Data Evaluation Report on the Acute Toxicity of JAU 6476 (Prothioconazole) to Bluegill (*Lepomis macrochirus*)
PMRA Submission Number 2004-0843 EPA MRID Number 46246022

Data Requirement:		
	PMRA DATA CODE	9.5.2.2
	EPA DP Barcode	D303488
	OECD Data Point	8.2.1
	EPA MRID	46246022
	EPA Guideline	§72-1a

Test material: JAU 6476 **Purity:** 98.4%
Common name: Prothioconazole
Chemical:
IUPAC name: **2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione**
CAS name: **2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione**
CAS No.: 178928-70-6
Synonyms: JAU6476 Technical

Primary Reviewer: Rebecca Bryan **Signature:**
Staff Scientist, Dynamac Corporation **Date:** 8/31/04

QC Reviewer: Gregory Hess **Signature:**
Staff Scientist, Dynamac Corporation **Date:** 9/7/04

Primary Reviewer: Kevin Costello **Date:**
OPP/EFED/ERB-IV

Secondary Reviewer: Christopher J. Salice **Date:** 9/8/05
OPP/EFED/ERB-IV Chris J. Salice 9-8-05

Secondary Reviewer: Émilie Larivière (#1269) **Date:** 7/11/05
HC, PMRA, EAD 7/11/05

Reference/Submission No.: 2004-0843

Company Code: BCZ
Active Code: PRB
Use Site Category: 7, 13, 14
EPA PC Code: 113961

Date Evaluation Completed:

CITATION: Dorgerloh, M. 1999. JAU6476-Acute Toxicity (96 hours) to Bluegill (*Lepomis macrochirus*) in a Static Test. Unpublished study performed by Bayer AG Crop Protection Business Group, Crop Protection Development, Institute of Metabolism Research and Residue Analysis, Leverkusen, Germany, Laboratory Study No. E 2521695-0, and sponsored by Bayer CropScience, RTP, NC. Experimental start date August 2, 1999 and experimental termination date August 11, 1999. Final report issued November 2, 1999.

EXECUTIVE SUMMARY:

The 96-hour acute toxicity of JAU 6476 (Prothioconazole) to Bluegill (*Lepomis macrochirus*) was studied under static conditions. Fish were exposed to JAU 6476 (Prothioconazole) at nominal concentrations of 0 (negative and solvent controls), 1.91, 3.19, 5.31, 8.86, and 14.8 ppm a.i. Mean-measured concentrations were <0.11 (<LOQ, controls), 1.69, 2.81, 4.81, 6.65, and 8.88 ppm a.i.

After 96 hours of exposure, there was 5, 45, 100, and 100% mortality in the mean-measured 2.81, 4.81, 6.65, and 8.88 ppm a.i. treament groups, respectively. There were no mortalities in the controls, or in the 1.69 ppm a.i. treatment group. The calculated 96-hour LC_{50} (with 95% C.I.) was 4.59 (4.02-5.09) ppm a.i., which categorizes JAU 6476 (Prothioconazole) as moderately toxic to Bluegill (*Lepomis macrochirus*) on an acute toxicity basis. Sub-lethal effects observed during the exposure period included loss of equilibrium, quiescent, lying on the aquarium bottom, and/or vertical oriented. After 96 hours of exposure, sub-lethal effects were observed in surviving fish from the mean-measured 2.81and 4.81 ppm a.i. treatment groups. The NOAEC and LOAEC values for mortality and sub-lethal effects were 1.69 and 2.81 ppm a.i., respectively.

This study is scientifically sound, but and satisfies the guideline requirements for an acute toxicity study with freshwater fish (§72-1). Study deficiencies include a deviation on mean fish weight; the mean weight of fish at study initiation was 0.4 g, which is less than the recommended initial weight range of 0.5 to 5 g. Also, there were observed solubility issues at the three highest treatment levels (note STUDY DEFICIENCIES section below). These deficiencies, however, do not significantly compromise the study and it is classified as ACCEPTABLE.

Results Synopsis

Test Organism Size/Age (mean Weight or Length):	Age not specified; 0.4 ± 0.1 g , 2.6 ± 0.2 cm(mean of sample at the start of the study)
Test Type (Flow-through, Static, Static Renewal):	Static

96-Hour

LC_{50}: 4.59 ppm a.i.	95% C.I.: 4.02-5.09 ppm a.i.
Probit Slope: 4.59	95% C.I.: 5.90-13.82
NOAEC: 1.69 ppm a.i.	
LOAEC: 2.81 ppm a.i.	

Endpoints affected: Mortality and sub-lethal effects (same conclusions)

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was based on procedures outlined in EC Methods for Determination of Ecotoxicity C. 1; OECD Guideline for the Testing of Chemicals No. 203, "Fish, Acute Toxicity Test"; and U.S. EPA OPP Guideline 72-1 and OPPTS Method 850.1075. Deviations from §72-1 were:

1. Mean fish wet weight (0.4 g) was determined from fish at the start of the study, and was less than the recommended initial range of 0.5-5g.

2. The age of the test organism at test initiation was not specified.

3. The particulate matter concentration in the dilution water was not reported.

4. It was not reported whether or not aeration was used during the exposure period.

5. Recoveries were <65% for the nominal 15 ppm a.i. treatment group on days 0 and 2 and test material was observed at the surface and/or on the bottom of the test vessels in the three highest treatment levels during the exposure period.

COMPLIANCE: Signed and dated GLP, No Data Confidentiality, and Quality Assurance statements were provided. This study was conducted in compliance with the Principles of Good Laboratory Practice (Chemicals Law (Chem G), dated July 25, 1994, Annex 1, and the OECD Principles of Good Laboratory Practice (1997), (pp. 1c and 2).

A. MATERIALS:

1. Test Material JAU 6476 (Prothioconazole)

Description: White powder

Lot No./Batch No. : Fl. 6233/0031

Purity: 98.4%

Stability of Compound Under Test Conditions: Recoveries (all test levels) were 56-104% of nominal concentrations in day 0 samples, 64-86% in day 2 samples, and 77-84% in day 4 samples (5.8 Table 7, p. 18). The day 4 test concentration for the nominal 8.86 ppm a.i. treatment group was measured on day 3 due to 100% mortality. In the highest treatment group, nominal 14.8 ppm a.i., the recoveries were <65% on days 0 and 2 (test termination due to 100% mortality).

Storage conditions of test chemicals: The test chemical was stored at room temperature.

Water Solubility: 89 mg/L (23°C, pH 7)

Hydrolytic Stability: t½: >500h (50°C, pH 4-9)
OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound. All OECD requirements were not reported.

2. Test organism:

Species: Bluegill (*Lepomis macrochirus*)

Age at test initiation: Not reported

Weight at test initiation: 0.4 ± 0.1 g (average at study start)

Length at test initiation: 2.6 ± 0.2 cm (average at study start)

Source: Osage Catfisheries, Inc., Osage Beach, MO, USA

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study: Definitive test concentrations were based upon historical data. No range-finding study was 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 (observed for at least 14 days). Same as test Commercial trout diet provided daily, except during the 48 hours prior to testing. Mortality was <3% in the 48 hours prior to testing.	A prophylactic treatment of Oxytetracyclin-Hydrochlorid (4 g/100 l water, 3 x 24h) was used immediately after arrival of the fish on July 15, 16 and 19th (p. 7). Fish were not used for testing until 2 weeks after the last treatment. *EPA requires: minimum 14 days; no feeding during test OECD requires minimum of 12 days.*
Duration of the test	96 hours	*EPA/OECD requires: 96 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: Must provide reproducible supply of toxicant, with a consistent flow rate of 5-10 vol/24 hours, and meter systems calibrated before study and checked twice daily during test period*

Parameter	Details	Remarks Criteria
Aeration, if any	Dilution water was aerated prior to use in the study. It was not reported whether or not aeration was used during the exposure period.	*EPA requires: no aeration; OECD permits aeration*
Test vessel Material: (glass/stainless steel) Size: Fill volume:	Glass aquaria 32 x 36 x 38 cm (l x d x h) 40 L	*EPA requires: Size 19 L (5 gal) or 30 x 60 x 30 cm* *Fill volume: 15-30 L of solution*
Source of dilution water	The dilution water was reconstituted water (salt stock solutions were added to demineralized water). The water was aerated to oxygen saturation prior to testing.	Results of analysis of the diluent water supply (July 8, 1999) for various parameters including metals, pesticides, and contaminants are provided in Appendices C-E, pp. 24-26. *EPA 1975; Soft reconstituted water or water from a natural source, **not** dechlorinated tap water;* *OECD permits dechlorinated tap water.*

Parameter	Details	Remarks Criteria
Water parameters: Hardness	40-60 mg $CaCO_3$/L	
pH	7.0-7.3	
Dissolved oxygen	98-105% saturation	
Total Organic Carbon	<2 mg/L	***Hardness and pH*** *EPA requires hardness of 40-48 mg/L as $CaCO_3$ and pH of 7.2-7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes; monthly range <0.8. OECD allows hardness of 10-250 mg/L as $CaCO_3$ and pH between 6 and 8.5.* ***Dissolved Oxygen*** *Renewal: ≥60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs* *Flow-through: ≥60% through out test. OECD requires at least 80% saturation value.* ***Temperature*** *EPA requires 22 ± 1 °C for estuarine/marine. OECD requires range of 21 - 25 °C for bluegill and 13-17 °C for rainbow trout.* ***Salinity*** *30-34 ‰ (parts per thousand) salinity, weekly range < 6 ‰* ***EPA water quality*** *measured at beginning of test and every 48 hours*
Particulate Matter	Not reported	
Metals	<LOD; See Appendix C, p. 24	
Pesticides	<0.05 µg/L	
Chlorine	residual: <0.01 mg/L	
Temperature	22.2-23.5°C	
{Salinity for marine or estuarine species}	N/A	
Intervals of water quality measurement	DO, and pH were determined daily in the controls and treatment groups. Temperature was measured hourly in the control aquarium.	

Parameter	Details	Remarks Criteria
Concentration of test material: nominal: measured:	0 (negative and solvent controls), 1.91, 3.19, 5.31, 8.86, and 14.8 ppm a.i. <0.11 (<LOQ, controls), 1.69, 2.81, 4.81, 6.65, and 8.88 ppm a.i.	The nominal and measured treatment concentrations were corrected for the purity of the test material (98.4% a.i.; Table 7, p. 18). *EPA/OECD requires: Control and five treatment levels. Each conc. should be 60% of the next highest conc., and should be in a geometric series*
Solvent (type, percentage, if used)	Acetone, 0.1 ppm	*EPA requires: Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests; OECD requires solvent, exceed 100 mg/L.*
Number of fish/replicates: negative control: solvent control: treated:	20 fish, one replicate 20 fish, one replicate 20 fish, one replicate	*EPA: ≥ 10/concentration; OECD requires at least 7 fish/concentration*
Biomass loading rate	0.20 g fish/L (instantaneous)	*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*
Lighting	16-hours light/8-hours dark	*EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod.*
Feeding	Animals were not fed during testing.	*EPA/OECD requires: No feeding during the study*

Parameter	Details	Remarks Criteria
Stability of chemical in the test system	Recoveries (all test levels) were 56-104% of nominal concentrations in day 0 samples, 64-86% in day 2 samples, and 77-84% in day 4 samples (5.8 Table 7, p. 18).	In the highest treatment group, nominal 14.8 ppm a.i., the recoveries were <65% on days 0 and 2 (test termination due to 100% mortality). The day 4 test concentration for the nominal 8.86 ppm a.i. treatment group was measured on day 3 due to 100% mortality.
Recovery of chemical Level of Quantitation Level of Detection	56-104% of nominal 0.11 ppm a.i. Not reported	Based on mean measured concentrations (5.8 Table 7, p. 18).
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/toxicity symptoms	Mortality and sublethal effects	
Observation intervals	4, 24, 48, 72, and 96 hours of exposure	*EPA/OECD requires: minimally every 24 hours*
Were raw data included?	Yes, sufficient	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

After 96 hours of exposure, there was 5, 45, 100, and 100% mortality in the 2.81, 4.81, 6.65, and 8.88 ppm a.i. treament groups, respectively (Table 1, p. 11). There were no mortalities in the controls, or in the 1.69 ppm a.i. treatment group. The calculated 96-hour LC_{50} (with 95% C.I.) was 4.59 (4.02-5.09) ppm a.i. and the NOAEC and LOAEC values for mortality were 1.69 and 2.81 ppm a.i., respectively.

Table 3: Effect of JAU 6476 (Prothioconazole) on mortality of Bluegill (*Lepomis macrochirus*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	No. of Fish at Start of Study	Observation Period					
		4-24 Hours		48 Hours		72-96 Hours	
		No Dead	% Mortality	No Dead	% Mortality	No Dead	% Mortality
Negative control	20	0	0	0	0	0	0
Solvent control	20	0	0	0	0	0	0
1.69 (1.91)	20	0	0	0	0	0	0
2.81 (3.19)	20	1	5	1	5	1	5
4.81 (5.31)	20	2	10	5	25	9	45
6.65 (8.86)	20	6	30	13	65	20	100
8.88 (14.8)	20	7	35	20	100	20	100
NOAEC (mortality), ppm a.i.		1.69		1.69		1.69	
LC_{50} (95% C.I.), ppm a.i.		>8.88		5.56 (4.88-6.23)		4.59 (4.02-5.09)	
Positive control, if used mortality: LC_{50}:		N/A	N/A	N/A	N/A	N/A	N/A

N/A = Not applicable

B. NON-LETHAL TOXICITY ENDPOINTS:

Sub-lethal effects observed during the exposure period included loss of equilibrium, quiescence, lying on the aquarium bottom, and/or vertical orientation (Table 1, p. 11). After 96 hours of exposure, sub-lethal effects were observed in surviving fish from the mean-measured 2.81and 4.81 ppm a.i. treatment groups. The NOAEC and LOAEC values for sub-lethal effects were 1.69 and 2.81 ppm a.i., respectively.

Table 4: Sublethal effects of JAU 6476 (Prothioconazole) on Bluegill (*Lepomis macrochirus*).

Treatment, ppm a.i. Mean-Measured and (Nominal) Concn.	Observation Period			
	Endpoint at 4-24 Hours	Endpoint at 48 Hours	Endpoint at 72 Hours	Endpoint at 96 Hours
	% Affected	% Affected	% Affected	% Affected
Negative control	AN	AN	AN	AN
Solvent control	AN	AN	AN	AN
1.69 (1.91)	AN	AN	AN	AN
2.81 (3.19)	Quiescent - 100%	Quiescent - 100%	Quiescent - 100%	Quiescent - 100%
4.81 (5.31)	Quiescent - 100%	Loss of equilibrium, quiescent, and lying on the aquarium bottom - 100%	Loss of equilibrium, quiescent, and lying on the aquarium bottom - 100%	Quiescent, and lying on the aquarium bottom - 100%
6.65 (8.86)	Loss of equilibrium, quiescent, lying on the aquarium bottom, and vertically oriented - 100%	Quiescent and lying on the aquarium bottom-100%	--	--
8.88 (14.8)	Loss of equilibrium, quiescent, lying on the aquarium bottom, and vertical oriented - 100%	--	--	--
NOAEC, ppm a.i.	1.69			
LOAEC, ppm a.i.	2.81			
EC_{50}, ppm a.i.	Not determined			
Positive control, if used % sublethal effect: EC_{50}:	N/A	N/A	N/A	N/A

AN - Appeared normal.
– 100% mortality
N/A = Not applicable

C. REPORTED STATISTICS:

The LC_{50} values (every 24 hours) were calculated using the probit method (computer program of C.E. Stephan). NOAEC and LOAEC values were visually determined, based on the observed treatment-related mortality and sub-lethal effects. All reported toxicity values were determined using the mean-measured treatment concentrations.

96-Hour
LC_{50}: 4.59 ppm a.i. 95% C.I.: 4.02-5.09 ppm a.i.
NOAEC: 1.69 ppm a.i.
LOAEC: 2.81 ppm a.i.
Endpoints affected: Mortality and sub-lethal effects (same conclusions)

D. VERIFICATION OF STATISTICAL RESULTS:

The 96-hour LC_{50} was determined using theprobit method via TOXANAL statistical software. The NOAEC and LOAEC values were visually determined based on the sub-lethal effects data. All toxicity values were determined using the mean-measured treatment concentrations.

96-Hour
Mortality:
LC_{50}: 4.59 ppm a.i. 95% C.I.: 4.02-5.09 ppm a.i.
Probit slope: 9.86 95% C.I.: 5.90-13.82
Sub-lethal:
NOAEC: 1.69 ppm a.i.
LOAEC: 2.81 ppm a.i.
Endpoints affected: Mortality and sub-lethal effects
Most sensitive endpoint: Sub-lethal effects

E. STUDY DEFICIENCIES:

This study is scientifically sound, and satisfies the guideline requirements for an acute toxicity study with freshwater fish (§72-1). This study is classified as ACCEPTABLE.

A potential study deficiency is that the test material was observed from 0-48 hours at the surface and on the bottom of the test vessels in the mean-measured 6.65 and 8.88 ppm a.i. treatment groups, on the bottom of the test vessels in the 6.65 ppm a.i. treatment group at 72-hours (test termination for this level), and at the surface in the 4.81 ppm a.i. treatment group from 0-48 hours. The 1.69 and 2.81 ppm a.i. treatment groups were clear and showed no signs of test material insolubility throughout the 96-hour exposure period. However, since test concentrations were measured, the apparent solubility issues are not considered a major deficiency.

The percent of nominal analytical recoveries were 56 and 64% at 0 and 48 hours (day 2; test termination due to 100% mortality) for the nominal 15.0 ppm a.i. treatment group (highest treatment level). The study author considered the test material stable under test conditions (p. 10) and the limit of solubility was reported to be 89 ppm (at 23°C, pH7). No explanation of the low (<70% of nominal) analytical recoveries at the 15 ppm a.i. treatment level were reported. The reviewer does considers this deviation minor because identical biological results were observed in the mean-measured 6.65 ppm a.i. (the second highest treatment level) by 72-hours and the mean analytical recovery was 75% of nominal.

All other deficiencies were considered minor and did not affect the validity or acceptability of this study.

F. REVIEWER'S COMMENTS:

The results of the reviewer's statistical verification were identical to those of the study author. The reviewer and study author determined NOAEC and LOAEC values were identical.

G. CONCLUSIONS:

This study is scientifically sound, and satisfies the guideline requirements for an acute toxicity study with freshwater fish (§72-1). However, there were observed solubility issues at the three highest treatment levels. The study provides information that will be useful for future risk assessment purposes, and is classified ACCEPTABLE. Based on the results of this study, JAU 6476 (Prothioconazole) is categorized as moderately toxic to Bluegill (*Lepomis macrochirus*) on an acute toxicity basis. The NOAEC and LOAEC values for mortality and sublethal effects were 1.69 and 2.81 ppm a.i., respectively.

96-Hour
LC_{50}: 4.59 ppm a.i. 95% C.I.: 4.02-5.09 ppm a.i.
Probit slope: 9.86 95% C.I.: 5.90-13.82
NOAEC: 1.69 ppm a.i.
LOAEC: 2.81 ppm a.i.
Endpoints affected: Mortality and sublethal effects (same conclusions)

III. REFERENCES:

Brauhn J.L., Schoettger, R.A., " Aquisition Culture of Research Fish: Rainbow Trout, Fathead Minnows, Channel Catfish, and Bluegill Sunfish". Environmental Protection Agency, Ecological Research Series EPA-660/3-75-011, May 1975

Stephan, C.E., 1982, U.S. EPA, Environmental Research Laboratory, Duluth, MN. Personal Communication to Dr. Lowell Bahner, Chairman, ASTM Task Group on Calculating LC50.

Stephan, C.E. 1977, Methods for Calculating and LC50. In: Aquatic Toxicology and Hazard Evaluation. ASTM STP 634. F.L. Meyer and J.L. Hamelink, eds. American Society for Testing and Materials. Philadelphia, PA. pp. 65-84

ASTM Standard E 729-1988, Standard Guide for Conducting Acute Toxicity Tests with fishes, Macroinvertebrates, and Amphibians. Philadelphia, PA.

APPENDIX 1. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

TOXANAL Results:

RESULTS CALCULATED USING THE **MOVING AVERAGE METHOD**

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	4.499462E-02	**4.231507**	**3.792719**	**4.789524**

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.1614235	1	.2840802

SLOPE = 9.860205
95 PERCENT CONFIDENCE LIMITS = 5.898617 AND 13.82179

LC50 = 4.589748
95 PERCENT CONFIDENCE LIMITS = 4.01673 AND 5.085982

LC10 = 3.411837
95 PERCENT CONFIDENCE LIMITS = 2.567025 AND 3.923094

EAD Assessment of USEPA DER

Reviewer: Émilie Larivière (#1269); PMRA Date: July 11, 2005

PMRA Submission Number: 2004-0843

Study Type: Acute Toxicity to Warm Water Fish (bluegill sunfish)

Dorgerloh, M. 1999. JAU6476-Acute Toxicity (96 hours) to Bluegill (*Lepomis macrochirus*) in a Static Test. Unpublished study performed by Bayer AG Crop Protection Business Group, Crop Protection Development, Institute of Metabolism Research and Residue Analysis, Leverkusen, Germany, Laboratory Study No. E 2521695-0, and sponsored by Bayer CropScience, RTP, NC. Experimental start date August 2, 1999 and experimental termination date August 11, 1999. Final report issued November 2, 1999.

PMRA DATA CODE: 9.5.2.2
EPA DP Barcode: D303488
OECD Data Point: 8.2.1
EPA MRID: 46246022
EPA Guideline: §72-1a

Reviewing Agency: US EPA

EAD Executive Summary:

The 96-hour acute toxicity of prothioconazole (JAU 6476; purity 98.4%) to bluegill (*Lepomis macrochirus*) was studied under static conditions. The study was conducted in accordance with EC Methods for Determination of Ecotoxicity C. 1, OECD Guideline 203, and U.S. EPA OPP Guideline 72-1, and in compliance with German and OECD principles of GLP. Fish were exposed to prothioconazole at nominal concentrations of 0 (negative and solvent controls), 1.91, 3.19, 5.31, 8.86, and 14.8 mg a.i./L. Mean measured concentrations were <0.11 (<LOQ, controls), 1.69, 2.81, 4.81, 6.65, and 8.88 mg a.i./L.

After 96 hours of exposure, 5, 45, 100, and 100% mortality was observed in the mean measured 2.81, 4.81, 6.65, and 8.88 mg a.i./L treament groups, respectively. There were no mortalities in the controls, or in the 1.69 mg a.i./L treatment group. The calculated 96-hour LC_{50} (with 95% C.I.) was 4.59 (4.02-5.09) mg a.i./L, which categorizes prothioconazole as moderately toxic to bluegill (*Lepomis macrochirus*) on an acute toxicity basis, according to the classification scheme

of the U.S. EPA (1985). Sub-lethal effects observed during the exposure period included loss of equilibrium, quiescence, lying on the aquarium bottom, and/or vertical orientation. After 96 hours of exposure, sub-lethal effects were observed in surviving fish from the mean-measured 2.81and 4.81 mg a.i./L treatment groups. The NOEC and LOEC values for mortality and sub-lethal effects were 1.69 and 2.81 mg a.i./L, respectively.

Results Synopsis:

Test Organism Size/Age (mean Weight or Length):	Age not specified; 0.4 ± 0.1 g , 2.6 ± 0.2 cm(mean of sample at the start of the study)
Test Type (Flow-through, Static, Static Renewal):	Static

96-Hour

LC_{50}: 4.59 mg a.i./L 95% C.I.: 4.02-5.09 mg a.i./L
Probit Slope: 4.59 95% C.I.: 5.90-13.82
NOEC: 1.69 mg a.i./L
LOEC: 2.81 mg a.i./L
Endpoints affected: Mortality and sub-lethal effects (same conclusions)

EAD comments:

1. The appropriate PMRA information (PMRA Submission Number, PMRA Data Code, PMRA company code, PMRA active ingredient code, PMRA use site category, OECD data point, name of PMRA secondary reviewer) was added to the EPA-DER as well as information on the chemical name (IUPAC name, CAS name and synonym) available from the PMRA Chemistry review. The CAS name of prothioconazole is reported on p. 36 of the study report.

2. Health Canada PMRA DACO No. 9.5.2.1 was removed for the list of guidelines followed in the EPA-DER, as DACO 9.5.2.1 is a data requirement and not a guideline.

3. The PMRA-EAD agrees with the conclusions reached by the EPA reviewer.

Study Acceptability: This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with bluegill sunfish. This study is classified as ACCEPTABLE.