DATA EVALUATION RECORD
• 72-3(B) -- ACUTE EC_{50} TEST WITH AN ESTUARINE/MARINE MOLLUSK SHELL DEPOSITION STUDY

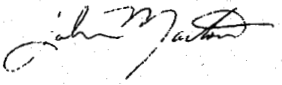
1. **CHEMICAL:** Pyrasulfotole — PC Code No.: 000692

2. **TEST MATERIAL:** AE 0317309 — Purity: 95.4%

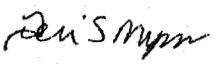
3. **CITATION**

Authors:	Dionne, Emily
Title:	AE 0317309-Acute Toxicity to Eastern Oysters (*Crassostrea virginica*) Under Flow-Through Conditions
Study Completion Date:	August 5, 2004
Laboratory:	Springborn Smithers Laboratories, Wareham, MA
Sponsor:	Bayer CropScience, Stilwell, KS
Laboratory Report ID:	13798.6159
MRID No.:	468017-22
DP Barcode:	D328639

4. **REVIEWED BY:** John Marton, Staff Scientist, Cambridge Environmental, Inc.

Signature:  **Date:** 5/05/06

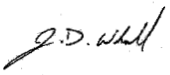
APPROVED BY: Teri S. Myers, Senior Scientist, Cambridge Environmental, Inc.

Signature:  **Date:** 5/21/06

5. **REVIEWED BY:** Melissa Panger, Biologist, OPP/EFED/ERB-4

Signature:  **Date:** 11/29/06

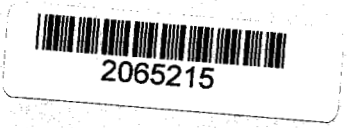
REVIEWED BY: J.D. Whall (Officer #1268), PMRA

Signature:  **Date:** 11/22/06

REVIEWED BY: David McAdam, Australian Government Department of the Environment and Heritage (DEH)

Signature:  **Date:** 11/06/06

6. **DISCLAIMER:** This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to shell deposition in oysters. It is not intended to prescribe conditions to any



external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study

7. STUDY PARAMETERS

Age or Size of Test Organism:	Mean Valve Height- 38±3 mm (N=30)
Definitive Test Duration:	96-hours
Study Method:	Flow-through
Type of Concentrations:	Mean-Measured

8. CONCLUSIONS:

Results Synopsis
EC_{50}: >104 mg ai/L 95% C.I.: N/A
NOAEC: 104 mg ai/L
Probit Slope: N/A

9. ADEQUACY OF THE STUDY

A. Classification: Acceptable

B. Rationale: The study is scientifically sound and the deviations from guideline requirements (see below) did not appear to affect the results of the study.

C. Repairability: N/A

10. BACKGROUND

11. GUIDELINE DEVIATIONS

1. Filtered sea water was used instead of the recommended unfiltered sea water.
2. The TOC of the dilution water was not reported.

12. SUBMISSION PURPOSE: This study was submitted for the purpose of new chemical registration for Pyrasulfotole (AE 0317309).

Physicochemical properties of Pyrasulfotole.

Parameter	Value	Comment
Molecular weight	362.3 g/mol	
Water Solubility (g/L) at 20°C	4.2 at pH 4 69.1 at pH 7 49.0 at pH 9	Very soluble
Vapor Pressure/Volatility	2.7×10^{-7} Pa at 20°C 6.8×10^{-7} Pa at 25°C	Non-volatile
UV Absorption	water $\lambda_{max} = 264$ 0.1M HCl $\lambda_{max} = 241$ 0.1M NaOH $\lambda_{max} = 216$	Not likely to undergo photolysis.
Pka	4.2 ± 0.15	
log K_{ow} at 23°C	0.276 at pH 4 -1.362 at pH 7 -1.58 at pH 9	Not likely to bioaccumulate
Stability of compound at room temperature, if provided		No significant degradation over 12 months at ambient temperatures.

Data obtained from pyrasulfatole chemistry review of Submission 2006-2445.

13. MATERIALS AND METHODS

A. 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	38 mm (SD 3 mm)
Supplier	Circle C Oysters, Ridge, Maryland
Are all oysters from same source?	Yes
Are all oysters from the same year class?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 10 days	14 days
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No. If any oyster appeared to be unsuitable for testing, it was immediately discarded.
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	3-5 mm

Guideline Criteria	Reported Information
Feeding during the acclimation Must be fed to avoid stress.	During acclimation, oysters were fed a supplementary algal diet of *Tetraselmus caulata*.
Pretest Mortality <3% mortality 48 hours prior to testing	No mortality was observed 7 days prior to test initiation.

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Natural unfiltered seawater from an uncontaminated source.	Filtered sea water from Cape Cop Canal, Bourne, MA was pumped from about 1-4 m offshore at a depth of approximately 0.5 m.
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 15E-30E C, consistent in all test vessels	19-22°C
pH	7.4-8.0
Dissolved Oxygen ∃ 60% throughout	Range: 7.0-7.3 mg/L (>60% DO saturation)
Total Organic Carbon	Not reported
Test Aquaria Should be constructed of glass or stainless steel.	Glass aquaria (49.5 x 25.5 x 29 cm) with an approximate fill volume of 18 L.
Type of Dilution System	Constant-flow serial diluter. The test solution

Guideline Criteria	Reported Information
Must provide reproducible supply of toxicant	was delivered from the stock tank directly into the diluter's splitter cell which served to divide the test solution into two separate replicates.
Flow rate Consistent flow rate	6 vol/24 hours
Was the loading of organism such that each individual sits on the bottom with water flowing freely around it?	Yes
Photoperiod 16 hours light, 8 hours dark	16 hours light, 8 hours dark; sudden transitions in light to dark, and vice versa, were avoided.
Solvents Not to exceed 0.5 ml/L	Solvent: N/A Maximum conc.: N/A; a solvent control was not used

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If EC_{50} >100 mg/L with 30 or more oysters, then no definitive test is required.	A range-finding study was conducted for 96-hours under flow-through conditions by exposing 20 oysters to concentrations of 0 (negative control) and 100 mg ai/L. At test termination, mean shell growth was 2.9 and 2.8 mm in the negative control and 100 mg ai/L treatment groups, respectively.
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	0 (negative control) and 100 mg ai/L; this study was conducted as a limit test note: 100 mg a.i./L reported as functional limit of solubility of test material in natural

Guideline Criteria	Reported Information
	seawater.
Number of Test Organisms Minimum 20 individual per test level and in each control	20 oysters/replicate, 2 replicates for the control and nominal 100 mg ai/L treatment group, 40 oysters total for the control and treatment group.
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	 Measured daily in each test vessel and continuously in Replicate B of the negative control. Measured daily in each test vessel.
Was chemical analysis performed to determine the concentration of the test material at the beginning and end of the test? (Optional)	Yes. Measured concentrations were 98 – 110 mg a.i./L; authors report mean measured value of 100 mg a.i./L, however data suggest mean actually 104 mg a.i./L

14. REPORTED RESULTS

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes

Guideline Criteria	Reported Information
Control Mortality Not more than 10% of control organisms may die or show abnormal behavior.	0%
Control Shell Deposition Must be at least 2 mm.	3.0 mm
Recovery of Chemical	98-100%
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Shell Growth

Concentration (ppm)		Number Per Level	Number Dead	Mean Shell Deposition (mm)	Mean Percent Reduction
Nominal	Mean Measured				
Negative Control	<3.2-3.6	40	0	3.0	--
100	104	40	0	2.5	17%

B. Statistical Results

Method: Due to the lack of a 50% reduction in mean shell deposition, the EC_{50} value was empirically estimated. The NOAEC value was determined by a t-Test comparing the treatment and control responses.

96-hr EC_{50}: >100 mg ai/L 95% C.I.: N/A
NOAEC: 100 mg ai/L
Probit Slope: N/A

15. VERIFICATION OF STATISTICAL RESULTS

Parameter	Result
Statistical Method for EC_{50}	Visual determination due to lack of ≥50% reduction of shell growth in the 104 mg ai/L treatment group relative to the negative control
EC_{50} (95% C.I.)	>104 mg ai/L
Probit Slope	N/A
Statistical Method for NOAEC	2 Sample t-Test Assuming Unequal Variances (Microsoft Excel)
NOAEC	104 mg ai/L

16. REVIEWERS' COMMENTS:

The reviewers' results were similar to those of the study author.

During the definitive test, oysters were fed a supplemental algal diet of *Tetraselmus macualata*. Concentrated algal suspensions of 180 mL (approximately 10^7 cells/mL) were added to each test vessel three times daily.

The sponsor-reported limit of solubility of the test material in sea water was 100 mg ai/L.

Quality control samples of 100 mg ai/L were analyzed concurrently with the test solutions and yielded percent recoveries of 96.4 and 98.0% of nominal at 0 and 96 hours, respectively.

According to the study report, the concentration of pyrasulfotole was 110 and 98 mg ac/L for 0 and 96 hours respectively, giving a mean concentration of 104 mg ac/L. Therefore, the reviewers consider the 96 h EC_{50} for shell growth to be > 104 mg ac/L and the NOEC = 104 mg ac/L.

The study shows that pyrasulfotole can be rated as practically non-toxic to Eastern oysters. The study is considered acceptable.

The in-life portion of the definitive test was conducted between May 28 and June 1, 2004.

APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

Mean Shell Deposition (mm); Control and 100 mg ai/L treatment data
t-Test: Two-Sample Assuming Unequal Variances

	Negative Control	*100 mg ai/L*
Mean	2.985	2.54
Variance	0.14045	0.0968
Observations	2	2
Hypothesized Mean Difference	0	
df	2	
t Stat	1.292027919	
P(T<=t) one-tail	**0.162752954**	
t Critical one-tail	2.91998558	
P(T<=t) two-tail	0.325505909	
t Critical two-tail	4.30265273	

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