Data Evaluation Report on the Acute Toxicity of JAU 6476 SC (Prothioconazole Formulation) to Freshwater Invertebrates - *Daphnia magna*

PMRA Submission Number 2004-0844 EPA MRID Number 46246010

Data Requirement:		
	PMRA DATA CODE	9.3.5
	EPA DP Barcode	D303495
	OECD Data Point	IIIA 10.2.2
	EPA MRID	46246010
	EPA Guideline	§72-2

Test material: JAU 6476 480 SC **Purity:** 41.4%
Common name: Prothioconazole Formulation
Active Ingredient: Prothioconazole
Chemical name: IUPAC: 2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3*H*-1,2,4,-triazole-3-thione
CAS name:2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-3*H*-1,2,4,-triazole-3-thione
CAS No.: 178928-70-6
Synonyms: JAU6476

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Staff Scientist, Dynamac Corporation
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Date: 8/26/2004

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Date: 7/21/2005
7/21/05

Reference/Submission No.: 2004-0844

Company Code: BCZ
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Use Site Category: 7, 13, 14
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Date Evaluation Completed:

CITATION: Kern, M.E. and C.V. Lam. 2003. Acute Toxicity of JAU 6476 480 SC Formulation to the Waterflea (*Daphnia magna*) Under Static Renewal Conditions. Unpublished study performed by Bayer CropScience, Research and Development Department, Ecotoxicology, Stilwell, Kansas, Laboratory Study No. EBJAX072 (J6820701), and sponsored by Bayer CropScience, RTP, NC. Experimental start date September 25, 2001 and experimental termination date September 27, 2001. The final report issued December 15, 2003.


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EXECUTIVE SUMMARY:

The 48-hour acute toxicity of JAU 6476 480 SC (Prothioconazole Formulation) to the water flea, *Daphnia magna*, was studied under static renewal conditions. Daphnids were exposed to the test material at nominal concentrations of 0, 0 (negative and formulation blank controls), 0.15, 0.38, 0.96, 2.4, and 6.0 ppm a.i. Mean-measured concentrations were <0.03 (<LOQ, controls), 0.14, 0.34, 0.81, 2.20, and 5.47 ppm a.i.

After 48-hours of exposure, mortality was 0% in the negative and formulation controls and mean-measured 0.34, 0.81, and 2.20 ppm a.i. treatment groups; and 10 and 80% in the 0.14 and 5.47 ppm a.i. treatment groups, respectively. The 10% mortality observed in the 0.14 ppm a.i. treatment group was not considered to be treatment related by the study authors or the reviewer. The 48-hour LC_{50} (with 95% C.I.) was 4.1 (2.2-5.47) ppm a.i., which categorizes JAU 6476 480 SC (Prothioconazole Formulation) as moderately toxic to the water flea (*Daphnia magna*) on an acute toxicity basis. All surviving daphnids from the control groups and mean-measured 0.14 through 0.81 ppm a.i. treatment levels were reported to be normal. Surviving daphnids from the 2.20 (45%) and 5.47 (80%) ppm a.i. treatment groups were reported to be lying on the bottom test vessels and /or lethargic. The NOAEC and LOAEC values based on sub-lethal effects were 0.81 and 2.20 ppm a.i., respectively.

This study is scientifically sound and satisfies the guideline requirements for an acute toxicity study with freshwater invertebrates (§72-2). This study is classified as ACCEPTABLE.

Results Synopsis

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

48-Hour
EC_{50}: 4.1 ppm a.i. 95% C.I.: 2.2-5.47 ppm a.i.
Probit Slope: N/A
NOAEC: 2.20 ppm a.i. (Mortality/immobility)
LOAEC: 5.47 ppm a.i. (Mortality/immobility)
Sublethal Effects
NOAEC: 0.81 ppm a.i.
LOAEC: 2.20 ppm a.i.
Endpoint/s Affected: Mortality/immobility and sub-lethal (most sensitive)

I. MATERIALS AND METHODS

GUIDELINES FOLLOWED: The study was based on procedures outlined in U.S. EPA (1975, 1982, 1985, 1989) and ASTM (1998). Deviations from §72-2 included:

1. The water hardness (164-174 mg $CaCO_3$/L) was significantly higher than recommended (40-48 mg/L as $CaCO_3$). The pH (8.1-8.2) was slightly greater than recommended (7.2-7.6).

2. The biomass loading rate in terms of g/L was not provided.

The above deviations were considered minor and did not affect the acceptability or the validity of this study.

COMPLIANCE: Signed and dated GLP, Confidentiality, and Quality Assurance statements were provided. The test was conducted according to the U.S. EPA (40 CFR, Part 160).

A. MATERIALS:

1. Test Material JAU 6476 480 SC (Prothioconazole Formulation)

Description: White, milky liquid.

Lot No./Batch No. : 003-0115

Purity: 41.4%

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 test solution), 24 (new test solution), and 48 (old test solution) hours. Recoveries (all test levels) were 90-95% of nominal concentrations in 0-hour samples, 85-95% in 24-hour samples, and 77-93% in 48-hour samples (Table 2, p. 17). The 24-hour old test solutions were apparently not analytically verified prior to renewal.

Storage conditions of test chemicals: The test chemical was stored at 4°C in the dark.

Water solubility: 0.3 g/L in distilled water at 20°C and approximately pH 8.0.
(OECD requires water solubility, stability in water and light, pK_a, P_{ow}, and vapor pressure of the test compound. All the OECD requirements were not reported.)

2. Test organism:

Species: *Daphnia magna* (Straus)

Age at test initiation: First instars, <24 hours old

Source: In-house laboratory cultures (original supplier: Aquatic Biosystems, Fort Collins, CO).

B. STUDY DESIGN:

1. Experimental Conditions

a. Range-finding Study: Not reported

b. Definitive Study:

Table 1: Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	Continuous laboratory cultures were maintained. Same as test *Daphnia* cultures were fed at least 3 times per week with algae *(Seleanstrum capricornutum* and/or *Ankistrodesmus falcatus).* No ephippia or immobilization observed in the subculture isolated on 9/11/01 to obtain neonates for testing.	Original obtained from aquatic Biosystems, Fort Collins, CO (February 2000). *EPA requires 7 day minimum acclimation period.*
Duration of the test	48 hours	*EPA requires 48 hours*
Test condition - static/flow through Type of dilution system (for flow through method) Renewal rate (for static renewal)	Static renewal N/A At 24 hours only	*EPA requires consistent flow rate of 5 - 10 volumes/24 hours, meter systems calibrated before study and checked twice daily during test period*
Aeration, if any	No aeration was used during the study.	
<u>Test vessel</u> Material: *(glass/stainless steel)* Size: Fill volume:	Borosilicate glass beakers 1 L 900 mL (depth of ~11 cm)	*EPA requires: size 250 ml or 3.9 L fill 200 ml*

Parameter	Details	Remarks *Criteria*
Source of dilution water	The dilution water was spring water blended with city water and reverse osmosis water. The spring water was filtered , dechlorinated (p. 11), and sterilized. The dilution water was aerated prior to use.	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 *Daphnia magna*, which indicated no detrimental effects. The reviewer does not consider this a deviation given the dechlorination and monitoring methods used. Characterization of the medium is provided in Table 1, p. 15. *EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap water.*
Water parameters: Hardness pH Dissolved oxygen Temperature Total Organic Carbon Particulate matter Metals Pesticides Chlorine	 164-174 mg $CaCO_3$/L 8.1-8.2 8.4-8.8 mg/L (92-99% saturation) 19.1-20.5°C 11 ppm in spring water and <0.50 in RO water. 2 mg/L (total suspended solids) See Table 1, p. 15 <LOD; Not detected <0.003 mg/L (residual chlorine)	The hardness and pH of the dilution water were higher than recommended by the EPA, but are acceptable according to the OECD guideline. Alkalinity ranged from 88-104 mg $CaCO_3$/L and conductivity ranged from 454-462 µmhos/cm. *EPA requires:* *hardness: 40 - 48 mg/L as $CaCO_3$* *pH: 7.2 - 7.6* *-Temperature: 20°C (measured continuously or if water baths are used, every 6 hr, may not vary > 1°C* *Dissolved oxygen:* *Static: ≥ 60% during 1st 48 hr and ≥ 40% during 2nd 48 hr* *Flow-through: ≥60%*

Parameter	Details	Remarks *Criteria*
Number of organisms per replicate Solvent control: Negative control: Treatments:	10 (formulation blank) 10 10	The loading was 90 mL/daphnid, but was not provided in terms of g/L. *EPA requires 5 treatment levels plus control with a minimum of 20 daphnid per treatment. Biomass loading rate for static ≤ 0.8 g/L at ≤ 17 °C, ≤ 0.5 g/L at > 17 °C; flow-through: ≤ 1 g/L/day.*
Number of replicates Solvent control: Negative control: Treatments:	2 (formulation blank) 2 2	
Treatment concentrations nominal: measured:	0 (negative and formulation blank controls), 0.15, 0.38, 0.96, 2.4, and 6.0 ppm a.i. <0.03 (<LOQ, controls), 0.14, 0.34, 0.81, 2.20, and 5.47 ppm a.i.	On day 2 measured recoveries in the controls were <0.05 ppm a.i., which is slightly above the 0.03 LOQ and was attributed to sample handling or glassware contamination (p. 17). No adverse effects were observed by 48-hours in either control group. *EPA requires a geometric series with each concentration being at least 60% of the next higher one.*
Solvent (type, percentage, if used)	Formulation blank at 6 ppm	*EPA requires solvents not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-though tests.*
Lighting	16 hours light/8 hours dark with a 30 minute transition period.	The mean light intensity was 569 lux. *EPA requires 16 hours light, 8 hours dark.*
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	Verified. at 0 (new test solution), 24 (new test solution), and 48 (old test solution) hours. Recoveries (all test levels) were 90-95% of nominal concentrations in 0-hour samples, 85-95% in 24-hour samples, and 77-93% in 48-hour samples (Table 2, p. 17). The 24-hour old test solutions were apparently not analytically verified prior to renewal.	
Recovery of chemical Level of Quantitation Level of Detection	90-91% of nominal <0.03 ppm a.i. Not reported	Matrix fortifications at 1.17, 1.13, and 1.12 ppm a.i. were analyzed concurrently with test samples on days 0, 1, and 2, respectively. Recoveries were 90-91% of nominal (APPENDIX 1, Table 2, p. 30).
Positive control {if used, indicate the chemical and concentrations}	N/A	
Other parameters, if any	None	

2. Observations:

Table 2: Observations

Criteria	Details	Remarks *Criteria*
Parameters measured including the sub-lethal effects	Immobility and sublethal effects	
Observation intervals	After 24 and 48 hours	
Were raw data included?	Yes, sufficient (Table 6, p. 21)	
Other observations, if any	N/A	

II. RESULTS AND DISCUSSION

A. MORTALITY:

After 48-hours of exposure, mortality was 0% in the negative and formulation controls and mean-measured 0.34, 0.81, and 2.20 ppm a.i. treatment groups; and 10 and 80% in the 0.14 and 5.47 ppm a.i. treatment groups, respectively. The 10% mortality observed in the 0.14 ppm a.i. treatment group was not considered to be treatment related by the study authors or the reviewer. The 48-hour EC_{50} was reported to be 4.1 ppm a.i. and the NOAEC and LOAEC values for mortality/immobility were 2.20 and 5.47 ppm a.i., respectively.

Table 3: Effects of JAU 6476 SC (Prothioconazole Formulation) on Mortality/Immobilization of *Daphnia magna*.

Treatment, ppm a.i. 0-Hour Measured and (Nominal) Concn.	Observation Period			
	24 Hours		48 Hours	
	No. Dead	% Affected	No. Dead	% Affected
Dilution water Control	0	0	0	0
Formulation Control	0	0	0	0
0.14 (0.15)	0	0	2[a]	10
0.34 (0.38)	0	0	0	0
0.81 (0.96)	0	0	0	0
2.20 (2.4)	0	0	0	0
5.47 (6.0)	9	45	16	80
NOAEC, ppm a.i.	2.20			
LOAEC, ppm a.i.	5.47			
EC_{50} (with 95% C.I.), ppm a.i.	4.1 (not reported)			

[a] The study author noted that due to their low occurrence (10%), these effects were considered to be within acceptable background immobility limits and were not treatment related (p. 21).

B. SUB-LETHAL TOXICITY ENDPOINTS:

After 48-hours of exposure, all surviving daphnids from the control groups and mean-measured 0.14 through 0.81 ppm a.i. treatment levels were reported to be normal. Surviving daphnids from the 2.20 (45%) and 5.47 (80%) ppm a.i. treatment groups were reported to be lying on the bottom test vessels and /or lethargic. The study authors did not report NOAEC and LOAEC values in terms of the observed sub-lethal effects.

C. REPORTED STATISTICS:

The NOAEC and LOAEC were visually estimated based on mortality/immobility data. The EC_{50} values were calculated (method not specified) using the LC50 computer program of C.E. Stephan (1984). All toxicity values were determined in terms of the mean-measured test concentrations.

48-Hour
EC_{50}: 4.1 ppm a.i. 95% C.I.: Not reported
Probit Slope: N/A
NOAEC: 2.20 ppm a.i. (Mortality/immobility)
LOAEC: 5.47 ppm a.i. (Mortality/immobility)
Endpoint/s Affected: Mortality/immobility (only endpoint assessed for treatment related effects)

D. VERIFICATION OF STATISTICAL RESULTS:

The 48-hour EC_{50} was determined using the binomial method via TOXANAL statistical software; the data did not adequately fit the probit method. NOAEC and LOAEC values for mortality/immobility were determined using Fisher's Exact Test via TOXSTAT statistical software. NOAEC and LOAEC values were also visually determined based on the reported sub-lethal effects. All toxicity values were determined in terms of the mean-measured treatment concentrations.

48-Hour
EC_{50}: 4.1 ppm a.i. 95% C.I.: 2.2-5.47 ppm a.i.
Probit Slope: N/A
Mortality/immobility
NOAEC: 2.20 ppm a.i.
LOAEC: 5.47 ppm a.i.
Sub-lethal Effects
NOAEC:0.81 ppm a.i.
LOAEC: 2.20 ppm a.i.
Endpoint/s Affected: Mortality/immobility and sub-lethal (most sensitive)

E. STUDY DEFICIENCIES:

There were no significant deviations from U.S. EPA guideline §72-2 that affected the acceptability of this study.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions were similar to the study authors'. The study authors did not include a 95% confidence interval with the reported LC_{50} value. Consequently, the identical reviewer-determined LC_{50} value and associated 95% confidence interval are reported in the EXECUTIVE SUMMARY and CONCLUSION sections of this DER. The reviewer-determined NOAEC and LOAEC values based on mortality/immobility were identical to those reported by the study authors. However, the reviewer also determined NOAEC and LOAEC values (0.81 and 2.20 ppm a.i., respectively) based on the reported sub-lethal effects, which included surviving daphnids from the 2.20 and 5.47 ppm a.i. treatment groups that were reported to be lying on the bottom test vessels and /or lethargic. The study authors did not include NOAEC and LOAEC values based on the reported sub-lethal effects. Consequently, the reviewer-determined values (based on sub-lethal effects) are

reported in the EXECUTIVE SUMMARY and CONCLUSION sections of this DER because they are a more conservative estimate of the acute toxicity of JAU 6476 480 SC (Prothioconazole Formulation) to the water flea, *Daphnia magna*.

G. CONCLUSIONS:

This study is scientifically sound and fulfills U.S. EPA guideline §72-2, and is classified as ACCEPTABLE. Based on the results of this study, JAU 6476 480 SC (Prothioconazole Formulation) is categorized as moderately toxic to the water flea, *Daphnia magna*, on an acute toxicity basis.

48-Hour
EC_{50}: 4.1 ppm a.i. 95% C.I.: 2.2-5.47 ppm a.i.
Probit Slope: N/A
NOAEC: 0.81 ppm a.i.
LOAEC: 2.20 ppm a.i.
Endpoint/s Affected: Mortality/immobility and sub-lethal (most sensitive)

III. REFERENCES:

American Public Health Association, 1989. **Standard Methods for the Examination of Water and Wastewater.** 17th Edition Washington, D.C.

American Society for Testing and Materials (ASTM), 1988. Standard Guide for Conducting Acute Toxicity Tests with Fishes, Macroinvertebrates, and Amphibians. ASTM Standard E729. Philadelphia, PA.

OECD Test Guideline 202: Daphnia, Acute Toxicity Test, April 4, 2000.

SAS Institute, 1996. PC-SAS Version 6.12. Cary, NC.

Schneider, J. 2001. Physical and Chemical Properties of JAU 6476. Bayer AG, Leverkusen, Germany. Laboratory Project ID: 14 0120 0950.

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

Stephan, C.E. *et al.* 1984. TOXCALC-PC based program for calculating LC50.

USEPA, 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. EPA-660/3-75-009. Office of Research and Development, Corvallis, OR. 61 pp.

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 Invertebrates. EPA-540/9-85-005. 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.

USEPA Amendment to Ecological Effects Standard Evaluation Procedures, 1990.

APPENDIX 1. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

TOXANAL Results:

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROS. (PERCENT)
5.47	20	16	80	.5908966
2.2	20	0	0	9.536742E-05
.81	20	0	0	9.536742E-05
.34	20	0	0	9.536742E-05
.14	20	2	10	2.012253E-02

THE BINOMIAL TEST SHOWS THAT **2.2 AND 5.47** 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 LCSO FOR THIS SET OF DATA IS 4.121059**

THE MOVING AVERAGE METHOD CANNOT BE USE!) WITH THIS DATA SET
BECAUSE NO SPAN WHICH PRODUCES MOVING AVERAGE ANGLES THAT
BRACKET 45 DEGREES ALSO USES TWO PERCENT DEAD BETWEEN 0 AND
100 PERCENT.

RESULTS CALCULATED USING THE PROBIT METHOD
ITERATIONS (3 H GOODNESS OF FIT PROBABILITY
7 9.166462 15.3496
A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001.
SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED USING THE PROBIT METHOD
PROBABLY SHOULD NOT BE USED.
SLOPE = 1.597471
95 PERCENT CONFIDENCE LIMITS =-3.239058 AND 6.434
LCSO = 5.191079
95 PERCENT CONFIDENCE LIMITS - 0 AND +INFINITY
LC1O = .8322445
95 PERCENT CONFIDENCE LIMITS = 0 AND +INFINITY

TOXSTAT Results:

SUMMARY OF FISHERS EXACT TESTS

GROUP	IDENTIFICATION	NUMBER EXPOSED	NUMBER DEAD	SIG (P=.05)
	CONTROL	20	0	
1	0.14	20	2	
2	0.34	20	0	
3	0.81	20	0	
4	**2.20**	**20**	**0**	
5	5.47	20	16	*

EAD Assessment of USEPA DER

Reviewer: Émilie Larivière (#1269); PMRA Date: July 21, 2005

PMRA Submission Number: 2004-0844

Study Type: Laboratory Studies with the End-use Product

Kern, M.E. and C.V. Lam. 2003. Acute Toxicity of JAU 6476 480 SC Formulation to the Waterflea (*Daphnia magna*) Under Static Renewal Conditions. Unpublished study performed by Bayer CropScience, Research and Development Department, Ecotoxicology, Stilwell, Kansas, Laboratory Study No. EBJAX072 (J6820701), and sponsored by Bayer CropScience, RTP, NC. Experimental start date September 25, 2001 and experimental termination date September 27, 2001. The final report issued December 15, 2003.

PMRA DATA CODE	9.3.5
EPA DP Barcode	D303495
OECD Data Point	IIIA 10.2.2
EPA MRID	46246010
EPA Guideline	§72-2

Reviewing Agency: US EPA

EAD Executive Summary:

The 48-hour acute toxicity of JAU 6476 480 SC (prothioconazole formulation; purity 41.4%) to the water flea, *Daphnia magna*, was studied under static renewal conditions. The study was conducted following guidance provided in U.S. EPA (1975, 1982, 1985, 1989) and ASTM (1998), and was in compliance with U.S. EPA (40 CFR, Part 160). Daphnids were exposed to the test material at nominal concentrations of 0, 0 (negative and formulation blank controls), 0.15, 0.38, 0.96, 2.4, and 6.0 mg a.i./L. Mean measured concentrations were <0.03 (<LOQ, controls), 0.14, 0.34, 0.81, 2.20, and 5.47 mg a.i./L.

After 48-hours of exposure, mortality was 0% in the negative and formulation controls and mean measured 0.34, 0.81, and 2.20 mg a.i./L treatment groups; and 10 and 80% in the 0.14 and 5.47 mg a.i./L treatment groups, respectively. The 10% mortality observed in the 0.14 mg a.i./L treatment group was not considered to be treatment related by the study authors or the reviewer. The 48-hour LC_{50} (with 95% C.I.) was 4.1 (2.2-5.47) mg a.i./L, which categorizes JAU 6476 480 SC as moderately toxic to the water flea (*Daphnia magna*) on an acute toxicity basis, according to the classification scheme of the U.S. EPA (1985). All surviving daphnids from the control groups and mean measured 0.14 through 0.81 mg a.i./L treatment levels were reported to be normal. Surviving daphnids from the 2.20 (45%) and 5.47 (80%) mg a.i./L treatment groups

were reported to be lying on the bottom test vessels and /or lethargic. The NOEC and LOEC values based on mortality/immobility were 2.20 and 5.47 mg a.i./L respectively, while they were 0.81 and 2.20 mg a.i./L based on sublethal effects.

Results Synopsis

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

48-Hour
EC_{50}: 4.1 mg a.i./L 95% C.I.: 2.2-5.47 mg a.i./L
Probit Slope: N/A
NOEC (mortality/immobility): 2.20 mg a.i./L
LOEC (mortality/immobility): 5.47 mg a.i./L
NOEC (sub-lethal effects): 0.81 mg a.i./L
LOEC (sub-lethal effects): 2.20 mg a.i./L
Endpoints Affected: Mortality/immobility and sub-lethal (most sensitive)

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 (CAS name and synonym) available from the PMRA Chemistry review.

2. The hardness of the dilution water (164-174 mg/L as $CaCO_3$) is within the range recommended by the OECD guideline (40-250 mg/L as $CaCO_3$ for *Daphnia magna*). The pH range of the dilution water (8.1-8.2) is also within the range recommended by the OECD guideline 202 (pH 6-9). Both the hardness and the pH are considered acceptable to the PMRA. A comment as to the acceptability of these two parameters was added to the 'Remarks' on water parameters in Table 1.

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 of the formulation with freshwater invertebrates. This study is classified as ACCEPTABLE.