# DATA EVALUATION RECORD
## § 72-1(C) -- ACUTE $LC_{50}$ TEST WITH A COLDWATER FISH

1. **CHEMICAL:** Cloquintocet-mexyl PC Code No.: 999999

2. **TEST MATERIAL:** CGA-185072 Purity: 91.6%

3. **CITATION**

| | |
|---|---|
| Authors: | H.Rufli, R.Dieterle, and A.de Morsier |
| Title: | Acute Toxicity Test of CGA-185072 technical to rainbow trout |
| Study Completion Date: | June 21, 1988 |
| Laboratory: | Ciba-Geigy, Ltd.<br>CH-4002 Basle, Switzerland |
| Sponsor: | Novartis Crop Protection, Inc.<br>P.O. Box 18300<br>Greensboro, NC 27419 |
| Laboratory Report ID: | 871684 |
| MRID No.: | 443874-11 |
| DP Barcode: | D240854 |

4. **REVIEWED BY:** Stephen Carey, Biologist, EFED, ERBIII

**Signature:** Stephen Carey **Date:** 10/18/99

5. **APPROVED BY:** Harry Craven, EFED, ERBIII

**Signature:** Harry Craven **Date:** 10/21/99

6. **STUDY PARAMETERS**

| | |
|---|---|
| **Scientific Name of Test Organism:** | *Oncorhynchus mykiss* |
| **Age or Size of Test Organism:** | 40-46 mm in length |
| **Definitive Test Duration:** | 96 hours |
| **Study Method:** | Static |
| **Type of Concentrations:** | Measured |

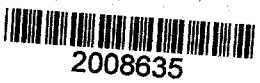
7. **CONCLUSIONS:**

**Results Synopsis**

$LC_{50}$: >63.8 ppm ai 95% C.I.: N/A

NOEL: 63.8 ppm ai Probit Slope: N/A

8. **ADEQUACY OF THE STUDY**



**A. Classification:** Supplemental

**B. Rationale:** Despite no mortalities, this study contains useful information. Test containers were aerated and dechlorinated water used as dilution water.

**C. Repairability:** No

## 9. GUIDELINE DEVIATIONS

1. The solvent, alkylphenol-polyglykol-ether, is not from one of EFED's solvent recommendations for study purposes. The test organism in the solvent control level survived, not affecting the category of the study.

2. The test containers were gently aerated throughout the study.

3. pH of the study at 7.8 - 8.0 exceeded the recommended range 7.2 - 7.6

4. Hardness at 176 mg CaCO3/L exceeded the recommended range of 40 - 48 ppm.

5. Dechlorinated water

## 10. SUBMISSION PURPOSE:

## 11. MATERIALS AND METHODS

**A. Test Organisms**

| Guideline Criteria | Reported Information |
|---|---|
| **Species**<br>Preferred species is the rainbow trout (*Oncorhynchus mykiss*) | *Oncorhynchus mykiss* |
| **Mean Weight**<br>0.5-5 g | 0.97g (0.75 - 1.08g) |
| **Mean Standard Length**<br>Longest not > 2x shortest | Mean: 44 mm<br>Range: 40 - 46 mm |
| **Supplier** | P. Hohler<br>CH-4314 Zeiningen |
| **All fish from same source?** | Yes |

| Guideline Criteria | Reported Information |
|---|---|
| **All fish from same source?** | Yes |
| **All fish from the same year class?** | Not Reported |

**B. Source/Acclimation**

| Guideline Criteria | Reported Information |
|---|---|
| **Acclimation Period**<br>Minimum 14 days | 13 days |
| **Wild caught organisms were quarantined for 7 days?** | Yes |
| **Were there signs of disease or injury?** | No |
| **If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?** | N/A |
| **Feeding**<br>No feeding during the study | Last fed 24 hours prior to test initiation |
| **Pretest Mortality**<br>< 3% mortality 48 hours prior to testing | 0 % mortality prior to testing. |

**C. Test System**

| Guideline Criteria | Reported Information |
|---|---|
| **Source of dilution water**<br>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**<br>12°C | 14 ± 1°C |
| **pH**<br>Prefer 7.2 to 7.6 | 7.8 - 8.0 pH |

| Guideline Criteria | Reported Information |
|---|---|
| **Dissolved Oxygen**<br>Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60% | Aeration was used throughout study.<br>1st 48 hrs: 92 %<br>2nd 48 hrs: 94 % |
| **Total Hardness**<br>Prefer 40 to 48 mg/L as $CaCO_3$ | 176 mg CACO3/l |
| **Test Aquaria**<br>1. Material:<br>Glass or stainless steel<br>2. Size:<br>Volume of 18.9 L (5 gal) or<br>30 x 60 x 30 cm<br>3. Fill volume:<br>15-30 L of solution | <br>Glass<br><br>20 L<br>36 x 22 x 25 cm<br><br>15 L |
| **Type of Dilution System**<br>Must provide reproducible supply of toxicant | Static |
| **Flow Rate**<br>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**<br>Static: ≤ 0.8 g/L at ≤ 17°C,<br>≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day | 0.65 g/L |
| **Photoperiod**<br>16 hours light, 8 hours dark | 16-h light, 8-h dark |
| **Solvents**<br>Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests | Solvent: alkylphenol-polyglykolether<br>Maximum conc.: .0038 ml/L. |

**D. Test Design**

| Guideline Criteria | Reported Information |
|---|---|
| **Range Finding Test**<br>If $LC_{50}$ >100 mg/L with 30 fish, then no definitive test is required. | Not reported |
| **Nominal Concentrations of Definitive Test**<br>Control & 5 treatment levels;<br>dosage should be 60% of the next highest concentration; concentrations should be in a geometric series | Blank & vehicle controls with 10, 18, 32, 58, 100 mg ai/L treatment levels |
| **Number of Test Organisms**<br>Minimum 10/level, may be divided among containers | 10 fishes per concentration and control<br>10 fishes per aquarium |
| **Test organisms randomly or impartially assigned to test vessels?** | Yes |
| **Biological observations made every 24 hours?** | Yes |
| **Water Parameter Measurements**<br>1. Temperature<br>Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1 °C<br>2. DO and pH<br>Measured at beginning of test and every 48 h in the high, medium, and low doses and in the control | Temperature, Oxygen, and pH were measured daily in each test chamber. Temperature was continuously monitored in the test tanks using min/max thermometers. |
| **Chemical Analysis**<br>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 collected from each test vessel at day 0 and day 4 were analyzed by 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**<br>Percent of nominal:<br>Analytical capability:<br>Limit of quantitation (LOQ): | <br>21-81 %<br>101 - 109 %<br>Not reported |
| **Control Mortality**<br>Not more than 10% control organisms may die or show abnormal behavior. | 0 % |
| **Raw data included?** | Yes |
| **Signs of toxicity (if any) were described?** | No |

Mortality

| Concentration (ppm) | | | | Number of Fish | Cumulative Number Dead | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Hour of Study | | | |
| Nominal | Initial Measured | 96 hr Measured | Mean Measured | | 24 | 48 | 72 | 96 |
| Control | N/A | N/A | N/A | 10 | 0 | 0 | 0 | 0 |
| Solvent Control | N/A | N/A | N/A | 10 | 0 | 0 | 0 | 0 |
| 10 | 7.43 | 2.09 | 4.76 | 10 | 0 | 0 | 0 | 0 |
| 18 | 14.5 | 6.90 | 12.2 | 10 | 0 | 0 | 0 | 0 |
| 32 | 25.1 | 12.2 | 18.65 | 10 | 0 | 0 | 0 | 0 |
| 58 | 46.2 | 28.3 | 37.25 | 10 | 0 | 0 | 0 | 0 |
| 100 | 76.3 | 51.3 | 63.8 | 10 | 0 | 0 | 0 | 0 |

Other Significant Results: None

**14. REVIEWER'S COMMENTS:** Based on the report, the study is scientifically sound but does not fulfill the section 158 requirements. The study partially conforms to the procedures of the subdivision guideline requirements for an acute toxicity test using rainbow trout. Based on mean measured concentrations, the 96-hour LC50 was >63.8 ppm, which classifies CGA-185072 as slightly toxic to the trout. The NOEC was determined to be≥63.8 ppm.

Hardness (176 mg/L) and pH (7.8 - 8.0) exceed the recommended protocol requirements. ASTM recommends the use of dechlorinated water only as a last resort for dilution water. The EPA Rejection Rate Analysis guidebook rejects using dechlorinated water unless other water quality parameters meet acceptable criteria. The test containers were gently aerated with the test concentration at 96-hour maintained at >70% of initial-measured concentrations. The solvent, alkylphenol-polyglykol-ether, is acceptable for the study since no morality occurred in the solvent control. This study is classified as **supplemental** because a definitive LC50 was not determined.