

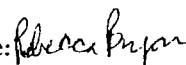
(10-31-03)

Data Evaluation Report on the Acute Toxicity of XDE-638 to Freshwater Invertebrates - *Planorbella trivolvis*
PMRA Submission Number {.....} EPA MRID Number 45831025

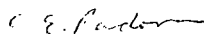
Data Requirement:
PMRA DATA CODE {.....}
EPA DP Barcode D288160
OECD Data Point
EPA MRID 45831025
EPA Guideline §72-2

Test material: XDE-638 **Purity:** 97.5%
Common name: Penoxsulam
Chemical name: IUPAC: Not reported
CAS name: 2-(2,2-Difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-C]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide
CAS No.: Not reported
Synonyms: None reported

Primary Reviewer: Rebecca Bryan
Staff Scientist, Dynamac Corporation

Signature: 
Date: 10/31/03

QC Reviewer: Christie E. Padova
Staff Scientist, Dynamac Corporation

Signature: 
Date: 10/31/03

Primary Reviewer: ~~William Erickson - Biologist~~
OPP/EFED/ERB - III **James J. Goodyear, Ph.D.**
Ecological Effects Biologist
Office of Pesticide Programs
703-305-7726

Date:

Secondary Reviewer(s):
{EPA/OECD/PMRA}

Date:

Reference/Submission No.:

Company Code:

Active Code:

EPA PC Code: 19903T

Date Evaluation Completed: 119031

CITATION: Boeri, R.L., et al. 2001 (amendment). XDE-638: Acute Toxicity to the Ramshorn Snail, *Planorbella trivolvis*. Unpublished study performed by T.R. Wilbury Laboratories, Inc., Marblehead, MA. Laboratory Study No. 1845-DO. Study submitted by The Dow AgroSciences LLC, Indianapolis, IN. Study initiated August 19, 1999 and completed January 6, 2000. Amendment submitted February 28, 2001.



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EXECUTIVE SUMMARY:

The 96-hour acute toxicity of XDE-638 (penoxsulam) to the Ramshorn snail, was studied under static conditions. Snails were exposed to the test material at nominal concentrations of 0 (negative control), 16, 26, 43, 72, and 120 ppm. Mean-measured concentrations were <0.0138 (LOQ, negative control), 16.6, 26.6, 45.5, 75.5, and 126 ppm a.i.

After 96 hours, survival was 100% in the control group, and $\geq 90\%$ in all treatment groups. The 96-hour LC_{50} was >126 ppm a.i., which categorizes XDE-638 (penoxsulam) as practically nontoxic to the Ramshorn snail, *Planorbella trivolvis*, on an acute toxicity basis. No sub-lethal effects were observed during the study. Based on lack of effects, the NOAEC and LOAEC were 126 and >126 ppm a.i., respectively.

This study is scientifically sound. However, since the Ramshorn snail is not an accepted species, this study does not satisfy the guideline requirements for an acute toxicity study with freshwater invertebrates (§72-2). This study provides useful information and is classified as SUPPLEMENTAL.

Results Synopsis

Test Organism Age (e.g. 1st instar): Not reported.
Test Type (Flow-through, Static, Static Renewal): Static

96-hour

LC_{50} : >126 ppm a.i.
NOAEC: 126 ppm a.i.
LOAEC: >126 ppm a.i.
Endpoints affected: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in the EC Commission Directive 96/12/EC, Annex II, Point 8.2.4 (1996) and OECD Guideline No. 202 (1984). Deviations from U.S. EPA FIFRA Guideline §72-2 include:

1. The Ramshorn snail is not recognized as an acceptable species for use in acute freshwater invertebrate studies.
2. The age of the snails was not specified.
3. The test conditions (static) differed from the acclimation conditions (flow-through).
4. The percent saturation values for dissolved oxygen were not provided.
5. The hardness (176 mg/L as $CaCO_3$) was significantly higher than recommended (40-48 mg/L as $CaCO_3$).
6. The pH range (8.1-8.5) was higher than recommended (7.2-7.6).

These deviations did not affect the acceptability of the study; however, this study does not satisfy guideline requirements.

COMPLIANCE: Signed and dated GLP, Confidentiality, and Quality Assurance statements were provided. This study was conducted in compliance with the GLP standards of the U.S. EPA, Japanese MAFF, and the OECD.

A. MATERIALS:

1. Test Material XDE-638 (penoxsulam)

Description: Light pink powder

Lot No./Batch No. : ND05167938

Purity: 97.5%

Stability of Compound

Under Test Conditions: The stability of the test substance in the dilution water during the course of the study was verified by analytical determination at 0 (101-106% of nominal) and 96 hours (103-107% of nominal; Table 2, p. 17).

Storage conditions of

test chemicals: Stored at room temperature in the dark.

OECD requires water solubility, stability in water and light, pK_a , P_{ow} , and vapor pressure of the test compound. OECD requirements were not reported.

2. Test organism:

Species: Ramshorn snail, *Planorbella trivolvis*

Age at test initiation: Not reported

Source: Carolina Biological Supply Company,
Burlington, NC

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study: A static range-finding study was conducted at nominal concentrations of 0 (control), 0.98, 10, 50, 100, and 500 ppm (p. 12). After 96 hours, ≥80% survival was observed in the control and all treatment groups. No sub-lethal effects were observed in any group. Insoluble test material was observed in the ≥10 ppm test vessels during the test (adhered to sides of test vessel, floating on surface, and/or settled on the bottom).

b. Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation period:	14-17 days	<p>The test conditions (static) differed from the acclimation conditions (flow-through).</p> <p>EPA requires 7 day minimum acclimation period.</p>
Conditions: (same as test or not)	Not the same; snails were acclimated under flow-through conditions.	
Feeding:	Snails were fed algae plants.	
Health: (any mortality observed)	<3% during 48 hours prior to test initiation.	
Duration of the test	96 hours	EPA requires 48-96 hours
Test condition - static/flow through	Static	EPA requires consistent flow rate of 5 - 10 volumes/24 hours, meter systems calibrated before study and checked twice daily during test period
Type of dilution system (for flow through method)	N/A	
Renewal rate (for static renewal)	N/A	
Aeration, if any	No aeration during testing.	
Test vessel	Glass aquaria 20 L 15 L (18-cm depth)	Test vessels were loosely covered.
Material: (glass/stainless steel)		EPA requires: size 250 mL with 200 mL fill volume for daphnids or midge larvae or 3.9 L with 2-3 L fill volume
Size:	The dilution water was carbon-filtered, deionized laboratory water. The water was adjusted to a hardness of 160-180 mg/L as CaCO ₃ , and stored in polyethylene tanks where it as aerated, filtered, and UV-sterilized.	Chemical characterization of the dilution water is provided in Table 1, p. 11.
Fill volume:		EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap
Source of dilution water		

Parameter	Details	Remarks
		Criteria
		water.
Water parameters:		
Hardness	176 mg/L as CaCO ₃	The hardness was significantly higher than recommended.
pH	8.1-8.5	The pH range was higher than recommended.
Dissolved oxygen	7.5-9.6 mg/L (mean = 9.1 mg/L)	DO was not provided in terms of percent saturation.
Temperature	19.0-20.5°C (mean = 19.8°C)	<i>EPA requires:</i> hardness: 40 - 48 mg/L as CaCO ₃ pH: 7.2 - 7.6 -Temperature: 20°C (measured continuously or if water baths are used, every 6 hr, may not vary > 1°C Dissolved oxygen: Static: ≥ 60% during 1 st 24 hr and ≥ 40% during 2 nd 24 hr Flow-through: ≥ 60%
Total Organic Carbon	<0.30 mg/L	
Particulate matter	<10 mg/L (total suspended solids)	
Metals	See Table 1, p. 11	
Pesticides	Not detected	
Chlorine	Not reported	
Number of replicates	N/A	
Solvent control:	2	
Negative control:	2	
Treatments:		
Number of organisms per replicate		
Solvent control:	N/A	The loading rate, determined at study termination, was 0.33 g/L.
Negative control:	10	<i>EPA requires 5 treatment levels plus control with a minimum of 20 organisms per treatment.</i> Biomass loading rate for static ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day.
Treatments:	10	
Treatment concentrations nominal:	0 (negative control) 16, 26, 43, 72, and 120 ppm.	Measured concentrations are provided in Table 2, p. 17.
measured:	<0.0138 (LOQ, negative control), 16.6, 26.6, 45.5, 75.5, and 126 ppm a.i.	<i>EPA requires a geometric series with 1.5 to 2.0 ratio.</i>

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Parameter	Details	Remarks
		Criteria
Solvent (type, percentage, if used)	N/A	<i>EPA requires solvents not to exceed 0.1 mL/L.</i>
Lighting	16 hours light/8 hours dark, with a 15-minute transition period.	Light intensity was approximately 31 foot candles (p. 13).
		<i>EPA requires 16 hours light, 8 hours dark with a 15 to 30 minute transition period.</i>
Feeding	Snails were not fed during testing.	
		<i>EPA/OECD requires: No feeding during the study</i>
Stability of chemical in the test system	Verified. Analyzed concentrations were 101-106% of nominal concentrations for 0 Hour samples and 103-107% for 96 Hour samples. The mean-measured concentrations were 102-106% of nominal.	
Recovery of chemical	101-107% of nominal	Based on sample analyses (Table 2, p. 17).
Level of Quantitation	0.0138 ppm a.i.	
Level of Detection	Not reported.	
Positive control {if used, indicate the chemical and concentrations}	N/A	
Other parameters, if any	N/A	

2. Observations:

Table 2: Observations

Criteria	Details	Remarks
		Criteria
Parameters measured including the sublethal effects	Mortality and other sub-lethal effects	
Observation intervals	Every 24 hours	
Were raw data included?	Yes, sufficient	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION

A. MORTALITY

After 96 hours, survival was 100% in the control group, 95% in the 16.6, 26.6, and 75.5 ppm a.i. treatment levels, and 90% in the 45.5 and 126 ppm a.i. treatment levels (Table 3, p. 18). The 96-hour LC_{50} was >126 ppm a.i., the highest concentration tested.

Table 3: Effect of XDE-638 on mortality of Ranshorn snail, *Planorbella trivolvis*.

Treatment, ppm a.i., measured and (nominal conc.)	No. of amphipods at start of study	Observation Period					
		24 Hours		72 Hours		96 Hours	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Negative control	20	0	0	0	0	0	0
16.6 (16)	20	0	0	1	5	1	5
26.6 (26)	20	0	0	1	5	1	5
45.5 (43)	20	0	0	2	10	2	10
75.5 (72)	20	0	0	1	5	1	5
126 (120)	20	0	0	2	10	2	10
NOAEC (mortality)	126 ppm a.i.						
LC_{50} (95% C.I.)	>126 ppm a.i.						

Positive control, mortality: LC ₅₀ :	N/A	N/A	N/A	N/A	N/A	N/A	N/A
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B. SUB-LETHAL TOXICITY ENDPOINTS:

No sub-lethal effects were observed (Table 4, p. 19).

C. REPORTED STATISTICS:

The LC₅₀ value was estimated because there was <50% mortality during the study. The NOAEC was determined based on the concentration of test substance that allowed at least 90% survival and did not cause any sub-lethal effects. The results were based on mean-measured concentrations.

96-hour

LC₅₀: >126 ppm a.i.

NOAEC: 126 ppm a.i.

LOAEC: >126 ppm a.i.

Endpoints affected: None

D. VERIFICATION OF STATISTICAL RESULTS:

The LC₅₀ could be determined visually because mortality did not exceed 50% in this study. The NOAEC was determined using Fisher's Exact Test via TOXSTAT statistical software. Mean-measured concentrations were used in all estimations.

96-hour

LC₅₀: >126 ppm a.i.

NOAEC: 126 ppm a.i.

LOAEC: >126 ppm a.i.

Endpoints affected: None

E. STUDY DEFICIENCIES:

This study is scientifically sound. However, the Ramshorn snail (*Planorbella trivolvis*) is not recognized as an acceptable species for use in acute freshwater invertebrate studies. As a result, this study does not fulfill a guideline requirement for an acute toxicity study with a freshwater invertebrate (§72-2) and is classified SUPPLEMENTAL.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions were identical to the study authors.

Small amounts of insoluble material were observed floating on the test solution surface and/or on the sides of the test vessels at the air-water interface at all treatment levels during the study (p. 16).

G. CONCLUSIONS:

This study is scientifically sound, but does not satisfy the guideline for an acute toxicity study with a freshwater invertebrate (§72-2) because the Ramshorn snail is not recognized as an acceptable species for use in these studies. This study provides useful information and is classified as SUPPLEMENTAL. The 96-hour LC_{50} was >126 ppm a.i., the highest concentration tested. Based on the results of this study, XDE-638 (penoxsulam) is categorized as practically nontoxic to the Ramshorn snail, *Planorbella trivolvis*, on an acute toxicity basis.

96-hour

LC_{50} : >126 ppm a.i.

NOAEC: 126 ppm a.i.

LOAEC: >126 ppm a.i.

Endpoints affected: None

III. REFERENCES:

- ASTM. 1986. Standard Practice for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. E-729-80. In Annual Book of Standards.
- ECC. 1996. EC Commission Directive 96/12/EC, Annex II Point 8.2.4 Acute Toxicity to Aquatic Invertebrates. Published in the Official Journal of the European Communities, No. L 65/24. 15 March 1996.
- Japan MAFF. 1984. Good Laboratory Practice Standard. 59 NohSan No. 3850.
- OECD. 1997. OECD Guidelines for Testing of Chemicals. Annex 2. OECD Principles of Good Laboratory Practice. [C(97)186/Final].
- OECD. 1984. OECD Guidelines for Testing of Chemicals. Section 2: Effects on Biotic Systems. Method 202, *Daphnid* sp. Acute Immobilization Test and Reproduction Test. Adopted 4 April 1984.
- Stephan, C.E. 1983. Computer Methods for the Calculation of LC_{50} Values. Personal Communication. U.S. EPA, Duluth, MN.
- U.S. EPA. 1993. 40 CFR Part 160. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Good Laboratory Practice Standards. Final Rule.

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APPENDIX 1. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

SUMMARY OF FISHERS EXACT TESTS

GROUP	IDENTIFICATION	NUMBER EXPOSED	NUMBER DEAD	SIG (P=.05)
	CONTROL	20	0	
1	16.6	20	1	
2	26.6	20	1	
3	45.5	20	2	
4	75.5	20	1	
5	126	20	2	