Data Evaluation Report on the acute toxicity of JAU6476-Desthio to Fathead Minnow (*Pimephales promelas*)
PMRA Submission Number 2004-0843 EPA MRID Number 46246026

Data Requirement:	PMRA DATA CODE	9.5.2.3
	EPA DP Barcode	D303488
	OECD Data Point	8.2.1
	EPA MRID	46246026
	EPA Guideline	§72-1a

Test material: JAU6476-desthio **Purity:** 96.5%
Common name: JAU6476-desthio
Chemical: IUPAC name: 2-(1-Chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1, 2, 4-triazol-l-yl)-propan-2-ol
CAS name: 2-(1-Chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1, 2, 4-triazol-l-yl)-propan-2-ol
CAS No.: 120983-64-4
Synonyms: SXX 0665

Primary Reviewer: John Marton
Staff Scientist, Dynamac Corporation
Signature:
Date: 8/03/04

QC Reviewer: Gregory Hess
Staff Scientist, Dynamac Corporation
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Date: 9/13/04

Primary Reviewer: Bill Evans, Biologist
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Date:

Secondary Reviewer(s): Christopher J. Salice
OPP/EFED/ERB - IV Chi J. Salice 6-30-05
Date: 6/30/2005

Secondary Reviewer: Émilie Larivière (#1269)
HC, PMRA, EAD
Date: 7/13/2005 7/13/05

Reference/Submission No.: 2004-0843

Company Code: BCZ
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Date Evaluation Completed:

CITATION: Kern, M.E. and C.V. Lam. 2003. Acute Toxicity of JAU6476-Desthio to the Fathead Minnow (*Pimephales promelas*) Under Static-Renewal Conditions. Unpublished study performed by Bayer CropScience, Research and Development Department, Ecotoxicology, Stilwell, Kansas, Laboratory Study No. EBJAX071 (J68111202), and sponsored by Bayer CropScience, RTP, NC. Experimental start date October 22, 2001 and experimental termination date October 26, 2001. The final report issued December 16, 2003.

EXECUTIVE SUMMARY:

In a 96-hour acute toxicity study, Fathead Minnow (*Pimephales promelas*) were exposed under static-renewal conditions (renewed at 48 hours) to JAU6476-Desthio at nominal concentrations of 0 (negative and solvent controls), 0.94, 1.88, 3.75, 7.50, and 15.0 ppm. Mean-measured concentrations were <0.08 (<LOQ, controls), 0.96, 2.06, 3.85, 7.99, and 16.3 ppm a.i.

After 96 hours of exposure, mortality was 0% in the controls and mean-measured 0.96 through 2.06 and 7.99 ppm a.i. treatment groups. Mortality was 5 and 100% in the 3.85 and 16.3 ppm a.i. treatment groups, respectively. The 96-hour LC_{50} (with 95% C.I.) was 11.41 (7.99-16.30) ppm a.i., which classifies JAU6476-Desthio as slightly toxic to Fathead Minnow (*Pimephales promelas*) on an acute toxicity basis. The NOAEC and LOAEC, based on mortality, were 7.99 and 16.3 ppm a.i., respectively. Sub-lethal effects observed during the exposure period included fish at the surface and on the bottom of the test vessel, loss of equilibrium, quiescence, darkened coloration, and erratic behavior. Treatment related effects were observed in 15% of surviving fish from the mean-measured 7.99 ppm a.i. treatment group. No sub-lethal effects were observed in the controls or the 0.96 through 3.85 ppm a.i. treatment groups. The NOAEC and LOAEC, based on sub-lethal effects, were 3.85 and 7.99 ppm a.i., respectively.

This study is scientifically sound, and satisfies the guideline requirements for an acute toxicity study with freshwater fish, warm water species (§72-1a). The study is classified as ACCEPTABLE. The NOAEC and LOAEC, based on sub-lethal effects, were 3.85 and 7.99 ppm a.i., respectively.

Results Synopsis

Test Organism Size/Age (mean Weight or Length):	0.14 to 0.57 g (wet, mean = 0.29 g) and 21 to 33 mm (mean = 0.29 g); in the negative control at test termination. Approx. 78 days old at test initiation.
Test Type (Flow-through, Static, Static Renewal):	Static-renewal

96-Hour
LC_{50}: 11.4 ppm a.i. 95% C.I.: 7.99-16.3 ppm a.i.
Probit slope: N/A
NOAEC: 3.85 ppm a.i.
LOAEC: 7.99 ppm a.i.
Endpoints affected: Mortality and sub-lethal (most sensitive)

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was based on procedures outlined in U.S. EPA (1975, 1982, 1985, and 1989) and ASTM (1996). Deviations from U.S. EPA §72-1a included:

1. The weights of the negative (dilution water) control fish at test termination 0.14 to 0.57 g (wet, mean = 0.29 g) ranged less than the US EPA recommended initial weight range of 0.5 to 5 g.

2. The concentration of total organic carbon found in the dilution water was not reported.

The use of smaller than recommended fish did not affect the acceptability of this study since the fish were larger

than the sac-fry stage; exposure to fish in the sac-fry stage may differ compared to the juvenile stage.

COMPLIANCE: Signed and dated GLP, No Data Confidentiality, and Quality Assurance statements were provided. This study was conducted in accordance with the GLP standards of the U.S. EPA (40 CFR Part 160) with the exception of the dilution water screening analysis.

A. MATERIALS:

1. Test Material JAU6476-Desthio

Description: White powder

Lot No./Batch No.: RUX76-105/8a

Purity: 96.5% a.i.

Stability of Compound Under Test Conditions: The stability of the test substance in the dilution water during the course of the study was demonstrated by analytical determinations at 0 "new", 2"new", and 4 "old" days. Recoveries (all test levels) were 99-109% of nominal concentrations in the 0 and 2 day "new" samples and 101-111% in 4 day "old" samples (Table 2, p. 18). Mean-measured recoveries ranged from 102-110% of nominal concentrations.

Storage conditions of test chemicals: Stored in the dark at approx. 4°C.

Water Solubility: Solubility was determined to be approximately 25 mg metabolite/L with a solvent load of 0.5 ml of acetone per liter of water (p. 10).

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: Fathead Minnow (*Pimephales promelas*)

Age at test initiation: Approx. 78 days old at test initiation

Weight at study initiation: 0.14 to 0.57 g (wet, mean = 0.29 g) in the negative control at test termination.

Length at study initiation: 21 to 33 mm (mean = 26.5 mm) in the negative control at test termination.

Source: Aquatic Bio Systems, Fort Collins, Colorado.

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study: The nominal definitive treatment concentrations were based on historical data and preliminary tests with the Fathead Minnow (*Pimphales promelas*). A range-finding test was performed at nominal 0 (solvent control), 0.75, 1.5, 6.25, 15, and 25 ppm a.i. treatment concnetrations. Sub-lethal effects and mortalities were noted in the 6.25 and 15 ppm groups and 100% mortality was observed at the 15 and 25 ppm a.i. treatment levels within 24 hours of exposure. No treatment related effects were observed in the 0.75 and 1.5 ppm a.i. treatment groups.

b. Definitive Study: Based on the results from the range-finding study, nominal concentrations in the definitive test were set at 0 (negative and solvent control), 0.94, 1.88, 3.75, 7.50, and 15.0 ppm a.i..

Table 1. Experimental Parameters

Parameter	Details	Remarks Criteria
Acclimation period:	At least 14 days prior to testing	
Conditions: (same as test or not)	Same as test	
Feeding:	Fed newly hatched brine shrimp and/or commercial fish food (Tetramin Trout Chow). Fish were not fed two days prior to and during testing.	*EPA requires: minimum 14 days; no feeding during test OECD requires minimum of 12 days.*
Health: (any mortality observed)	During the 48 hours prior to testing, fish showed no signs of disease or stress and only one mortality was observed.	
Duration of the test	96-hour	*EPA/OECD requires: 96 hour*

Parameter	Details	Remarks Criteria
Test condition static/flow through Type of dilution system- for flow through method. Renewal rate for static renewal	 Static-renewal N/A Renewed on Day 2	 *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.*
Aeration, if any	Not aerated during the exposure period.	*EPA requires: no aeration; OECD permits aeration*
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	 Glass aquaria 48 L (52.0 x 30.5 x 30.5 cm; LxWxH) 34 L (21.5-cm depth)	 *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 spring water, filtered with a multimedia filter, activated carbon, and UV sterilizer, and blended with reverse osmosis water. This was then blended with filtered, decholorinated city water.	The dechlorinated water used in the test is not recommended according to US EPA guidance, however, modern dechlorination and monitoring techniques were used to ensure that the residual chlorine concentration was <0.003 ppm (p. 11). The adequacy of the dilution water was verified w/ development and reproduction tests using the fathead minnow, which indicated no detrimental effects. The reviewer does not consider this a deviation given the dechlorination and monitoring methods used.

Parameter	Details	Remarks Criteria
		EPA 1975; Soft reconstituted water or water from a natural source, ***not*** *dechlorinated tap water;* *OECD permits dechlorinated tap water.*
Water parameters: Hardness	48-52 mg $CaCO_3$/L	The dilution water hardness ranged higher than EPA recommended values (40-48 mg $CaCO_3$).
pH	7.4-7.7	
Dissolved oxygen	5.6-8.6 mg/L (≥64% saturation)	Mean alkalinity was 41 mg/L as $CaCO_3$.
Total Organic Carbon	Not reported	
Particulate Matter	<1 ppm as total suspended solids.	Mean conductivity was 132 µmhos/cm.
Metals	See Table 1, p. 16.	Results of the analysis of the lab dilution water for July 18, 2001 for pesticides, organics, and metals are provided in Table 1, p. 16-17.
Pesticides	<LOD	
Chlorine	residual: <0.003 ppm	
Temperature	21.3-23.2°C	***Hardness and pH*** *EPA requires hardness of 40-48 mg/L as $CaCO_3$ and pH of 7.2-7.6. 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 12 °C for coldwater species and 17-22 °C for warmwater species. OECD requires range of 21 - 25 °C for bluegill and 13-17 °C for rainbow trout.* ***EPA water quality*** *measured at beginning of test and every 48 hours*
Intervals of water quality measurement	The hardness, pH, conductivity, and alkalinity were measured in all aquaria on Day 0, 2, and 4. DO was measured daily in each aquaria and in the "old" and "new" test solutions on day 2. Temperature was measured hourly.	

Parameter	Details	Remarks Criteria
Concentration of test material: nominal:	0 (negative and solvent controls), 0.94, 1.88, 3.75, 7.50, and 15.0 ppm a.i.	Mean-measured concentrations are provided in Table 2, p. 18.
measured:	<0.08 (LOQ; negative and solvent controls), 0.96, 2.06, 3.85, 7.99, and 16.3 ppm a.i.	*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 (0.5mL/L)	*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:	20 fish, one replicate	
solvent control:	20 fish, one replicate	*EPA: ≥ 10/concentration; OECD requires at least 7 fish/concentration*
treated:	20 fish, one replicate	
Biomass loading rate	0.17 g fish/L	*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, with a 30-minute transition period.	Mean light intensity of 730 lux at the water surface during daylight hours. *EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod.*

Parameter	Details	Remarks Criteria
Feeding	Animals were not fed during testing.	*EPA/OECD requires: No feeding during the study*
Recovery of chemical Level of Quantitation Level of Detection	95-107% of nominal. 0.08 ppm a.i. Not reported	Based on quality control matrix spikes fortified at 0.98 ppm a.i and analyzed concurrently with exposure samples on days 0, 2, and 4 (Table 2, p. 18).
Positive control {if used, indicate the chemical and concentrations}	N/A	
Other parameters, if any		

2. Observations:

Table 2: Observations

Criteria	Details	Remarks/Criteria
Parameters measured including the sub-lethal effects/toxicity symptoms	Mortality and sub-lethal effects	
Observation intervals	at 4, 24, 48, 72, and 96 hours.	*(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, mortality was 0% in the controls and mean-measured 0.96 through 2.06 and 7.99 ppm a.i. treatment groups. Mortality was 5 and 100% in the 3.85 and 16.3 ppm a.i. treatment groups, respectively (Table 7, p. 23). The 96-hour LC_{50} was 11.41 ppm a.i.

Table 3: Effect of JAU6476-Desthio on Mortality of Fathead Minnow (*Oncorhynchus mykiss*).

Treatment, ppm a.i. 0-96 hrs Mean-Measured and (Nominal) Concn.	No. of Fish at Start of Study	Observation Period			
		4 Hours		24-96 Hours	
		No Dead	% Mortality	No Dead	% Mortality
Negative Control	20	0	0	0	0
Solvent Control	20	0	0	0	0
0.96 (0.94)	20	0	0	0	0
2.06 (1.88)	20	0	0	0	0
3.85 (3.75)	20	0	0	1	5
7.99 (7.50)	20	0	0	0	0
16.3 (15.0)	20	20	100	20	100
NOAEC (mortality)	7.99 ppm a.i.				
LC_{50} (95% C.I.)	11.41 ppm a.i.				
Positive control, if used mortality: LC_{50}:	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 fish at the surface and on the bottom of the test vessel, loss of equilibrium, quiescence, darkened coloration, and erratic behavior (Table 7, p. 23). Treatment related effects were observed in 15% of surviving fish from the mean-measured 7.99 ppm a.i. treatment group. No sub-lethal effects were observed in the controls or the 0.96 through 3.85 ppm a.i. treatment groups. The NOAEC and LOAEC values were 3.85 and 7.99 ppm a.i., respectively.

Table 4. Sub-Lethal Effects of JAU6476-Desthio (Prothioconazole) on Fathead Minnow (*Pimephales promelas*).

Treatment, ppm a.i. 0 -96 hr Mean Measured and (Nominal) Concn.	Observation Period				
	Endpoint at 4 Hours	Endpoint at 24 Hours	Endpoint at 48 Hours	Endpoint at 72 Hours	Endpoint at 96 Hours
	% Affected	% Affected	% Affected	% Affected	% Affected
Negative Control	AN	AN	AN	AN	AN
Solvent Control	AN	AN	AN	AN	AN
0.96 (0.94)	AN	AN	AN	AN	AN
2.06 (1.88)	AN	AN	AN	AN	AN
3.85 (3.75)	AN	AN	AN	AN	AN
7.99 (7.50)	40% LE, Q; 60% Q	25% OB, LE,Q; 10% AS, LE, Q; 5% LE; 15% Q;	15% AS, DC, Q, LE; 10% OB, DC, Q, LE; 20% Q	5% AS, Q, LE; 5% OB, Q, LE; 5% E, LE; 5% Q; 5% DC	5% OB, LE, Q; 5% AS, LE, Q; 5% E, LE
16.3 (15.0)	--	--	--	--	--
NOAEC (sub-lethal)	3.85 ppm a.i.				
LOAEC (sub-lethal)	7.99 ppm a.i.				
EC_{50}	Not determined				
Positive control, if used % sub-lethal effect: EC_{50}:		N/A	N/A	N/A	N/A

AN - All surviving fish appeared normal.
– All fish dead.
LE-Loss of equilibrium; Q-Quiescent; OB- On bottom; AS- At surface; DC- Darkened coloration; E- Erratic behavior.
N/A - Not applicable

C. REPORTED STATISTICS:

Since mortality only occurred at the 16.3 ppm treatment level, the binomial probability test was used to determine the 96-hour LC_{50}. The NOAEC and LOAEC values were visually determined based on the observed mortality and sub-lethal and effects (p 14).

96-Hour
LC_{50}: 11.4 ppm a.i. 95% C.I.: Not reported
Probit slope: N/A
NOAEC: 3.85 ppm a.i.
LOAEC: 7.99 ppm a.i.
Endpoints affected: Mortality and sub-lethal (most sensitive)

D. VERIFICATION OF STATISTICAL RESULTS:

The 96-hour LC_{50} was determined using the binomial 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 in terms of the mean-measured treatment concentrations.

96-Hour
LC_{50}: 11.41 ppm a.i. 95% C.I.: 7.99-16.30 ppm a.i.
Probit slope: N/A
Sub-lethal
NOAEC: 3.85 ppm a.i.
LOAEC: 7.99 ppm a.i.
Endpoints affected: Mortality and sub-lethal (most sensitive)

E. STUDY DEFICIENCIES:

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with freshwater fish (§72-1a). All deficiencies/deviations, including the smaller than recommended fish weight, were considered minor and did not affect the validity or acceptability of this study.

F. REVIEWER'S COMMENTS:

Results of the reviewer's statistical verification were identical to those of the study author with the exception of the 95% confidence interval associated with the LC_{50} value. The study author failed to report a confidence interval (C.I.). The reviewer was able to determine an LC_{50} value (identical to that of the study author) and a 95% C.I., and it is reported in the EXECUTIVE SUMMARY and CONCLUSION sections of this DER.

All test solutions were reported to be clear and colorless throughout the exposure period.

G. CONCLUSIONS:

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with freshwater fish, warm water species (§72-1a). The study is classified as ACCEPTABLE. This study provides information that may be useful for future risk-assessment purposes. The 96-hour LC_{50} (with 95% C.I.) was 11.41 (7.99-16.3) ppm a.i., which classifies JAU6476-Desthio as slightly toxic to Fathead Minnow (*Pimephales promelas*) on an acute toxicity basis. The NOAEC and LOAEC, based on sub-lethal effects, were 3.85 and 7.99 ppm a.i., respectively.

96-Hour
LC_{50}: 11.41 ppm a.i. 95% C.I.: 7.99-16.30 ppm a.i.
Probit slope: N/A
NOAEC: 3.85 ppm a.i.
LOAEC: 7.99 ppm a.i.
Endpoints affected: Mortality and sub-lethal (most sensitive)

III. REFERENCES:

American Public Health Association, 1998. "Standard Methods for the Examination of Water and Wastewater", 17th edition. Washington, D.C.

ASTM, 1996. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. ATM Standard E729. Philadelphia, PA.

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USEPA, 1982. Pesticide Assessment Guidelines, Subdivision E- Hazard Evaluation: Wildlife and Aquatic Organisms. EPA-540/9-82-024. Office of Pesticide Programs, Washington , D.C. 86 pp.

USEPA, 1985. Standard Evaluation Procedure, Acute Toxicity Test for Freshwater Fish. EPA-540/9-85-006. Office of Pesticide Programs, Washington, D.C.

USEPA, 1989. Pesticide Programs; Good Laboratory Practice Standards; Final Rule (40 CFR, Part 160). Federal Register, Vol. 54, No. 158: 34067-34074.

APPENDIX I: RESULTS OF REVIEWER'S STATISTICAL VERIFICATION:

TOXANAL Results:

	EXPOSED	DEAD	DEAD	PROB.(PERCENT)
16.3	20	20	100	9.536742E-05
7.99	20	0	0	9.536742E-05
3.85	20	1	5	2.002716E-03
2.06	20	0	0	9.536742E-05
.96	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT **7.99 AND 16.3 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS**, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 11.41214

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

EAD Assessment of USEPA DER

Reviewer: Émilie Larivière (#1269); PMRA **Date:** July 13, 2005

PMRA Submission Number: 2004-0843

Study Type: Acute Toxicity to Warm Water Fish

Kern, M.E. and C.V. Lam. 2003. Acute Toxicity of JAU6476-Desthio to the Fathead Minnow (*Pimephales promelas*) Under Static-Renewal Conditions. Unpublished study performed by Bayer CropScience, Research and Development Department, Ecotoxicology, Stilwell, Kansas, Laboratory Study No. EBJAX071 (J68111202), and sponsored by Bayer CropScience, RTP, NC. Bayer No. 200151. Experimental start date October 22, 2001 and experimental termination date October 26, 2001. The final report issued December 16, 2003.

PMRA DATA CODE	9.5.2.3
EPA DP Barcode	D303488
OECD Data Point	8.2.1
EPA MRID	46246026
EPA Guideline	§72-1a

Reviewing Agency: US EPA

EAD Executive Summary:

In a 96-hour acute toxicity study, fathead minnow (*Pimephales promelas*) were exposed under static-renewal conditions (renewed at 48 hours) to the transformation product JAU6476-desthio (purity 96.5%) at nominal concentrations of 0 (negative and solvent controls), 0.94, 1.88, 3.75, 7.50, and 15.0 mg/L. Mean measured concentrations were <0.08 (<LOQ, controls), 0.96, 2.06, 3.85, 7.99, and 16.3 mg JAU6476-desthio/L. The study was based on procedures outlined in U.S. EPA (1975, 1982, 1985, and 1989) and ASTM (1996) and was in accordance with the GLP standards of the U.S. EPA (40 CFR Part 160) with the exception of the dilution water screening analysis.

After 96 hours of exposure, no mortality was observed in the controls or the 0.96, 2.06 and 7.99 mg JAU6476-desthio/L treatment groups. Mortality was 5 and 100% in the 3.85 and 16.3 mg JAU6476-desthio/L treatment groups, respectively. The 96-hour LC_{50} (with 95% C.I.) was 11.41 (7.99-16.30) mg JAU6476-desthio/L, which classifies JAU6476-desthio as slightly toxic to fathead minnow (*Pimephales promelas*) on an acute toxicity basis, according to the classification scheme of the U.S. EPA (1985). The NOEC and LOEC based on mortality were 7.99 and 16.3 mg JAU6476-desthio/L, respectively. Sub-lethal effects observed during the exposure period included fish at the surface and on the bottom of the test vessel, loss of

equilibrium, quiescence, darkened coloration, and erratic behaviour. Treatment-related effects were observed in 15% of surviving fish from the 7.99 mg JAU6476-desthio/L treatment group. No sub-lethal effects were observed in the controls or the 0.96 through 3.85 mg JAU6476-desthio/L treatment groups. The NOEC and LOEC, based on sub-lethal effects, were 3.85 and 7.99 mg JAU6476-desthio/L, respectively.

Results Synopsis

Test Organism Size/Age (mean Weight or Length):0.14 to 0.57 g (wet, mean = 0.29 g) and 21 to 33 mm (mean = 0.29 g); in the negative control at test termination. Approx. 78 days old at test initiation.
Test Type: Static-renewal

96-Hour
LC_{50}: 11.4 mg JAU6476-desthio/L 95% C.I.: 7.99-16.3 mg JAU6476-desthio/L
Probit slope: N/A
NOEC (mortality): 7.99 mg JAU6476-desthio/L
LOEC (mortality): 16.3 mg JAU6476-desthio/L
NOEC (sub-lethal effects): 3.85 mg JAU6476-desthio/L
LOEC (sub-lethal effects): 7.99 mg JAU6476-desthio/L
Endpoints affected: Mortality and sub-lethal (most sensitive)

Evaluator 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 Chemistry review.

2. The name Prothioconazole was removed from the title of the DER, the Executive Summary, the Methods and the Conclusions, and the name JAU6476-desthio was added where appropriate, because the study was conducted with the transformation product JAU6476-desthio (SXX 0665) and not the parent compound prothioconazole.

3. One mortality was observed in the 3.85 mg JAU6476-desthio/L treatment after 1 day of exposure. As no sub-lethal effects were observed at this concentration and no mortalities occurred at the next higher concentration, this mortality was not considered to be dose-related.

4. The PMRA reviewer agrees with the conclusions of the EPA reviewer.

Study Acceptability: This study is scientifically sound, and satisfies the guideline requirements

for an acute toxicity study of the transformation product JAU6476-desthio on freshwater fish, warm water species. The study is classified as ACCEPTABLE.