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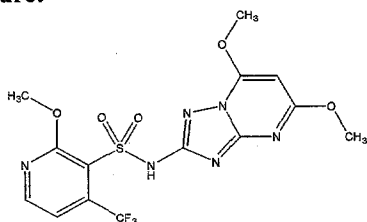
Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout (*Oncorhynchus mykiss*)

PMRA Submission Number 2006-4727; ID 1283207 EPA MRID Number 460984-23 APVMA ATS 40362

Data Requirement: PMRA DATA CODE: 9.5.2.1
 EPA DP Barcode: D332116
 OECD Data Point: IIA 8.2.1.1
 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: Reg. No. 5022335 and, from Mercer, 2006, XR-742, X666742

Chemical Structure:



Primary Reviewer: Daryl Murphy *D. Murphy 2/2/08* **Date:** December 8, 2006
 Australian Government Department of the Environment, Water, Heritage and the Arts (DEWHA)

Secondary Reviewers: Jack Holland *J. Holland 2/2/08* **Date:** December 12, 2006
 Australian Government Department of the Environment, Water, Heritage and the Arts

Thomas Steeger, Ph.D., Senior Biologist *T. Steeger 4/13/08* **Date:** January 15, 2007
 Environmental Fate and Effects Division, U. S. Environmental Protection Agency

Catherine Evans **Date:** June 29, 2007
 Environmental Assessment Directorate, PMRA

Émilie Larivière *É. Larivière 05/03/08* **Date:** July 4, 2007
 Environmental Assessment Directorate, PMRA

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

CITATION: Zok, S. 2003. XDE-742/BAS 770H Acute Toxicity Study on the Rainbow Trout (*Oncorhynchus mykiss*) in a Static System over 96 Hours. Experimental Toxicology and Ecology BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany. BASF Project Number 12F0298/035031. BASF Aktiengesellschaft 67056 Ludwigshafen/Germany. December 19, 2003. Unpublished report.

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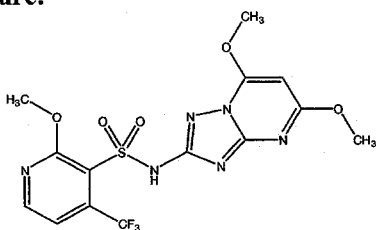
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EXECUTIVE SUMMARY:

In a 96-h acute toxicity limit study, juvenile rainbow trout (*Oncorhynchus mykiss*) were exposed to nominal pyroxsulam (XDE-742; 98%) concentrations of 0 (control) and 100 mg/L under static conditions. Mean measured concentrations were <0.005 (LOQ) and 87 mg/L. The study was conducted in accordance with EPA guideline 72-1 (1982), EPA-SEP (Standard Evaluation Procedure) No. 540/9-85-006 (1985), EEC directive 92/69, Annex V, C1 and OECD Guideline No. 203 (1992). Observations on mortality and toxic signs (changes in appearance, swimming behaviour and behaviour in comparison to the control group) were conducted after 1, 4, 24, 48, 72 and 96 hours of exposure. No mortality or sublethal effects were observed in the control or the 87 mg pyroxsulam/L groups. The 96-h EC₅₀ and NOEC/NOAEC values, based on mortality or sublethal effects, were >87 and 87 mg pyroxsulam/L (mean, measured), respectively. Based on the results of this study, pyroxsulam (98% active constituent) would be classified as, at worst, slightly toxic to rainbow trout in accordance with the acute toxicity classification systems of the Australian Government Department of the Environment and Water Resources and of the US EPA (96 hour LC₅₀ and EC₅₀ both >10 but less than or equal to 100 mg/L), based on mean-measured concentrations).

This toxicity study is classified as acceptable and is consistent with the guideline requirement for a 96 hour acute limit toxicity study on the rainbow trout.

Results Synopsis

Test Organism Size/Age:

Mean wet weight: 2.40 g (range 1.51-3.08 g)

Mean length: 6.6 cm (range 5.3-7.2 cm)

Age: Approximately 7 months

Test Type:

Static 96 hours

96 h LC₅₀:

>100 mg a.i. (pyroxsulam)/L (nominal)

>87 mg a.i. (pyroxsulam)/L (mean, measured);

95% C.I.: Not applicable

96 h NOEC/NOAEC

87 mg a.i. (pyroxsulam)/L; Probit Slope: Not applicable

96 h EC₅₀:

>87 mg a.i. (pyroxsulam)/L (mean, measured);

95% C.I.:

Not applicable

Endpoint(s) Effected: There were no compound related effects (survival or sublethal) noted during this study.

**Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout
(*Oncorhynchus mykiss*)**

PMRA Submission Number 2006-4727; ID 1283207 EPA MRID Number 460984-23 APVMA ATS 40362

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

The study was reported as conducted to the following test guidelines

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, C1

OECD Guideline for Testing of Chemicals No. 203, July 1992 ("Fish Acute Toxicity Test")

Guidelines appear to have been generally followed with some minor deviations (fill volume of aquaria, maximum fish length, total hardness, pH, temperature and dissolved oxygen contents) reported (see relevant text entries below and also the Study Deficiencies entry on page 14 of this DER).

COMPLIANCE:

The study was reported as conducted in accordance with the OECD Principles of Good Laboratory Practice and the GLP Principles of the German "Chemikaliengesetz" (Chemicals Act) and meets the United States Environmental Protection Agency Good Laboratory Practice Standards [40 CFR Part 160 (FIFRA) and Part 792 (TSCA)], with the exception that recognized differences existed between the GLP Principles/Standards of OECD and the Principles/Standards of FIFRA and TSCA.

The signed and dated GLP Compliance Statement for the study was provided.

The signed and dated Statement of the Quality Assurance Unit for the study was provided.

The signed and dated Statement of No Data Confidentiality for the study was provided.

A. MATERIALS:

1. Test Material

XDE-742/BAS 770 H (i.e. pyroxsulam)

Description:

Solid (powder)/white-beige

Lot No./Batch No. :

E0952-52-01

Purity:

98% active constituent

**Stability of compound
under test conditions:**

Stability under storage conditions over the exposure period were stated to have been guaranteed by the sponsor, with the sponsor stated to be responsible for this information.

The analytical data (see page 9 of this DER) over the exposure period indicate that pyroxsulam was stable under the test conditions with the mean measured concentration over 96 hours calculated as 87% of nominal.

Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout (*Oncorhynchus mykiss*)

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Storage conditions of test chemicals:

Stored at room temperature. No other information provided.

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	<1 X 10 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: 12F0298/035031.SPT, DAS study number: 035031.SPT (Mercer, 2006)).

2. Test organism:

Species:	Rainbow trout (<i>Oncorhynchus mykiss</i>)
Age at test initiation: (mean and range)	Approximately 7 months, mean and age range not provided.
Weight at study initiation: (mean and range)	2.40 g (1.51-3.08 g)
Length at study initiation: (mean and range)	6.6 cm (5.3-7.2 cm) (Body length was taken from top of snout to end of the caudal fin).

Note that the mean length and upper length exceed the OECD recommended lengths for rainbow trout (see the deficiencies/deviation table on page 14 of this DER).

Source: Forellenzucht Troststadt GbR, Dorfstrasse 7, 98646 Troststadt, Germany.

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study: The test concentrations were reported as chosen on the basis of results from a non-GLP range finding study with fathead minnows with the raw data (reference made to 15F0298/035032, the BASF study number for the study of the acute toxicity of pyroxsulam to the fathead minnow (Zok, 2003)) archived with the raw data of the present study. The 96 hour LC50 derived from the range finding study was reported as >100 mg pyroxsulam/L.

b) Definitive Study

Table 1. Experimental Parameters

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Parameter	Details	Remarks
		Criteria
<p><u>Acclimation:</u> Period: Conditions: (same as test or not)</p> <p>Feeding:</p> <p>Health: (any mortality observed)</p>	<p>14 days Indicated as using same test water, light/dark conditions, pH during acclimatisation "generally 7.5-8.5". Oxygen content during acclimitisation >80% saturation. Acclimatisation temperature ~11-12°C.</p> <p>Ecostart 17 (Bio Mar), supplier Kofu Tiernahrung, Wesel, Germany. <i>Ad libitum</i> additionally (generally on work days) of frozen brine shrimp (<i>Artemia</i>). Fish were fasted 24 hours prior to test initiation.</p> <p>0.5% mortality during last week before start of exposure. No medical treatment was provided during the acclimatisation period.</p>	<p>See deficiency table (page 14 of this DER).</p> <p><i>(EPA requires minimum 14 days; no feeding during test; OECD requires minimum of 12 days)</i></p> <p>But note: OECD 203 and US EPA OPPTS 850.1075 require holding water to have pH 6.0 to 8.5, >80% oxygen saturation and a temperature range of 13-17°C.</p>
Duration of the test	96 hours	<p>Requirements met.</p> <p><i>(EPA/OECD require 96 hour)</i></p>
<p>Test condition: Static/flow through</p> <p>Type of dilution system for flow through method</p> <p>Flow rate</p> <p>Renewal rate for static renewal</p>	<p>Static</p> <p>Not applicable</p> <p>Not applicable</p> <p>Not renewed</p>	<p>Requirements considered met.</p> <p><i>(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)</i></p>
Aeration, if any	No aeration	<p>Requirements considered met.</p> <p><i>(EPA requires: no aeration; OECD permits aeration)</i></p>

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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, stainless steel frame</p> <p>60 cm long, 35 cm wide and 40 cm high, water depth ~27 cm.</p> <p>50 L</p>	<p>Volume exceeds US fill volume referred to below. See deficiency table (page 14 of this DER).</p> <p>(EPA requires: size 19 L (5 gal) or 30 x 60 x 30 cm)</p> <p>Fill volume: 15-30 L of solution)</p>
<p>Source of dilution water</p>	<p>Non-chlorinated, charcoal filtered tap water (Frankenthal, Germany).</p>	<p>Requirements considered met. (EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap water); OECD permits dechlorinated tap water)</p>
<p>Water parameters:</p> <p>Hardness</p> <p>pH</p>	<p>For the test water:</p> <p>Total hardness ~2.5 mmol/L or 250 mg CaCO₃/L</p> <p>Over 96 hours, the pH ranged from 8.1 to 8.4 in the controls and 8.0 to 8.1 in the test vessels.</p> <p>(Two controls and three 100 mg pyroxsulam/L nominal solutions were analysed for pH etc determinations).</p>	<p>See deficiency table (page 14 of this DER).</p> <p><u>Hardness</u> EPA : 40 – 48 mg as CaCO₃/L OECD: 10 -250 mg as CaCO₃/L Total hardness exceeds US EPA limit and is at upper limit of the OECD recommended range (OECD 203, 17.07.92 specifies that hardness should range between 10 and 250 mg CaCO₃/L).</p> <p><u>pH</u> EPA: 7.2 – 7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline (Able to live in waters of a wide range of salinities) fishes, monthly range <0.8. OECD: 6.0 – 8.5 pH within OECD range but above US EPA range.</p>

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Parameter	Details	Remarks
		Criteria
Dissolved oxygen	Over 96 hours, the dissolved oxygen content ranged from 6.4 to 10.0 mg/L in the controls and 7.0 to 10.4 mg/L in the test solutions. Control values at 96 hours: 6.4 and 6.5 mg/L	<p><u>Dissolved Oxygen</u> <i>EPA: Static: >60% during 1st 48 hrs and >40% during 2nd 48 hrs, flow-through: >60%)</i> <i>OECD: at least 80% saturation value.</i></p> <p>The test report states that as only one dissolved oxygen concentration fell below 60% maximum saturation (reported as 6.4 mg/L, equivalent to 58% of the saturation value, in one of the control aquaria) and no effects on appearance or behaviour were seen, the deviation was considered to have had no effect on the study results.</p> <p>The other control replicate at 96 hours had a dissolved oxygen content of 6.5 mg/L to 59% saturation.</p> <p>The absence of mortality or sub-lethal effects in the controls at 96 hours indicates the falling below 60% most likely had no significant effect.</p>

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Parameter	Details	Remarks
		Criteria
Total organic carbon Particulate matter Metals Pesticides Chlorine	Not reported Not reported Not reported Not reported Not reported	The study report stated the test water is regularly assayed for chemical contaminants and microbial quality and has been shown suitable for toxicity tests. German drinking water guidelines (Trinkwasserverordnung, Bundesgesetzblatt December 05, 1990) serve as a guideline for maximum tolerable contaminant concentrations. Assay results stated to be available in the archives of the testing facility.
Temperature	Over 96 hours, the temperature ranged from 11 to 13°C in the controls and 11 to 12°C in the test vessels.	Temperature was 1 to 2°C below the OECD minimum of 13°C but within the 10-14°C range specified by US EPA OPPTS850.1075. <u>Temperature:</u> EPA: estuarine/marine: 22 ± 1°C OECD: 21 – 25°C for bluegill and 13 – 17°C for rainbow trout
{Salinity for marine or estuarine species}	Not relevant	<u>Salinity</u> EPA: 30-34 ‰ (parts per thousand) salinity, weekly range < 6 ‰ (EPA water quality: measured at beginning of test and every 48 hours)
Intervals of water quality measurement	1, 24, 48, 72 and 96 hours after test commencement.	
<u>Number of replicates/groups:</u> Control (dilution water): Solvent control: Treatments:	Two replicates for controls No solvent controls used Three replicates for test solutions. Only one test concentration, i.e. 100 mg/L, used (limit test).	Requirement met. Test done as a limit test (permitted under OECD 203). <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>
Number of organisms per replicate per group:		Requirement met.
Control (dilution water): Solvent control: Treatments:	10 Not relevant 10	<i>(EPA: ≥10/concentration); OECD requires at least 7 fish/concentration)</i>

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Parameter	Details	Remarks																																		
		Criteria																																		
Biomass loading rate	~0.5 g fish/L water (based on a mean weight of 2.40 g/fish with 10 fish in 50 L).	Requirement met. (EPA: static: ≤0.8 g/L at ≤17°C, ≤0.5 g/L at >17°C; flow-through: ≤1 g/L/day; OECD requires: maximum of 1 g fish/L for static and semi-static with higher rates accepted for flow-through)																																		
<u>Test concentrations:</u> <u>Nominal:</u> <u>Measured:</u>	0 and 100 mg pyroxsulam/L <table border="1"> <thead> <tr> <th rowspan="2">Nom-inal</th> <th colspan="4">Analytically determined concentration, mg/L</th> </tr> <tr> <th>0 h</th> <th>96 h</th> <th>Mean</th> <th>%*</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>nd**</td> <td>nd</td> <td colspan="2">Not applicable</td> </tr> <tr> <td>0</td> <td>nd</td> <td>nd</td> <td colspan="2">Not applicable</td> </tr> <tr> <td>100</td> <td>87.34</td> <td>90.31</td> <td>88.8</td> <td>89</td> </tr> <tr> <td>100</td> <td>87.42</td> <td>85.60</td> <td>86.5</td> <td>87</td> </tr> <tr> <td>100</td> <td>83.36</td> <td>88.14</td> <td>85.6</td> <td>86</td> </tr> </tbody> </table> <p>* Percentage of nominal concentrations. ** nd = not detected.</p> <p>Mean measured concentration (0-96 hours) calculated as 87 mg pyroxsulam/L (87% of nominal).</p>	Nom-inal	Analytically determined concentration, mg/L				0 h	96 h	Mean	%*	0	nd**	nd	Not applicable		0	nd	nd	Not applicable		100	87.34	90.31	88.8	89	100	87.42	85.60	86.5	87	100	83.36	88.14	85.6	86	Requirement met. Analytically determined concentrations of pyroxsulam in the test water were within ±20% of the nominal concentration of 100 mg/L in all test batches. Note: nominal test concentrations of 100 mg/L were made up from ~5 g of pyroxsulam dissolved in 50 L of water. No reference was found to correction to 100% active constituent.
Nom-inal	Analytically determined concentration, mg/L																																			
	0 h	96 h	Mean	%*																																
0	nd**	nd	Not applicable																																	
0	nd	nd	Not applicable																																	
100	87.34	90.31	88.8	89																																
100	87.42	85.60	86.5	87																																
100	83.36	88.14	85.6	86																																
Solvent (type, percentage, if used)	No solvent (or dispersant) used.	Requirement met. (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 to exceed 100 mg/L)																																		
Lighting	16 hours light, 8 hours dark. ~82-280 Lux at the surface of the aquaria.	Requirement met. (EPA requires: 16 hours light/8 hours dark); OECD requires 12-16 hours photoperiod)																																		
Feeding	None (feeding stated to be withdrawn on the day before the start of the exposure).	Requirement met. (EPA/OECD requires: no feeding during the study)																																		
Recovery of chemical: Frequency of determination		Requirement considered met.																																		

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Parameter	Details	Remarks
		Criteria
Level of Detection Level of Quantitation	Samples taken within the first hour after the start of the exposure and after approximately 96 hours. Not reported 0.005 mg pyroxsulam/L	
Positive control {if used, indicate the chemical and concentrations}	Not used	Requirement met.
Other parameters, if any	The test water was reported as having: Conductivity ~550 μ S/cm at 25°C Ca ⁺⁺ content ~80 mg/L Mg ⁺⁺ content ~10 mg/L Acid capacity ~5.5 mmol/L	Because of absence of mortality and sub-lethal effects in the controls, the test water is considered to have been satisfactory.

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2. Observations:

Table 2. Observations

Parameter	Details	Remarks Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Survival and toxic signs (changes in appearance, swimming behaviour and behaviour in comparison to the control group). Fish considered dead if there was no visible movement and no reaction after touching.	Requirement considered met.
Observation intervals	Within 1 hour of the start of the exposure and then at 4, 24, 48, 72 and 96 hours after the start of the exposure.	Requirement met. <i>(EPA/OECD requires: minimally every 24 hours)</i>
Water quality was acceptable (Yes/No)	Yes	Requirement considered met.
Were raw data included?	Tabulated mortality and behaviour results 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." (OPPTS 850.1075 (4) Observations (g) Data and reporting (2) Test report (xv)). This decision on the absence of 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	Observations of the control and test solutions were made at 1, 24, 48, 72 and 96 hours after the start of the exposure period. All solutions were reported as clear with no untoward observations noted.	

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II. RESULTS and DISCUSSION:

A. MORTALITY:

Table 3. Effect of pyroxsulam on mortality of rainbow trout.

Treatment (mg pyroxsulam/L) [record measured and nominal conc. Used]	No. of fish at start of study	Observation period											
		1 hour		4 hours		24 hours		48 hours		72 hours		96 hours	
		No. Dead	% mortality	No. Dead	% mortality	No. Dead	% mortality	No. Dead	% mortality	No. Dead	% mortality	No. Dead	% mortality
Control (dilution water only), if used	10	0	0	0	0	0	0	0	0	0	0	0	0
Control (dilution water only), if used	10	0	0	0	0	0	0	0	0	0	0	0	0
Solvent control, if used	Solvent control not used.												
Test concentration 1 (nominal 100 mg/L)	10	0	0	0	0	0	0	0	0	0	0	0	0
Test concentration 2 (nominal 100 mg/L)	10	0	0	0	0	0	0	0	0	0	0	0	0
Test concentration 3 (nominal 100 mg/L)	10	0	0	0	0	0	0	0	0	0	0	0	0
NOEC	24, 48, 72 and 96 h NOEC/s all 100 mg pyroxsulam (98% of active constituent)/L (nominal) from 1 through to 96 hours. 24, 48, 72 and 96 h NOECs all 87 mg pyroxsulam/L (mean, analytically determined) from 1 through to 96 hours.												
LC ₅₀	24, 48, 72 and 96 h LC50s all >100 mg pyroxsulam (98% of active constituent)/L (nominal) from 1 through to 96 hours. 24, 48, 72 and 96 h LC50s all >87 mg pyroxsulam/L (mean, analytically determined) from 1 through to 96 hours.												
Positive control, if used mortality: LC ₅₀ :	Positive control not used												

Fish were considered dead if there was no visible movement and no reaction after touching. No mortalities were recorded in any of the control or test solutions.

Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout (*Oncorhynchus mykiss*)

PMRA Submission Number 2006-4727; ID 1283207 EPA MRID Number 460984-23 APVMA ATS 40362

B. NON-LETHAL TOXICITY ENDPOINTS:

Table 4. Sub-lethal effects of pyroxsulam on rainbow trout.

Treatment (mg pyroxsulam/L) [record measured and nominal conc. Used]	Observation period					
	Endpoint ^a at:					
	1 hour	4 hours	24 hours	48 hours	72 hours	96 hours
	% affected					
Control (dilution water only), if used	0 ^b	0	0	0	0	0
Control (dilution water only), if used	0	0	0	0	0	0
Solvent control, if used	Solvent control not used					
Test concentration 1 (nominal 100 mg/L)	0	0	0	0	0	0
Test concentration 2 (nominal 100 mg/L)	0	0	0	0	0	0
Test concentration 3 (nominal 100 mg/L)	0	0	0	0	0	0
NOEC/NOAEC	24, 48, 72 and 96 h NOEC/NOAECs all 100 mg pyroxsulam (98% active constituent)/L (nominal) from 1 through to 96 hours. 24, 48, 72 and 96 h NOEC/NOAECs all 87 mg pyroxsulam/L (mean, analytically determined) from 1 through to 96 hours.					
LOEC/LOAEC	24, 48, 72 and 96 h LOEC/LOAECs all >100 mg pyroxsulam (98% of active constituent)/L (nominal) from 1 through to 96 hours. 24, 48, 72 and 96 h LOEC/LOAECs all >87 mg pyroxsulam/L (mean, analytically determined) from 1 through to 96 hours.					
EC ₅₀	24, 48, 72 and 96 h LC50s all >100 mg pyroxsulam (98% active constituent)/L (nominal) from 1 through to 96 hours. 24, 48, 72 and 96 h LC50s all >87 mg pyroxsulam/L (mean, analytically determined) from 1 through to 96 hours.					
Positive control, if used % sublethal effect: EC ₅₀ :	Positive control not used					

a. Sub-lethal effects and toxic signs reported as looked for were changes in appearance, swimming behaviour and behaviour in comparison to the control group.

b. Results were reported as “no symptoms observed”.

No sub-lethal effects were recorded in any of the control or test solutions.

C. REPORTED STATISTICS:

Mean measured analyte concentrations over 96 hours were determined.

Due to the study results (absence of mortality and sub-lethal effects), the statistical evaluation of the biological data was not attempted. The 24-, 48-, 72-, and 96-hour LC50, EC50 and LOEC values were all empirically determined to be greater than the nominal and maximum mean measured limit concentration tested over 96 hours. The 96-hour NOEC was determined as the nominal and maximum mean measured limit concentration

Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout (*Oncorhynchus mykiss*)

PMRA Submission Number 2006-4727; ID 1283207 EPA MRID Number 460984-23 APVMA ATS 40362

tested that exhibited no mortality or sub-lethal effects.

D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

The mortality and sub-lethal results reported support the study author's conclusions and the non-use of statistical analyses.

Statistical Method: None used. Statistical analysis was not considered necessary based on the absence of death and sub-lethal effects in the controls and test concentrations. The LC50, EC50, LOEC and NOEC values was estimated from visual inspection of the mortality and sub-lethal effects data and set at:

Mortality

24, 48, 72 and 96 h LC50s all >100 mg pyroxsulam (98% of active constituent)/L (nominal) or all >87 mg pyroxsulam/L (mean, analytically determined)

24, 48, 72 and 96 h NOECs all 100 mg pyroxsulam (98% of active constituent)/L (nominal) or all 87 mg pyroxsulam/L (mean, analytically determined).

Sublethal effects

24, 48, 72 and 96 h EC50s all >100 mg pyroxsulam (98% active constituent)/L (nominal) or all >87 mg pyroxsulam/L (mean, analytically determined).

24, 48, 72 and 96 h LOECs all >100 mg pyroxsulam (98% of active constituent)/L (nominal) or all >87 mg pyroxsulam/L (mean, analytically determined).

24, 48, 72 and 96 h NOECs all 100 mg pyroxsulam (98% active constituent)/L (nominal) or all 87 mg pyroxsulam/L (mean, analytically determined).

E. STUDY DEFICIENCIES:

The following deviations from guidelines or deficiencies were noted but not considered to have significantly affected the study's outcome:

Table 5. Study deficiencies/deviations from guidelines.

Parameter	Study report result	Template reference to unidentified US/OECD Guideline	US EPA OPPTS 850.1075 Fish Acute Toxicity Test, Freshwater and Marine, April 1996	OECD Guideline 203 for Testing Chemicals, Fish Acute Toxicity Test, adopted 17/07/92
<u>Fish length</u>	Mean length 6.6 cm, range 5.3-7.2 cm.	<i>EPA requires: Longest not > 2x shortest; OECD requires ... 5.0 ± 1.0 cm for rainbow trout</i>	The longest should not be more than twice the length of the shortest (p. 5, iii of OPPTS 850.1075). Therefore this guideline requirement is met.	Recommended total length of test fish: Rainbow trout 5.0 ± 1.0 (4-6 cm). Some fish were oversize. The Guideline states this should be reported and the rationale given.
<u>Acclimation:</u> Conditions: (same as test or not)	Acclimatisation temperature ~11-12°C, test temperature 11-13°C.		OECD 203 and US EPA OPPTS 850.1075 require holding water to have a temperature range of 13-17°C. The temperature range of 11-13°C is not expected to have adversely affected the fish or the study outcome. OPPTS 850.1075, p. 5, paragraph F: "Any changes in water temperature should not exceed 3°C per day. Fish should be held for a minimum of 7 days at the test	

Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout (*Oncorhynchus mykiss*)

PMRA Submission Number 2006-4727; ID 1283207 EPA MRID Number 460984-23 APVMA ATS 40362

			temperature prior to testing." Therefore, this guideline requirement is met.	
Test vessel Fill volume:	50 L	<i>EPA requires fill volume: 15-30 L of solution)</i>	The size, shape, and depth of the test chamber are acceptable if the specified flow rate and loading requirements can be achieved.	Equivalent requirement not located. The loading, in the study, was 0.5 g fish/L which meets the OECD requirement of a maximum of 1.0 g of fish/L in static tests.
Water parameters: Hardness	Total hardness ~2.5 mmol/L or 250 mg CaCO ₃ /L	<u>(Hardness</u> <i>EPA: 40 - 48 mg as CaCO₃/L</i> <i>OECD: 10 -250 mg as CaCO₃/L</i> NOTE: PMRA advised that the 40-48 mg/L range in the template is outdated as it is from an old guideline. PMRA do not use that range any more; instead referring to OECD and the more recent OPPTS guidelines.	Hardness should range between 40 and 180 mg/L as CaCO ₃ for freshwater species (Noted that this range is much larger than the 40-48 mg/L range in the template).	Hardness should range between 10 and 250 mg CaCO ₃ /L.
pH	Over 96 hours ranged from 8.1 to 8.4 in the controls and 8.0 to 8.1 in the test vessels.	<u>pH</u> <i>(EPA: 7.2 - 7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes, monthly range <0.8)</i> <i>OECD: 6.0 - 8.5</i>	pH must remain > 6.0 and < 8.0 for freshwater testing	A pH of 6.0 to 8.5 is preferable.
Dissolved oxygen	Over 96 hours ranged from 6.4 to 10.0 mg/L in the controls with the 6.4 mg/L result (=58% maximum saturation) occurring at 96 hours. The other control replicate at this time had an oxygen content of 6.5 mg/L, calculated as 59% of the maximum saturation value.	<u>Dissolved Oxygen</u> <i>EPA: Static: > 60% during 1st 48 hrs and > 40% during 2nd 48 hrs, flow-through: > 60%</i> <i>OECD: at least 80% saturation value.</i>	In static tests, the dissolved oxygen (DO) in each replicate should at all times be greater than 60 percent saturation.	The dissolved oxygen concentration must have been at least 60 per cent of the air saturation value throughout the test.
Temperature	Over 96 hours 11 to 13°C in the controls and 11 to 12°C in the test vessels	<u>Temperature:</u> <i>OECD: 13 - 17°C for rainbow trout</i>	10-14°C temperature range for rainbow trout.	13-17°C for rainbow trout

F. REVIEWER'S COMMENTS: This study was conducted as a limit test with a nominal concentration of 100 mg technical grade material/L (or as a mean-measured concentration, 87.0 mg pyroxsulam (XDE-742)/L). Consequently, technical grade pyroxsulam or XDE-742 is considered as, at worst, slightly toxic to the rainbow trout (i.e. 10 < 96 hour LC50 and EC50 ≤ 100 mg/L) based on mean measured concentrations of pyroxsulam.

Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout (*Oncorhynchus mykiss*)

PMRA Submission Number 2006-4727; ID 1283207 EPA MRID Number 460984-23 APVMA ATS 40362

The in-life portion of the definitive toxicity test was conducted between August 18 and August 22, 2003.

The analytical report (Genari, 2003) provided in the study report contained a signed GLP Compliance Statement, a signed Statement of the Quality Assurance Unit and a signed Certification statement which stated the analytical study was performed under the Study Director's supervision according to the procedures described and that the report presents a true and accurate record of the results obtained. Analysis was by HPLC/UV with calibration via an external standard. HPLC chromatograms of the untreated control (nominally 0 mg pyroxsulam/L), a sample with a nominal concentration of 100 mg pyroxsulam/L and a standard solution with a nominal concentration of 0.2334 mg pyroxsulam/L were presented. The control showed no peak associated with pyroxsulam while the sample and standard showed equivalent peaks.

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

The PMRA reviewer agrees with the conclusions of the APVMA reviewer. This study is acceptable to the PMRA. The PMRA will use the endpoint based on mean-measured concentrations for risk assessment purposes.

G. CONCLUSIONS:

This study is acceptable. The 96-h acute static toxicity (limit test) study with rainbow trout resulted in a 96-h LC50 and 96-h EC50 (based on sublethal effects) both of >87 mg pyroxsulam/L (>100 mg pyroxsulam/L based on nominal concentrations).

The 96 h NOEC/NOAECs for mortality and sub-lethal effects, as appropriate, were 87 mg pyroxsulam/L (100 mg pyroxsulam/L based on nominal concentrations).

Based on the results of this study, pyroxsulam (98% active constituent) would be classified as, at worst, slightly toxic to rainbow trout in accordance with the acute toxicity classification systems of the Australian Government Department of the Environment and Water Resources and of the US EPA (96 hour LC50 and EC50 both >10 but less than or equal to 100 mg/L), based on mean-measured concentrations).

Data Evaluation Report on the acute toxicity of pyroxsulam (XDE-742) to rainbow trout (*Oncorhynchus mykiss*)

PMRA Submission Number 2006-4727; ID 1283207 EPA MRID Number 460984-23 APVMA ATS 40362

III. REFERENCES:

Note: for the purpose of this parallel process work, references to standard guidelines or methodologies have been included at this time in the list of references.

No list of references was presented in the study report. The following list of references includes the company's study profile template and the references listed therein.

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 (referenced in Mercer, 2006 but not sighted for the preparation of the Australian DER of the study by Zok (2003)).

Genari G (2003). "Concentration Control Analysis of XDE-742/BAS 770 H TGAI in Water (Project No.: 12F0298/035031)", BASF Aktiengesellschaft, Crop Protection Division, Ecology and Environmental Analytics, 67114 Limbergerhof Germany, unpublished report. BASF Study Code 156301_1, 2 December 2003.

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, Dow AgroSciences Study ID NAFST814, BASF Study ID 155842_1 (referenced in Mercer, 2006 and sighted for the preparation of the DER of the study by Zok (2003)).

Mercer J (2006). "XDE-742/BAS 770 H - Acute toxicity on the rainbow trout (*Oncorhynchus mykiss*) in a static system over 96 hours". BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany. Dow AgroSciences. BASF Study No. 15F0298/035031.SPT and DAS Study Number 035031.SPT. 8 February 2006. Unpublished report.

Turner B J (2004a). "Determination of Water Solubility for XDE-742", 22 December 2004. Unpublished report of Dow AgroSciences LLC, Indianapolis, Indiana (referenced in Mercer, 2006 but not sighted for the preparation of the Australian DER of the study by Zok (2003)).

Turner B J (2004b). "Determination of Octanol/Water Partition Coefficient for XDE-742", 22 December 2004. Unpublished report of Dow AgroSciences LLC, Indianapolis, Indiana (referenced in Mercer, 2006 but not sighted for the preparation of the Australian DER of the study by Zok (2003)).

Zok S. (2003): "XDE-742/BAS 770 H - Acute toxicity study on the fathead minnow (*Pimephales promelas*)". BASF Aktiengesellschaft, 67056 Ludwigshafen/Rhein, Germany. Dow AgroSciences, unpublished report, BASF Study No. 15F0298/035032.

Approved 04/01/01 C.K.