File

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

NOV 15 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Sulfentrazone (129081): review of acute oyster toxicity test (72-3b); D228154; S508577; Case 044863

FROM: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

TO: Joanne Miller/Dianne Morgan
Product Manager 23
Registration Division (7505C)

EEB has completed the review of the acute oyster toxicity test (MRID 440549-01) submitted by FMC Corporation, Princeton, NJ, to support registration of the new chemical sulfentrazone. The DER is attached. The study citation and summary of results are provided below.

Cunningham, F.J. 1996. Sulfentrazone technical: acute effect on new shell growth of the eastern oyster (*Crassostrea virginica*). Conducted by Toxikon Environmental Sciences, Jupiter, FL. Lab. Report ID J9601008.

Gdlne No.	Species	EC50 (ppm ai)	MRID No.	Classification
72-3b	Eastern oyster (*Crassostrea virginica*)	>10.5	440549-01	supplemental

In a memo dated 10/23/96, EFGWB validated the analytical method used to determine sulfentrazone concentrations in this study. The oyster toxicity study is supplemental, however, because an EC50 value was not established nor was it determined to exceed 100 ppm. The study should be repeated at higher test concentrations. However, because the mysid shrimp is more sensitive (LC50 = 1 ppm) than the oyster, the value of a repeat study is low.

Contact Bill Erickson at 305-6212 or Harry Craven at 305-5320 if you have any questions about this review.

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DP Barcode : D228154
PC Code No : 129081
EEB Out :

To: Joanne Miller/Dianne Morgan
Product Manager 23
Registration Division (7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 279-GRUO Sulfentrazone Technical
Chemical Name : Sulfentrazone
Type Product : Herbicide
Product Name :
Company Name : FMC Corporation, Princeton, NJ
Purpose : Acute mollusk toxicity test (72-3b) to support registration of new chemical
Action Code : 101 Date Due : 11/19/96
Reviewer : William Erickson Date In : 07/24/96

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

Gdln No.	MRID No.	Cat.	Gdln No.	MRID No.	Cat.	Gdln No.	MRID No.	Cat.
71-1(a)			72-2(a)			72-7(a)		
71-1(b)			72-2(b)			72-7(b)		
71-2(a)			72-3(a)			122-1(a)		
71-2(b)			72-3(b)	440549-01	S	122-1(b)		
71-3			72-3(c)			122-2		
71-4(a)			72-3(d)			123-1(a)		
71-4(b)			72-3(e)			123-1(b)		
71-5(a)			72-3(f)			123-2		
71-5(b)			72-4(a)			124-1		
72-1(a)			72-4(b)			124-2		
72-1(b)			72-5			141-1		
72-1(c)			72-6			141-2		
72-1(d)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

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DATA EVALUATION RECORD
§ 72-3(B) -- ACUTE EC50 TEST WITH AN ESTUARINE/MARINE MOLLUSK
SHELL DEPOSITION STUDY

1. **CHEMICAL:** Sulfentrazone (129081)

2. **TEST MATERIAL:** Sulfentrazone technical; 92.5%

3. **CITATION:**

Authors:	Cunningham, F.J.
Title:	Sulfentrazone technical: acute effect on new shell growth of the eastern oyster (*Crassostrea virginica*)
Date:	1996
Laboratory:	Toxikon Environmental Sciences, Jupiter, FL
Lab. Report ID:	J9601008
Sponsor:	FMC Corporation, Princeton, NJ
MRID No.:	440549-01

4. **REVIEWED BY:**

William Erickson
Biologist
EEB/EFED/EPA

Signature: W. Erickson
Date: 10/28/96

5. **APPROVED BY:**

Harry Craven
Section Head 4
EEB/EFED/EPA

Signature: Harry Craven
Date: 10/7/96

6. **STUDY PARAMETERS/RESULTS SYNOPSIS:**

Age/Size of Test Organism:	juveniles
Test Duration:	96 hours
Study Method:	flow-through
Type of Concentrations:	mean measured
EC50:	>10.5 ppm ai
NOEC:	10.5 ppm ai

7. **CONCLUSIONS:** The study is scientifically sound but does not satisfy the guideline requirement (72-3b) for an acute toxicity test with an estuarine/marine mollusk.

8. **ADEQUACY OF THE STUDY:** Supplemental; an EC50 value was not established nor was it determined that the EC50 value exceeds 100 ppm ai. The study should be conducted at higher test concentrations.

9. **GUIDELINE DEVIATIONS:** The following deviations occurred:

The acclimation period was only 4 days; mollusks should be acclimated at least 10 days prior to testing.

10. **SUBMISSION PURPOSE:** New chemical.

11. **MATERIALS AND METHODS:**

Test Organisms:

Guideline Criteria	Reported Information
Species Preferred species are the Pacific oyster (*Crassostrea gigas*) and the Eastern oyster (*Crassostrea virginica*)	*Crassostrea virginica*
Mean valve height 25 - 50 mm along the long axis	29 ± 3.9 mm
Supplier	Harbor Branch Oceanographic Institute, Ft. Pierce, FL
Are all oysters from same source?	Yes
Are all oysters from the same year class?	Yes

Source/Acclimation:

Guideline Criteria	Reported Information
Acclimation Period Minimum 10 days	4 days
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
Amount of peripheral shell growth removed prior to testing	2 - 5 mm

Guideline Criteria	Reported Information
Feeding during the acclimation Must be fed to avoid stress.	Fed algae diet continuously during the test
Pretest Mortality <3% mortality 48 hours prior to testing	None reported

Test System:

Guideline Criteria	Reported Information
Source of dilution water Natural unfiltered seawater from an uncontaminated source.	Natural unfiltered saltwater from the Jupiter River
Does water support test animals without observable signs of stress?	Yes
Salinity 30-34 ‰ (parts per thousand) salinity, weekly range < 6 ‰	32 - 34 ‰
Water Temperature 15°-30° C, consistent in all test vessels	25 ± 1°C
pH	7.8 - 8.0
Dissolved Oxygen ≥ 60% throughout	Yes
Total Organic Carbon <20 mg/L for shell deposition tests; <5 mg/L for other tests	1.11 mg/L
Test Aquaria Should be constructed of glass or stainless steel.	11.4-l glass aquaria

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Guideline Criteria	Reported Information
Type of Dilution System Must provide reproducible supply of toxicant	The exposure system consisted of a glass head box fitted with glass tubing calibrated to provide saltwater to each test chamber at a rate of 400 ± 20 ml/min. Test concentrations were prepared in glass mixing boxes positioned under the dilution water head box on magnetic stirrers. Sulfentrazone was delivered from 60-ml syringes.
Flow rate Consistent flow rate	77 vol/24 hours
Was the loading of organism such that each individual sits on the bottom with water flowing freely around it?	Yes; 1.5 g/l instantaneous loading
Photoperiod 16 hours light, 8 hours dark	16 hours light, 8 hours dark
Solvent Not to exceed 0.5 ml/L	DMF (0.1 ml/L)

Test Design:

Guideline Criteria	Reported Information
Range Finding Test If EC_{50} >100 mg/L with 30 oysters, no definitive test is required.	Nominal concentrations were 0.1, 1.0, 10.0, and 25.0 mg ai/l. After 96 h, shell growth was reduced 15% at 1.0 mg ai/l and 19% at 25.0 mg ai/l but increased 15-19% at 0.1-10.0 mg ai/l
Nominal Concentrations of Definitive Test Control & 5 treatment levels; each conc. should be 60% of the next highest conc.; concentrations should be in a geometric series	1.30, 2.16, 3.60, 6.00, and 10.0 mg ai/L
Number of Test Organisms Minimum 20 individual per test level and in each control	20

Guideline Criteria	Reported Information
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured hourly in at least one chamber 2. DO and pH Measured at beginning of test and every 48 h in the high, medium, and low doses and in the control	yes measured daily in all test solutions
Was chemical analysis performed to determine the concentration of the test material at the beginning and end of the test? (Optional)	Yes (see comment below)

Comments: EFGWB/EFED (10/23/96) reviewed the analytical method used for determining the sulfentrazone concentrations in this study and found it to be valid.

12. **REPORTED RESULTS:**

General Results:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Control Mortality Not more than 10% of control organisms may die or show abnormal behavior.	None
Control Shell Deposition Must be at least 2 mm.	Yes
Recovery of Chemical	97 - 128 %
Raw data included?	Yes

Guideline Criteria	Reported Information
Signs of toxicity (if any) were described?	None reported

Shell Growth:

Concentration (ppm)		Number Per Level	Number Dead	Mean Shell Deposition (mm)	Mean Percent Reduction
Nominal	Measured				
Control	--	20	0	4.59	--
Solvent Control	--	20	0	5.01	--
1.30	1.26	20	0	5.36	+
2.16	2.22	20	0	5.43	+
3.60	3.63	20	0	5.23	+
6.00	7.65	20	0	4.05	19.2
10.0	10.5	20	0	4.73	5.6

* compared to solvent control

Statistical Results:

Method: Visual inspection of data
96-hr EC50: >10.5 ppm ai
NOEC: 10.5 ppm ai

13. **VERIFICATION OF STATISTICAL RESULTS:** Visual inspection of the data confirms that the EC50 value is >10.5 mg ai/l. Based on the Williams' Test (results attached), the NOEC is 10.5 mg ai/l.

14. **REVIEWER'S COMMENTS:** The study is scientifically sound but does not satisfy the guideline requirement (72-3b) for an acute toxicity test with an estuarine/marine mollusk. An EC50 value was not established nor was it determined that the EC50 value exceeds 100 ppm ai. The study should be conducted at higher test concentrations.

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Oyster Shell Growth
File: a:oyster.dat Transform: NO TRANSFORMATION

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 1 of 2

GRP	IDENTIFICATION	N	MIN	MAX	MEAN
1	Solvent Control	20	2.800	8.600	5.010
2	1.26 ppm	20	3.000	8.400	5.360
3	2.22 ppm	20	3.000	7.300	5.425
4	3.63 ppm	20	3.000	8.500	5.225
5	7.65 ppm	20	1.700	7.800	4.050
6	10.5 ppm	20	2.900	9.000	4.730

Oyster Shell Growth
File: a:oyster.dat Transform: NO TRANSFORMATION

SUMMARY STATISTICS ON TRANSFORMED DATA TABLE 2 of 2

GRP	IDENTIFICATION	VARIANCE	SD	SEM
1	Solvent Control	2.062	1.436	0.321
2	1.26 ppm	2.517	1.587	0.355
3	2.22 ppm	1.263	1.124	0.251
4	3.63 ppm	2.087	1.445	0.323
5	7.65 ppm	3.003	1.733	0.387
6	10.5 ppm	1.854	1.362	0.304

Oyster Shell Growth
File: a:oyster.dat Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Solvent Control	20	5.010	5.010	5.265
2	1.26 ppm	20	5.360	5.360	5.265
3	2.22 ppm	20	5.425	5.425	5.265
4	3.63 ppm	20	5.225	5.225	5.225
5	7.65 ppm	20	4.050	4.050	4.390
6	10.5 ppm	20	4.730	4.730	4.390

Oyster Shell Growth
File: a:oyster.dat Transform: NO TRANSFORMATION

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. WILLIAMS	SIG P=.05	TABLE WILLIAMS	DEGREES OF FREEDOM
Solvent Control	5.265				
1.26 ppm	5.265	0.552		1.67	k= 1, v=114
2.22 ppm	5.265	0.552		1.75	k= 2, v=114
3.63 ppm	5.225	0.466		1.77	k= 3, v=114
7.65 ppm	4.390	1.343		1.78	k= 4, v=114
10.5 ppm	4.390	1.343		1.79	k= 5, v=114

s = 1.460

Note: df used for table values are approximate when v > 20.