

Data Evaluation Report on the Acute Toxicity of XDE-638 Metabolite TPSA to Freshwater Invertebrates - *Daphnia magna*

PMRA Submission Number{.....}

EPA MRID Number 45831018

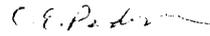
Data Requirement:	PMRA DATA CODE	
	EPA DP Barcode	D288160
	OECD Data Point	
	EPA MRID	45831018
	EPA Guideline	§72-2

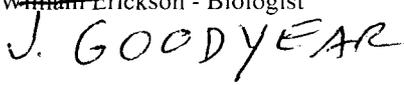
Test material: XDE-638 Metabolite TPSA **Purity:** 99% as triethylene salt (72% acid)
Common name: Metabolite of penoxsulam
Chemical name: IUPAC: Not reported
 CAS name: Triethylene salt of (5,8-dimethoxy[1,2,4]triazolo[1,5-C]pyrimidin-2-yl)sulfamic acid
 CAS No.: Not reported
 Synonyms: XDE-638 TPSA; TPSA

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Staff Scientist, Dynamac Corporation

Signature: 
Date: 10/17/03

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

Date:

Reference/Submission No.:

Company Code:

Active Code:

EPA PC Code: ~~499031~~

119031

Date Evaluation Completed:

CITATION: Marino, T.A. and A.M. Yaroch. 2002. XDE-638 Metabolite TPSA: An Acute Toxicity Study with the Daphnid, *Daphnia magna* Straus. Unpublished study performed by Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, MI. Laboratory Study No. 021052. Study submitted by Dow AgroSciences, Indianapolis, IN. Study initiated April 16, 2002 and completed June 4, 2002.



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EXECUTIVE SUMMARY:

The 48-hour acute toxicity of XDE-638 Metabolite TPSA (a metabolite of penoxsulam) to the water flea, *Daphnia magna*, was studied under static conditions. Ten daphnids were exposed to the test material at a single nominal concentration 1.4 ppm with a negative control. The mean-measured concentration was not determined.

No mortality/immobilization was observed in either the control or test group during the 48-hour study. The 48-hour LC/EC₅₀ was >1.4 ppm, which categorizes XDE-638 Metabolite TPSA (a metabolite of penoxsulam) as moderately toxic to the water flea (*Daphnia magna*) on an acute toxicity basis. The 48-hour NOAEC level, based on mortality/immobilization, was 1.4 ppm, the only concentration tested.

This study is scientifically sound. However, since only ten daphnids were used in a limit study and since analytical measurements of metabolite in the dilution water was not performed (to verify concentration level and stability), this study does not fulfill guideline requirements for an acute toxicity study with the daphnia (§72-2) using a metabolite of penoxsulam and is classified SUPPLEMENTAL.

Results Synopsis

Test Organism Age (eg. 1st instar): <24 hours old
Test Type (Flow-through, Static, Static Renewal): Static

48-Hour

LC/EC₅₀: >1.4 ppm
NOAEC: 1.4 ppm (based on mortality/immobilization)
LOAEC: >1.4 ppm

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study protocol was based on procedures outlined in U.S. EPA Pesticide Assessment Guidelines, Series 72-2, and U.S. EPA Standard Evaluation Procedure. Deviations from §72-2 included:

1. The test was conducted with a single, nominal test concentration of 1.4 ppm (as a limit test). This was reported to be 100X the projected environmental concentration of 14 ppb (p. 9).
2. Mean-measured concentrations were not determined to verify the test concentration and stability of the metabolite.
3. The storage conditions of the test material were not reported.
4. Pre-test health (including mortality) of the laboratory culture and/or brood was not described.
5. The hardness (174 mg/L as CaCO₃) was significantly higher than recommended (40-48 mg/L as CaCO₃).
6. The loading rate was not specified.

7. Sub-lethal effects were not monitored.

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

COMPLIANCE: Signed and dated GLP, Confidentiality, and Quality Assurance statements were provided.

A. MATERIALS:

1. Test Material XDE-638 Metabolite TPSA (a metabolite of penoxsulam)

Description: Solid

Lot No./Batch No. : F-380-205a

Purity: 99% as triethylene salt; 72% acid equivalent

Stability of Compound Under Test Conditions: Not determined.

Storage conditions of test chemicals: Not reported.

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: *Daphnia magna* Straus

Age at test initiation: <24 hours old

Source: In-house laboratory cultures (initially obtained from Yale University, New Haven, Connecticut).

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study: None conducted.

b) Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	Continuous laboratory cultures were maintained. Same as test <i>Daphnia</i> cultures were fed 5 times/week with mixed diet of <i>Selenastrum capricornutum</i> (algae) and YCT trout chow (yeast-ceraphyll trout). Not specified	EPA requires 7 day minimum acclimation period.
Duration of the test	48 hours	EPA requires 48 hours
Test condition - static/flow through Type of dilution system (for flow through method) Renewal rate (for static renewal)	Static N/A N/A	EPA requires consistent flow rate of 5 - 10 volumes/24 hours, meter systems calibrated before study and checked twice daily during test period
Aeration, if any	No aeration during testing.	
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	Glass beakers 250 mL 200 mL	Vessels were covered to reduce evaporation. EPA requires: size 250 ml or 3.9 L fill 200 ml
Source of dilution water	The dilution water was pumped to the laboratory from the upper Saginaw Bay of Lake Huron. The water was filtered (sand and carbon), pH-adjusted, and UV-irradiated. The hardness was adjusted to	EPA requires soft reconstituted water

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Parameter	Details	Remarks
		Criteria
	approximately 170 mg/L as CaCO ₃ , then the water was autoclaved for 30 minutes and aerated for 24 hours prior to use.	<i>or water from a natural source, not dechlorinated tap water.</i>
<u>Water parameters:</u> Hardness pH Dissolved oxygen Temperature Total Organic Carbon Particulate matter Metals Pesticides Chlorine	174 mg/L as CaCO ₃ 7.4-7.5 9.3-9.8 mg/L (≥104% saturation) 19.9-20.9°C <1000 µg/mL (<LOD) 1000 µg/mL (total suspended solids) See Table 1, p. 16 <LOD (Table 2, p. 17) <1 ppb	The hardness was higher than recommended. Results from inorganic and organic analysis of the dilution water are provided in Tables 1 and 2, pp. 16-17. <i>EPA requires:</i> <i>hardness: 40 - 48 mg/L as CaCO₃</i> <i>pH: 7.2 - 7.6</i> <i>-Temperature: 20°C (measured continuously or if water baths are used, every 6 hr, may not vary > 1°C</i> <i>Dissolved oxygen:</i> <i>Static: ≥ 60% during 1st 24 hr and ≥ 40% during 2nd 24 hr</i> <i>Flow-through: ≥60%</i>
Number of replicates Solvent control: Negative control: Treatments:	N/A 3 3	
Number of organisms per replicate Solvent control: Negative control: Treatments:	N/A 10 10	The biomass loading rate was not specified. <i>EPA requires 5 treatment levels plus control with a minimum of 20 daphnid per treatment. 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.</i>
Treatment concentrations nominal: measured:	0 (negative control) and 1.4 ppm Not determined	A limit test was conducted with a single, nominal concentration of 1.4 ppm, with was reported to be 100X the projected environmental concentration for this metabolite (p. 9). The measured test concentrations were not determined. <i>EPA requires a geometric series</i>

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Parameter	Details	Remarks
		Criteria
		<i>with each concentration being at least 60% of the next higher one.</i>
Solvent (type, percentage, if used)	N/A	<i>EPA requires solvents not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests.</i>
Lighting	16 hours light/8 hours dark	Light intensity ranged from 1036-1653 lux. <i>EPA requires 16 hours light, 8 hours dark.</i>
Feeding	Animals were not fed during testing.	<i>EPA/OECD requires: No feeding during the study</i>
Stability of chemical in the test system	Not determined.	
Recovery of chemical	Not determined.	
Level of Quantitation		
Level of Detection		
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 sub-lethal effects	Mortality/immobility	
Observation intervals	After 24 and 48 hours	
Were raw data included?	Yes, sufficient	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION

A. MORTALITY

After 48 hours, no mortality/immobilization was observed in either the control or test group (p. 13).

Table 3: Effect of XDE-638 Metabolite TPSA on mortality/immobilization of *Daphnia magna*.

Treatment, ppm Nominal concn.	No. of organisms	Observation period			
		24 Hours		48 Hours	
		No.	%	No	%
Negative Control	30	0	0	0	0
1.4	30	0	0	0	0
NOAEC, ppm	Not determined				
LC/EC ₅₀ (95% C.I.), ppm	>1.4				

B. SUB-LETHAL TOXICITY ENDPOINTS:

Not observed.

C. REPORTED STATISTICS:

The 48-hour LC/EC₅₀ value was determined visually. The results were based on mean-measured concentrations.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical analyses were not required, as there was no immobility in this study. The LC₅₀ and NOAEC (for mortality/immobilization) could be visually determined.

48-Hour

LC/EC₅₀: >1.4 ppm

NOAEC: 1.4 ppm (based on mortality/immobilization)

LOAEC: >1.4 ppm

E. STUDY DEFICIENCIES:

This study is scientifically valid. However, since the concentration of XDE-638 Metabolite TPSA in dilution water was not measured, and since the stability of the chemical was not assessed during the 48-hour exposure period, this study does not fulfill guideline requirements for an acute toxicity study with the daphnia (§72-2) and is classified SUPPLEMENTAL.

F. REVIEWER'S COMMENTS:

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

The study was conducted as a limit test, with a single nominal concentration level of 1.4 ppm. This concentration was reported to be 100X the projected environmental concentration of 14 ppb for this metabolite (p. 9). However, test solutions were not analyzed during the study for the metabolite.

The study followed the U.S. EPA (40 CFR, Part 160) Good Laboratory Practice with the exception that measured verification of test material concentrations within the dosing solutions were not performed (p. 3).

G. CONCLUSIONS:

This study is scientifically sound. However, since only ten daphnids were used in a limit study and since analytical measurements of metabolite in the dilution water was not performed (to verify concentration level and stability), this study does not fulfill guideline requirements for an acute toxicity study with the daphnia (§72-2) and is classified SUPPLEMENTAL. The 48-hour LC/EC₅₀ was >1.4 ppm, the only concentration tested. Based on the results of this study, XDE-638 Metabolite TPSA (a metabolite of penoxsulam) is categorized as moderately toxic to the water flea, *Daphnia magna*, on an acute toxicity basis.

48-Hour

LC/EC₅₀: >1.4 ppm

NOAEC: 1.4 ppm (based on mortality/immobilization)

LOAEC: >1.4 ppm

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III. REFERENCES:

EPA-FIFRA. Environmental Protection Agency. Hazard Evaluation Division, Standard Evaluation Procedure: Acute Toxicity Test for Freshwater Invertebrates. EPA-540/9-85-005.

Environmental Protection Agency. Office of Pesticide and Toxic Substances. Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms. Guideline 72-2, Acute Toxicity Test For Freshwater Aquatic Invertebrates. EPA-540/09-87-198.

Organisation for Economic Cooperation and Development. OECD Guideline for Testing of Chemicals. Method 202, *Daphnia* sp., Acute Immobilization Test, Part 1. ISBN 92-64-12221-4.

European Community (EC) Directive 91/414 Annex I 8.2.5.

Official Journal of the European Communities. (EEC) Method C.1. Acute Toxicity Test for *Daphnia*. ISSN 0378-6978. 29 December 1992.

Environmental Protection Agency-FIFRA GLPS; Title 40 CFR Part 160-Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Good Laboratory Practice Standards, Final Rule.

OECD Series on Principles on Good Laboratory Practice and Compliance Monitoring, Number 1. OECD Principles on Good Laboratory Practice (as revised in 1997) ENV/MC/CHEM(98)17.

EC Directive 99/11/EC of 8 March 1999 (OJ No. L 77/8-21, 23/3/1999).

Dow AgroSciences LLC, Test Substance Distribution Certificate. TSN103594, Dow AgroSciences LLC, Indianapolis, Indiana. 05 March 2002.

Nelson, R.M. Certificate of Analysis for Test/Reference/Control Substances: FA&PC Number 013347. Dow AgroSciences LLC, Indianapolis, Indiana. 07 January 2002.