



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,  
PESTICIDES AND TOXIC  
SUBSTANCES

JUL - 3 2000

MEMORANDUM

**SUBJECT:** Review of Metolachlor (CGA 51202) - Shaughnessy Code 108801  
Studies Submitted under Barcodes D260006, D260007, D260009, D260010 and  
Submission Numbers S569370, S569375, S569376, S569377

**TO:** Betty Shackelford, Product Manager53  
Reregistration Division (7508C)

**From:** Brian Montague, Fisheries Biologist  
Environmental Risk Branch I  
Environmental Fate and Effects Division (7507C)

*Brian Montague* 6/28/2000

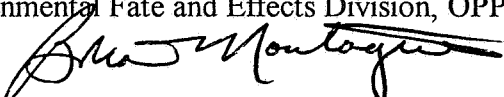
**Through:** Arnet Jones, Chief  
Environmental Risk Branch I  
Environmental Fate and Effects Division (7507C)

*Arnet Jones* 07/03/2000

The Environmental Fate and Effects Division has completed review of 7 studies with metolachlor identified as CGA 51202. Unfortunately in most of these studies the purity of the test material was not properly identified. Two of the acute studies with fish were found invalid (44929501 and 44929502) due to departures from accepted Agency test methodology. The study with *Daphnia magna* (MRID 44929503) was found supplemental with results showing low toxicity to this species (EC50 = 15.4 ppm) from this test material. The study with the alga *Scenedesmus subspicatus* (MRID 44929515) was only conducted for 3 days, is not generally an accepted species, and test material purity was unidentified, thus classifying this study as supplemental data. The acute test with *Lemna gibba* (MRID 44929514) was classified as core and the observed EC50 of >95.4 ppm would place this chemical in the category of practically non-toxic to this species. Tier I terrestrial plant studies (MRID 44929513) with the chemical were considered core, as test levels equivalent to the maximum reported rate of 0.5 lbs ai/A caused < 25% growth or phytotoxic effect to seedlings or early emergent plants for the 10 tested species.

Questions regarding this memorandum and the results of these studies may be directed to Brian Montague at 305-6438 or Arnet Jones at 305-7416.

**DATA EVALUATION RECORD**  
**§ 72-1 - ACUTE LC<sub>50</sub> TEST WITH A COLDWATER FISH**

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 to Rainbow Trout (*Onchorhynchus mykiss*)  
Study Date: August 12, 1991  
Laboratory: Ciba-Geigy Limited, Crop Protection Division, Basle, Switzerland  
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC  
Laboratory ID: 918150  
MRID No.: 449295-01  
DP Barcode: D260006
  
4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,  
Golder Associates Inc.  
  
**Signature:** **Date:**  
  
**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 or Size of Test Organism:** Mean: 57 mm  
**Definitive Test Duration:** 96 hours  
**Study Method:** Static  
**Type of Concentrations:** Mean measured
  
7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill Agency guideline requirements for an acute toxicity test with the rainbow trout. The 96-hour LC<sub>50</sub> was determined to be >100 ppm nominal (>96.3 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the rainbow trout. The NOEC was 100 ppm nominal (96.3 ppm mean measured concentration).

**Results Synopsis**LC<sub>50</sub>: >100 ppm

(&gt;96.3 ppm mean measured)

95% C.I.: N/A

NOEC: 100 ppm

Probit Slope: N/A

**8. ADEQUACY OF THE STUDY:**

- A. **Classification:** Invalid  
 B. **Rationale:** The purity of the test substance was not reported. De-chlorinated water was employed.  
 C. **Repairability:** No

**9. GUIDELINE DEVIATIONS:**

1. The percent purity of the test substance was not reported.
2. Dilution water was dechlorinated tap water.
3. Temperature was not measured continuously as recommended by the guidelines. The test temperature (14°C) was greater than recommended (12°C).
4. Pretest mortality was not reported.
5. Test solutions were aerated during the test.

**10. SUBMISSION PURPOSE:** Submitted to support registration of metolachlor products.

**11. MATERIALS AND METHODS:****A. Test Organisms**

Guideline Criteria	Reported Information
<b><u>Species</u></b> Preferred species is the rainbow trout ( <i>Oncorhynchus mykiss</i> )	<i>Oncorhynchus mykiss</i>
<b><u>Mean Weight</u></b> 0.1-5 g	Mean: 1.71 g Range: 1.02-2.50 g
<b><u>Mean Standard Length</u></b> Longest not > 2x shortest	Mean: 57 mm Range: 50-63 mm
<b><u>Supplier</u></b>	P. Hohler/CH-4314 Zeiningen
<b>All fish from same source?</b>	Yes
<b>All fish from the same year class?</b>	Not reported

**B. Source/Acclimation**

Guideline Criteria	Reported Information
<b>Acclimation Period</b> Minimum 14 days	48 days
<b>Wild caught organisms were quarantined for 7 days?</b>	N/A
<b>Were there signs of disease or injury?</b>	Not reported
<b>If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?</b>	Fish were treated with 0.15 mg malachite green/L for 5 hours on April 6, 1991, approximately 6 weeks before test initiation.
<b>Feeding</b> No feeding during the study	Last fed 24 hours prior to testing
<b>Pretest Mortality</b> < 3% mortality 48 hours prior to testing	Not reported

**C. Test System**

Guideline Criteria	Reported Information
<b>Source of dilution water</b> Soft reconstituted water or water from a natural source, <b>not</b> dechlorinated tap water	Carbon filtered, dechlorinated tap water.
<b>Does water support test animals without observable signs of stress?</b>	Yes
<b>Water Temperature</b> 12°C	14°C
<b>pH</b> Prefer 7.2 to 7.6	7.6 - 8.3
<b>Dissolved Oxygen</b> Static: ≥ 60% during 1 <sup>st</sup> 48 hrs and ≥ 40% during 2 <sup>nd</sup> 48 hrs, flow-through: ≥ 60%	≥90% during the test

Guideline Criteria	Reported Information
<b>Total Hardness</b> Prefer 40 to 200 mg/L as CaCO <sub>3</sub>	164 mg/L as CaCO <sub>3</sub>
<b>Test Aquaria</b> 1. <u>Material</u> : Glass or stainless steel 2. <u>Size</u> : Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. <u>Fill volume</u> : 15-30 L of solution	Glass  20 L  15 L
<b>Type of Dilution System</b> Must provide reproducible supply of toxicant	Not reported but test assumed to be static test.
<b>Flow Rate</b>	Not applicable if static test
<b>Biomass Loading Rate</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	0.57 g/L
<b>Photoperiod</b> 16 hours light, 8 hours dark	16 h light, 8 h dark
<b>Solvents</b> Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: none Maximum conc.: N/A

#### D. Test Design

Guideline Criteria	Reported Information
<b>Range Finding Test</b> If $LC_{50} > 100$ mg/L with 30 fish, then no definitive test is required.	Pretests were conducted, but the results were not reported.

Guideline Criteria	Reported Information
<p><b><u>Nominal Concentrations of Definitive Test</u></b> Control &amp; 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series</p>	Negative control, 10, 18, 32, 58, and 100 mg/L, not corrected for percent purity.
<p><b><u>Number of Test Organisms</u></b> Minimum 10/level, may be divided among containers</p>	10 fish per treatment level or control, 5 per replicate
<p><b>Test organisms randomly or impartially assigned to test vessels?</b></p>	Not reported
<p><b>Biological observations made every 24 hours?</b></p>	Yes
<p><b><u>Water Parameter Measurements</u></b> 1. <u>Temperature</u> Measured constantly or, if water baths are used, every 6 hrs, may not vary &gt; 1°C 2. <u>DO and pH</u> Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control</p>	Temperature, DO, and pH were measured daily in each test chamber.
<p><b><u>Chemical Analysis</u></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</p>	Samples were collected from each test vessel at test initiation and termination for analysis.

**12. REPORTED RESULTS:****A. General Results**

Guideline Criteria	Reported Information
<b>Quality assurance and GLP compliance statements were included in the report?</b>	Yes, however, the compliance was with OECD and Swiss GLP.
<b>Recovery of Chemical</b> 1. Mean recovery 2. Detection limit 3. Method validation	1. 91-99% of nominal 2. <1.0 mg/L 3. 108% of nominal
<b>Control Mortality</b> Not more than 10% control organisms may die or show abnormal behavior.	0% mortality in control
<b>Raw data included?</b>	Yes
<b>Signs of toxicity (if any) were described?</b>	No signs of test material toxicity were observed.

Analytical Results

Nominal	Toxicant Concentration (mg/L)			Mean Measured (SD)	Percent of Nominal
	Hour of Study				
	0	96			
Control	<1	<1	-	-	
10	9.90	8.30	9.10 (1.1)	91	
18	17.80	16.70	17.3 (0.8)	96	
32	29.10	29.20	29.2 (0.1)	91	
58	57.10	57.20	57.2 (0.1)	99	

100	98.60	93.90	96.3 (3.3)	96
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### Mortality

Concentration (mg/L)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Negative Control	<0.10	10	0	0	0	0
10	9.10	10	0	0	0	0
18	17.3	10	0	0	0	0
32	29.2	10	0	0	0	0
58	57.2	10	0	0	0	0
100	96.3	10	0	0	0	0

Other Significant Results: No sublethal signs of test material toxicity were observed.

### **B. Statistical Results**

Statistical method: Visual observation using nominal concentrations

LC<sub>50</sub>: >100 mg/L

95% C.I.: N/A

Probit Slope: N/A

NOEC: 100 mg/L

### **13. VERIFICATION OF STATISTICAL RESULTS:**

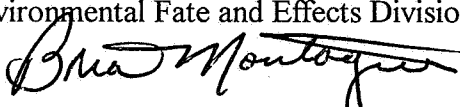
Parameter	Result
Binomial Test LC <sub>50</sub> (95% C.I.)	N/A
Moving Average Angle LC <sub>50</sub> (95% C.I.)	N/A



Probit LC <sub>50</sub> (95% C.I.)	N/A
Probit Slope	N/A
NOEC	100 ppm

14. **REVIEWER'S COMMENTS:** This study is scientifically sound but does not fulfill the EPA criteria requirements for a fully acceptable acute toxicity test with the rainbow trout. The percent active ingredient of the test substance was not reported and de-chlorinated tap water was employed. Several other omissions of data regarding test organisms and test methods were also noted. Based on nominal concentrations, the 96-hour LC<sub>50</sub> was determined to be >100 ppm (>96.3 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the rainbow trout. The NOEC was 100 ppm (96.3 ppm mean measured concentration). This study is classified as **invalid**.

**DATA EVALUATION RECORD**  
**§ 72-1 - ACUTE LC<sub>50</sub> TEST WITH A WARMWATER FISH**

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 to Common Carp (*Cyprinus carpio*)  
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: 918151  
MRID No.: 449295-02  
DP Barcode: D260006
  
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 or Size of Test Organism:** 32-43 mm  
**Definitive Test Duration:** 96 hours  
**Study Method:** Static  
**Type of Concentrations:** Mean measured
  
7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill Agency guideline requirements. The 96-hour LC<sub>50</sub> for carp exposed to CGA-51202 was determined to be >100 ppm nominal (>93.1 ppm mean measured), which classifies this compound as practically non-toxic to the carp.  
**Results Synopsis**  
LC<sub>50</sub>: >100 ppm nominal (>93.1 mean measured)      95% C.I.: N/A  
NOEC: 100 ppm nominal
  
8. **ADEQUACY OF THE STUDY:**      A.      **Classification:** Invalid

**B. Rationale:** The percent purity of the test substance was not reported. Study was conducted with de-chlorinated tapwater. See deviations below.

**C. Repairability:** No.

**9. GUIDELINE DEVIATIONS:**

1. The percent purity of the test material was not reported.
2. The test was conducted with a species other than the recommended species.
3. Dilution water was dechlorinated tap water.
4. Pretest mortality was not reported.
5. Test solutions were aerated.

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

**11. MATERIALS AND METHODS:**

**A. Test Organisms**

Guideline Criteria	Reported Information
<b><u>Species</u></b> Preferred species is the bluegill sunfish ( <i>Lepomis macrochirus</i> )	Carp, <i>Cyprinus carpio</i>
<b><u>Mean Weight</u></b> 0.5-5 g	Mean: 0.74 g Range: 0.41-0.96 g
<b><u>Mean Standard Length</u></b> Longest not > 2x shortest	Mean: 39 mm Range: 32-43 mm
<b><u>Supplier</u></b>	P. Hohler / CH-4314 Zeiningen
<b>All fish from same source?</b>	Yes
<b>All fish from the same year class?</b>	Not reported

**B. Source/Acclimation**

Guideline Criteria	Reported Information
<b><u>Acclimation Period</u></b> Minimum 14 days	24 days

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>	Not reported
<b>Feeding</b> No feeding during the study	Last fed 24 hours prior to testing
<b>Pretest Mortality</b> < 3% mortality 48 hours prior to testing	Pretest mortality not reported

### C. Test System

Guideline Criteria	Reported Information
<b>Source of dilution water</b> Soft reconstituted water or water from a natural source, <b>not</b> dechlorinated tap water	Carbon filtered dechlorinated tap water
<b>Does water support test animals without observable signs of stress?</b>	Yes
<b>Water Temperature</b> 17°C or 22°C	23 °C
<b>pH</b> Prefer 7.2 to 7.6	7.6 - 8.4
<b>Dissolved Oxygen</b> Static: ≥ 60% during 1 <sup>st</sup> 48 hrs and ≥ 40% during 2 <sup>nd</sup> 48 hrs, flow-through: ≥ 60%	≥87% of saturation during the test
<b>Total Hardness</b> Prefer 40 to 200 mg/L as CaCO <sub>3</sub>	164 mg/L as CaCO <sub>3</sub>
<b>Test Aquaria</b> 1. <b>Material:</b> Glass or stainless steel 2. <b>Size:</b> Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. <b>Fill volume:</b> 15-30 L of solution	Glass  20-L 15 L
<b>Type of Dilution System</b> Must provide reproducible supply of toxicant	N/A
<b>Flow Rate</b>	N/A

Guideline Criteria	Reported Information
<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	0.50 g/L
<b><u>Photoperiod</u></b> 16 hours light, 8 hours dark	16 h light, 8 h 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	Solvent: none Maximum conc.: N/A

#### D. Test Design

Guideline Criteria	Reported Information
<b><u>Range Finding Test</u></b> If $LC_{50} > 100$ mg/L with 30 fish, then no definitive test is required.	Pretests were conducted, however, the results were not reported.
<b><u>Nominal Concentrations of Definitive Test</u></b> Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series	Control, 10, 18, 32, 58, and 100 mg/L
<b><u>Number of Test Organisms</u></b> Minimum 10/level, may be divided among containers	10 fish per treatment level or control
<b>Test organisms randomly or impartially            assigned to test vessels?</b>	Yes
<b>Biological observations made every 24            hours?</b>	Yes

Guideline Criteria	Reported Information
<p><b><u>Water Parameter Measurements</u></b></p> <p>1. <u>Temperature</u> Measured constantly or, if water baths are used, every 6 hrs, may not vary &gt; 1°C</p> <p>2. <u>DO and pH</u> Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control</p>	<p>Temperature, DO, and pH measured daily in each control and treatment replicate</p>
<p><b><u>Chemical Analysis</u></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</p>	<p>Yes, solutions collected at 0 and 96 hours were analyzed by HPLC</p>

## 12. REPORTED RESULTS:

### A. General Results

Guideline Criteria	Reported Information
<p><b>Quality assurance and GLP compliance statements were included in the report?</b></p>	<p>Yes, but compliance was with OECD and Swiss GLP. A QA statement was also included in the report.</p>
<p><b><u>Recovery of Chemical</u></b></p> <p>1. Percent of nominal 2. Limit of detection 3. Method validation</p>	<p>1. 85 - 93% 2. 1 mg/L 3. Not reported</p>
<p><b><u>Control Mortality</u></b> Not more than 10% control organisms may die or show abnormal behavior.</p>	<p>0% control mortality</p>

Guideline Criteria	Reported Information
Raw data included?	Yes
Signs of toxicity (if any) were described?	No signs of test material toxicity were reported

### Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1	<1	-	-
10	8.50	8.80	8.70 (0.21)	87
18	16.70	16.60	16.70 (0.07)	93
32	27.20	27.20	27.20 (0.0)	85
58	54.50	52.30	53.40 (1.56)	92
100	92.50	93.70	93.10 (0.85)	93

### Mortality

Concentration (ppm)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Control	-	10	0	0	0	0
10	8.7	10	0	0	0	0

Concentration (ppm)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
18	16.7	10	0	0	0	0
32	27.2	10	0	0	0	0
58	53.4	10	0	0	0	0
100	93.1	10	0	0	0	0

Other Significant Results: No signs of test material toxicity were reported.

### B. Statistical Results

Statistical method: Visual observation using nominal concentrations

96-hr LC<sub>50</sub>: >100 ppm                      95% C.I.: N/A

Probit Slope: N/A                                      NOEC: 100 ppm

### 13. VERIFICATION OF STATISTICAL RESULTS:

Parameter	Result
Binomial Test LC <sub>50</sub> (C.I.)	N/A
Moving Average Angle LC <sub>50</sub> (95% C.I.)	N/A
Probit LC <sub>50</sub> (95% C.I.)	N/A
Probit Slope	N/A
NOEC	100 ppm (93.1 ppm mean measured concentration)

14. REVIEWER'S COMMENTS: This study is scientifically sound but does not fulfill the



guideline requirements for an acute toxicity test using a freshwater fish. The percent purity of the test material was not reported. Aeration of test dilution water was employed during study. De-chlorinated tap water was employed as dilution water. The 96-hour  $LC_{50}$  for carp was determined to be >100 ppm (>93.1 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the carp. The NOEC was determined to be 100 ppm (93.1 ppm mean measured concentration).

**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

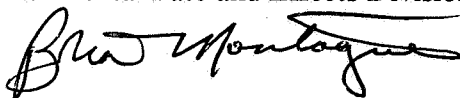
4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,  
 Golder Associates Inc.

**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>Feeding</b> No feeding during the study.	No feeding during the study
<b>Pretest Mortality</b> No more than 3% mortality 48 hours prior to testing.	Not reported

### C. Test System

Guideline Criteria	Reported Information
<b>Source of dilution water</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>Water Temperature</b> Daphnia: 20°C Amphipods and mayflies: 17°C Midges and mayflies: 22°C Stoneflies: 12°C	20 - 22°C
<b>pH</b> Prefer 7.2 to 7.6.	7.8 - 7.9
<b>Dissolved Oxygen</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>Total Hardness</b> Prefer 40 to 200 mg/L as CaCO <sub>3</sub> .	240 mg/L as CaCO <sub>3</sub>

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

#### D. Test Design

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

Guideline Criteria	Reported Information
<p><b>Number of Test Organisms</b> Minimum 20/level, may be divided among containers.</p>	20 per level, 5 per replicate
<p><b>Test organisms randomly or impartially assigned to test vessels?</b></p>	Yes
<p><b>Water Parameter Measurements</b></p> <p>1. <u>Temperature</u> Measured continuously or, if water baths are used, every 6 h, may not vary &gt; 1°C.</p> <p>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.</p>	Temperature, DO, and pH were measured at test initiation and termination.
<p><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</p>	Solutions collected at 0 and 48 hours and analyzed for CGA-51202 using HPLC.

## 12. REPORTED RESULTS:

### A. General Results

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

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<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.



"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

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**DATA EVALUATION RECORD  
SEEDLING EMERGENCE TIER I TEST  
§ 122-1**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: 99.9%
3. **CITATION: Author:** D. Schwab  
Title: Evaluating the Effects of CGA-51202 on the Emergence and Vegetative Vigor of Non-Target Terrestrial Plants  
Study Completion Date: November 13, 1997  
Laboratory: ABC Laboratories, Inc., Columbia, MO  
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC  
Laboratory Study ID: 43901  
MRID No.: 449295-13  
DP Barcode: D260009

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

Signature:

Date:

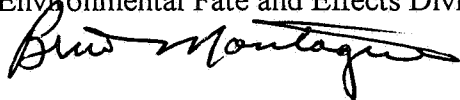
**APPROVED BY:** Pim Kosalwat, Ph.D., Senior Scientist  
Golder Associates Inc.,

Signature:

Date:

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

Signature:



Date: March 2000

6. **STUDY PARAMETERS:**

**Definitive Study Duration:** 21 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for a seedling emergence study with terrestrial plants. None of the ten test species exposed to the maximum labeled rate of CGA-51202 (0.5 lb ai/A) were affected by 25% when compared to the pooled controls for each measured parameter.

**Results Synopsis:**

EC25 > 0.5 lb ai/A NOEL (onion, corn, tomato, cucumber) < 0.5 lbs ai/A

8. **ADEQUACY OF THE STUDY:**

- A. **Classification:** Core.
- B. **Rationale:** N/A.

C. **Repairability:** N/A.

9. **GUIDELINE DEVIATIONS:** The organic matter content of the soil (2.7%) was greater than recommended (1.0%).
10. **SUBMISSION PURPOSE:** Submitted to support reregistration.
11. **MATERIALS AND METHODS:**

**A. Test Organisms**

Guideline Criteria	Reported Information
<b>Species</b> 6 dicots in 4 families, including soybean and a rootcrop; 4 monocots in 2 families, including corn.	<u>Dicots:</u> cabbage, carrot, cucumber, lettuce, soybean, tomato <u>Monocots:</u> corn, oat, onion, ryegrass
<b>Number of seeds per rep</b> 10	10
<b>Source of Seed</b>	Commercial suppliers
<b>Historical % Germination of Seed</b>	≥85%

**B. Test System**

Guideline Criteria	Reported Information
<b>Solvent</b>	Deionized water
<b>Site of test</b>	Greenhouse
<b>Planting method / type of pot</b>	Planted within 24 hours prior to application/10-cm square pots
<b>Method of application</b>	Spray application
<b>Method of watering</b>	Watered by hand
<b>Growth stage at application</b> Seed or plant.	Seed

## C. Test Design

Guideline Criteria	Reported Information
Dose range 2x or 3x	N/A
Doses At least 5	Single at 0.5 lb ai/A
Controls Negative and solvent	Deionized well water and formulation blank (water) control groups
Replicates per dose At least 3	4 replicates
Duration of test 14 days	3 weeks
Were observations made at least weekly?	Yes
Maximum labeled rate	0.5 lb ai/A

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Was an NOEL observed for each species?	No 25 % effects at up to 0.5 lb ai/A equivalent
Phytotoxic observations	No phytotoxic effects were noted in any of the test species
Were initial chemical concentrations measured? (Optional)	Yes, 95 - 98% of nominal
Were adequate raw data included?	Yes

Results for the most sensitive parameter of each species \*

Species	Parameter	Inhibition (%)
Cabbage	emergence	3
Carrot	No parameter affected	0
Cucumber	shoot length	7
Lettuce	emergence	1
Soybean	dry weight	4
Tomato	dry weight	8
Corn	dry weight	6
Oat	No parameter affected	0
Onion	emergence	21
Ryegrass	emergence	1

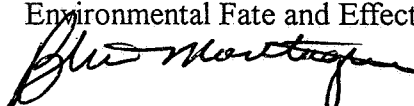
\*The most sensitive parameter is based on percent inhibition and comparisons were made to the pooled control group.

Observations: None of the ten test species were affected by treatment based on phytotoxicity observations.

Statistical Method: Analysis of variance was conducted for each species parameter. It was stated that effects on measured parameters were not greater than 25%.

13. **VERIFICATION OF STATISTICAL RESULTS:** Comparisons were made between the formulation control group and the treatment group for all parameters. None of the measured parameters were affected by 25% or more.
14. **REVIEWER'S COMMENTS:** The organic matter content of the soil used in the study was reported to be 2.7%. The maximum organic matter content suggested by EPA for a seedling emergence test is 1%. This study is scientifically sound and fulfills the guideline requirements. The study is classified as **Core**.

**DATA EVALUATION RECORD  
VEGETATIVE VIGOR TIER I TEST  
§ 122-1**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
  
2. **TEST MATERIAL:** CGA-51202 Purity: 99.9%
  
3. **CITATION:**
  - Author: D. Schwab
  - Title: Evaluating the Effects of CGA-51202 on the Emergence and Vegetative Vigor of Nontarget Terrestrial Plants
  - Study Completion Date: November 13, 1997
  - Laboratory: ABC Laboratories, Inc., Columbia, MO
  - Sponsor: Novartis Crop Protection, Inc., Research Triangle Park, NC
  - Laboratory Study ID: 43901
  - MRID No.: 449295-13
  - DP Barcode: D260009
  
4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,  
Golder Associates Inc.
  - Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_
  
  - APPROVED BY:** Pim Kosalwat, Ph.D., Senior Scientist,  
Golder Associates Inc.,
    - Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_
  
5. **APPROVED BY:** Brian Montague, Biologist  
Environmental Fate and Effects Division
  - Signature:**  **Date:** March 2000
  
6. **STUDY PARAMETERS:**
  - Definitive Study Duration:** 21 days
  
7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for a Tier I vegetative vigor study with terrestrial plants. CGA-51202 at the maximum application rate (0.5 lb ai/A) was applied to ten species of terrestrial plants. None of the ten species tested were affected.
  
8. **ADEQUACY OF THE STUDY:**
  - A. **Classification:** Core.
  - B. **Rationale:** N/A.
  - C. **Repairability:** N/A.

9. **GUIDELINE DEVIATIONS:** No deviations of consequence were noted.

10. **SUBMISSION PURPOSE:** Submitted to support reregistration.

11. **MATERIALS AND METHODS:**

**A. Test Organisms**

Guideline Criteria	Reported Information
<b>Species</b> 6 dicots in 4 families, including soybean and a rootcrop; 4 monocots in 2 families, including corn.	<u>Dicots</u> : cabbage, carrot, cucumber, lettuce, soybean, tomato <u>Monocots</u> : corn, oat, onion, ryegrass
<b>Number of plants per rep</b> At least 5	6 for cabbage, carrot, and lettuce, and 5 for the remaining 7 species
<b>Source of Seed</b>	Commercial suppliers

**B. Test System**

Guideline Criteria	Reported Information
<b>Solvent</b>	None
<b>Site of test</b>	Greenhouse
<b>Planting method / type of pot</b>	Planted within 24 hours prior to application/10-cm square pots
<b>Method of application</b>	Spray booth
<b>Method of watering</b>	Hand watered avoiding foliage
<b>Growth stage at application</b> 1-3 true leaf stage	2-4 true leaf stage

**C. Test Design**

Guideline Criteria	Reported Information
<b>Dose range</b> 2x or 3x	N/A
<b>Doses</b> At least 5	0.5 lb active ingredient (ai)/A
<b>Controls</b> Negative and solvent	Deionized well water and formulation blank (water) control groups
<b>Replicates per dose</b> At least 3	4 replicates
<b>Duration of test</b> 14 days	3 weeks
<b>Were observations made at least weekly?</b>	Yes
<b>Maximum labeled rate</b>	0.5 lb ai/A

**12. REPORTED RESULTS:**

Guideline Criteria	Reported Information
<b>Quality assurance and GLP compliance statements were included in the report?</b>	Yes
<b>Was an NOEL observed for each species?</b>	Only for certain species-others unaffected
<b>Phytotoxic observations</b>	Yes
<b>Were initial chemical concentrations measured? (Optional)</b>	No
<b>Were adequate raw data included?</b>	Yes

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Results for the most sensitive parameter of each species\*

Species	Parameter	Inhibition (%)
Cabbage	shoot length	2
Cucumber	no parameter inhibited	N/A
Lettuce	no parameter inhibited	N/A
Carrot	no parameter inhibited	N/A
Soybean	no parameter inhibited	N/A
Tomato	no parameter inhibited	N/A
Corn	dry weight	2
Oat	shoot length	4
Onion	no parameter inhibited	N/A
Ryegrass	shoot length	1

\*The most sensitive parameter is based on percent inhibition.

Observations: No visual phytotoxicity signs were observed on any of the tested species.

Statistical Method: Analysis of variance was conducted for each species parameter. It was stated that effects on measured parameters were less than 25% for all species.

13. **VERIFICATION OF STATISTICAL RESULTS:** No statistical analysis was performed since the highest inhibition was only 4% when compared to the controls.
14. **REVIEWER'S COMMENTS:** This study is scientifically sound, fulfills the guideline requirements, and can be classified as **Core**.

**DATA EVALUATION RECORD  
AQUATIC PLANT EC<sub>50</sub> TEST  
GUIDELINE 123-2 (TIER II)**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: >99.9%

3. **CITATION:**

Authors: R.L. Boeri, J.P. Magazu, and T.J. Ward  
Title: Acute Toxicity of CGA-51202 to the Duckweed, *Lemna gibba* G3  
Study Completion Date: September 18, 1997  
Laboratory: T.R. Wilbury Laboratories, Inc., Marblehead, MA  
Sponsor: Novartis Crop Protection, Greensboro, NC  
Laboratory Report ID: 1233-NO  
MRID No.: 449295-14  
DP Barcode: D260010

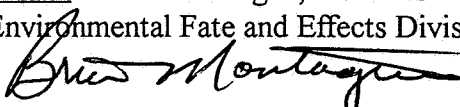
4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,  
Golder Associates Inc.

**Signature:** **Date:** 11/10/99

**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:** April 2000

6. **STUDY PARAMETERS:** **Definitive Test Duration:** 14 days  
**Type of Concentrations:** Initial measured

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an aquatic plant toxicity test.

**Results Synopsis:**

EC<sub>50</sub>: >95.4 ppm ai 95% C.I.: N/A  
NOEC: 95.4 ppm ai Probit Slope: N/A

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

**B. Rationale:** Fulfills guideline requirements.

**C. Repairability:** N/A

9. **GUIDELINE DEVIATIONS:** The maximum label rate was not reported.

10. **SUBMISSION PURPOSE:** Submitted to support registered uses and fulfill 123-2 guideline requirements.

11. **MATERIALS AND METHODS:**

**A. Test Organisms**

Guideline Criteria	Reported Information
<b>Species</b> <i>Lemna gibba</i>	<i>Lemna gibba</i>
<b>Number of Plants/Fronds</b> 5 plants, 3 fronds each	3 plants, 3-4 fronds each, total of 11-12 fronds per replicate
<b>Nutrients</b> Standard formula, e.g. 20XAAP	M-Hoagland's medium without sucrose or EDTA

**B. Test System**

Guideline Criteria	Reported Information
<b>Solvent</b>	None
<b>Temperature</b> 25°C	23.0 - 24.6°C
<b>Light Intensity</b> 5.0 KLux (±15%)	5.4 KLux
<b>Photoperiod</b> Continuous	Continuous
<b>Test System</b> Static or Renewal	Static
<b>pH</b> Approx. 5.0	Initial: 3.7 - 4.9 Final: 5.7 - 6.2

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**C. Test Design**

Guideline Criteria	Reported Information
<b><u>Dose range</u></b> 2X or 3X progression	2X
<b><u>Doses</u></b> at least 5	6.0, 13, 25, 50, and 100 mg ai/L
<b><u>Controls</u></b> negative and/or solvent	Negative control
<b><u>Replicates per dose</u></b> 3 or more	3
<b><u>Duration of test</u></b> 14 days	14 days
<b>Daily observations were made?</b>	Counts and observations made on days 1, 4, 6, 8, 11, 13, and 14
<b><u>Method of Observations</u></b>	Number of normal and chlorotic fronds
<b><u>Maximum Labeled Rate</u></b>	Not reported

**12. REPORTED RESULTS:**

Guideline Criteria	Reported Information
<b>Initial and 14 day frond numbers were measured?</b>	Yes
<b>Control frond at 14 days <math>\geq</math>2X initial count?</b>	Yes
<b>Initial chemical concentrations measured? (Optional)</b>	Samples were collected at initiation and termination and analyzed by HPLC.
<b>Raw data included?</b>	Yes

Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<2.00	<2.00	-	-
6.0	5.25	2.80	4.0 (1.73)	67
13	12.2	6.33	9.3 (4.15)	72
25	24.6	17.5	21.1 (5.02)	84
50	46.9	37.1	42.0 (6.93)	84
100	95.4	82.2	88.8 (9.33)	89

Dose Response

Initial Measured concentration (ppm ai)	14-day Avg. Number of Normal Fronds	% Inhibition*	14-day pH
Control	142	N/A	6.0
5.25	138	2.8	6.1
12.2	149	-4.9	6.2
24.6	140	1.4	6.2
46.9	133	6.3	6.1
95.4	146	-2.8	5.9

\* Compared to the control; negative sign indicates stimulation.

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**Other Significant Results:** No sublethal effects were observed other than the presence of a small number of chlorotic fronds in the control and all treatment groups. No flowers were noted in any group.

**Statistical Results:**

Statistical Methods: Visual observation for EC<sub>50</sub>; analysis of variance coupled with Dunnett's test for NOEC.

EC<sub>50</sub>: >95.4 ppm ai                                   95% C.I.: N/A

Probit Slope: N/A                                   NOEC: 95.4 ppm ai

13. **VERIFICATION OF STATISTICAL RESULTS:** Williams' test was used to confirm the NOEC. The EC<sub>50</sub> value could not be calculated because there was at least 94% of the control growth at all tested concentrations.

EC<sub>50</sub>: >95.4 ppm ai                                   95% C.I.: N/A

Probit Slope: N/A                                   NOEC: 95.4 ppm ai

14. **REVIEWER'S COMMENTS:** The maximum label rate of the test material is well below the the rate which would result in an aquatic concentration of 95.4 ppm ai when applied on the surface of a 15-cm deep water body.

This study is scientifically sound, and fulfills the guideline requirements. Based on initial measured concentrations, the EC<sub>50</sub> was determined to be >95.4 ppm ai, the highest concentration tested. The NOEC was determined to be 95.4 ppm ai.

MRID No. 449295-14

CGA-51202: Acute Lemna - Growth

File: 44929514 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	ORIGINAL N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Control	3	142.333	142.333	140.000
2	5.25	3	137.667	137.667	140.000
3	12.2	3	149.000	149.000	140.778
4	24.6	3	140.333	140.333	140.778
5	46.9	3	133.000	133.000	140.778
6	95.4	3	146.000	146.000	146.000

CGA-51202: Acute Lemna - Growth

File: 44929514 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. SIG WILLIAMS	TABLE P=.05	DEGREES OF WILLIAMS	FREEDOM
Control	140.000				
5.25	140.000	0.125	1.78	k= 1, v=12	
12.2	140.778	0.083	1.87*	k= 2, v=12	
24.6	140.778	0.083	1.90	k= 3, v=12	
46.9	140.778	0.083	1.92	k= 4, v=12	
95.4	146.000	0.196	1.93	k= 5, v=12	

s = 22.902

Note: df used for table values are approximate when  $v > 20$ .

**DATA EVALUATION RECORD  
ALGAE OR DIATOM EC<sub>50</sub> TEST  
GUIDELINE 123-2 (TIER II)**

1. **CHEMICAL:** Metolachlor PC Code No.: 108801
2. **TEST MATERIAL:** CGA-51202 Purity: Not reported
3. **CITATION:** Author: A. Vial  
Title: Report on the Growth Inhibition Test of CGA-51202 to Green Algae (*Scenedesmus subspicatus*)  
Study Completion Date: August 12, 1991  
Laboratory: Ciba-Geigy Ltd., Crop Protection Division, Basle, Switzerland  
Sponsor: Novartis Crop Protection, Inc., Greensboro, NC  
Laboratory Project ID: 918152  
DP Barcode: D260010  
MRID No.: 449295-15

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

**Signature:**

**Date:** 11/10/99

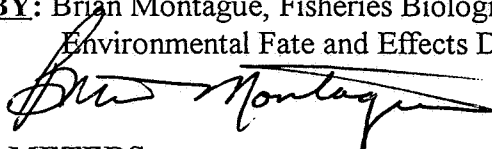
**APPROVED BY:** Pim Kosalwat, Ph.D., Senior Scientist,  
Golder Associates Inc.

**Signature:**

**Date:**

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

**Signature:**



**Date:** April 2000

6. **STUDY PARAMETERS:**

**Definitive Test Duration:** 72 hours  
**Type of Concentrations:** Initial measured

7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill the guideline requirements for a Tier-II algal toxicity test. The percent purity of the test substance was not reported, and the test was conducted for only 3 days.

**Results Synopsis**

72-hour EC<sub>50</sub> = 57.1 (29.3 to inf.) NOEC 29.3 ppm Slope = N/A

8. **ADEQUACY OF THE STUDY:**

A. **Classification:** Supplemental.



**B. Rationale:** The percent purity of the test substance was not reported and the test was conducted for only 3 days. Species is not generally accepted by the Agency.

**C. Repairability:** No.

**9. GUIDELINE DEVIATIONS:**

1. The percent purity of the test substance was not reported.
2. The study was conducted for 3 days rather than the required 4 days.
3. The maximum labelled rate was not reported.
4. The nutrients used in the test were not reported.

**10. SUBMISSION PURPOSE:**

**11. MATERIALS AND METHODS:**

**A. Test Organisms**

Guideline Criteria	Reported Information
<b><u>Species</u></b> <i>Skeletonema costatum</i> <i>Anabaena flos-aquae</i> <i>Selenastrum capricornutum</i> <i>Navicula pelliculosa</i>	<i>Scenedesmus subspicatus</i>
<b><u>Initial Number of Cells</u></b> 3,000 - 10,000 cells/mL	9,400 cells/mL
<b><u>Nutrients</u></b> Standard formula, e.g. 20XAAP	Not reported

**B. Test System**

Guideline Criteria	Reported Information
<b><u>Solvent</u></b>	None
<b><u>Temperature</u></b> Skeletonema: 20°C Others: 24-25°C	23 ±1°C
<b><u>Light Intensity</u></b> Anabaena: 2.0 KLux (±15%) Others: 4.0-5.0 KLux (±15%)	10.8 KLux
<b><u>Photoperiod</u></b> Skeletonema: 14 h light, 10 h dark or 16 h light, 8 h dark Others: Continuous	Continuous
<b><u>pH</u></b> Skeletonema: approx. 8.0 Others: approx. 7.5	Initial: 6.7-7.9 Final: 7.6-7.9

**C. Test Design**

Guideline Criteria	Reported Information
<b><u>Dose range</u></b> 2X or 3X progression	3X
<b><u>Doses</u></b> at least 5	1.23, 3.7, 11, 33, and 100 mg/L, not corrected for percent active ingredient
<b><u>Controls</u></b> negative and/or solvent	Negative control group
<b><u>Replicates per dose</u></b> 3 or more	6 replicates in the control and 3 replicates per treatment
<b><u>Duration of test</u></b> 120 hours	72 hours
<b>Daily observations were made?</b>	Yes

Guideline Criteria	Reported Information
<b>Method of Observations</b>	"TOA" cell counter
<b>Maximum Labeled Rate</b>	Not reported

12. **REPORTED RESULTS:**

Guideline Criteria	Reported Information
<b>Initial and 72 h cell densities were measured?</b>	Yes
<b>Control cell count at 72 hr <math>\geq</math>2X initial count?</b>	Yes
<b>Initial chemical concentrations measured?</b> (Optional) 1. Percent of nominal 2. Detection limit 3. Method validation	1. 89 - 95% of nominal 2. <1.0 mg/L 3. 108.1% of nominal
<b>Raw data included?</b>	Yes

Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1.0	<1.0	-	-
1.23	1.1	1.0	1.1 (0.07)	85
3.7	3.5	3.5	3.5 (0)	95

11	10.4	10.3	10.4 (0.07)	94
33.0	29.3	32.2	30.8 (2.05)	93
100.0	92.2	81.7	87.0 (7.42)	87

#### Dose Response

Initial Measured Concentration (ppm)	72-hour Avg. Cell Density ( $\times 10^4$ cells/mL)	Inhibition* (%)	Final pH
Control	146.4	-	7.9
1.1	155.3	-6.1	7.9
3.5	154.7	-5.7	7.9
10.4	168.0	-14.8	7.9
29.3	174.0	-18.9	7.9
92.2	8.8	94.0	7.6

\*Negative inhibition indicates stimulation

Other Significant Results: None.

Statistical Results for Cell Density:

Statistical Methods: The  $EC_{50}$  values were calculated according to Berkson (1953); NOEC calculated according to the modified Dunnett's test. Results are based on nominal concentrations and areas under the growth curves.

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EC<sub>50</sub>: 77.6 mg/L

95% C.I.: 73.1-80.8 mg/L

Probit Slope: N/A

NOEC: 33 mg/L

**13. VERIFICATION OF STATISTICAL RESULTS:**

Statistical Methods: Analyses were based on initial measured concentrations and cell density. The probit method could not be used since it requires at least two concentrations at which the percent inhibition is between 0 and 100. Non-linear regression could not be used to estimate the EC<sub>50</sub> value because it relies upon estimates generated from the probit analysis. Therefore, the EC<sub>50</sub> was estimated using the binomial method, although 95% confidence intervals could not be estimated. Williams' test was used to determine the NOEC.

EC<sub>50</sub>: 57.1 ppm

95% C.I.: N/A

Probit Slope: N/A

NOEC: 29.3 ppm

- 14. REVIEWER'S COMMENTS:** This study is scientifically sound but does not fulfill the guideline requirements for an algal toxicity test. The percent purity of the test material was not reported and the test was only conducted for 3 days rather than the required 4 days. Based on initial measured concentrations, the 72-hour EC<sub>50</sub> and NOEC for *S. subspicatus* were 57.1 and 29.3 ppm, respectively. This study can be categorized as **Supplemental**.

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CGA-51202: Acute Green Algae Test  
 File: 44929515 Transform: NO TRANSFORM

WILLIAMS TEST (Isotonic regression model) TABLE 1 OF 2

GROUP	IDENTIFICATION	N	ORIGINAL MEAN	TRANSFORMED MEAN	ISOTONIZED MEAN
1	Control	6	146.417	146.417	157.472
2	1.1	3	155.333	155.333	157.472
3	3.5	3	154.667	154.667	157.472
4	10.4	3	168.000	168.000	157.472
5	29.3	3	174.000	174.000	157.472
6	92.2	3	8.833	8.833	8.833

CGA-51202: Acute Green Algae Test  
 File: 44929515 Transform: NO TRANSFORM

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WILLIAMS TEST (Isotonic regression model) TABLE 2 OF 2

IDENTIFICATION	ISOTONIZED MEAN	CALC. MEAN	SIG. WILLIAMS	TABLE P=.05	DEGREES OF WILLIAMS	FREEDOM
Control	157.472					
1.1	157.472	0.574	1.75	k= 1, v=15		
3.5	157.472	0.574	1.84	k= 2, v=15		
10.4	157.472	0.574	1.87	k= 3, v=15		
29.3	157.472	0.574	1.88	k= 4, v=15		
92.2	8.833	7.149	*	1.89	k= 5, v=15	

s = 27.219

Note: df used for table values are approximate when v > 20.

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