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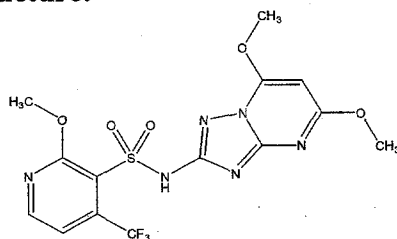
Data Evaluation Report on the Acute Toxicity of Pyroxsulam (XDE-742) to Fathead minnow (*Pimephales promelas*)

PMRA Submission Number 2006-4727; ID1283212 EPA MRID Number 469084-22 APVMA ATS 40362

Data Requirement: PMRA Data Code 9.5.2.3
 EPA DP Barcode D332116
 OECD Data Point IIA 8.2.1.2
 EPA MRID 469084-22
 EPA Guideline 72-1 (OPPTS 850.1075)

Test material: Pyroxsulam (XDE-742) Purity: 98%
 Common name: Pyroxsulam or XDE-742
 Chemical name: 3-pyridinesulfonamide, N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)
 IUPAC: N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)pyridine-3-sulfonamide
 CAS name: N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide
 CAS No.: 422556-08-9
 Synonyms: XR-742, X666742, Reg. No. 5022335

Chemical Structure:



Primary Reviewer: Daryl Murphy *D. Murphy 22/02/08* Date: 8 December 2006
 Australian Government, Department of the Environment, Water, Heritage and the Arts (DEWHA)

Secondary Reviewers: Jack Holland *J. Holland 12/12/08* Date: 12 December 2006
 Australian Government, Department of the Environment, Water, Heritage and the Arts

Thomas Steeger, Ph.D., Senior Biologist *T. Steeger 4/13/08* Date: 17 February 2006
 Environmental Fate and Effects Division, U. S. Environmental Protection Agency

Catherine Evans Date: 29 June 2007
 Environmental Assessment Directorate, Pest Management Regulatory Agency

Émilie Larivière *Emilie Lariviere 05/03/08* Date: 4 July 2007
 Environmental Assessment Directorate, Pest Management Regulatory Agency

Company Code DWE
 Active Code JUA
 Use Site Category: 13, 14
 EPA PC Code 108702

CITATION: Zok, S. 2003 XDE-742/BAS 770 H – Acute toxicity study on the fathead minnow (*Pimephales promelas*) in a static system over 96 hours. BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany. BASF Study No. 15F0298/035032. Dow AgroSciences LLC, Indianapolis, IN 46268 USA. December 19, 2003. Unpublished report.



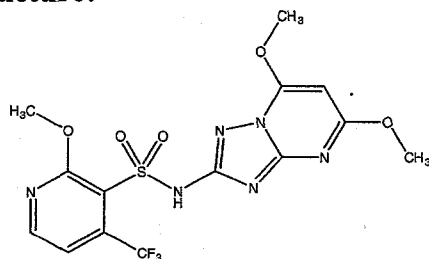
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CAS name: N-(5,7-dimethoxy[1,2,4]triazolo[1,5-a]pyrimidin-2-yl)-2-methoxy-4-(trifluoromethyl)-3-pyridinesulfonamide
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Reference/Submission No.: APVMA ATS40362 NCRIS 61286

Company Code DWE
Active Code JUA
Use Site Category: 13, 14
EPA PC Code 108702

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EXECUTIVE SUMMARY:

In a 96-h acute static toxicity study, fathead minnows (*Pimephales promelas*) were exposed to pyroxsulam (XDE-742; 98% purity) at nominal concentrations of 0, and 100 mg pyroxsulam/L. Mean-measured concentrations were <0.005 (LOQ) and 94.4 mg pyroxsulam/L, respectively. The study was conducted in accordance with US EPA Guideline 72-1 (1982), EPA-SEP (Standard Evaluation Procedure) No. 540/9-85-006 (1985), EEC directive 92/69, Annex V, CI and OECD Guideline No. 203 (1992). Mortality and sub-lethal effects were monitored after 1, 4, 24, 48, 72, and 96 hours of exposure. No mortality or sub-lethal effects were observed. The 96-h LC50 was >94.4 mg pyroxsulam/L and the NOEC/NOAEC was 94.4 mg pyroxsulam/L, based on mean measured concentrations. Based on the results of this study, pyroxsulam would be classified as, at worst, slightly toxic (i.e. 10 < 96 hour LC50 and EC50 ≤ 100 mg/L) to fathead minnow in accordance with the acute toxicity classification systems of the Australian Government Department of the Environment and Water Resources and of the US EPA.

This toxicity study is classified as acceptable and is consistent with the guideline requirement for a 96-h acute toxicity study on the fathead minnow.

Results Synopsis

Test Organism Size/Age:

Weight: 0.75 g (0.48-1.09 g)
Length: 4.2 cm (3.6 – 5.0 cm)
Age: approximately 10 months old

Test Type: Static 96 hours

LC₅₀: >94.4 mg pyroxsulam/L (mean, measured); 95% C.I.: not applicable
NOEC/NOAEC: 94.4 mg pyroxsulam/L (mean, measured).
Probit Slope: not applicable
EC₅₀: not applicable, 95% C.I.: not applicable
Endpoint(s) Effected: There were no compound related effects (survival or sub-lethal) noted during this study.

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: EPA guideline "Pesticide Assessment Guidelines, subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms", U.S. Environmental Protection Agency, Washington DC, para 72-1, 1982.

EPA-SEP (Standard Evaluation Procedure) No. 540/9-85-006 1985.

EEC directive 92/69, Annex V, Cl.

OECD Guidelines for testing of chemicals No. 203, July 1992 ("Fish Acute Toxicity Test").

COMPLIANCE: This study was conducted in accordance with the OECD principles of GLP and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act) and meets the USEPA GLP standards [40 CFR Part 160 (FIFRA) and Part 792 (TSCA)]. Signed and dated GLP, Quality Assurance and No Data Confidentiality statements were provided.

A. MATERIALS:

1. Test material XDE-742 (i.e. pyroxsulam)

Description: Solid, white beige

Lot No./Batch No. : E0952-52-01

Purity: 98% active constituent

Stability of compound under test conditions: According to the study report, the stability under storage conditions over the exposure period was guaranteed by the sponsor and the sponsor "holds" this responsibility.

Over 96 hours, the measured pyroxsulam concentrations were 93.1-96.7% of nominal (page 8 of this DER), indicating the pyroxsulam was stable under the test conditions.

Storage conditions of test chemicals: Stored at ambient room temperature.

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Physicochemical properties of pyroxsulam.

Parameter	Values	Comments
Water solubility at 20°C		
pH 4	0.0164 g/L	Turner (2004a)
pH 6	0.0626 g/L	Turner (2004a)
pH 7	3.2 g/L	Turner (2004a)
pH 9	13.7 g/L	Turner (2004a)
Vapour pressure	<1E-7 Pa	Madsen (2003)
UV absorption	NA	
pKa	4.670	Cathie (2004)
Kow		
pH 4	9.700E-02	Turner (2004b)
pH 7	2.400E-02	Turner (2004b)
pH 9	1.210E+01	Turner (2004b)

NA = not available at the time of publication of the study.

Note: The physicochemical properties of pyroxsulam were not reported in the study. The values recorded here come from the company's study profile template (BASF study number: 12F0298/035032.SPT, DAS study number: 035032.SPT (Mercer, 2006)).

2. Test organism:

Species: Fathead Minnow (*Pimephales promelas*)
Age at test initiation: Approx. 10 months
Weight at study initiation: 0.75 g (0.48-1.09 g) mean (range)
(EPA requires: mean 0.5 - 5 g)
Length at study initiation: 4.2 cm (3.6-5.0 cm) mean (range)
(EPA requires: Longest not > 2x shortest)
Source: Osage Catfisheries Inc., Osage Beach, MO 65065, USA

B. STUDY DESIGN:

1. Experimental Conditions

a. A range finding study using fathead minnows was conducted prior to the definitive test. The results of this study indicated a LC50 of > 100 mg/L for a 96 hour study, consequently, treatment levels of control (0) and 100 mg/L were selected for the definitive test.

b. Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation Period:	14 day acclimatisation period (to test water and light regime)	Feeding ceased during the last day before the start of the exposure to pyroxsulam. <i>(EPA requires minimum 14 days; no feeding during test; OECD requires minimum of 12 days)</i>

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Parameter	Details	Remarks
		Criteria
Conditions: (same as test or not) Feeding: Health: (any mortality observed)	Same as in test. Diet-Commercial fish diet (Tetramin) <i>ad libitum</i> , live and frozen brine shrimp (<i>Artemia</i>). No signs of sickness, injuries or abnormalities. Mortality during the last week before start of exposure = 0.1%	
Duration of the test	96-hours	Guideline requirements met. ----- (EPA/OECD require 96 hour)
<u>Test condition</u> Static/flow-through Type of dilution system - for flow-through method. Renewal rate for static renewal	Static system Not applicable Not applicable	Requirements considered met. ----- (EPA requires: must provide reproducible supply of toxicant) (EPA requires: consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period)
Aeration, if any	Slight, the aeration did not cause a decrease of the test concentration as demonstrated by the analytical measurements.	OECD Guideline met but EPA Guideline not met. ----- (EPA requires: no aeration; OECD permits aeration)

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Parameter	Details	Remarks
		Criteria
<p><u>Test vessel</u></p> <p>Material: (glass/stainless steel)</p> <p>Size:</p> <p>Fill volume:</p>	<p>Glass aquaria with stainless steel frame</p> <p>30 cm long, 22 cm wide, 24 cm high, water depth about 27 cm.</p> <p>10 L</p>	<p>The loading rate met US EPA 850.1075 requirements but not the fill volume.</p> <p><i>(EPA requires: size 19 L (5 gal) or 30 x 60 x 30 cm)</i></p> <p><i>Fill volume: 15-30 L of solution)</i></p>
<p>Source of dilution water Quality:</p>	<p>Non chlorinated charcoal filtered tap water (Frankenthal, Germany)</p>	<p>Guideline requirements met.</p> <p><i>(EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap water);</i></p> <p><i>OECD permits dechlorinated tap water)</i></p>

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Parameter	Details	Remarks
		<i>Criteria</i>
<u>Water parameters:</u>		
Hardness	~2.5 mmol/L = ~250 mg CaCO ₃ /L	<p>The reported hardness of the dilution water (~250 mg/L as CaCO₃) was higher than recommended by the US EPA 850.1075 (40-180 mg/L as CaCO₃) but at the upper limit of the OECD recommended range of 10-250 mg CaCO₃/L.</p> <p>The pH of the dilution water (generally 7.9-8.3) ranged higher than the US EPA recommended values (7.2-7.6) but met the OECD recommended range of 6.0 to 8.5. As no adverse effects were noted, these deviations are not considered to have affected the study.</p> <p><u>Hardness:</u> EPA recommends 40 - 48 mg/L as CaCO₃ (OECD recommends 10 - 250 mg/L)</p>
pH	Generally 7.5-8.5. During the 96 hours exposure, pH was 7.9-8.3.	<p><u>pH:</u> EPA recommends 7.2 - 7.6 (OECD recommends pH 6.0 - 8.5)</p>
Dissolved oxygen	>80% saturation. During the 96 hours exposure period, the oxygen content was 7.0 to 8.0 mg/L.	<p><u>Dissolved Oxygen:</u> EPA recommends: Static: ≥ 60% during first 48 hrs and ≥40% during second 48 hrs (OECD guideline recommends at least 60% saturation value).</p>
Total Organic carbon	Not reported	
Particulate Matter	Not reported	
Metals	Calcium content ~80 mg/L Magnesium content ~10 mg/L	
Pesticides	On basis of (unreported) analytical findings, water found to be suitable for toxicity tests.	
Chlorine	Not reported. Acceptable given that the water used is reported as non-chlorinated	

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Parameter	Details	Remarks
		Criteria
Temperature Intervals of water quality measurement	23-24°C Water quality (temperature, oxygen content and pH) measured within an hour after start of exposure then 24, 48, 72 and 96 hours after start of exposure.	Temperature: <i>EPA recommends 23±2°C for warm water species, (OECD recommends 21 - 25°C for fathead minnow).</i> <i>(EPA water quality: measured at beginning of test and every 48 hours)</i>
<u>Number of replicates/groups:</u> control: solvent control: treated groups:	2 No solvent or dispersants used 3	<i>EPA/OECD requires: Control & 5 treatment levels; each conc. should be 60% of the next highest conc.; concentrations should be in a geometric series)</i>
<u>Number of organisms per replicate /groups:</u> control: solvent control: treated groups:	10 No solvent or dispersant used 10	Guideline requirements met. <i>Number of organisms per replicate should be ≥10/concentration OECD guideline recommends at least 7 fish/concentration.</i>
Biomass loading rate	0.75 g fish/L	US EPA 850.1075 Guideline requirements met. <i>(EPA: static not exceed 0.8 g/L; flow-through: 0.5 g/L/day; OECD requires: maximum of 1 g fish/L for static and semi-static with higher rates accepted for flow-through).</i>
<u>Test concentrations:</u> nominal: measured:	0 and 100 mg/L 0 and 94.4 mg pyroxsulam/L (replicate values reported as 93.1-96.7% of nominal)	The nominal concentration of 100 mg pyroxsulam/L was not corrected for the purity of the active ingredient (98%).
Solvent (type, percentage, if used)	Not applicable; no solvent used	

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Parameter	Details	Remarks
		<i>Criteria</i>
		<i>(EPA requires: not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD requires solvent not exceed 100 mg/L)</i>
Lighting	16 h light and 8 h dark,	Light intensity was approximately 82-280 lux at the aquaria surfaces. <i>The recommended photo period is 16 hours of light and 8 hours of dark with a 15-30 minute transition period. OECD recommends a photo period of 12 -16 hours. (EPA requires: 16 hours light/8 hours dark);</i>
Feeding	None.	Feeding ceased during the last day before the start of the exposure to pyroxsulam. <i>(EPA/OECD requires: no feeding during the study)</i>
<u>Recovery of chemical</u> Frequency of determination	Within the first hour of the start of the exposure and at ~96-hours	Guideline requirements met.
Level of quantization (quantification)	0.005 mg pyroxsulam/L	
Level of detection	Not reported	
Positive control {if used, indicate the chemical and concentrations}	N/A; a positive control was not used	
Other parameters, if any	None	

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2. Observations:

Table 2: Observations

Parameter	Details	Remarks
		Criteria
Parameters measured including the sub-lethal effects/toxicity symptoms	Survival & toxic signs (changes in appearance, swimming behaviour and behaviour)	
Observation intervals	1, 4, 24, 48, 72 and 96 hours after start of exposure.	Guideline requirements met. <i>(EPA/OECD requires: minimally every 24 hours)</i>
Water quality was acceptable (Yes/No)	Yes	
Were raw data included?	Tabulated mortality and behaviour results were presented. The data, protocol, protocol changes, revisions, and final report are archived at Toxicology & Environmental Research and Consulting, The Dow Chemical Company, Midland, Michigan.	The absence of raw data is not considered a deficiency even though US EPA OPPTS 850.1075 requires that, "Raw data must be available to support study author's conclusions and should be presented with the study report." ((4) Observations (g) Data and reporting (2) Test report (xv)). This decision on the absence not being a deficiency is on the basis of advice from the US EPA that tabulated results are considered sufficient as they allow recalculation of dose response if necessary.
Other observations, if any	All test batches were present as clear solutions over the exposure period according to visual inspection.	

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II. RESULTS AND DISCUSSION:

A. MORTALITY:

Fish were considered dead if there was no visible movement and no reaction after touching. There were no deaths in any control or treatment (Table 1).

Table 1: Effect of pyroxsulam (XDE-742) on Mortality of Fathead minnow after 1 to 96 hours exposure.

Treatment (mg pyroxsulam/L) (nominal/ mean measured concentrations)	No. of fish at start of study	Observation period – number of dead fish					
		1 hour	4 hours	24 hours	48 hours	72 hours	96 hours
Control (0 mg/L)	20	0	0	0	0	0	0
100/94.4mg/L	30	0	0	0	0	0	0
NOEC	94.4 mg pyroxsulam/L (mean, analytically determined); 100 mg pyroxsulam/L (nominal)						
LC ₅₀	>94.4 mg pyroxsulam/L (mean, analytically determined) or >100 mg pyroxsulam/L (nominal)						
Positive control, if used mortality: LC ₅₀ :	N/A; a positive control was not used						

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B. NON-LETHAL TOXICITY ENDPOINTS:

No deaths or other symptoms were observed (Table 2).

Table 2: Sub-lethal Effects of pyroxsulam (XDE-742) on fathead minnow.

Treatment (mg pyroxsulam/L) Mean-Measured/Nominal	Number of fish	Observation period – number of fish with adverse symptoms						
		1 hour	4 hours	24 hours	48 hours	72 hours	96 hours	
Control (0 mg/L)	20	0	0	0	0	0	0	
94.4/100 mg/L	30	0	0	0	0	0	0	
NOEC/NOAEC	94.4 mg pyroxsulam/L (mean, analytically determined) or 100 mg pyroxsulam/L (nominal)							
LOEC/LOAEC	≥ 94.4 mg pyroxsulam/L (mean, analytically determined) or ≥ 100 mg pyroxsulam/L (nominal)							
EC ₅₀	≥ 94.4 mg pyroxsulam/L (mean, analytically determined) or ≥ 100 mg pyroxsulam/L (nominal)							
Positive control, if used % sub-lethal effect: EC ₅₀ :	N/A; a positive control was not used							

C. REPORTED STATISTICS:

No statistical analysis was carried out since no lethality was observed in the control or the tested concentration. The median lethal concentration (LC₅₀) was above this value.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method(s): The lack of mortality and sub-lethal effects precluded the use of statistical analyses. All toxicity values were therefore determined visually based on the mean-measured concentration

Mortality and effects

96 hour LC₅₀/EC₅₀: >94.4 mg pyroxsulam/L (mean, analytically determined) or >100 mg pyroxsulam/L (nominal)
(95% C.I.: Not applicable)

96 hour NOEC/NOAEC: 94.4 mg pyroxsulam/L (mean, analytically determined) or 100 mg pyroxsulam/L (nominal)

Probit Slope: Not applicable and 95% C.I.: Not applicable

E. STUDY DEFICIENCIES:

There were no significant deficiencies that affected the acceptability of the study.

The hardness was higher than recommended by US EPA Guideline 850.1075 but met the OECD TG 203. This also applies to the pH of the dilution water. Volume of fill less than 850.1075 Guideline but loading rate met Guideline. Slight aeration was reported to have occurred, which is only permitted by 850.1075 when the oxygen levels are in danger of dropping to below 60% saturation as a result of the chemical characteristics of

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the test material. Aeration is allowed under OECD TG 203. These slight deviations from US EPA requirements did not affect the study

The validity criteria for OECD 203 (adopted 17.07.92) and US EPA OPPTS 850.1075 were considered to have been met by the study.

F. REVIEWER'S COMMENTS:

This study was conducted as a limit test with a nominal concentration of 100 mg technical grade material/L with a mean measured concentration of 94.4 mg pyroxsulam/L. Consequently, technical grade pyroxsulam is considered as, at worst, slightly toxic to the fathead minnow (i.e. $10 < 96$ hour LC50 and $EC50 \leq 100$ mg/L) based on mean measured concentrations according to the acute toxicity classification of the Australian Government Department of the Environment and Water Resources and of the US EPA.

The in-life portion of the definitive toxicity test was conducted between October 28 and November 1, 2002.

The PMRA agrees with the conclusions of the Australian Government Department of the Environment and Water Resources. This study is acceptable to the PMRA.

G. CONCLUSIONS:

This study is acceptable. The 96-h acute toxicity study resulted in a LC50 of pyroxsulam as the technical grade material in fathead minnow of >94.4 mg/L based on the mean of the analytically determined concentrations (>100 mg/L based on nominal concentrations). The NOEC/NOAEC was 94.4 mg pyroxsulam/L.

III. REFERENCES:

No reference list was provided in the study report.

Cathie, C. (2004). "Determination of Dissociation Constant of XR-742 using UV-Visible Spectrophotometry", 30 August 2004. Unpublished report of Dow AgroSciences LLC, Indianapolis, Indiana.

Madsen S (2003). "Determination of the Surface Tension, Density, and Vapour Pressure of the Pure Active Ingredient XDE-742", 09 October 2003. Unpublished report of Dow AgroSciences LLC, Indianapolis, Indiana.

Mercer J (2006). Study Profile Template (SPT). "XDE-742/BAS 770 H - Acute toxicity on the fathead minnow (*Pimephales promelas*) in a static system over 96 hours". BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany. BASF Study No. 15F0298/035032.SPT and DAS Study Number 035032.SPT. Dow AgroSciences. 8 February 2006. Unpublished report.

Organization for Economic Cooperation and Development. 1992. *OECD Guidelines for Testing of Chemicals*; "Guideline 203, Fish Acute Toxicity Test," Paris.

Turner, B. J. (2004a). "Determination of Water Solubility for XDE-742", 22 December 2004. Unpublished report of Dow AgroSciences LLC, Indianapolis, Indiana.

Turner, B. J. (2004b). "Determination of Octanol/Water Partition Coefficient for XDE-742", 22 December 2004. Unpublished report of Dow AgroSciences LLC, Indianapolis, Indiana.