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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

AUG | 4 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

deal fort

TO:

Barbara Briscoe, PM51

Special Review and Reregistration Division

7508W

THRU:

Robert Hitch, Biologist

Ecological Risk Characterization Branch Environmental Fate and Effects Division

Peer Reviewer

THRU:

Elizabeth Leovey, Chief

Ecological Risk Characterization Branch

Environmental Fate and Effects Division

FROM:

Andrew C. Bryceland, Fishery Biologist

Ecological Risk Characterization Branck

Environmental Fate and Effects Division

7507C

SUBJECT:

Review of data for MAA (Methanearsonic Acid) submitted by

Luxembourg Industries (Pamol), LTD. (MRID No: 424141-01

& 02; DP Barcode: D181220)

The Ecological Risk Characterization Branch has completed the review of the data submitted by Malcolm Pirnie, Inc. for MAA (Methanearsonic Acid). The following is a brief summary of the data reviewed:

72-3 (f) - Acute Estuarine/Marine Toxicity Test for Mysidopsis bahia.

CITATION: Balcom, P.H. and J.S. Hughes. 1992. The Acute Toxicity of MAA (Methanearsonic Acid) to Mysidopsis bahia. Study ID No. B648-040-4. Performed by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by MAA Research Task Force Three, Tel Aviv, Israel. EPA MRID No. 424141-01.

<u>CONCLUSIONS</u>: This study is scientifically sound but does not meet the guideline requirements for a 96-hour acute toxicity test using estuarine shrimp. The test organisms were 24-48 hours old. Based on mean measured concentrations, the 96-hour LC₅₀ was 173 mg/l which classifies MAA as practically non-toxic to Mysidopsis bahia. The NOEC was 93.5 mg/l.

Adequacy of Study: This study ((MRID No. 424141-01) is scientifically sound but does not fulfill the guideline requirements for an acute estuarine/marine invertebrate study. It has been classified as supplemental and is irreparable. However, the study may be used in a risk assessment. This study does not need to be repeated because most likely no new information would be gained by repeating it.

72-3 (d) - Acute Estuarine/Marine Toxicity Test for Cyprinodon variegatus.

CITATION: Balcom, P.H. and J.S. Hughes. 1992. The Acute Toxicity of MAA (Methanearsonic Acid) to Cyprinodon variegatus. Study ID No. B648-040-3. Performed by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by MAA Research Task Force Three, Tel Aviv, Israel. EPA MRID No. 424141-02.

<u>CONCLUSIONS</u>: This study is scientifically sound and meets the guideline requirements for a 96-hour acute toxicity test using estuarine/marine fish. Based on mean measured concentrations, the 96-hour LC_{50} was 323 mg/l which classifies MAA as practically non-toxic to *Cyprinodon variegatus*. The NOEC was 170 mg/l.

If their are any questions contact Andrew Bryceland at (703) 305-6928.

For conversation w/A Bryceland this data is applicable to the TGAI testy for MSMA/DSMA and will also be used to assess GDENS 72-3 (W. E), 8/24/95 (FE)

DATA EVALUATION RECORD

- Shaughnessey Number: 013803. CHEMICAL: MSMA. 1.
- TEST MATERIAL: Methanearsonic Acid (MAA); CAS No. 124-58-3; 2. Batch No. 0030401; 99.44% active ingredient; a white crystalline solid.
- STUDY TYPE: Estuarine Shrimp Static Acute Toxicity Test. 3. Species Tested: Mysidopsis bahia.
- CITATION: Balcom, P.H. and J.S. Hughes. 1992. The Acute Toxicity of MAA (Methanearsonic Acid) to Mysidopsis bahia. Study ID No. B648-040-4. Performed by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by MAA Research Task Force Three, Signature: William Work

 Date: 10/8/57 Tel Aviv, Israel. EPA MRID No. 424141-01.
- 5. REVIEWED BY:

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

6. APPROVED BY: Andrew Bruce and Fishery Biologist Louis M. Rivici, W.S. Fishery Biologist Associate Scientist KBN Engineering and Applied Sciences, Inc.

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

- CONCLUSIONS: This study is scientifically sound but does not meet the guideline requirements for a 96-hour acute toxicity test using estuarine shrimp. The test organisms were 24-48 hours old. Based on mean measured concentrations, the 96-hour LC₅₀ was 173 mg/l which classifies MAA as practically non-toxic to Mysidopsis bahia. The NOEC was 93.5 mg/l.
- RECOMMENDATIONS: 8.
- **BACKGROUND:**
- DISCUSSION OF INDIVIDUAL TESTS:

11. MATERIALS AND METHODS:

- A. <u>Test Animals</u>: Mysids were obtained from a supplier in Hayes, VA. For 24 hours prior to testing, mysids were acclimated to a salinity of 20 parts per thousand (ppt), a temperature of 22°C, and a photoperiod of 16 hours light/8 hours dark. Mysids were fed live brine shrimp nauplii upon arrival and prior to distribution to the test vessels. No mortality was observed during the holding period. At test initiation, the mysids were 24-48 hours old.
- B. <u>Test System</u>: The test was conducted under static conditions in covered glass bowls (8" diameter) containing 400 ml of test solution. Test chambers were randomly positioned in an incubator.

The test photoperiod was the same as that used during holding with a light intensity of 528-1076 lumens/m². The target test temperature was 22 ±1°C.

The dilution water was artificial seawater which was prepared by dissolving dry ocean salts in ASTM Type 1 water and adjusting to 20 ± 3 ppt. The dilution water was prepared 9 days prior to use. At test initiation, the dilution water had a pH of 8.17 and an alkalinity of 60 mg/l as $CaCO_{2}$.

A primary stock solution (100 mg a.i./ml) was prepared by dissolving 2.5141 g MAA in Type 1 water to a volume of 25 ml. Subsequent dilutions of the primary stock solution were made to provide the nominal test concentrations.

- C. <u>Dosage</u>: Ninety-six-hour acute test. Based on results of preliminary testing, nominal test concentrations selected for this study were 100, 180, 320, 560, and 1000 mg/l. A dilution water control was also included.
- D. <u>Design</u>: The test was initiated when ten mysids were randomly distributed to each of two replicate chambers per treatment (i.e., 20 mysids/treatment). Mysids were fed live brine shrimp nauplii twice daily during the test.

Observations of mortality and abnormal effects were recorded daily. Dissolved oxygen concentration (DO), temperature, salinity, and pH were measured daily. Measured concentrations of MAA were determined, using gas chromatography, at test initiation and test



termination. Test termination for the three highest test levels was 24 hours since all test organisms at these levels were dead at this observation period.

- E. <u>Statistics</u>: The 96-hour LC₅₀ and its 95% confidence interval were calculated by the trimmed Spearman-Karber method using CT-TOX computer program.
- 12. <u>REPORTED RESULTS</u>: Mean measured concentrations were 93.5, 167, 282, 473, and 801 mg/l (Table 3, attached). The measured concentrations represented 78-97% of nominal concentrations.

Following 96 hours of exposure, 5% mortality was observed in the control and 5-100% mortality occurred in the exposure concentrations (Table 4, attached). Based on mean measured concentrations, the 96-hour LC₅₀ was 173 mg/l with a 95% confidence interval of 151-198 mg/l. The NOEL was 93.5 mg/l, since mortality at this level was no greater than that of the control.

During the test period, DO was ≥ 6.5 mg/l, the temperature was 21.6-22.8°C, and the salinity was 20-21 ppt. The pH was 3.54-8.17. "It should be noted that increasing concentrations of test material caused the pH to be depressed in the test solutions, most dramatically at 473 and 801 mg/l."

13. <u>STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:</u>
"The observed mortality in this study may be related to the effects on test solution pH, in part or in whole."

Statements of quality assurance and good laboratory practice compliance were included in the report, indicating that the study was conducted in accordance with EPA Good Laboratory Practice Regulations (40 CFR, Part 160).

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

A. <u>Test Procedure</u>: The test procedures were generally in accordance with the SEP, but deviated as follows:

The test organisms were 24-48 hours old; according to an amendment to the SEP dated September 5, 1990, mysids must be \leq 24 hours old at test initiation.

The SEP recommends test concentrations which are at least 60% of the next highest concentration. For this study, nominal concentrations were 56-57% of the next highest concentration.

The test solution volume (400 ml) per test vessel was less than recommended (2-3 1).

The SEP recommends the use of 15- to 30-minute dawn/dusk simulation periods. The use of simulation periods was not reported.

The SEP recommends that test temperature be measured hourly in at least one test chamber if test temperature is controlled by ambient air temperature. For this study, temperature was measured daily.

The salinity of the control was 20 ppt; the SEP recommends 10 to 17 ppt for euryhaline shrimp species.

- B. <u>Statistical Analysis</u>: The reviewer used EPA's Toxanal computer program to calculate the 96-hour LC₅₀ (95% confidence interval) and obtained results similar to those of the authors.
- c. <u>Discussion/Results</u>: This study is scientifically sound but does not meet the guideline requirements for a 96-hour acute toxicity test using estuarine shrimp. The test organisms were 24-48 hours old; the use of mysids ≤24 hours old at test initiation is required. Based on mean measured concentrations, the 96-hour LC₅₀ was 173 mg/l which classifies MAA as practically non-toxic to Mysidopsis bahia. The NOEC was 93.5 mg/l.
- D. Adequacy of the Study:
 - (1) Classification: Supplemental.
 - (2) Rationale: The test organism were 24-48 hours old.
 - (3) Repairability: No.
- 15. COMPLETION OF ONE-LINER: Yes, 5 October 1992.

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Pages 7 through 2 are not included.
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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.
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The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
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NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY, THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

Rosemary Graham Mora MAA M.bahia

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CONC.	NUMBER	NUMBER	PERCENT -	BINOMIAL	
	EXPOSED	DEAD	DEAD	PROB. (PERCENT)	
801	19	19	100	1.907348E-04	2
473	19	19	100	1.907348E-04	
282	19	19	100	1.907348E-04	•
167	19	7	36.8421	17.96417	
93.5	19	0	0	1.907348E-04	

THE BINOMIAL TEST SHOWS THAT 93.5 AND 282 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 181.4415

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.

Shaughnessey # 017407	·	Chemical Name M5MA		Chemical Class	Page	
Study/Species/Lab/ MRID # 48-Hour EC ₅₀ Species: Lab: MRID #	Chemical % a.i.	EC ₅₀ - pp (Slope - # Anime 48-Hour Dos (), (Results 95% G.L. pp () Contro Solvent Contro # Animals/Level = 48-Hour Dose Level pp /(% Eff	Results L.) Control Mortality (%) = Solvent Control Mortality (%) = el = Temperature = Temperature = (), (), ()	Reviewer/ Date	Validation Status
96-Hour LC50 Species: Mysidopsis bakia Lab: Malcol M Pirnie Inc MRID #	3	(77 1047 1047 1047	Lev C	95% C.L. Himmed Spearmon - Karber 51-198) Control Mortality (%) - 5%, Solvent Control Mortality (%) - MA 1s/Level - 20 Temperature - 21.6 Level pp M/(% Mortality) 1, 282(100), 477 (100), 801 (100)	22.8 10/5/42-	Suplement

comments: selledy missing concertation 10-1111121

-DATA EVALUATION RECORD

- Shaughnessey Number: 013803. CHEMICAL: MSMA.
- TEST MATERIAL: Methanearsonic Acid (MAA); CAS No. 124-58-3; 2. Batch No. 0030401; 99.44% active ingredient; a white crystalline solid.
- STUDY TYPE: Estuarine/Marine Fish Static Acute Toxicity 3. Test. Species Tested: Sheepshead Minnow Cyprinodon variegatus.
- CITATION: Balcom, P.H. and J.S. Hughes. 1992. The Acute Toxicity of MAA (Methanearsonic Acid) to Cyprinodon variegatus. Study ID No. B648-040-3. Performed by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by MAA Research Task Force Three, Tel Aviv, Israel. EPA MRID No. 424141-02.
- 5. REVIEWED BY:

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

Signature: MINNIF Stakan Min Date: 10/2/94

6. APPROVED BY:

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

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

Date:

signature: poleetkitte

Date: august 4, 19

- Robert Hetch, Biologist **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a 96-hour acute toxicity test using estuarine/marine fish. Based on mean measured concentrations, the 96-hour LC50 was 323 mg/l which classifies MAA as practically non-toxic to Cyprinodon variegatus. The NOEC was 170 mg/l.
- 8. RECOMMENDATIONS:
- **BACKGROUND:**
- DISCUSSION OF INDIVIDUAL TESTS:

11. MATERIALS AND METHODS:

A. Test Animals: Cyprinodon variegatus (21 days old) were obtained from a supplier in Fort Collins, CO. For 14 days prior to test initiation, the fish were acclimated to a salinity of 20 parts per thousand (ppt), a temperature of 22°C, and a photoperiod of 16 hours light/8 hours dark. Fish were fed live brine shrimp nauplii during holding except for at least 48 hours prior to test initiation.

Less than 3% mortality was observed during the acclimation period. Fish were 35 days old at test initiation. At test termination, ten control fish had a mean (range) length and weight of 10 (7-12) mm and 0.0184 (0.0100-0.0246) g, respectively.

B. Test System: The test was conducted under static conditions in covered 1-1 borosilicate glass beakers containing 800 ml of test solution. Test chambers were randomly positioned in an incubator. The biomass loading rate was 0.23 q/l.

The test photoperiod was the same as that used during holding with a light intensity of $528-1076 \text{ lumens/m}^2$. The target test temperature was $22 \pm 1^{\circ}C$.

The dilution water was artificial seawater which was prepared by dissolving dry ocean salts in ASTM Type 1 water and adjusting to 20 ±3 ppt. The dilution water was prepared a week prior to use. At test initiation, the dilution water had a pH of 8.26 and an alkalinity of 60 mg/l as CaCO₂.

A primary stock solution (200 mg a.i./ml) was prepared by dissolving 10.0565 g MAA in Type 1 water to a volume of 50 ml. Subsequent dilutions of the primary stock solution were made to provide the nominal test concentrations.

- C. <u>Dosage</u>: Ninety-six-hour acute test. Based on results of preliminary testing, nominal test concentrations selected for this study were 100, 180, 320, 560, and 1000 mg/l. A dilution water control was also included.
- Design: The test was initiated when ten fish were randomly distributed to each of two replicate chambers per treatment (i.e., 20 fish/treatment). Fish were not fed during the test.



Observations of mortality and abnormal effects were recorded daily. Dissolved oxygen concentration (DO), temperature, salinity, and pH were measured daily. Measured concentrations of MAA were determined, using gas chromatography, at test initiation and test termination. The two highest test levels were sampled after 24 hours but not after 96 hours since all fish were dead in these levels.

- E. <u>Statistics</u>: The 96-hour LC₅₀ and its 95% confidence interval were calculated by the trimmed Spearman-Karber method using CT-TOX computer program.
- 12. REPORTED RESULTS: Mean measured concentrations were 97.9, 170, 302, 506, and 836 mg/l (Table 4, attached). The measured concentrations represented 81-101% of nominal concentrations.

Following 24 hours of exposure, no mortality was observed in the control and 0-100% mortality occurred in the exposure concentrations (Table 5, attached). No additional mortality was observed by test termination. Based on mean measured concentrations, the 96-hour LC₅₀ was 323 mg/l with a 95% confidence interval of 288-363 mg/l. The NOEL was 170 mg/l.

During the test period, DO was ≥6.8 mg/l, the temperature was 21.4-22.8°C, and the salinity was 20-22 ppt. The pH was 3.50-8.26. "It should be noted that increasing concentrations of test material caused the pH to be depressed in the test solutions, most dramatically at 506 and 836 mg/l."

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
"The observed mortality in this study may be related to the effects on test solution pH, in part or in whole."

Statements of quality assurance and good laboratory practice compliance were included in the report, indicating that the study was conducted in accordance with EPA Good Laboratory Practice Regulations (40 CFR, Part 160).

- 14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:
 - A. <u>Test Procedure</u>: The test procedures were generally in accordance with the SEP, but deviated as follows:

The SEP recommends test concentrations which are at least 60% of the next highest concentration. For this study, nominal concentrations were 56-57% of the next highest concentration.

The test selution volume (800 ml) per test vessel was less than recommended (15 l).

The SEP recommends the use of 15- to 30-minute dawn/dusk simulation periods. The use of simulation periods was not reported.

The salinity of the control was 20 ±2 ppt; the SEP recommends 10 to 17 ppt for euryhaline fish species.

The SEP recommends that test temperature be measured hourly in at least one test chamber if test temperature is controlled by ambient air temperature. For this study, temperature was measured daily.

- B. <u>Statistical Analysis</u>: The reviewer used EPA's Toxanal computer program to calculate the 96-hour LC₅₀ (95% confidence interval) and obtained results similar to those of the authors.
- C. <u>Discussion/Results</u>: This study is scientifically sound and meets the guideline requirements for a 96-hour acute toxicity test using estuarine/marine fish. Based on mean measured concentrations, the 96-hour LC₅₀ was 323 mg/l which classifies MAA as practically non-toxic to Cyprinodon variegatus. The NOEC was 170 mg/l.
- D. Adequacy of the Study:
 - (1) Classification: Core.
 - (2) Rationale: N/A.
 - (3) Repairability: N/A.
- 15. COMPLETION OF ONE-LINER: Yes, 5 October 1992.

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Rosemary Graham Mora MAA C.variegatus

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CONC.	NUMBER	NUMBER	PERCENT	BINOMIAL	
	EXPOSED	DEAD	DEAD	PROB. (PERCENT)	
836	20	20	100	9.536742E-05	
506	20	20	100	9.536742E-05	
302	20	7	35	13.1588	
170	20	0	0	9.536742E-05	
97.9	20 -	0 ~	0.	9.536742E-05	

THE BINOMIAL TEST SHOWS THAT 170 AND 506 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 330.8539

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.

48-Hour EC ₅₀ EC ₅₀ - pp (.) Control Mortality (%) - Species: Species: Slope - # Animals/Level - Temperature - Lab: (), (), (), (), () WRID # Comments:	Study/Species/Lab/ MRID #	Chemical % a.i.		Results	Ø	Reviewer/ Date	Reviewer/ Validation Date Status
Slope = # Animals/Leve	48-Hour ECso			Ü	Control Mortality (%) =		• • • • • • • • • • • • • • • • • • • •
Slope = # Animals/Level = # An				Solven	t Control Mortality (%) -		
48-Hour Dose Level pp (), (), () ()	Species:			# Animals/Level =	Temperature =		-
Comments:	Lab:		Н-87	lour Dose Level pp	/(% Effect)		
	MRID #	,	^) '()), (), ()		·

Chemical Class

Chemical Name

Shaughnessey # 013403

Solvent Control Mortality (x) - MAControl Mortality (x) - 0Himmed Spearman - Karke 288-363) 99.44 LCso - 323 ppm 96-Hour LC₅₀

Slope - NA # Animals/Level - 20

Cyprindon variegatus

Lab:
Malcolm Dirnie, Inc.
MRID #

70-111h2h

979(0), 170(0), 302(35), 506(180), 836 (180

Temperature = 2/.4-22.9.0

Comments: & mean weatured concentrations