

US EPA ARCHIVE DOCUMENT



**Data Evaluation Report on the acute toxicity of the transformation product M670H05 to fish (rainbow trout, *Oncorhynchus mykiss*)**

**PMRA Submission Number 2003-0839**

**EPA MRID Number 46242706**

**Data Requirement:**

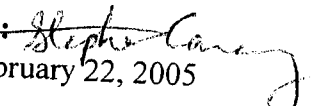
PMRA DATA CODE: 9.5.2.1  
EPA DP Barcode: D305000  
OECD Data Point: IIA 8.2.1 and IIA 8.2.1.2  
EPA Guideline: OPPTS 850.1075; OPP 72-1

**Test material:** M670H05 **Purity(%):** 99.3  
**Common name:** Metabolite of BAS 670 H  
**Chemical name:** 3-(4,5-dihydro-isoxazol-3-yl)-4-methylsulfonyl-2-methyl-benzoic acid  
**IUPAC:**  
**CAS name:**  
**CAS No.:**  
**Synonyms:** Reg. No. 388010

**Primary Reviewer (officer number):** 1269  
**PMRA**

**Date:** September 9, 2004

**Secondary Reviewer(s):** Stephen Carey, Biologist  
**EPA**

**Signature:**   
**Date:** February 22, 2005

**Company Code:** BAZ  
**Active Code:** MTN  
**Use Site Category:** 14 (Terrestrial Food Crops)  
**EPA PC Code:** 123009

**CITATION:** Bögi, C. 2003. Reg. No. 388010 (Metabolite of BAS 670 H) acute toxicity study on the rainbow trout (*Oncorhynchus mykiss*) in a static system over 96 hours. BASF AG, Germany. unpublished. Study No. 12F0165/025024. BASF Registration No. 2002/1012787. January 30, 2003.



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**EXECUTIVE SUMMARY:**

This study examined the acute toxic effects of M670H05 (guarantee 99.3%) to rainbow trout. M670H05 is a transformation product of the active ingredient BAS 670 H. The study was conducted under GLP and followed the U.S. EPA Subd. E, Part 72-1, the EEC Directive 92/69, Annex V, C1 and the OECD No. 203 guidelines. In this limit-test, fish were exposed to nominal concentrations of 0 (water control) and 100 mg M670H05/L for 96 hours in a static system. Mean measured concentrations were <0.00005 and 105.3 mg M670H05/L. Mortality and other effects were assessed at 1, 4, 24, 48, 72 and 96 hours following test initiation. No mortality or sublethal effects were seen in the control or the test concentration. The NOEC is 105.3 mg M670H05/L, the highest concentration tested. The 96-h LC<sub>50</sub> and EC<sub>50</sub> values are >105.3 mg M670H05/L. Based on the results of this study, M670H05 would be classified as practically non-toxic to rainbow trout in accordance with the classification system of the U.S. EPA.

This toxicity study is scientifically sound and satisfies the guideline requirement for an acute rainbow trout toxicity study using M670H05 (a metabolite of BAS 670 H); PMRA DACO 9.5.2.1 and US EPA guideline requirement §72-1c. The study is classified as acceptable.

**Results Synopsis**

Test organisms: rainbow trout (*Oncorhynchus mykiss*)

Mean wet weight and length: 1.6 g (0.81-2.48 g), 5.7 cm (4.8-6.6 cm)

Test Type: static

LC<sub>50</sub>: >105.3 mg M670H05/L      95% C.I.: n/a

NOEC: 105.3 mg M670H05/L      Probit Slope: n/a

EC<sub>50</sub>: >105.3 mg M670H05/L      95% C.I.: n/a

Endpoint(s) Effected: none



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**I. MATERIALS AND METHODS**

**GUIDELINE FOLLOWED:** The following guidelines were followed: U.S. EPA Subd. E, Part 72-1; EEC Directive 92/69, Annex V, C1; OECD No. 203. Deviations from U.S. EPA §72-1c included:

1. The pH range (8.2-8.7) was greater than recommended (7.2-7.6).
2. Dechlorinated tap water was used as dilution water.

The above deviations were considered minor and did not affect the validity or acceptability of the definitive test.

**COMPLIANCE:** The following GLP standards were used: OECD and Chemikaliengesetz (Chemicals Act, Annex 1). Also meets U.S. EPA Title 40 CFR Part 160. Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

**A. MATERIALS:**

**1. Test Material** M670H05 (a metabolite of BAS 670 H)

**Description:** pale yellow solid

**Lot No./Batch No. :** N3

**Purity:** 99.3%

**Stability of Compound Under Test Conditions:**

Mean measured concentrations of 1, 48 and 96 hours samples ranged from 102.5-108.2% of nominal concentrations. (OECD requires chemical stability in water and light)

**Storage conditions of test chemicals:**

room temperature





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**Table 1. Physicochemical properties of M670H05.**

Parameter	Values	Comments
Water solubility at 20°C	Deionised water at pH 7 >150 g/L	Highly soluble at neutral pH.
Vapour pressure		
UV absorption		
pKa		
Kow		

**2. Test organism:**

**Species:** rainbow trout (*Oncorhynchus mykiss*)

**Age at test initiation:** approximately 5 months

**Weight at study initiation:** mean of 1.6g (0.81-2.48 g)

**Length at study initiation:** mean of 5.7 cm (4.8-6.6 cm)

**Source:** Forellenzucht Trostadt GbR, Dorfstrasse 7, 98646 Trostadt, Germany

**B. STUDY DESIGN:**

**1. Experimental Conditions**

**a) Range-finding Study:** A range finding study was conducted to select the concentrations of the definitive study. The study was not performed according to GLP regulations. The LC<sub>50</sub> after 96 hours was > 100 mg/L.

**b) Definitive Study**

Table 2. Experimental Parameters.

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Parameter	Details	Remarks
		Criteria
<u>Acclimation:</u> Period: Conditions: Feeding: Health:	14 days Same test water, light regime and approximately the same temperature. Ecostart 17 (Bio Mar) <i>ad libitum</i> and live or frozen brine shrimp on weekdays. No feeding one day prior to test initiation and during exposure. No signs of sickness, injuries or abnormalities. No mortality observed during the last week prior to test initiation.	Acceptable ----- (EPA requires minimum 14 days; no feeding during test; OECD requires minimum of 12 days)
Duration of the test	96 hours	Acceptable ----- (EPA/OECD require 96 hour)
<u>Test condition:</u> Static/flow through Type of dilution system- for flow through method Flow rate Renewal rate for static renewal	static n/a n/a none	Acceptable ----- (EPA requires: must provide reproducible supply of toxicant) (EPA requires: consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period)
Aeration, if any	No aeration	Acceptable ----- (EPA requires: no aeration; OECD permits aeration)

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Parameter	Details	Remarks
		Criteria
<u>Test vessel</u>	aquaria	Acceptable
Material: (glass/stainless steel) Size: Fill volume:	glass with stainless steel frame 60 x 35 x 40 cm 50 L	<i>(EPA requires: size 19 L (5 gal) or 30 x 60 x 30 cm Fill volume: 15-30 L of solution)</i>
Source of dilution water	dechlorinated tap water from Frankenthal, Germany, aerated.	Partially acceptable, since controls survived throughout the test; however, a detailed dilution water analysis was not provided.
		<i>(EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap water); OECD permits dechlorinated tap water)</i>



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Parameter	Details	Remarks
		Criteria
<u>Water parameters:</u> Hardness pH Dissolved oxygen Total organic carbon Particulate matter Metals Pesticides Chlorine  Temperature  Intervals of water quality measurement	~250 mg CaCO <sub>3</sub> /L 8.2-8.7 07.6-11.4 mg/L (>60% saturation) not reported not reported not reported not reported not chlorinated  11-13 °C  pH, oxygen content and temperature were measured after 1, 24, 48, 72 and 96 hours. Hourly measurements of temperature were also taken in one aquarium.	pH slightly higher than recommended range. No effects were seen in the control fish.  Test water is regularly assayed for chemical contaminants by the municipal authorities of Frankenthal and the technical services of BASF Aktiengesellschaft as well as for presence of microbes by a contract laboratory.  Acceptable  <u>Hardness</u> EPA : 40 - 48 mg as CaCO <sub>3</sub> /L OECD: 10 -250 mg as CaCO <sub>3</sub> /L <u>pH</u> (EPA: 7.2 - 7.6; 8.0-8.3 for marine-stenohaline fishes, 7.7-8.0 for estuarine-euryhaline fishes, monthly range < 0.8) OECD: 6.0 - 8.5 <u>Dissolved Oxygen</u> EPA: <u>Static</u> : ≥ 60% during 1 <sup>st</sup> 48 hrs and ≥ 40% during 2 <sup>nd</sup> 48 hrs, <u>flow-through</u> : ≥ 60%) OECD: at least 80% saturation value. <u>Temperature:</u> EPA: estuarine/marine: 22 ± 1 °C OECD: 21 - 25°C for bluegill and 13 - 17°C for rainbow trout (EPA water quality: measured at beginning of test and every 48 hours)
<u>Number of replicates/groups:</u>  Control (dilution water): Solvent control: Treatments:	2 n/a 3	Acceptable  (EPA/OECD requires: Control & 5 treatment levels; each conc. should be 60% of the next highest conc.; concentrations should be in a geometric series)

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Parameter	Details	Remarks
		Criteria
<u>Number of organisms per replicate /groups:</u>		Acceptable
Control (dilution water): Solvent control: Treatments:	10 n/a 10	(EPA: $\geq 10/\text{concentration}$ ); OECD requires at least 7 fish/concentration)
Biomass loading rate	0.3 g/L	Acceptable  (EPA: static: $\leq 0.8 \text{ g/L}$ at $\leq 17^\circ\text{C}$ , $\leq 0.5 \text{ g/L}$ at $> 17^\circ\text{C}$ ; flow-through: $\leq 1 \text{ g/L/day}$ ; OECD requires: maximum of 1 g fish/L for static and semi-static with higher rates accepted for flow-through)
<u>Test concentrations:</u>		Acceptable
Nominal: Mean measured:	0 (control) and 100 mg/L n.d. and 105.3 mg/L	
Solvent (type, percentage, if used)	None used	Acceptable  (EPA requires: not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests; OECD requires solvent not exceed 100 mg/L)
Lighting	16 hours light: 8 hours dark (no intensity provided)	Acceptable  (EPA requires: 16 hours light/8 hours dark); OECD requires 12-16 hours photoperiod)
Feeding	No feeding during the study	Acceptable  (EPA/OECD requires: no feeding during the study)
<u>Recovery of chemical:</u>		Acceptable
Frequency of determination Level of Detection Level of Quantitation	1, 48 and 96 hours after test initiation not reported 0.00005 mg/L (0.05 $\mu\text{g/kg}$ )	



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Parameter	Details	Remarks
		Criteria
Positive control {if used, indicate the chemical and concentrations}	None used	Acceptable
Other parameters, if any		

**2. Observations:**

Table 3. Observations.

Parameter	Details	Remarks
		Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Survival and toxic signs (changes in appearance, swimming behaviour and behaviour in comparison to the control group)	Acceptable
Observation intervals	1, 4, 24, 48, 72 and 96 hours	Acceptable <i>(EPA/OECD requires: minimally every 24 hours)</i>
Water quality was acceptable (Yes/No)	Yes	Acceptable
Were raw data included?	Yes	Acceptable
Other observations, if any		

**II. RESULTS and DISCUSSION:**

**A. MORTALITY:** Pretreatment control mortality was 0%. No mortality was observed in the control or the 105.3 mg/L test concentration. The NOEC is 105.3 mg/L, the highest concentration tested. The LC<sub>50</sub> is >105.3 mg/L.

**B. NON-LETHAL TOXICITY ENDPOINTS:** No abnormalities were noted in the control or in the 105.3 mg/L test concentration. The NOEC is 105.3 mg/L, the highest concentration tested. The EC<sub>50</sub> is >105.3 mg/L.





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**C. REPORTED STATISTICS:** No statistics were employed, as no mortality or sublethal effects were observed in the control or in the test concentration.

**D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:** No statistics employed.

**E. STUDY DEFICIENCIES:** No significant deficiencies were noted.

**F. REVIEWER'S COMMENTS:** No comments.

**G. CONCLUSIONS:** This study is scientifically sound and satisfies the data requirements for an acute toxicity test on rainbow trout (DACO 9.5.2.1 and US EPA Guideline 72-1c) using M670H05 (a metabolite of BAS 670 H). This study is classified as acceptable. The NOEC is 105.3 mg M670H05/L, the highest concentration tested. The LC<sub>50</sub> and EC<sub>50</sub> values are estimated to be higher than 105.3 mg M670H05/L as no mortality or sublethal effects were observed in the control or the test concentration. Based on the results of this study, M670H05 would be classified as practically non-toxic to rainbow trout in accordance with the classification system of the U.S. EPA.

**III. REFERENCES:**

United States Environmental Protection Agency. 1985. Hazard Evaluation Division Standard Evaluation Procedure: Acute Toxicity Test for Freshwater Fish. Office of Pesticide Programs, Washington D.C. EPA-540/9-85-006.

Approved 04/01/01 C.K.