264395
RECORD NO.

057701-5
SHAUGHNESSEY NO

Repeat study or repeat submission?

REVIEW NO.

EEB REVIEW

DATE: IN 5-24-90 OUT 8-15-90

FILE OR REG. NO. 57875

PETITION OR EXP. NO.

DATE OF SUBMISSION 5-4-90

DATE RECEIVED BY EFED 5-18-90

RD REQUESTED COMPLETION DATE 8-17-90

EEB ESTIMATED COMPLETION DATE 8-17-90

RD ACTION CODE/TYPE OF REVIEW 660

TYPE PRODUCT(S) Insecticide

DATA ACCESSION NO(S) 41474501

PRODUCT MANAGER, NO. 74

PRODUCT NAME(S) Malathion

COMPANY NAME American Cyanamid

SUBMISSION PURPOSE Review Mysid Shrimp Study

SHAUGHNESSEY NO.	CHEMICAL	% A.I.
057701-5	Malathion	94%

(1)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

August 13, 1990

MEMORANDUM

SUBJECT: Review of toxicity data for Malathion (057701-5)

FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Joanne Edwards (PM 74)
Reregistration Branch
Special Review and Reregistration Division (H7508C)

EEB has completed the review of a new Malathion study submitted by American Cyanamid Company on behalf of the Malathion Reregistration Task Force in response to the Malathion Registration Standard (copy attached). The following is a brief summary of the review:

STUDY IDENTIFICATION: Forbis, Alan D., 1990, Acute Flow-Through Toxicity of CYTHION Technical to mysid shrimp (Mysidopsis bahia), conducted by Analytical Bio-Chemistry Laboratories, Inc., 7200 East ABC Lane, P.O. Box 1097, Columbia, MO 65205, submitted by American Cyanamid Company, Agricultural Research Division, Princeton, NJ 08540. MRID No. 414745-01.

CONCLUSIONS: The data submitted are scientifically sound and fulfill the Guideline requirements for a an Acute Toxicity Test for Estuarine and Marine Organisms (Shrimp 96-Hour Acute Toxicity Test). With a 96-hour LC_{50} of 2.2 g/L based on mean measured concentrations, Malathion is considered to be very highly toxic to mysids. The 96-hour NOEC was reported to be 1.5 g/L.

RECOMMENDATIONS: N/A

If you have any questions regarding these studies please contact Harry Winnik, Biologist, EFED/EEB, 557-7463.

2

CONCURRENCES								
SYMBOL	H7507C	H7507C		2				
SURNAME	WINNIK	Craven						
DATE	8-13-90	8/13/90						

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

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

August 13, 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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3

DATA EVALUATION RECORD

8/13/1990

1. **CHEMICAL:** Malathion.
Shaughnessey Number: 057701.

2. **TEST MATERIAL:** Cythion Technical; Lot No. AC-6015-136A; 94% active ingredient; a yellow liquid.

3. **STUDY TYPE:** Estuarine Invertebrate Acute Toxicity Test.
Species Tested: Mysid shrimp (Mysidopsis bahia).

4. **CITATION:** Forbis, A.D. 1990. Acute Flow-Through Toxicity of Cythion Technical to Mysid Shrimp (Mysidopsis bahia). Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri. Report No. 38414. Submitted by American Cyanamid Company, Princeton, New Jersey. MRID No. 414745-01.

5. **REVIEWED BY:**

Kimberly Rhodes
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Kimberly Rhodes
Date: July 19, 1990

6. **APPROVED BY:**

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

Signature: P. Kosalwat
Date: 7/19/90

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

Signature: 8-13-90
Date: 8/13/90

7. **CONCLUSIONS:** This study appears scientifically sound and fulfills the guideline requirements for a 96-hour acute flow-through study using estuarine shrimp. The 96-hour LC50 value for Mysidopsis bahia exposed to Cythion Technical was determined to be 2.2 µg/L mean measured concentration. Therefore, Cythion Technical is classified as very highly toxic to mysid shrimp. The NOEC was determined to be 1.5 µg/L after 96 hours of exposure.

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

6 hrs 4

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** One-day old mysid shrimp (Mysidopsis bahia) were obtained from a commercial supplier in Colorado. Upon arrival, the mysids were gradually acclimated to culture conditions (temperature and salinity) for five and one-half hours. Mysids were fed brine shrimp daily. During the eight-day holding period preceding the definitive study, no signs of stress, disease or mortality were noted in the culture. At test initiation, the mysids were 9-10 days old.

B. **Test System:** A half-liter proportional diluter system described by Mount and Brungs (1967), utilizing a syringe dispenser, was used for the intermittent introduction of dilution water and Cythion Technical test compound into test chambers. The proportional diluter system used for the project was set to provide test levels approximately 50 percent dilutions of each other. Flow-splitting chambers were utilized to thoroughly mix and divide each test concentration for delivery to the test chambers. To minimize turbulence, the influent water was introduced into the test chambers via 14-gauge hypodermic needles. One-liter glass beakers with notched drains, which were covered with 50-mesh stainless steel screen to prevent escape of the organisms, were used as test chambers. The test solution was delivered to each test chamber at a rate of 3.6 mL/chamber/minute, an amount which was sufficient to replace the 1-liter test volume approximately 5.2 times in a 24-hour period.

The test chambers were immersed in a temperature controlled water bath held at 22 ± 1°C. The lighting for the test system consisted of fluorescent light bulbs which provided an intensity of 50-70 footcandles. The photoperiod provided 16 hours of daylight and 8 hours of darkness with 30-minute transition periods daily.

The dilution water used for this study was ABC hard blended water mixed with Marine Mix® synthetic sea salts to a final salinity of 22 to 23 parts per thousand (ppt).

C. **Dosage:** 96-hour acute flow-through test. The nominal concentrations tested were 0.60, 1.2, 2.5, 5.0, and 10 µg/L.

D. **Design:** Based on the results of previous testing, a control, solvent control, and five nominal Cythion Technical concentrations were chosen for testing. The solvent control contained 0.1 mL/L DMF. The test was initiated by impartial assignment of five Mysidopsis bahia to each of the four replicate test chambers, for a total of twenty organisms per concentration. Mysids in all concentrations were observed every 24 hours for mortality and other abnormal effects.

Temperature, salinity, dissolved oxygen concentration and pH were measured and recorded once daily in the control, solvent control and each treatment level. Test solution temperature was also continuously monitored with a data logger throughout the study. Analytical determination of Cythion Technical was performed on all test solutions, control and solvent control at 0 and 96 hours using gas-liquid chromatography.

E. **Statistics:** The mean measured test concentrations and the corresponding mortality data derived from the toxicity test were used to estimate the median lethal concentrations (LC50) and 95% confidence intervals for each 24-hour interval of the exposure period by using a computer program developed by Stephan et al. (1978).

12. **REPORTED RESULTS:** Results of the determination of Cythion Technical in the test solutions during the 96-hour flow-through toxicity test are presented in Table 3 (attached). The mean measured concentrations of Cythion Technical in exposure solutions during the 96-hour definitive test were 0.31, 0.85, 1.5, 2.6, and 6.8 µg/L. The mean measured concentrations of Cythion Technical ranged from 52 to 71% of the nominal concentrations.

Individual mortality and behavioral observations during the acute toxicity test with Cythion Technical to Mysidopsis bahia are presented in Table 5 (attached). The 24-, 48-, 72-, and 96-hour LC50 values (with 95% confidence intervals) for mysid shrimp exposed to mean measured concentrations of Cythion Technical were calculated to be >6.8, 3.6 (2.6-6.8), 2.3 (1.5-6.8), and 2.2 (1.5-2.6) µg/L, respectively. The no-observed effect concentration (NOEC) based on the lack of mortality and abnormal effects was 1.5 µg/L after 96 hours. Mortality, erratic behavior, quiescence, and/or mysid shrimp

tending to the bottom of test chambers were observed in the mean measured concentrations of 2.6 and 6.8 µg/L.

Approximately 17 hours after the initiation of the study, two replicates (C & D) of the solvent control were observed not to have test organism present. Five mysids were added to the replicates and documented accordingly. The organism in these replicates were allowed to remain in the test system for a total duration of 96 hours. Observations after 96 hours indicated no effects and were consistent with the other solvent control replicates. Since no mortality occurred in any of the solvent control replicates, the 17-hour interval made no practical differences and it was not necessary to adjust for any control mortality in calculating the LC50. Therefore, the LC50 and NOEC presented in this report should be considered a valid and accurate estimate of the toxicity of Cythion Technical to mysid shrimp.

During the test the water quality parameters were characterized as having a pH range from 7.7 to 8.1, the dissolved oxygen concentration ranged from 6.3 to 7.9 mg/L (89% to 113% of saturation) and the salinity ranged from 22 to 23 ppt. The temperature (monitored continuously and measured daily) ranged from 21 to 22°C. Although the salinity for culturing and testing was higher than recommended for estuarine shrimp in the SEP guidelines, the salinity during testing was maintained at or near the salinity recommended by culture supplier, thereby reducing any additional stress to the organisms.

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

A GLP compliance statement was included in the report and the study was audited by ABC's QA unit. A statement of quality assurance was included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practice Standards: Pesticide Programs (40 CFR 160).

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

A. **Test Procedure:** The test procedures were in accordance with protocols recommended by the SEP with the following exceptions:

o The SEP states that natural or reconstituted seawater of 10 to 17 ppt salinity should be used when testing euryhaline shrimp species. The natural

seawater used during the toxicity study had a salinity range of 22 to 23 ppt.

o The SEP states that each designated treatment group should be exposed to a concentration of toxicant that is at least 60% of the next highest concentration. The proportional diluter system used in this test was set to provide test levels approximately 50 percent dilutions of each other.

B. **Statistical Analysis:** The reviewer used EEB's Toxanal computer program to calculate the LC50 values and the slope of the concentration-response curve. These calculations are attached. The results were the same as those reported by the author.

C. **Discussion/Results:** The study results appear to be scientifically valid. Although mysids in two replicates of the solvent control were added 17 hours after initiation of the study, this deviation probably did not affect the test results since no mortality occurred in any of the solvent control replicates. The binomial method provides a 96-hour LC50 value of 2.2 µg/L mean measured concentration with a 95 percent confidence interval of 1.5 to 2.6 µg/L. The NOEC, based on lack of mortality and abnormal effects, was determined to be 1.5 µg/L. Therefore, Cythion Technical is considered to be very highly toxic to mysid shrimp (Mysidopsis bahia).

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** Although the test procedures deviated from the guidelines, the reviewer does not believe they significantly affected the toxicity results.

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

15. **COMPLETION OF ONE-LINER FOR STUDY:** Yes, 06-29-90.

RIN 1244-00

Malathion EFED DER

Page 9 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

X FIFRA registration data.

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

_____ The document is not responsive to the request.

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

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16. **REFERENCES:**

Mount D.I., and W.A. Brungs. 1967. A Simplified Dosing Apparatus for Fish Toxicological Studies. Water Res. 1:21-29.

Stephan, C.E., K.A. Busch, R. Smith, J. Burke and R.W. Andrew. 1978. A Computer program for calculating an LC50. U.S. Environmental Protection Agency, Duluth, Minnesota. Pre-publication manuscript, August, 1978.

RIN 1244-00

Malathion EFED DER

Page 11 is not included in this copy.

Pages _____ through _____ are not included.

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Shaughnessey No. 057701 Chemical Name Malathion Chemical Class ____ Page ____ of ____

Study/Species/Lab/ Accession	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg (95% C.L.) Contr. Mort.(%)=		
Species ____		Slope= # Animals/Level= Age(Days)= Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L.) Contr. Mort.(%)=		
Species ____		Slope= # Animals/Level= Age(Days)= Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
48-Hour LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Temperature =		
Lab ____		48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
96-Hour LC_{50}		LC50 = 2.2 ppb (95% C.L. 1.5 - 2.6) # binomial method Con. Mor(%)= 0 Sol. Con. Mor.(%)=0	K.K. 6/29/90	Core
Species Mysidopsis bahia		Slope= N/A # Animals/Level= 20 Temp.= 22-23°C		
Lab Analytical Bio Chemistry Laboratories	94%	96-Hour Dose Level ppb /(%Mortality) 0.31 (0), 0.85 (0), 1.5 (0), 2.6 (75), 6.8 (100)		
Acc. MRID # - 414745-01		Comments: NOEC = 1.5 µg/L. Based on mean measured concentrations		
96-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mort.(%)= Sol. Con. Mort.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab ____		96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		

KIMBERLY RHODES MALATHION MYSIDOPSIS BAHIA 06-29-90

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
6.8	20	20	100	9.536742E-05
2.6	20	15	75	2.069473
1.5	20	0	0	9.536742E-05
.85	20	0	0	9.536742E-05
.31	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 1.5 AND 2.6 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 2.24239

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE
NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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