DATA EVALUATION RECORD
§ 72-1 - ACUTE LC_{50} TEST WITH A COLDWATER FISH

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

2. **TEST MATERIAL:** CGA-354743 (metolachlor metabolite)- 95% pure

3. **CITATION:** Author: H. Rufli
   Title: Acute Toxicity Test of CGA 354743 (Metabolite of CGA 24705) to Rainbow Trout (*Oncorhynchus mykiss*) in the Static System
   Study Completion Date: June 11, 1996
   Laboratory: Ciba-Geigy Limited, Basle, Switzerland
   Sponsor: Novartis Crop Protection, Inc., Greensboro, NC
   Laboratory Report ID: 961526
   MRID No.: 449317-02
   DP Barcode: D260387

4. **REVIEWED BY:** Mark Mossler, M.S., Environmental Scientist,
   Golder Associates Inc.
   Signature: **Date:** 4/13/00

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

5. **APPROVED BY:** Brian Montague, fisheries biologist
   ERB I, Environmental fate and Effects Division
   Signature: Brian Montague **Date:** 5/15/00

6. **STUDY PARAMETERS:**
   Age or Size of Test Organism: 44-57 mm
   Definitive Test Duration: 96 hours
   Study Method: Static
   Type of Concentrations: Mean measured

7. **CONCLUSIONS:** This study is scientifically sound and provides supplemental data, but does not fulfill the guideline requirements. A 96-hour LC_{50} of 48 ppm ai classifies CGA-354743 as slightly toxic to the rainbow trout. Dechlorinated tapwater was used and only seven test Fish per concentration were tested.
   Results Synopsis:
   LC_{50}: 48 ppm ai 95% C.I.: 36-64 ppm ai
   NOEC: 36 ppm ai Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. Classification: Supplemental but not usable to satisfy 72-1 data requirements.

B.Rationale: Only seven fish were tested per group, rather than the required ten fish per group.

C. Repairability: No.

9. GUIDELINE DEVIATIONS:

1. Only seven fish were tested per group.
2. Dechlorinated water was used as dilution water.
3. Temperature was measured every 24 hours, rather than the recommended every six hours for tests with waterbaths.

10. SUBMISSION PURPOSE: Submitted to support reregistration of metolachlor products.

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the rainbow trout (*Oncorhynchus mykiss*)	*Oncorhynchus mykiss*
Mean Weight 0.5-5 g	Range: 0.63-1.5 g Mean: 1.03 g
Mean Standard Length Longest not > 2x shortest	Range: 44-57 mm Mean: 50 mm
Supplier	P. Hohler, Zeiningen, Switzerland
All fish from same source?	Yes
All fish from the same year class?	Not reported

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 14 days	49 days
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	No treatments during the acclimation period
Feeding No feeding during the study	Last fed 24 hours prior to testing
Pretest Mortality < 3% mortality 48 hours prior to testing	≤5% mortality in the 7 days prior to testing

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Dechlorinated tap water - carbon filtered
Does water support test animals without observable signs of stress?	Yes
Water Temperature 12°C	12.8-12.9°C
pH Prefer 7.2 to 7.6	7.8-8.2
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%	Slight aeration of the solutions maintained O_2 concentration at ≥92% of saturation during the test

Guideline Criteria	Reported Information
Total Hardness Prefer 40 to 200 mg/L as $CaCO_3$	120 mg/L as $CaCO_3$
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	 Glass 20-L 15 L
Type of Dilution System Must provide reproducible supply of toxicant	N/A
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	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	0.48 g/L
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	Solvent: none Maximum conc.: N/A

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L with 30 fish, then no definitive test is required.	Test concentrations were based on preliminary testing.

Guideline Criteria	Reported Information
Nominal Concentrations of Definitive Test 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 ppm, concentrations not adjusted for percent active ingredient (ai)
Number of Test Organisms Minimum 10/level, may be divided among containers	Seven fish per group
Test organisms randomly or impartially assigned to test vessels?	Not reported
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1°C 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	Temperature was measured daily in each test chamber DO and pH were measured daily in each test chamber
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	Samples were collected from each vessel at 0 and 96 hours after test initiation and analyzed using HPLC.

12. REPORTED RESULTS:

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Recovery of Chemical Percent of nominal, procedural recovery, limit of detection (LOD)	106-114% of nominal, procedural recovery = 99%, LOD = 0.4 ppm ai
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0% mortality
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Analytical results

Nominal concentration (ppm)	Measured concentration (ppm ai)	
	Hour of Study	
	0	96
Control	<LOD	<LOD
10	10.7	10.6
18	20.5	20.4
32	36.4	34.8
58	64.1	64.4
100	112	112

Mortality

Concentration		Number of Fish	Cumulative Number Dead			
			Hour of Study			
Nominal (ppm)	Mean Measured (ppm ai)		24	48	72	96
Control	<LOD	7	0	0	0	0
10	10.7	7	0	0	0	0
18	20.5	7	0	0	0	0
32	35.6	7	0	0	0	0
58	64.3	7	0	0	1	7
100	112	7	0	5	7	7

Other Significant Results: Signs of test material toxicity noted at the two highest-concentration treatment levels were erratic swimming, loss of equilibrium, and pigmentation changes.

B. Statistical Results

Method: probit analysis (based on nominal concentrations)

96-hr LC_{50}: 43 ppm
Probit Slope: 25.7
95% C.I.: not reported
NOEC: 32 ppm

13. VERIFICATION OF STATISTICAL RESULTS:

Method: binomial method (based on mean measured conc.s)

96-hr LC_{50}: 48 ppm ai
Probit Slope: N/A
95% C.I.: 36-64 ppm ai
NOEC: 36 ppm ai

14. **REVIEWER'S COMMENTS:** No mention was made by the author why only seven fish were tested per group. The minimum number of fish per group is ten. Consequently, this study is scientifically sound but does not fulfill the guideline requirements, and is classified as **Supplemental**. Based on mean measured concentrations, the 96-hour LC_{50} of 48 ppm ai classifies CGA-354743 as slightly toxic to the rainbow trout.

"MOSSLER","04-03-00","METOLACHLOR","T","108801","95%",
"ONCORHYNCHUS MYKISS","S","FLOW","CIBA-GEIGY",
"96 H","","13","SUPPL",7,0,5,7,47.84432,35.6,64.3,
0,0,0,0,6,0,0,0,0,0