

**DATA EVALUATION RECORD**  
**§ 72-2 - ACUTE EC<sub>50</sub> TEST WITH A FRESHWATER INVERTEBRATE**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: Not reported
3. **CITATION:** Author: A. Vial  
Title: Report on the Acute Toxicity Test of CGA-51202 On Daphnia (*Daphnia magna* STRAUS 1820)  
Study Completion Date: August 12, 1991  
Laboratory: Ciba-Geigy Limited, Crop Protection Division, Basle, Switzerland  
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC  
Laboratory Report ID: 918162  
MRID No.: 449295-03  
DP Barcode: D260007

4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,  
Golder Associates Inc.

Signature:

Date: 11/99

**APPROVED BY:** Pim Kosalwat, Ph.D., Senior Scientist,  
Golder Associates Inc.

Signature:

Date:

5. **APPROVED BY:** Brian Montague, Fisheries Biologist  
Environmental Fate and Effects Division, OPP

Signature:

Date: March 2000

6. **STUDY PARAMETERS:**

Age of Test Organism:	≤24 hours
Definitive Test Duration:	48 hours
Study Method:	Static
Type of Concentrations:	Mean measured

7. **CONCLUSIONS:** This study is scientifically sound, but does not fulfill the guideline requirements. The percent purity of the test material was not reported.

**Results Synopsis**

EC<sub>50</sub>: 15.4 ppm

95% C.I.: 13.0 - 18.4 ppm

NOEC: 5.2 ppm

Probit Slope: 6.1

8. **ADEQUACY OF THE STUDY:** A. **Classification:** Supplemental.



**B. Rationale:** The percent purity of the test material was not reported. Hardness of 240 mg/L as CaCO<sub>3</sub> used in study.

**C. Repairability:** No-hardness too high.

**9. GUIDELINE DEVIATIONS:**

1. The percent purity of the test material was not reported.
2. The reported pH (7.8 -7.9) and hardness (240 mg CaCO<sub>3</sub>/L) is higher than recommended (pH: 7.2 - 7.6; hardness: 40 - 200 mg CaCO<sub>3</sub>/L).
3. Temperature was measured at test initiation and termination; guideline protocol recommends continuous temperature monitoring for a test system controlled by the room temperature.

**10. SUBMISSION PURPOSE:** To support reregistration of metolachlor products.

**11. MATERIALS AND METHODS:**

**A. Test Organisms**

Guideline Criteria	Reported Information
<b><u>Species</u></b> Preferred species is <i>Daphnia magna</i> .	<i>Daphnia magna</i>
<b>All organisms are approximately the same size and weight?</b>	Not reported
<b><u>Life Stage</u></b> Daphnids: 1 <sup>st</sup> instar (<24 h)	1 <sup>st</sup> instar (≤24 h)
<b><u>Supplier</u></b>	In-house cultures
<b>All organisms from the same source?</b>	Yes

**B. Source/Acclimation**

Guideline Criteria	Reported Information
<b><u>Acclimation Period</u></b> Minimum 7 days	Cultures were maintained under conditions similar to testing.

Guideline Criteria	Reported Information
<b>Wild caught organisms were quarantined for 7 days?</b>	N/A
<b>Were there signs of disease or injury?</b>	None reported
<b>If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?</b>	N/A
<b><u>Feeding</u></b> No feeding during the study.	No feeding during the study
<b><u>Pretest Mortality</u></b> No more than 3% mortality 48 hours prior to testing.	Not reported

### C. Test System

Guideline Criteria	Reported Information
<b><u>Source of dilution water</u></b> Soft reconstituted water or water from a natural source, <b>not</b> dechlorinated tap water.	Reconstituted water prepared from bi-distilled water.
<b>Does water support test animals without observable signs of stress?</b>	Not reported
<b><u>Water Temperature</u></b> Daphnia: 20°C Amphipods and mayflies: 17°C Midges and mayflies: 22°C Stoneflies: 12°C	20 - 22°C
<b><u>pH</u></b> Prefer 7.2 to 7.6.	7.8 - 7.9
<b><u>Dissolved Oxygen</u></b> Static: ≥ 60% during 1 <sup>st</sup> 48 h and ≥ 40% during 2 <sup>nd</sup> 48 h, flow-through: ≥ 60%.	≥99% during the test
<b><u>Total Hardness</u></b> Prefer 40 to 200 mg/L as CaCO <sub>3</sub> .	240 mg/L as CaCO <sub>3</sub>

Guideline Criteria	Reported Information
<b><u>Test Aquaria</u></b> 1. <u>Material</u> : Glass or stainless steel. 2. <u>Size</u> : 250 mL (daphnids and midges) or 3.9 L (1 gal). 3. <u>Fill volume</u> : 200 mL (daphnids and midges) or 2-3 L.	Glass  Not reported  100 mL
<b><u>Type of Dilution System</u></b> Must provide reproducible supply of toxicant.	N/A
<b><u>Flow Rate</u></b>	N/A
<b><u>Biomass Loading Rate</u></b> Static: $\leq 0.8$ g/L at $\leq 17^{\circ}\text{C}$ , $\leq 0.5$ g/L at $> 17^{\circ}\text{C}$ ; flow-through: $\leq 1$ g/L/day.	1 daphnid/20 mL
<b><u>Photoperiod</u></b> 16 hours light, 8 hours dark.	16 hours light, 8 hours dark
<b><u>Solvents</u></b> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests.	None used

#### D. Test Design

Guideline Criteria	Reported Information
<b><u>Range Finding Test</u></b> If $\text{EC}_{50} > 100$ mg/L, then no definitive test is required.	Results of pretests were not reported.
<b><u>Nominal Concentrations of Definitive Test</u></b> Control & 5 treatment levels; a geometric series with each concentration being at least 60% of the next higher one.	Negative control, 5.8, 10, 18, 32, and 58 mg/L, not corrected for percent purity.

Guideline Criteria	Reported Information
<b>Number of Test Organisms</b> Minimum 20/level, may be divided among containers.	20 per level, 5 per replicate
<b>Test organisms randomly or impartially assigned to test vessels?</b>	Yes
<b>Water Parameter Measurements</b> 1. <u>Temperature</u> Measured continuously or, if water baths are used, every 6 h, may not vary > 1°C. 2. <u>DO and pH</u> Measured at beginning of test and every 48 h in the high, medium, and low doses and in the control.	Temperature, DO, and pH were measured at test initiation and termination.
<b>Chemical Analysis</b> Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	Solutions collected at 0 and 48 hours and analyzed for CGA-51202 using HPLC.

## 12. REPORTED RESULTS:

### A. General Results

Guideline Criteria	Reported Information
<b>Quality assurance and GLP compliance statements were included in the report?</b>	The study was conducted in accordance with OECD and Swiss GLP guidelines. A QA statement was also included in the report.
<b>Control Mortality</b> Static: ≤10% Flow-through: ≤5%	0% mortality in the control
<b>Percent Recovery of Chemical</b> 1. Percent of nominal 2. Detection limit 3. Method validation	1. Range 89 - 103% 2. 1.0 mg/L 3. Average recovery = 108.1%

Guideline Criteria	Reported Information
Raw data included?	Yes

### Analytical Results

Nominal	Toxicant Concentration (mg/L)			
	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1	<1	-	-
5.8	4.80	5.50	5.15 (0.49)	89
10	7.80	10.30	9.05 (1.77)	91
18	16.20	16.70	16.45 (0.35)	91
32	32.50	33.30	32.90 (0.57)	103
58	56.70	55.60	56.15 (0.78)	97

Mortality/Immobilization

Nominal Concentration (mg/L)	Mean measured Concentration (mg/L)	Number of Daphnids	Cumulative Number Immobile/Dead	
			24-hr	48-hr
Control	<1.0	20	0	0
5.8	5.15	20	0	0
10	9.05	20	1	1
18	16.45	20	12	13
32	32.90	20	17	19
58	56.15	20	20	20

Other Significant Results: No sublethal signs of toxicity were reported.

**B. Statistical Results:** Results based on nominal concentrations. Method: Probit

48-hr EC<sub>50</sub>: 16.6 mg/L      95% C.I.: 14.2 - 19.4 mg/L  
 Probit Slope: N/R      NOEC: 5.8 mg/L

**13. VERIFICATION OF STATISTICAL RESULTS:**

Method: Probit analysis using mean measured concentrations

48-hr EC<sub>50</sub>: 15.4 ppm      95% C.I.: 13.0 - 18.4 ppm  
 Probit Slope: 6.1      NOEC: 5.2 ppm

- 14. REVIEWER'S COMMENTS:** This study is scientifically sound but does not fulfill the guideline requirements, and is classified as **Supplemental**. The percent purity of the test substance was not reported. The hardness of the test dilution water was above recommended limits for OECD and USEPA testing requirements which may effect the chemical characteristics and toxicity of the test material. The EC50 for daphnia exposed to CGA-51202 was determined to be 15.4 ppm, which classifies CGA-51202 as slightly toxic to the daphnid. The NOEC was determined to be 5.2 ppm.

MRID No. 449295-03

"Karl

Bullock", "10-25-99", "Metolachlor", "?", "108801", "?", "Daphnia", "Acute", "STAT", "Ciba-Geigy", "48

h", "", "20", "Suppl", 20, 0, 5, 5, 14.43565, 9.05, 32.9, 4, 15.93281, 13.20306, 19.09389, 6.061267, 15.41759, 13.03811, 18.42952, .6832855, 9.516766



**PAGES 9 THROUGH 14 HAVE BEEN REMOVED FROM THIS COPY. THOSE  
PAGES CONSIST OF REGISTRANT-SUBMITTED DATA.**

Karl Bullock Metolachlor Daphnia 10-25-99

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
56.15	20	20	100	9.536742E-05
32.9	20	19	95	2.002716E-03
16.45	20	13	65	13.1588
9.05	20	1	5	2.002716E-03
5.15	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT 9.05 AND 32.9 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 14.43565

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
4	5.135009E-02	15.93281	13.20306 19.09389

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.1428227	1	.6832855

SLOPE = 6.061267  
95 PERCENT CONFIDENCE LIMITS = 3.770599 AND 8.351934

LC50 = 15.41759 MEAN MEASURED  
95 PERCENT CONFIDENCE LIMITS = 13.03811 AND 18.42952

LC10 = 9.516766  
95 PERCENT CONFIDENCE LIMITS = 6.78832 AND 11.4839

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