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December 11, 2006

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Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW.
Washington, D.C. 20460-0001



ATTN: 8(d) Auto-ITC

Subject Chemical: CAS No. 13826-35-2

Submitting Company: FMC Corporation
1735 Market Street
Philadelphia, PA 19103

Submitting Official: Natalie A. Shevchuk
Global Regulatory Manager
(215) 299-6680

To Whom It May Concern:

We are pleased to provide our response to the TSCA 8(d) final rule issued on August 16, 2006. This submission is after the original November 28 deadline, but within the two-week extension granted by Priscilla Flattery (Chief of Staff for the Director of the Office of Pollution Prevention and Toxics (OPPT)) and Jim Willis (Director of OPPT's Chemical Control Division) as communicated in a November 28, 2006 e-mail from Greg Schweer to Pat Nevrincean.

In accordance with 40 CFR 716.5(a)(1), FMC Corporation is submitting herewith copies of three unpublished health and safety studies conducted on the subject chemical, CAS No. 13826-35-2. We are also submitting robust summaries for your reference. Please find a list of the unpublished studies below:

FMC

References

1. Permethrin Acid and 3-Phenoxybenzyl Alcohol: Toxicity to first instar *Daphnia magna*, ICI Plant Protection Division, ICI Report Series RJ 0042B, FMC Study Number A1991-3529-02, October 1978.
2. An Acute Inhalation Toxicity Study of FMC 30953 in the Rat, Bio/dynamics Inc., Study Number NCT 572.04-01, May 1978.
3. Acute Toxicity of Nine Compounds to Sheepshead Minnows (*Cyprinodon variegatus*), Bionomics – EG&G, Inc., Study Number NCT609.61, October 1975.

FMC Corporation makes no claims of confidentiality for this submission.

Sincerely yours,



Natalie A. Shevchuk
Global Regulatory Manager
FMC Corporation
215-299-6680

ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Test Substance: M-Phenoxybenzyl Alcohol (MPBA)

Method / Guideline: U.S. EPA (1975) Methods for Acute Toxicity with Fish, Macroinvertebrates and Amphibians

Species / Strain / Supplier: Cladoceran (*Daphnia magna*) / unknown / ICI (in-house)

Test Concentrations: 1.56, 3.125, 6.25, 12.5, 25, 50, 100 and 200 mg/L (nominal)
1.6, 3.1, 7.2, 12.9, 24, 54, 101 and 197 mg/L (measured)

Exposure Period: 48 hours (static conditions)

Analytical Monitoring: Yes (HPLC)

GLP: No

Year: 1978

Methods: Permethrin Acid and 3-Phenoxybenzyl Alcohol: Toxicity to first instar *Daphnia magna*, was conducted for FMC Corporation for 48 hours from September 26 to 28, 1978 at ICI Plant Protection Division, Jealott's Hill, Berkshire, United Kingdom.

The test was performed under static conditions with eight concentrations of M-Phenoxybenzyl Alcohol (MPBA) and a dilution water control. The dilution water was reconstituted water. Nominal concentrations of MPBA were 0 mg/L (control), 1.56, 3.125, 6.25, 12.5, 25, 50, 100, and 200 mg/L. Measured concentrations of MPBA following test solution preparation were 1.6, 3.1, 7.2, 12.9, 24, 54, 101 and 197 mg/L. The results of the measured concentrations were in reasonable agreement with the nominal concentrations. Therefore, the results of the study were based on the nominal concentrations.

A 200 mg/L test solution was prepared by dissolving 400 mg of MPBA in 10 mL of acetone and then diluted with 2L of reconstituted water. The remaining test solutions were prepared by serially diluting with dilution water until the lowest concentration was achieved. The solvent concentration in the control test solution (without test material) was equal to the solvent concentration in the highest treatment group.

Organisms used the test were obtained from an in-house culture and were of an age of 12 ± 12 hours old. Ten daphnids were distributed to each of three replicates for each treatment group and control. The test was performed in 250 ml beakers that contained 200 ml of test solution. A 16 hour light and 8 hour dark photoperiod maintained with warm-white fluorescent lights that provide a light intensity of approximately 2000 lux. Observations were performed at 3, 6, 24 and 48 hours of exposure. Dissolved oxygen and pH was measured in the 0 (control), 1.56, 25 and 200 mg/L treatment groups at test initiation and termination. Dissolved oxygen ranged from 93 to 96% saturation and pH ranged from 8.0 to 8.2.

The EC₅₀ values and the 95% confidence limits were calculated statistically using weighted linear regression of log concentration plotted against logit transformation of the biological response.

Results: At 48-hours, the percent immobility in the 1.56, 3.125, 6.25, 12.5, 25, 50, 100, and 200 mg/L treatment groups was 6.7, 10, 3.3, 27, 73, 100, 100 and 100%, respectively. There was one (3.3%) immobilized organism in the control at 24 hours.

After 48-hours, the percent immobility in the 1.56, 3.125, 6.25, 12.5, 25, 50, 100, and 200 mg/L treatment groups was 6.7, 30, 17, 53, 83,

100, 100 and 100%, respectively. There was one (3.3%) immobilized organism in the control at test termination.

24-hour EC_{50} = 17 mg/L with 95% confidence limits of 13 and 22 mg/L (based on nominal concentrations)

48-hour EC_{50} = 10 mg/L with 95% confidence limits of 7 and 14 mg/L (based on nominal concentrations)

Data Quality:

Code 2c

References:

ICI Plant Protection Division, Permethrin Acid and 3-Phenoxybenzyl Alcohol: Toxicity to first instar, *Daphnia magna*. ICI Report Series RJ 0042B; FMC Study Number: A1991-3529-02. (1978)



Plant Protection Division

REPORT SERIES
RJ 0042B

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Fmc 30062 A91-3529-01
Fmc 30953 A91 3 529-02
RESEARCH DEPARTMENT

PERMETHRIN ACID AND 3-PHENOXYBENZYL ALCOHOL: Toxicity to first instar
Daphnia magna

Authors: C Getty, W Wilkinson

Authorised by: D Riley

Date of Issue:

27 OCT 1978

Authentication

We, the undersigned, hereby declare that this study was performed under our supervision according to the procedures herein described, and that this report represents a true and accurate record of the results obtained.

Caryl Getty (C Getty)
(Experimental Officer, Ecologist)

Walter Wilkinson (W Wilkinson)
(Responsible Scientist, Ecologist)

Peter J. Davies (P J Davies)
(Statistician)

SUMMARY

Daphnia magna, 12 \pm 12 hours old, were exposed to a series of concentrations of (+)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid, (permethrin acid) and 3-phenoxybenzyl alcohol, (3-PBA), in reconstituted hard water at a temperature of 17 \pm 1 $^{\circ}$ C. The EC50 values for permethrin acid were 200 mg/l and 130 mg/l for 24 and 48 hours respectively. The EC50 values for 3-PBA were 17 mg/l and 10 mg/l for 24 and 48 hours respectively.

1. INTRODUCTION

Permethrin acid and 3-phenoxybenzyl alcohol (3-PBA) are the two hydrolysis products of the insecticide permethrin in water. Tests were carried out in September 1978 to determine their toxicity to first instar Daphnia magna according to the protocol given in Appendix 1. The toxicity of permethrin technical, and 25% EC formulation (JF 5855) were tested in September 1976 (Ref. 1) and a 24% EC formulation (JFU 5054) was tested in April 1977 (Ref. 2).

2. MATERIALS AND METHODS

2.1. Test Compounds

2.1.1. The compounds were identified for this study using NMR (Ref. 3). GLC was used to determine purity, and the percentage of cis and trans isomers for permethrin acid (Ref. 4).

2.1.2. Permethrin acid. (R110074). The full chemical name of the compound was (-)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid. The two isomers from which it was made were obtained from Dr J P Leahy (Metabolism and Residues Section, Jealott's Hill Research Station). The cis isomer (batch No. B1935/173) was a creamy coloured powder, 99.2% pure and contained 91.5% cis and 8.5% trans acid. The trans isomer was a white crystal 91.7% pure, containing 8.3% cis and 91.7% trans acid. The sample number was P557 QN01/CL. The two isomers were combined to give a 40:60 cis:trans mixture.

2.1.3. 3-Phenoxybenzyl alcohol (R79406). This was a clear viscous liquid >99% pure, acquired from Mr P D Bentley (Synthetic Chemistry Section, Jealott's Hill Research Station). The sample number was PP557 QN01/CL2.

2.2. Preparation of Test Solutions

2.2.1. Permethrin Acid. A 400 mg/l solution was made up by dissolving 304 mg of cis permethrin acid and 496 mg of trans permethrin acid in 2 litres of reconstituted water. 8 additional concentrations between 200 mg/l and 1.56 mg/l were prepared by serial dilution.

2.2.2. 3-PBA. A 400 mg/l solution was made up by dissolving 800 mg of 3-PBA in 10 ml of acetone and making up to 2 litres with reconstituted water. 8 further concentrations between 200 and 1.56 mg/l were prepared by serial dilution. The test started on 26/9/78 had 200 mg/l solution as the highest concentration, which was prepared by dissolving 400 mg of 3-PBA in 10 ml of acetone and making up to 2 litres with reconstituted water. The remaining concentrations were prepared as before.

2.3. Test Animals

The Daphnia were 12 ± 12 hours old, cultured at Jealott's Hill by the process described in Ref. 5 and supplied by Mr S Doma.

2.4. Test Method

The test method is based on that suggested by the US Environmental Protection Agency (Ref. 6).

The test vessels were 250 ml beakers containing 200 ml of solution. For each test there were 8 or 9 concentrations of chemical and a control, replicated 3 times. The control contained reconstituted water in the permethrin acid tests and reconstituted water with 5 ml of acetone/l in the 3-PBA tests, being the highest acetone concentration used. The formula for reconstituted hard water is given in Ref. 5 and 6.

Ten Daphnia were added to each beaker, and the number affected was assessed after 3, 6, 24 and 48 hours.

The Daphnia were recorded as affected if they were immobilised or showed only minor movements of their appendages after the beaker was agitated for 5 seconds. The beakers were placed in a water bath at 17±1°C under fluorescent lighting (30 watt warm white tubes giving about 2000 lux) on a 16 hour day. The Daphnia were not fed during the test. Following range finding tests there were two tests on permethrin acid and five on 3-PBA, two of which were invalid due to control mortality, (27% at 24 hours in test I and 60% at 48 hours in test V).

At the beginning and end of each test, pH and dissolved oxygen concentration were measured in the 1.56 mg/l, 25 mg/l and 400 mg/l or 200 mg/l concentrations and the control, using an EIL model 7030 meter to measure pH and a YSI model 57 meter to measure dissolved oxygen.

The ECSO and its 95% confidence limits were calculated using weighted linear regression of log concentration plotted against logit transformation of the Daphnia response. The nominal concentrations were used for the calculations.

2.5. Analysis of Test Solutions

In all the tests 2 litres of solution was mixed for each concentration, from this were taken three 200 ml replicates for the test, 250 ml for analysis, and 1 litre for dilution to the next concentration.

The actual concentrations of the solutions were measured using HPLC (Ref. 4). With permethrin acid, analysis was only undertaken down to 12.5 mg/l which is below the no effect level. The permethrin acid results are shown in Appendix 3 and those for 3-PBA in Appendix 5.

3. RESULTS AND DISCUSSION

The full results are given in Appendices 2-5.

3.1. Permethrin Acid

24 hr EC50 199 mg/l (95% confidence limits 179-223 mg/l)
48 hr EC50 128 mg/l (95% confidence limits 94-175 mg/l)

Dissolved oxygen remained high throughout the tests, varying between 84 and 92% saturation. The pH varied between 6.7 and 8.1.

The analysed concentrations of the solutions were in reasonable agreement with the nominal ones.

3.2. 3-Phenoxybenzyl alcohol

24 hr EC50 17 mg/l (95% confidence limits 13-22 mg/l)
48 hr EC50 10 mg/l (95% confidence limits 7-14 mg/l)

Dissolved oxygen remained high throughout the tests (89-96% saturation). The pH varied between 8.0 and 8.2.

In the 3-PBA tests problems occurred with Daphnia being affected at lower concentrations in at least one of the three replicates but not consistently at any one concentration. Additional tests were carried out because of this. The results of three valid tests are given in Appendix 4, two other tests being invalid due to control mortalities.

The analysed concentrations of the solutions were in reasonable agreement with the nominal ones.

4. CONCLUSIONS

Both these breakdown products are very much less toxic than the parent compound.

5. ACKNOWLEDGEMENTS

We should like to thank Mr P J Davies for the statistical analysis of the results, Mr P D Francis and Mr M R Kipps for carrying out the chemical analysis, Mr S Doma for supplying the Daphnia and Miss A Winter for assistance in setting up the tests.

REFERENCES

1. Doma, S and Evered, P, (1977) PP557: Acute toxicity and reproduction studies on first instar and ephippia of Daphnia magna. ICI Plant Protection Division Report No. TMJ 1455B.
2. Evered, P and Doma, S, (1977) PP557: Acute toxicity of emulsifiable concentrate (JFU 5054) to first instar Daphnia magna. ICI Plant Protection Division Report No. TMJ 1504B.
3. ICI Plant Protection Division, SOP No. 09/001/01.
4. ICI Plant Protection Division, TRAM 46.
5. Doma, S and Evered, P, (1976) Daphnia magna: Determination of acute toxicity of pesticides. ICI Plant Protection Division Report No. TMJ 1405A.
6. US Environmental Protection Agency (1975). Methods for acute toxicity tests with fish, macroinvertebrates and amphibians. Ecol. Res. Ser. EPA-660/3-75-009.

DATA SOURCES

1. Laboratory Notes Folder PP557/CN/01.
2. Laboratory Notebook C4546 (p 78-80) (NMR).
3. Laboratory Notebook C4761 (GLC and HPLC).

Appendix 1

PROTOCOL - Daphnia Toxicity Testing
on 3-phenoxy benzyl alcohol and
permethrin mono-acid

STUDY NO. PP557/CN/01
RESPONSIBLE SCIENTIST:
MR W WILKINSON
ISSUED: SEPT 78

The toxicity to first instar Daphnia magna will be tested on two degradation products of permethrin; 3-phenoxybenzylalcohol and 3-(2,2 dichlorovinyl)2,2 dimethyl cyclopropane carboxylic acid. Two tests will be carried out on each chemical with three replicates per concentration. The concentration range will be determined by a preliminary range finding test.

At each concentration one solution will be prepared, using hard reconstituted water, to provide three replicates of 200 ml in a 250 ml beaker. There will be a reconstituted water control. Ten Daphnia 12 ± 12 hours old, will be added to each beaker which will be placed in a water-bath at 17°C ± 1°C under fluorescent lighting (30 watt warm white tubes) on a 16 hour day. The Daphnia will not be fed during the test.

The effect will be assessed after 3, 6, 24 and 48 hours. Daphnia are recorded as affected if they are immobilized or showing only minor movements of their appendages. At the beginning and end of each test pH and dissolved oxygen will be measured in the lowest middle and highest concentrations and the control.

The EC₅₀ and its 95% confidence limits will be calculated statistically using weighted linear regression of log concentration plotted against logit transformation of the Daphnia response.

Data will be recorded on dated loose leaf sheets identified by the study number.

The culture method for the Daphnia is described in TMJ 1405A

STUDY AUTHORISATION

Responsible Scientist: W Wilkinson W. Wilkinson date 18. Sep. 78

Ecology Section Manager: D Riley D. Riley date 18. Sept 1978

Appendix 2

Toxicity of permethrin acid to Daphnia magna

Each replicate contained 10 Daphnia, the figure is the number affected.

Test I : 19/9/1978												
Time	3 hour			6 hour			24 hour			48 hour		
Replicate	a	b	c	a	b	c	a	b	c	a	b	c
mg/l concentration												
400	10	10	10	10	10	10	10	10	10	10	10	10
200	0	0	0	0	0	0	6	5	7	9	10	10
100	0	0	0	0	0	0	1	0	2	3	4	2
50	0	0	0	0	0	0	0	0	0	4	4	6
25	0	0	0	0	0	0	0	0	0	0	0	0
12.5	0	0	0	0	0	0	0	0	0	0	0	1
6.25	0	0	0	0	0	0	0	0	0	0	0	2
3.125	0	0	0	0	0	0	1	1	0	2	1	0
1.56	0	0	0	0	0	0	0	0	0	0	1	0
control	1	0	0	1	0	0	1	1	1	1	1	2
Test II : 20/9/1978												
mg/l												
400	10	10	10	10	10	10	10	10	10	10	10	10
200	0	0	0	0	0	1	3	4	4	8	3	6
100	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
12.5	0	0	0	0	0	0	0	0	0	0	0	0
6.25	0	0	0	0	0	0	0	0	0	0	0	0
3.125	0	0	0	0	0	0	0	0	0	0	0	0
1.56	0	0	0	0	0	0	0	0	0	0	0	0
control	0	0	0	0	0	0	0	0	0	0	0	0
	Dissolved oxygen %					pH						
	TEST I		TEST II			TEST I		TEST II				
	0 hr	48 hr	0 hr	48 hr		0 hr	48 hr	0 hr	48 hr			
400	84	89	92	86		6.7	7.8	6.8	7.4			
25	91	89	92	90		8.1	8.1	8.0	8.1			
1.56	91	89	92	92		8.1	8.1	8.1	8.1			
control	90	89	92	92		8.1	8.1	8.1	8.1			

Appendix 3

Nominal and analysed concentrations of permethrin acid in test solutions.

Nominal concentration mg/l	Analysed concentration mg/l	
	Test I	Test II
400	439	406
200	194	215
100	92	101
50	54	51
25	27	25
12.5	12.8	11.7

On analysis the mean cis:trans ratio was 39:61

Appendix 4

Toxicity of 3-phenoxybenzyl alcohol to Daphnia magna
 Each replicate contained 10 Daphnia, the figure is the number affected.

Test II													20/9/1978		
Time	3 hour			6 hour			24 hour			48 hour					
Replicate	a	b	c	a	b	c	a	b	c	a	b	c			
mg/l concentration															
400	10	10	10	10	10	10	10	10	10	10	10	10			
200	10	10	10	10	10	10	10	10	10	10	10	10			
100	10	10	10	10	10	10	10	10	10	10	10	10			
50	10	10	10	10	10	10	10	10	10	10	10	10			
25	6	7	6	9	8	6	9	8	6	8	9	9			
12.5	0	0	0	0	0	0	0	0	0	2	1	1			
6.25	0	0	0	0	0	0	0	0	2	3	0	3			
3.125	0	0	0	0	0	0	0	0	2	1	0	6			
1.56	0	0	0	0	0	0	0	0	0	0	1	1			
control	0	0	0	0	0	0	0	0	0	0	0	1			
Test III													21/9/1978		
400	10	10	10	10	10	10	10	10	10	10	10	10			
200	10	10	10	10	10	10	10	10	10	10	10	10			
100	10	10	10	10	10	10	10	10	10	10	10	10			
50	10	10	10	10	10	10	10	10	10	10	10	10			
25	5	4	5	5	4	5	5	4	5	8	8	8			
12.5	0	0	0	0	0	0	1	0	2	1	1	4			
6.25	2	0	0	6	0	1	10	1	1	10	3	3			
3.125	0	0	0	0	0	0	3	0	2	4	3	2			
1.56	0	1	0	0	1	0	6	1	1	7	1	6			
control	0	0	0	0	0	0	0	0	0	0	0	1			
Test IV													26/9/78		
200	10	10	10	10	10	10	10	10	10	10	10	10			
100	10	10	10	10	10	10	10	10	10	10	10	10			
50	10	10	10	10	10	10	10	10	10	10	10	10			
25	1	1	0	1	6	0	6	8	8	9	8	8			
12.5	0	0	0	0	0	0	2	0	6	6	4	6			
6.25	0	0	0	0	0	0	1	0	0	4	1	1			
3.125	0	0	0	0	0	0	1	0	2	4	3	2			
1.56	0	0	0	0	0	0	1	0	1	1	0	1			
control	0	0	0	0	0	0	1	0	0	1	0	0			

Appendix 4

	Dissolved Oxygen %		pH	
	0 hr	48 hr	0 hr	48 hr
Test II				
400 mg/l	90	93		
25 mg/l	91	90	8.1	8.2
1.56 mg/l	93	93	8.1	8.1
Solvent control	91	93	8.1	8.2
			8.1	8.2
Test III				
400 mg/l	89	94		
25 mg/l	93	93	8.2	8.2
1.56 mg/l	93	94	8.1	8.2
Solvent control	94	94	8.1	8.1
			8.1	8.1
Test IV				
200 mg/l	95	95		
25 mg/l	95	95	8.2	8.2
1.56 mg/l	94	95	8.2	8.2
Solvent control	93	96	8.2	8.1
			8.1	8.0

Appendix 5

Nominal and analysed concentrations of 3-PBA in test solutions

Nominal Concentrations mg/l	Analysed concentrations mg/l		
	Test II	Test III	Test IV
400	412	406	-
200	205	204	197
100	102	94	101
50	53	47	54
25	27	26	24
12.5	9.6	11.4	12.9
6.25	5.2	6.1	7.2
3.125	2.5	2.3	3.1
1.56	1.7	1.3	1.6

ACUTE TOXICITY

TEST SUBSTANCE

- Identity: **MPB alcohol (FMC 30953)**
- Lot No.: **P-24**
- Physical description: **Clear amber liquid**

METHOD

- Method/guideline followed (experimental/calculated): **None followed, similar to OPPTS 870.13.**
- Type: **Acute Inhalation toxicity**
- GLP: **No**
- Year: **1978**
- Species/Strain: **Sprague-Dawley Rat**
- Sex: **Male and Female**
- No. of animals per sex per dose: **5**
- Vehicle: **None**
- Route of administration (if inhalation - aerosol, vapor, gas, particulate): **Aerosol**

 Remarks field for Test Conditions. Detail and discuss any significant protocol deviations and detail differences from the guideline followed including the following as appropriate:

The test material was placed in a 1L, three-neck flask fitted with a Laskin nebulizer. Dry air (flow rate=9L/min) was passed through the nebulizer. The resulting aerosol was directed into a glass exposure chamber. The test animals were whole body exposed to the test material for four hours, removed from the chamber and observed for clinical signs every 15 minutes for the first hour, hourly for the rest of the exposure period. After four hours of exposure, the animals were removed from the chamber and clinical signs were checked hourly for four hours, and daily thereafter for 14 days. Individual body weights were recorded on Day 0, 1, 2, 4, 7, and 14. All animals were sacrificed on day 14 and gross necropsies were performed.

- Age: **None indicated, body weight ranged from 203 to 278 grams.**
- Doses: **2.27 mg/L**
- Doses per time period: **One**
- Volume administered or concentration **2.27 mg/L**
- Post dose observation period: **14 days**
- Exposure duration (for inhalation studies): **4 hours**

RESULTS

- Value [LD50 or LC50] with confidence limits if calculated: **LC50>2.27 mg/L**
- Number of deaths at each dose level: **No deaths reported.**

 Remarks field for Results. Describe additional information that may be needed to

adequately assess data for reliability and use, including the following, if available:

- Time of death **No deaths**
- clinical signs: **During exposure: 10/10 animals labored breathing was observed. Other clinical signs observed during exposure were red and mucoid discharge, excessive salivation, and excessive lacrimation (no onset time or duration indicated).**

Post-exposure clinical signs included: Mucoid nasal discharge (5/10), red nasal discharge (6/10), dry rales (4/10), and excessive salivation (2/10). These signs fluctuated throughout the four hour post-exposure period. Excessive salivation disappeared at one hour post-exposure, and moist rales was observed at one through three hour post-exposure.

During the 14-day observation period the following signs were observed: mucoid nasal discharge (5/10), red nasal discharge (3/10), dry rales (9/10), moist rales (2/10), and excessive lacrimation (1/10).

- Necropsy findings: **lung discoloration in 5/10 animals.**

CONCLUSIONS

A four hour exposure to an aerosol of FMC 30953, at a nominal concentration of 2.27 mg/L, did not produce mortality; therefore, the LC50>2.27 mg/L.

 Remarks field with the ability to identify source of comment, i.e. author and/or submitter

DATA QUALITY

- Reliabilities (Klimisch Code 2): **Reliable with restrictions**

 **Although not carried out under GLP guidelines, the study demonstrated no mortality at a dose above the OPPTS 870.13 guideline specified limit dose of 2 mg/L.**

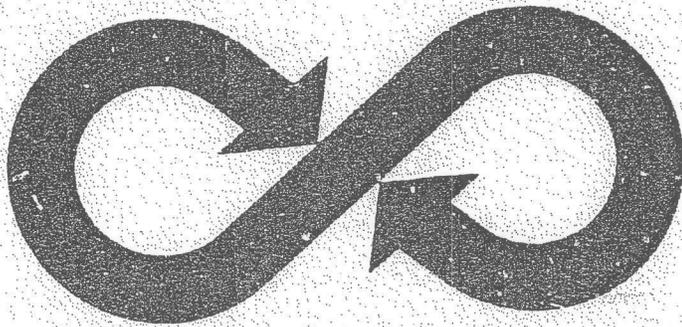
REFERENCES (Free Text)

An Acute Inhalation Toxicity Study of FMC 30953 in the Rat, Bio/dynamics Inc., Project No. 77-1972, Study No. NCT572.04-01, May 4, 1978.

OTHER

- Last changed (administrative field for updating)
- Order number for sorting (administrative field)

 Remarks field for General Remarks (Use for any other comments necessary for clarification.)



Bio/dynamics Inc.

Division of Biology and Safety Evaluation

PROJECT NO. 77-1972

NCT572-04-01

AN ACUTE INHALATION TOXICITY STUDY
OF FMC 30953 IN THE RAT

Submitted to: FMC Corporation
Middleport, New York 14105

Attention: Dr. Jerry Schoenig

Date: May 4, 1978

77-1972

I. GENERAL

An experiment was performed on the acute inhalation toxicity of FMC 30953 in the rat. The test material, received from FMC Corporation, was labeled, "FMC Corporation, FMC 30953, Hardwicke Lot P-24," and was in the form of a clear, amber liquid.

II. EXPERIMENTAL

The test material was placed in a 1000-milliliter, three-neck flask fitted with a Laskin nebulizer. Dry air, at a flow rate of 9.0 liters per minute, was passed through the nebulizer. The resulting aerosol was directed into a 26.5-liter, glass exposure chamber containing the test animals for a period of 4.0 hours. The flask containing the test material was weighed before and after the exposure period to determine the nominal exposure concentration.

The test animals consisted of five male and five female Sprague-Dawley rats, weighing from 203 to 278 grams. The animals were observed for abnormal signs at 15-minute intervals during the first hour of the exposure period, hourly throughout the remainder of the exposure, upon removal from the exposure chamber, hourly post-exposure for four hours, and daily thereafter for 14 days.

Individual body weights were recorded on Day 0 (prior to exposure), Day 1, Day 2, Day 4, Day 7 and Day 14 (terminus). On Day 14, all animals were sacrificed (ethyl ether) and gross necropsy examinations were performed.

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III. RESULTS AND DISCUSSION

During the exposure period, a total of 4.90 grams of the test material was delivered, yielding a nominal exposure concentration of 2.27 milligrams per liter.

Labored breathing was observed in all test animals throughout the exposure period. Other signs observed in the test animals during the exposure were red and mucoid nasal discharge, excessive salivation, and excessive lacrimation.

Upon removal from the exposure chamber, abnormal signs observed in the animals were mucoid nasal discharge (five of ten animals), red nasal discharge (six of ten animals), dry rales (four of ten animals), and excessive salivation (two of ten animals). These signs fluctuated throughout the four-hour post-exposure period. Excessive salivation disappeared at one hour post-exposure. Moist rales was observed at one through three hours post-exposure.

Abnormalities observed during the 14-day observation period were mucoid nasal discharge (five of ten rats), red nasal discharge (three of ten rats), dry rales (nine of ten rats), moist rales (two of ten rats), and excessive lacrimation (one of ten rats).

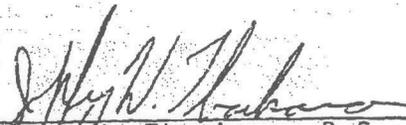
Necropsy examinations revealed lung discoloration in five of ten test animals. Individual necropsy observations are presented in Table I.

Body weights were considered normal and are presented, with the necropsy observations, in Table I.

77-1972

IV. CONCLUSION

A 4.0-hour exposure to an aerosol of FMC 30953, at a nominal exposure concentration of 2.27 milligrams per liter, did not produce mortality in rats so exposed. The test material exposure did produce signs of immediate toxicity and some possible residual toxicity in the test animals.



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Table I
 An Acute Inhalation Toxicity Study
 of FMC 30953 in the Rat
 Individual Body Weights and Necropsy Observations

Animal Number	Sex	Body Weights (g)							Necropsy Observations*
		Day 0	Day 1	Day 2	Day 4	Day 7	Day 14		
30	M	278	257	268	283	302	328	N.O.A.	
31	M	242	232	240	250	268	297	B. Lobes of lungs mottled light and dark red.	
32	M	239	219	219	233	256	290	B. Lobes of lungs mottled light and dark red.	
33	M	264	252	257	268	286	303	N.O.A.	
34	M	268	257	262	270	290	325	N.O.A.	
40	F	206	198	203	210	223	221	B. Lobes of lungs mottled light and dark red.	
41	F	213	207	211	219	225	231	N.O.A.	
42	F	203	198	198	204	216	225	N.O.A.	
43	F	216	209	215	212	224	226	B. Lobes of lungs mottled light and dark red.	
44	F	233	226	221	229	247	260	B. Lobes of lungs mottled light and dark red.	

* N.O.A. - no observed abnormalities.

Key: R = right; L = left; B = bilateral.

ACUTE TOXICITY TO FISH

Test Substance: M-Phenoxybenzyl Alcohol (MPBA); CAS# 13826-35-2

Method / Guideline: U.S. EPA (1975) Methods for Acute Toxicity with Fish, Macroinvertebrates and Amphibians

Species / Strain / Supplier: Sheepshead minnow (*Cyprinodon variegatus*) / unknown / EG&G Bionomics, Inc.

Test Concentrations: 1.8, 3.2, 4.9, 6.5 and 8.7 mg/L (nominal)

Exposure Period: 96 hours (static conditions)

Analytical Monitoring: No

GLP: No

Year: 1975

Method: Sheepshead minnows (*Cyprinodon variegatus*), were exposed to five nominal test concentrations for 96 hours under static conditions at Bionomics – EG&G, Inc., in Pensacola, Florida, October 1975. Nominal concentrations of M-Phenoxybenzyl Alcohol (MPBA) were 0 (control), 1.8, 3.2, 4.9, 6.5 and 8.7 mg/L. The results of the study were based on nominal concentrations.

MPBA, dissolved in reagent grade acetone, was pipetted into sea water to obtain the desired test concentrations. The solvent concentration in the control test solution (without test material) was equal to the solvent concentration in the highest treatment group.

Sheepshead minnows used in the test were obtained from stocked ponds at EG&G Bionomics, Inc. Marine Research Laboratory and were acclimated to test conditions for a minimum of 7 days, prior to testing. Mortality during the acclimation period was less than 3%. All organisms appeared to be in excellent condition at test initiation. One replicate with ten minnows (juveniles – ranging from 10-15 mm in standard length), for each treatment and control group, were exposed for 96 hours. Aeration was not added during the test. The test was performed in 19-liter glass aquaria that contained 15 liters of test solution. The test was performed under static conditions at $19 \pm 1^\circ\text{C}$. Salinity ranged from 17-22. pH ranged from 7.5 and 8.5 for each treatment group and control. Observations were conducted at 24, 48 and 96 hours.

Based on the results of the study at test termination, a 96-hour LC_{50} was calculated. The test concentrations were converted to logarithms and corresponding percentages of fish mortality were converted to probits. The LC_{50} value was then calculated by linear regression.

Results: After 96-hours, the percent mortality in the 1.8, 3.2, 4.9, 6.5 and 8.7 mg/L treatment groups was 0, 70, 100, 100 and 100%, respectively. There were no mortalities in the control throughout the entire exposure.

96-hour $\text{LC}_{50} = 2.9$ mg/L with 95% confidence limits of 1.7 and 5.0 mg/L (based on nominal concentrations)

Data Quality: Code 2e

References: Bionomics – EG&G, Inc. Acute toxicity of nine compounds to sheepshead minnows, *Cyprinodon variegatus*. FMC Study Number NCT 609.61-01. (1975)

Acute toxicity of nine compounds to
sheepshead minnows (Cyprinodon
variegatus)

NCI 6.9.61

Toxicity Test Report
Submitted to
FMC Corporation
Agricultural Chemical Division
Middleport, New York

CONFIDENTIAL

Bionomics - EG&G, Inc.
Marine Research Laboratory
Route 6, Box 1002
Pensacola, FL 32507
October 1975

Marine toxicity tests were performed to determine the effect of nine compounds on sheepshead minnows, Cyprinodon variegatus. The criterion for effect was death. Results of the tests are reported as 96-hour LC50's (the concentrations of the test materials which were lethal to 50% of the test animals).

MATERIALS AND METHODS

Test materials

Approximately 25-gram (g) samples of each material were received in separate glass bottles. There were eight liquid samples labeled FMC 30953, MR R861; FMC 30061, MR R900; FMC 30063, MR R902; FMC 30075, MR R879; FMC 30077, MR R903; FMC 30078, MR R981; FMC 30080, MR R904; and FMC 33297 Technical, MR R176, C6699-65, 8/4/75. One sample, FMC 30062, MR R901, was a powder. Test concentrations of each compound are reported here as microliters (μl) or milligrams (mg) of material per liter (l) of sea water or parts per million (ppm) and as nanoliters (nl) of material per l of sea water or parts per billion (ppb).

Test animals

The sheepshead minnows, 10-15 millimeters (mm) standard length, were collected from stocked ponds at Bionomics Marine Research Laboratory and were acclimated to laboratory conditions for a minimum of 7 days prior to testing. Mortality was <3% during the acclimation period. The animals appeared to be in excellent condition at initiation of the tests.

Test conditions

Methods for the toxicity tests were those described in "Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and

Amphibians," (U.S. Environmental Protection Agency, 1975), except as noted. All tests were conducted in 19-liter uncovered jars which contained 15 % of natural, filtered (10 micrometers) sea water. Salinity ranged from 17-22 parts per thousand (‰) during the period of testing. Temperature was maintained at $19 \pm 1^\circ\text{C}$. Initial pH was 8 ± 0.5 for all test concentrations and controls. Each test jar contained 10 fish. There was no aeration.

Sheepshead minnows were exposed to five test concentrations of compounds FMC 30953, 30061, 30062, 30078, 30080, and 33297 and to concentrations up to 100 ppm of compounds FMC 30063, 30075, and 30077. Each test material, dissolved in reagent grade acetone, was pipetted into sea water in the appropriate test containers to obtain the desired concentrations. Control jars received volumes of acetone equal to those added to the highest test concentrations of their respective series but no test material.

Statistical analyses

Based on the results of the tests, 96-hour LC50's were calculated. The test concentrations were converted to logarithms and corresponding percentages of dead fish were converted to probits. The LC50's were then calculated by linear regression.

RESULTS AND DISCUSSION

The 96-hour LC50's for the nine compounds tested with sheepshead minnows in static, unaerated sea water ranged from the low ppb's for FMC 33297 to >100 ppm for FMC 30063, 30075, and 30077 (Tables 1-7).

Sheepshead minnows were not apparently affected after 96 hours of exposure to compounds FMC 30063, 30075, and 30077 at test concen-

trations ≤ 100 ppm. No tests were conducted at concentrations > 100 ppm because such concentrations would have exceeded the solubility of the compounds in sea water (personal communication, Jack R. Graham, FMC).

Dissolved oxygen (DO) remained $> 80\%$ of saturation in all test concentrations and controls for the duration of all the tests.

Final pH was 8 ± 0.5 for all test concentrations and controls.

TABLE 1. Acute toxicities of nine compounds to sheeps-head minnows (*Cyprinodon variegatus*). Fish were exposed for 96 hours in static, unaerated sea water. Salinity ranged from 17-22 ‰. Temperature was maintained at 19±1°C.

Test material	Calculated 96-hour LC50 (μl or mg/l;ppm)	95% confidence limits (μl or mg/l;ppm)
FMC 30953	2.9	1.7 - 5.0
FMC 30061	3.4	2.4 - 5.0
FMC 30062	.83	49 - 141
FMC 30063	>100	-
FMC 30075	>100	-
FMC 30077	>100	-
FMC 30078	0.60	0.32 - 1.1
FMC 30080	32	22 - 47
FMC 33297	0.0047	0.0035 - 0.0062

TABLE 2. Mortality of sheepshead minnows (*Cyprinodon variegatus*) exposed to FMC 30953 for 96 hours in static, unaerated sea water. Salinity was 22 ‰ and temperature, 19±1°C.

Nominal concentration (μ l/l;ppm)	Mortality (%)		
	24 h	48 h	96 h
Control	0	0	0
1.8	0	0	0
3.2	20	50	70
4.9	70	100	100
6.5	100	100	100
8.7	100	100	100

TABLE 3. Mortality of sheepshead minnows (Cyprinodon variegatus) exposed to FMC 30061 for 96 hours in static, unaerated sea water. Salinity was 18 ‰ and temperature, 19±1°C.

Nominal concentration ($\mu\text{g}/\text{L}$; ppm)	Mortality (%)		
	24 h	48 h	96 h
Control	0	0	0
1.4	0	0	0
2.8	0	10	10
5.6	0	40	90
7.5	10	60	100
8.7	80	100	100

TABLE 4. Mortality of sheepshead minnows (Cyprinodon variegatus) exposed to FMC 30062 for 96 hours in static, unaerated sea water. Salinity was 17 ‰ and temperature, 19±1°C.

Nominal concentration (mg/L; ppm)	Mortality (%)		
	24 h	48 h	96 h
Control	0	0	0
18	0	0	0
32	0	0	0
56	0	0	0
75	0	30	30
100	30	40	90

TABLE 5. Mortality of sheepshead minnows (Cyprinodon variegatus) exposed to FMC 30078 for 96 hours in static, un-aerated sea water. Salinity was 18 ‰ and temperature, 19±1°C.

Nominal concentration ($\mu\text{l/l}$; ppm)	Mortality (%)		
	24 h	48 h	96 h
Control	0	0	0
0.10	0	0	0
0.27	10	10	10
0.49	10	10	10
0.75	10	60	90
1.0	100	100	100

TABLE 6. Mortality of sheepshead minnows (Cyprinodon variegatus) exposed to FMC 30080 for 96 hours in static, unaerated sea water. Salinity was 22 ‰ and temperature, 19±1°C.

Nominal concentration ($\mu\text{g}/\text{L}$; ppm)	Mortality (%)		
	24 h	48 h	96 h
Control	0	0	0
16	0	0	0
28	10	20	60
49	0	30	80
75	0	50	100
100	0	40	100

TABLE 7. Mortality of sheepshead minnow (*Cyprinodon variegatus*) exposed to FMC 33297. Technical for 96 hours in static, unaerated sea water. Salinity was 18 ‰ and temperature, 19±1°C.

Nominal concentration (ng/l;ppb)	Mortality (%)		
	24 h	48 h	96 h
Control	0	0	0
2.1	0	0	0
2.7	10	10	10
4.9	20	40	40
7.5	40	70	80
10.0	100	100	100

SUBMITTED BY:

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October 1975

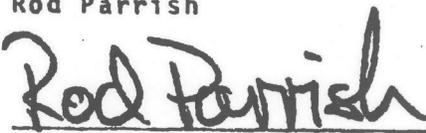
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