

Page _____ is not included in this copy.

Pages 58 through 61 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.

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE
OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY,
THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

(FML 56701)

RIFICI CYPERMETHRIN-S MYSIDOPSIS BAHIA 3-5-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
6.2	19	19	100	1.907348E-04
3.3	19	17	89.4737	3.643036E-02
1.8	19	7	36.8421	17.96417
1.5	19	1	5.2632	3.814697E-03
1	19	0	0	1.907348E-04

THE BINOMIAL TEST SHOWS THAT 1.5 AND 3.3 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 2.068161

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	5.954798E-02	2.332	2.020157	2.651311

2.651311

LMR
3/5/92

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	.1348075	1	.5983103

SLOPE = 7.672359
95 PERCENT CONFIDENCE LIMITS = 4.855365 AND 10.48935

LC50 = 2.169896
95 PERCENT CONFIDENCE LIMITS = 1.923956 AND 2.53208

LC10 = 1.482209
95 PERCENT CONFIDENCE LIMITS = 1.194749 AND 1.689486

****

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE
OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY,
THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

RIFICI CYPERMETHRIN TECHNICAL MYSIDOPSIS BAHIA 3-5-92

****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
7.9	19	19	100	1.907348E-04
5.4	19	11	57.8947	32.3803
3.9	19	4	21.0526	.9605406
3.7	19	0	0	1.907348E-04
3.4	19	1	5.2632	3.814697E-03

THE BINOMIAL TEST SHOWS THAT 3.9 AND 7.9 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 5.050999

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	6.120838E-02	← 5.032968	4.698499	5.415646

5.415646

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.1073089	1	.2770197

SLOPE = 10.81821
95 PERCENT CONFIDENCE LIMITS = 7.27438 AND 14.36205

LC50 = 5.007734
95 PERCENT CONFIDENCE LIMITS = 4.636204 AND 5.543461

LC10 = 3.821612
95 PERCENT CONFIDENCE LIMITS = 3.382158 AND 4.147026

****