

US EPA ARCHIVE DOCUMENT



Data Evaluation Report on the acute toxicity of BAS 670 H to fish (rainbow trout, *Oncorhynchus mykiss* WALBUM 1792)

PMRA Submission Number 2003-0839

EPA MRID Number 45902314

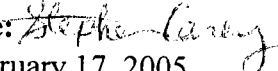
Data Requirement: PMRA DATA CODE: 9.5.2.1
EPA DP Barcode: D290076
OECD Data Point: IIA 8.2.1 and IIA 8.2.1.2
EPA Guideline: OPPTS 850.1075; OPP 72-1c

Test material: BAS 670 H **Purity (%):** 95.8
Common name: BAS 670H
Chemical name:
IUPAC: [3-(4,5-dihydro-isoisoxazol-3-yl)-4-methanesulfonyl-2-methyl-phenyl]-(5-hydroxy-1-methyl-1H-pyrazol-4-yl)methanone
CAS name: [3-(4,5-dihydro-3-isoxazolyl)-2-methyl-4-(methylsulfonyl)phenyl](5-hydroxy-1-methyl-1H-pyrazol-4-yl)-
CAS No.: 210631-61-8
Synonyms: Reg. No. 375080, methanone

Primary Reviewer (officer number): 1269
PMRA

Date: September 8, 2004

Secondary Reviewer(s): Stephen Carey, Biologist
EPA

Signature: 
Date: February 17, 2005

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

CITATION: Zok, S. 2000. BAS 670 H: Acute toxicity study on the rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792) in a static system (96 hours). BASF AG, Germany. unpublished. Study No. 12F0124/985132. BASF Registration No. 2000/1018814. December 15, 2000.



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EXECUTIVE SUMMARY:

This study examined the acute toxic effects of BAS 670 H (guarantee 95.8%) to rainbow trout (*Oncorhynchus mykiss* WALBUM 1792). The study was GLP compliant and followed the U.S. EPA Subdivision 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), 10, and 100 mg a.i./L for 96 hours in a static system. Mean measured concentrations were <0.06, 9.9 and 97.4 mg a.i./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 observed in the control or in any of the test concentrations. The NOEC is 97.4 mg a.i./L, the highest concentration tested. The 96-h LC₅₀ and EC₅₀ values are > 97.4 mg a.i./L. Based on the results of this study, BAS 670 H 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 classified as scientifically sound and satisfies the guideline requirement for an acute rainbow trout toxicity study (DACO 9.5.2.1 and U.S. EPA Subdivision E, Part 72-1). This study is classified as acceptable.

Results Synopsis

Test organisms: rainbow trout (*Oncorhynchus mykiss* WALBUM 1792)

Mean wet weight and length: 0.59 g (0.50-0.72 g), 4.2 cm (3.5-5.0 cm)

Test Type: static

LC ₅₀ : >97.4 mg a.i./L	95% C.I.: n/a
NOEC: 97.4 mg a.i./L	Probit Slope: n/a
EC ₅₀ : > 97.4 mg a.i./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 water hardness (approx. 250 mg/L as CaCO₃) was significantly higher than recommended (40-48 mg/L as CaCO₃).
2. The pH range (7.7-8.4) was greater than recommended (7.2-7.6).

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 (1981) and Chemikaliengesetz (Chemicals Act, Annex 1) (1994/97). 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

BAS 670 H

Description: Solid, yellow-brown

Lot No./Batch No. : N26

Purity: 95.8%

Stability of Compound

Under Test Conditions: Mean measured concentrations taken at 1 and 96 h were 99.1% and 96.8% of nominal values, respectively. (OECD requires chemical stability in water and light)





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Storage conditions of test chemicals: Room temperature

Table 1. Physicochemical properties of BAS 670 H.

Parameter	Values	Comments
Water solubility at 20°C	510 mg/L in deionized H ₂ O at 20°C >100 g/L at pH >9	Highly soluble
Vapour pressure	<1.0 x 10 ⁻¹² mbar (= <1.01 x 10 ⁻¹⁰ Pa) at 20°C	Low volatility
UV absorption	207 nm: 0.7637 272 nm: 0.2426 300 nm: 0.1636 410 nm: 0.0027	Potential for phototransformation (i.e. absorbance occurring within 285 - 350 nm range)
pKa	4.06 @ 20°C	Dissociated at environmentally relevant pHs
Kow	-1.52 @ 20°C	Not likely to bioaccumulate

2. Test organism:

Species: rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792)

Age at test initiation: About 2 months

Weight at study initiation: mean of 0.59 g (0.50-0.72 g)

Length at study initiation: mean of 4.2 cm (3.5-5.0 cm)

Source: Fertilized eggs obtained from Trout Breeding, Erber Soehne, Eusserthal/Pfalz, 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 LC₅₀ after 96 hours was > 220 mg a.i./L.

b) Definitive Study





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Table 2. Experimental Parameters.

Parameter	Details	Remarks
		Criteria
<u>Acclimation:</u>		Acceptable
Period:	14 days	
Conditions:	Flow through tank in tap water which was not chlorinated, passed through a charcoal filter and aerated with oil-free air.	
Feeding:	Growing feed <i>ad libitum</i> and live brine shrimp on weekdays. No feeding one day prior to test initiation and during exposure.	(EPA requires minimum 14 days; no feeding during test; OECD requires minimum of 12 days)
Health:	Mortality during the last 7 days prior to test initiation was 0.1%	
Duration of the test	96 hours	Acceptable
		(EPA/OECD require 96 hour)
<u>Test condition:</u>		Acceptable. No evidence of material loss during the 96 hours.
Static/flow through	static	
Type of dilution system- for flow through method	n/a	(EPA requires: must provide reproducible supply of toxicant)
Flow rate	n/a	(EPA requires: consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period)
Renewal rate for static renewal	None	
Aeration, if any	None	Acceptable
		(EPA requires: no aeration; OECD permits aeration)





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Parameter	Details	Remarks
		Criteria
<u>Test vessel</u>	aquaria	Acceptable
Material: Size: Fill volume:	glass with stainless steel frame 80x35x46 cm 100 L	(EPA requires: size 19 L (5 gal) or 30 x 60 x 30 cm Fill volume: 15-30 L of solution)
Source of dilution water	Municipal water of the city of Frankenthal, not chlorinated and passed through a charcoal filter, aerated.	Dechlorinated tap water; will partially accept dilution water since controls survived thoroughly out the test. A detailed dilution water analysis should be supplied. (EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap water); OECD permits dechlorinated tap water)
<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 ₃ /L 7.7-8.4 >60% saturation (≥9.5 mg/L) not reported not reported not reported not reported not chlorinated 12 °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.	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 (Hardness EPA: 40 - 48 mg as CaCO ₃ /L OECD: 10 -250 mg as CaCO ₃ /L pH (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 Dissolved Oxygen EPA: Static: ≥ 60% during 1 st 48 hrs and ≥ 40% during 2 nd 48 hrs, flow-through: ≥ 60%) OECD: at least 80% saturation value. Temperature: 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)



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Parameter	Details	Remarks
		Criteria
<u>Number of replicates/groups:</u>		Acceptable
Control (dilution water): Solvent control: Treatments:	1 n/a 10 mg a.i./L: 1 100 mg a.i./L: 3	(EPA/OECD requires: Control & 5 treatment levels; each conc. should be 60% of the next highest conc.; concentrations should be in a geometric series)
<u>Number of organisms per replicate /groups:</u>		Acceptable
Control (dilution water): Solvent control: Treatments:	10 n/a 10	(EPA: ≥ 10 /concentration); OECD requires at least 7 fish/concentration)
Biomass loading rate	~0.1 g/L	Acceptable
		(EPA: static: ≤ 0.8 g/L at $\leq 17^\circ\text{C}$, ≤ 0.5 g/L at $> 17^\circ\text{C}$; flow-through: ≤ 1 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), 10 and 100 mg a.i./L <0.06, 9.94 and 97.43 mg a.i./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)





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Parameter	Details	Remarks
		Criteria
Recovery of chemical:	Mean measured concentrations taken at 1 and 96 h were 99.1% and 96.8% of nominal values, respectively.	Acceptable
Frequency of determination	1 and 96 hours	
Level of Detection Level of Quantitation	not reported 0.06 mg a.i./L	
Positive control	None used	Acceptable
Other parameters, if any		

2. Observations:

Table 3. Observations.

Parameter	Details	Remarks
		Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Symptoms and mortality	Acceptable
Observation intervals	1, 4, 24, 48, 72 and 96 hours after study initiation.	Acceptable <i>(EPA/OECD requires: minimally every 24 hours)</i>
Water quality was acceptable?	Yes	Acceptable
Were raw data included?	Yes	Acceptable
Other observations, if any		



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II. RESULTS and DISCUSSION:

A. MORTALITY:

Pretreatment control mortality was 0.1%. No mortality was observed in the control or any of the test concentrations. The NOEC is 97.4 mg a.i./L, the highest concentration tested. The 96-h LC₅₀ is estimated to be >97.4 mg a.i./L.

B. NON-LETHAL TOXICITY ENDPOINTS:

No abnormalities were noted in the control or in any of the test concentrations. The NOEC based on sublethal effects is 97.4 mg a.i./L, the highest concentration tested. The 96-h EC₅₀ is estimated to be >97.4 mg a.i./L.

C. REPORTED STATISTICS: No statistics were employed, as no mortality was observed in the control or in any of the test concentrations.

D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER: No statistics were 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 U.S. EPA Subdivision E, Part 72-1). This study is classified as acceptable. The NOEC is 97.4 mg a.i./L, the highest concentration tested. The LC₅₀ and EC₅₀ values are estimated to be higher than 97.4 mg a.i./L as no mortality or sublethal effects were observed in the control or test concentrations. Based on the results of this study, BAS 670 H 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.