DATA EVALUATION RECORD
§ 72-2 - ACUTE EC_{50} TEST WITH A FRESHWATER INVERTEBRATE

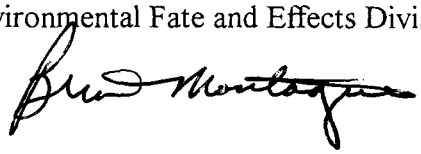
1. **CHEMICAL:** Metolachlor PC Code No.: 108801

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_{50}: 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 CaCO3 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 $CaCO_3$/L) is higher than recommended (pH: 7.2 - 7.6; hardness: 40 - 200 mg $CaCO_3$/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
Species Preferred species is *Daphnia magna.*	*Daphnia magna*
All organisms are approximately the same size and weight?	Not reported
Life Stage Daphnids: 1st instar (<24 h)	1st instar (≤24 h)
Supplier	In-house cultures
All organisms from the same source?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 7 days	Cultures were maintained under conditions similar to testing.

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

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water.	Reconstituted water prepared from bi-distilled water.
Does water support test animals without observable signs of stress?	Not reported
Water Temperature Daphnia: 20°C Amphipods and mayflies: 17°C Midges and mayflies: 22°C Stoneflies: 12°C	20 - 22°C
pH Prefer 7.2 to 7.6.	7.8 - 7.9
Dissolved Oxygen Static: ≥ 60% during 1st 48 h and ≥ 40% during 2nd 48 h, flow-through: ≥ 60%.	≥99% during the test
Total Hardness Prefer 40 to 200 mg/L as $CaCO_3$.	240 mg/L as $CaCO_3$

Guideline Criteria	Reported Information
Test Aquaria 1. Material: Glass or stainless steel. 2. Size: 250 mL (daphnids and midges) or 3.9 L (1 gal). 3. Fill volume: 200 mL (daphnids and midges) or 2-3 L.	 Glass Not reported 100 mL
Type of Dilution System Must provide reproducible supply of toxicant.	N/A
Flow Rate	N/A
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day.	1 daphnid/20 mL
Photoperiod 16 hours light, 8 hours dark.	16 hours light, 8 hours dark
Solvents 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
Range Finding Test If EC_{50} >100 mg/L, then no definitive test is required.	Results of pretests were not reported.
Nominal Concentrations of Definitive Test 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
Number of Test Organisms Minimum 20/level, may be divided among containers.	20 per level, 5 per replicate
Test organisms randomly or impartially assigned to test vessels?	Yes
Water Parameter Measurements 1. Temperature Measured continuously or, if water baths are used, every 6 h, may not vary > 1°C. 2. DO and pH 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.
Chemical Analysis 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
Quality assurance and GLP compliance statements were included in the report?	The study was conducted in accordance with OECD and Swiss GLP guidelines. A QA statement was also included in the report.
Control Mortality Static: ≤10% Flow-through: ≤5%	0% mortality in the control
Percent Recovery of Chemical 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

Toxicant Concentration (mg/L)				
Nominal	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_{50}: 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_{50}: 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 hardess 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.

"Karl
Bullock","10-25-99","Metolachlor","?","108801","?","Daphnia","Acute","STAT","Ciba-Geigy","
48
h","","20","Suppl",20,0,5,5,14.43565,9.05,32.9,4,15.93281,13.20306,19.09389,6.061267,15.417
59,13.03811,18.42952,.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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