

MRID No. 447388-01

## DATA EVALUATION RECORD

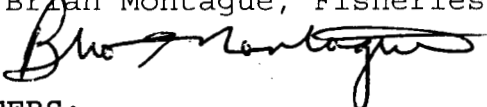
§ 72-1 - ACUTE LC<sub>50</sub> TEST WITH A COLDWATER FISH

1. **CHEMICAL:** Captan PC Code No.: 081301
2. **TEST MATERIAL:** THPAM, Purity: 95%  
(A metabolite of Captan)
3. **CITATION:**  
Authors: H. Kelso, S.J. Kent, D.S. Morris, J.E. Caunter, and S.E. Magor  
Title: THPAM: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*)  
Study Completion Date: April 28, 1995  
Laboratory: Brixham Environmental Laboratory, ZENECA Limited, Brixham, United Kingdom  
Sponsor: ZENECA Agrochemicals, Fernhurst, United Kingdom  
Laboratory Report ID: BL5445/B  
MRID No.: 447388-01  
DP Barcode: D252798

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

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

5. **APPROVED BY:** Brian Montague, Fisheries Biologist

Signature: 

Date: 6/17/99

6. **STUDY PARAMETERS:**

**Age or Size of Test Organism:** Control average: 40 mm  
**Definitive Test Duration:** 96 hours  
**Study Method:** Static renewal  
**Type of Concentrations:** Mean measured

7. **CONCLUSIONS:** This study is scientifically sound but does not fully meet USEPA guideline requirements for an acute toxicity limit test with a coldwater fish. Only 10 fish were subjected to the single concentration of test material instead of the required 30. The 96-hour LC<sub>50</sub> was determined to be >126 ppm. The NOEC was determined to be 126 ppm.

**Results Synopsis**

LC<sub>50</sub>: >126 ppm

95% C.I.: N/A

NOEC: 126 ppm

Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:**

A. **Classification:** Supplemental



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

Signature: *Karl Bullock* Date: 4/28/99

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

Signature: *P. Kosalwat* Date: 4/29/99
5. **APPROVED BY:**

Signature: Date:
6. **STUDY PARAMETERS:**

<b>Age or Size of Test Organism:</b>	Control average: 40 mm
<b>Definitive Test Duration:</b>	96 hours
<b>Study Method:</b>	Static renewal
<b>Type of Concentrations:</b>	Mean measured
7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an acute toxicity test with a coldwater fish. The 96-hour LC<sub>50</sub> was determined to be >126 ppm, which classifies THPAM as practically non-toxic to the rainbow trout. The NOEC was determined to be 126 ppm.

B. **Rationale:** Inadequate number of test fish for this type of study.

C. **Repairability:** N/A

9. **GUIDELINE DEVIATIONS:**

1. Only 10 fish were used in the treatment group; 30 fish are required for a limit test.
2. Dilution water was dechlorinated tap water with residual chlorine below the detection limit (<4 µg/L).
3. The test temperature (14.9 - 15.6°C) was greater than recommended (12°C).
4. The pH (5.57 - 8.01) was outside of the preferred range (7.2 - 7.6).
5. Total hardness (33 mg/L as CaCO<sub>3</sub>) was less than recommended (40 - 200 mg/L as CaCO<sub>3</sub>).
6. The size of the test vessels (16.5 L) and fill volume (10 L) were slightly smaller than recommended (19 - 54 L size, 15 - 30 L fill volume).

10. **SUBMISSION PURPOSE:** Submitted to support reregistration of captan 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: 0.73 g Range: 0.33 - 1.00 g
<b><u>Mean Standard Length</u></b> Longest not > 2x shortest	Mean: 40 mm Range: 35 - 44 mm

Guideline Criteria	Reported Information
<b>Mean Standard Length</b> Longest not > 2x shortest	Mean: 40 mm Range: 35 - 44 mm
<b>Supplier</b>	Exmoor Trout Farm, North Molton, UK
<b>All fish from same source?</b>	Yes
<b>All fish from the same year class?</b>	Yes

**B. Source/Acclimation**

Guideline Criteria	Reported Information
<b>Acclimation Period</b> Minimum 14 days	13 days
<b>Wild caught organisms were quarantined for 7 days?</b>	N/A
<b>Were there signs of disease or injury?</b>	No sickness or injury within the 13 days prior to testing
<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	Fish were last fed 48 hours before testing.
<b>Pretest Mortality</b> < 3% mortality 48 hours prior to testing	0% pretest mortality

**C. Test System**

Guideline Criteria	Reported Information
<b>Source of dilution water</b> Soft reconstituted water or water from a natural source, not dechlorinated tap water	Dechlorinated tap water, filtered through activated carbon, an UV sterilizer, and a second set of 25 and 10- $\mu$ m filters. Residual chlorine was below the detection limit (<4 $\mu$ g/L).

Guideline Criteria	Reported Information
<b>Does water support test animals without observable signs of stress?</b>	Yes
<b><u>Water Temperature</u></b> 12°C	14.9 - 15.6°C
<b><u>pH</u></b> Prefer 7.2 to 7.6	Control: 7.33 - 8.01 Treatment: 5.57 - 6.01
<b><u>Dissolved Oxygen</u></b> Static: ≥ 60% during 1 <sup>st</sup> 48 hrs and ≥ 40% during 2 <sup>nd</sup> 48 hrs, flow-through: ≥ 60%	≥93% of saturation during the test
<b><u>Total Hardness</u></b> Prefer 40 to 200 mg/L as CaCO <sub>3</sub>	33 mg/L as CaCO <sub>3</sub>
<b><u>Test Aquaria</u></b> 1. <b><u>Material:</u></b> Glass or stainless steel 2. <b><u>Size:</u></b> Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. <b><u>Fill volume:</u></b> 15-30 L of solution	Glass  16.5 L  10 L
<b><u>Type of Dilution System</u></b> Must provide reproducible supply of toxicant	Solutions were renewed after 48 hours.
<b><u>Flow Rate</u></b> Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	N/A
<b><u>Biomass Loading Rate</u></b> Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day	0.73 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
<p><b><u>Range Finding Test</u></b>            If LC<sub>50</sub> &gt;100 mg/L with 30 fish, then no definitive test is required.</p>	<p>No range finding tests were reported.</p>
<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>	<p>Control and 120 mg/L, not corrected for percent active ingredient.</p>
<p><b><u>Number of Test Organisms</u></b>            Minimum 10/level, may be divided among containers</p>	<p>10 fish per treatment level or control</p>
<p><b>Test organisms randomly or impartially assigned to test vessels?</b></p>	<p>Yes</p>
<p><b>Biological observations made every 24 hours?</b></p>	<p>Yes</p>
<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>	<p>Temperature, DO, and pH measured at test initiation and daily thereafter in each test vessel. Temperature was also monitored hourly in the control.</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, 48, and 96 hours and analyzed by HPLC.</p>

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

Guideline Criteria	Reported Information
<b>Quality assurance and GLP compliance statements were included in the report?</b>	Yes, OECD compliance.
<b>Recovery of Chemical</b> 1. % of nominal 2. Limit of detection 3. Method validation	1. Measured concentrations ranged from 100 - 108% of nominal (average = 105%).  2. 0.093 mg/L  3. Quality control samples not reported.
<b>Control Mortality</b> Not more than 10% control organisms may die or show abnormal behavior.	0% mortality in the dilution water control group after 96 hours.
<b>Raw data included?</b>	Yes
<b>Signs of toxicity (if any) were described?</b>	No signs of toxicity were observed.

**Measured Concentrations**

Toxicant Concentration (mg/L)						
Nominal	0 hour	48 hour		96 hour	Mean Measured (SD)	% of Nominal
	"New"	"Old"	"New"	"Old"		
Control	<0.093	<0.093	<0.093	<0.093	<0.093	-
120	123	120	130	130	126 (5.2)	105

Mortality

Concentration (mg/L)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Control	<0.093	10	0	0	0	0
120	126	10	0	0	0	0

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

**B. Statistical Results**

Statistical method: Visual observation

96-hr LC<sub>50</sub>: >120 mg/L                      95% C.I.: Not determined

Probit Slope: N/A                                      NOEC: 120 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	126 ppm

**14. REVIEWER'S COMMENTS:** This study is scientifically sound and meets the guidelines for an acute toxicity test with a coldwater fish. The 96-hour LC<sub>50</sub> of >126 ppm classifies THPAM as practically non-toxic to the rainbow trout. The NOEC was determined to be 126 ppm. This study is classified as **Core**.



14. **REVIEWER'S COMMENTS:** This study is scientifically sound and but only partially meets the guidelines for an acute toxicity limit test with a coldwater fish. Only 10 test fish were subjected to the single concentration when 30 are required under current Agency guidelines for a limit test conducted in lieu of a normal multi-concentration study. The 96-hour LC<sub>50</sub> of >126 ppm classifies THPAM as practically non-toxic to the rainbow trout. The NOEC was determined to be 126 ppm. This study is classified as **Supplemental**. Though only supplemental a repeat of this study is not required as a second test would not be expected to change the overall toxicity results for this degradate.

