



Data Evaluation Report on the acute toxicity of BAS 670 H to fish (bluegill sunfish, *Lepomis macrochirus* RAF.)

PMRA Submission Number 2003-0839

EPA MRID Number 45902315

Data Requirement: PMRA DATA CODE: 9.5.2.2
EPA DP Barcode: D290076
OECD Data Point: IIA 8.2.1 and IIA 8.2.1.2
EPA Guideline: OPPTS 850.1075; OPP 72-1

Test material: BAS 670 H **Purity (%):** 95.8

Common name: BAS 670H

Chemical name:

IUPAC: [3-(4,5-dihydro-isoaxazol-3-yl)-4-methane-sulfonyl-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 bluegill (*Lepomis macrochirus* RAF.) in a static system (96 hours). BASF AG, Germany. unpublished. Study No. 14F0124/985133. BASF Registration No. 2000/1018813. December 15, 2000.



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EXECUTIVE SUMMARY:

This study examined the acute toxic effects of BAS 670 H (guarantee: 95.8%) to bluegill sunfish. The study was GLP compliant and followed the U.S. EPA FIFRA, Part 72-1, the EEC Directive 92/69, Annex V, C1 and the OECD No. 203 guidelines. Fish were exposed to nominal concentrations of 0 (water control), 40, 63, 100, 160, and 250 mg a.i./L for 96 hours in a static system. Mean measured concentrations were <0.06, 38.7, 60.4, 98.7, 155.8 and 239.4 mg a.i./L. Mortality and other effects were assessed at 1, 4, 24, 48, 72 and 96 hours following test initiation. No mortalities or sublethal effects were seen in the controls or any of the test concentrations. The NOEC is 239.4 mg a.i./L, the highest concentration tested. The 96-h LC₅₀ and EC₅₀ values are >239.4 mg a.i./L. Based on the results of this study, BAS 670 H would be classified as practically non-toxic to bluegill sunfish in accordance with the classification system of the U.S. EPA.

This study is acceptable for an acute toxicity test in bluegill sunfish, PMRA data code 9.5.2.2. The study is scientifically sound and fulfills the U.S. EPA guideline requirements for an acute toxicity study in bluegill sunfish (*Lepomis macrochirus*, (§ 72-1a)). The study is classified as acceptable.

Results Synopsis

Test organisms: bluegill sunfish (*Lepomis macrochirus* RAF.)

Mean wet weight and length: 2.9 g (1.9-3.6 g), 6.5 cm (5.7-6.9 cm)

Test Type: static

LC₅₀: >239.4 mg a.i./L

95% C.I.: n/a

NOEC: 239.4 mg a.i./L

Probit Slope: n/a

EC₅₀: >239.4 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 FIFRA, Part 72-1; EEC Directive 92/69, Annex V, C1; OECD No. 203. Deviations from U.S. EPA §72-1a included:

1. Temperature variations in 2 test vessels were greater than ± 1 °C.
2. The water hardness (approx. 250 mg/L as CaCO₃) was significantly higher than recommended (40-48 mg/L as CaCO₃).
3. The pH range (7.3-8.3) 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 standard was used: OECD (1981); 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. :

N 26

Purity:

95.8%

Stability of Compound





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Under Test Conditions: Average concentrations of test material taken at 1 and 96 h ranged from 95.8 - 98.7% of nominal values, with no evidence of loss over the 96 hours.
(OECD requires chemical stability in water and light)

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: Bluegill (*Lepomis macrochirus* RAF.)

Age at test initiation: No data available.

Weight at study initiation: 2.9 g (1.9-3.6 g)

Length at study initiation: 6.5 cm (5.7-6.9 cm)

Source: Osage catfisheries INC., Lake Road 54-56; Rt 4 Box 1500; Osage Beach, Missouri 65065.

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



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96 hours was about 100 mg a.i./L.

b) Definitive Study

Table 2. Experimental Parameters.

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





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Parameter	Details	Remarks
		Criteria
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	aquaria glass with stainless steel frame 80x35x46 cm 100 L	Acceptable <hr/> <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	Municipal water of the city of Frankenthal, not chlorinated and passed through a charcoal filter, aerated.	Partially acceptable, dechlorinated tap water was used as dilution water; however, controls survived throughout the test. A detailed dilution water should be supplied. <hr/> <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 ₃ /L 7.3-8.3 5.5-8.8 mg/L not reported not reported not reported not reported not chlorinated 18.8-22.4 °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.	Temperature variations in 2 test vessels were greater than ±1 °C. This was considered to have no impact on the test results. Acceptable. <hr/> <u>(Hardness)</u> EPA : 40 - 48 mg as CaCO ₃ /L OECD: 10 -250 mg as CaCO ₃ /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 st 48 hrs and ≥ 40% during 2 nd 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:	1 n/a 1	Acceptable <hr/> (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> Control (dilution water): Solvent control: Treatments:	10 n/a 10	Acceptable <hr/> (EPA: ≥ 10/concentration); OECD requires at least 7 fish/concentration)





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Parameter	Details	Remarks
		Criteria
Biomass loading rate	~0.3 g/L	Acceptable <i>(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)</i>
<u>Test concentrations:</u> Nominal: Mean measured:	0 (control), 40, 63, 100, 160 and 250 mg a.i./L <0.06, 38.67, 60.35, 98.71, 155.79, 239.42 mg a.i./L	Acceptable
Solvent (type, percentage, if used)	None used	Acceptable <i>(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)</i>
Lighting	16 hours light: 8 hours dark (no intensity provided)	Acceptable <i>(EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod)</i>
Feeding	No feeding during the study.	Acceptable <i>(EPA/OECD requires: no feeding during the study)</i>
<u>Recovery of chemical:</u> Frequency of determination Level of Detection Level of Quantitation	Average concentrations taken at 1 and 96 h ranged from 95.8-98.7% of nominal values. 1 and 96 hours not reported 0.06 mg a.i./L	Acceptable
Positive control	None used	Acceptable
Other parameters, if any		





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2. Observations:

Table 3. Observations.

Parameter	Details	Remarks Criteria
Parameters measured including the sublethal effects/toxicity symptoms	Mortality and symptoms	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		

II. RESULTS and DISCUSSION:

A. MORTALITY:

Pretreatment control mortality was 0%. No mortality was observed in the control or any of the test concentrations. The NOEC is 239.4 mg a.i./L, the highest concentration tested. The 96-h LC₅₀ is estimated to be >239.4 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 is 239.4 mg a.i./L, the highest concentration tested. The 96-h EC₅₀ is estimated to be >239.4 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



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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 the bluegill sunfish (DACO 9.5.2.2 and U.S. EPA FIFRA, Part 72-1). This study is classified as Acceptable. The NOEC is 239.4 mg a.i./L, the highest concentration tested. The LC_{50} and EC_{50} values are estimated to be higher than 239.4 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 the bluegill sunfish 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.