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Data Evaluation Report on the acute toxicity of BAS 670 00 H to fish (rainbow trout, *Oncorhynchus mykiss*)

PMRA Submission Number 2003-0839 **EPA MRID Number 45901813**

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 00 H **Purity:** 336.5 g BAS 670 H/L (approx. 30% a.i.)

Common name: BAS 670H
Chemical name:
IUPAC: [3-(4,5-dihydro-iosoxazol-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 **Date:** September 8, 2004
PMRA

Secondary Reviewer(s): Stephen Carey, Biologist
EPA

Signature: Stephen Carey
Date: February 17, 2005

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

CITATION: Zok, S. 2001. BAS 670 00 H: Acute toxicity study on the rainbow trout (*Oncorhynchus mykiss*) in a static system (96 hours). BASF AG., Germany, unpublished. Study No. 12F0440/005023. BASF Registration No. 2001/1010728. June 27. 2001.

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EXECUTIVE SUMMARY:

This study examined the acute toxic effects of the end-use product BAS 670 00 H (guarantee: 335.6 g BAS 670 H/L, equivalent to approximately 30% a.i.) to rainbow trout. The study was conducted under GLP and followed the U.S. EPA OPPTS, 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 EP/L for 96 hours in a static system. Mean measured concentrations were <0.17 and 94.6 mg EP/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 94.6 mg EP/L, the highest concentration tested. The 96-h LC_{50} and EC_{50} values are >94.6 mg EP/L. Based on the results of this study, BAS 670 00 H (an end-use product containing approximately 30% a.i.) 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 acceptable and satisfies the PMRA guideline requirement for an acute rainbow trout toxicity study. It is scientifically sound, is classified as acceptable for a formulated product and fulfills the U.S. EPA guideline requirements (§72-1c).

Results Synopsis

Test organisms: rainbow trout (*Oncorhynchus mykiss*)
Mean wet weight and length: 3.0 g (2.1-3.7 g), 7.0 cm (6.4-7.5 cm)
Test Type: static

LC_{50}: >94.6 mg EP/L 95% C.I.: n/a
NOEC: 94.6 mg EP/L Probit Slope: n/a
EC_{50}: > 94.6 mg EP/L 95% C.I.: n/a
Endpoint(s) Effected: none

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: The study was conducted according to the following guidelines: U.S. EPA OPPTS, Part 72-1; EEC Directive 92/69, Annex V, C1; OECD No. 203. Deviations from §72-1 included:

1. The water hardness and pH ranges exceeded recommendations.

2. Oxygen levels declined to 47% saturation at 96 h in one vessel, but no abnormal effects in the fish were observed, and was not considered to have an adverse effect on the study.

3. The total organic carbon, particulate matter, metal, pesticide, and chlorine concentrations in the dilution water were not reported.

4. Dechlorinated water was used as dilution water, however, the control group survived throughout the test. A detailed dilution water analysis is recommended to accept the use of dechlorinated tap water.

These deviations do not affect the acceptability or the validity of the study.

COMPLIANCE: The following GLP standards were 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 00 H

Description: Liquid, pink-cloudy

Lot No./Batch No. : 2000-2

Purity: 335.6 g BAS 670 H/L (≈30% a.i.)

Stability of Compound Under Test Conditions: Mean measured concentrations taken at 1 and 96 h were 94.8% and 94.3% of nominal values, respectively. *(OECD requires chemical stability in water and light)*

Storage conditions of test chemicals: Room temperature

Density: 1.134 g/mL

Table 1. Physicochemical properties of BAS 670 H.

Parameter	Values	Comments
Water solubility at 20°C	510 mg/L in deionized H_2O at 20°C >100 g/L at pH >9	Highly soluble
Vapour pressure	$<1.0 \times 10^{-12}$ mbar ($=<1.01 \times 10^{-10}$ 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*)
Age at test initiation: About 6 months
Weight at study initiation: mean of 3.0 g (2.1-3.7 g)
Length at study initiation: mean 7.0 cm (6.4-7.5 cm)
Source: Forellenhof Fredelsloh, Moringen, 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_{50} after 96 hours was > 100 mg EP/L.

b) Definitive Study

Table 2. Experimental Parameters.

Parameter	Details	Remarks Criteria
Acclimation:		
Period: Conditions:	14 days Flow through tank in tap water which was not chlorinated, passed through a charcoal filter and aerated with oil-free air.	Acceptable
Feeding:	Growing feed *ad libitum* 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:	No mortality observed during the last 7 days prior to test initiation.	
Duration of the test	96 hours	Acceptable *(EPA/OECD require 96 hour)*
Test condition:		
Static/flow through	static	Acceptable. No evidence of material loss over the 96 hours.
Type of dilution system- for flow through method	n/a	
Flow rate	n/a	*(EPA requires: must provide reproducible supply of toxicant)*
Renewal rate for static renewal	none	*(EPA requires: consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period)*

Parameter	Details	Remarks Criteria
Aeration, if any	None	Acceptable *(EPA requires: no aeration; OECD permits aeration)*
Test vessel Material: Size: Fill volume:	aquaria glass with stainless steel frame 80x35x46 cm 100 L	Acceptable *(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.	Acceptable to PMRA; partially acceptable to EPA because controls survived throughout the test. A detailed dilution water analysis should be supplied. *(EPA normally requires soft reconstituted water or water from a natural source, not dechlorinated tap water); OECD permits dechlorinated tap water)*

Parameter	Details	Remarks Criteria
Water parameters: Hardness pH Dissolved oxygen Total organic carbon Particulate matter Metals Pesticides Chlorine Temperature Intervals of water quality measurement	 ~250 mg $CaCO_3$/L 7.9-8.3 >60% saturation (≥6.4 mg/L), except one vessel on the last day, which had 47% saturation (5.0 mg/L) not reported not reported not reported not reported not chlorinated 12.4-13.8 °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 to PMRA; partially acceptable to EPA (see below) *(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 1st 48 hrs and ≥ 40% during 2nd 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)*
Number of replicates/groups: Control (dilution water): Solvent control: Treatments:	 1 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)*

Parameter	Details	Remarks Criteria
Number of organisms per replicate /groups: Control (dilution water): Solvent control: Treatments:	 10 n/a 10	Acceptable *(EPA: ≥ 10/concentration); OECD requires at least 7 fish/concentration)*
Biomass loading rate	0.3 g/L	Acceptable *(EPA: static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°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)*
Test concentrations: Nominal: Mean measured:	 0 (control) and 100 mg EP/L <0.17 and 94.57 mg EP/L	Acceptable
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)*

Parameter	Details	Remarks Criteria
Recovery of chemical: Frequency of determination Level of Detection Level of Quantitation	Mean measured concentrations taken at 1 and 96 h were 94.8% and 94.3% of nominal values, respectively. 1 and 96 hours not reported 0.17 mg EP/L	Acceptable
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	Sublethal symptoms and mortality	Acceptable
Observation intervals	1, 4, 24, 48, 72 and 96 hours after study initiation.	Acceptable *(EPA/OECD requires: minimally every 24 hours)*
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 the 94.6 mg EP/L test concentration. The NOEC is 94.6 mg EP/L, the highest concentration tested. The LC_{50} is >94.6 mg EP/L.

B. NON-LETHAL TOXICITY ENDPOINTS:

No abnormalities were noted in the control or in the test concentrations. The NOEC is 94.6 mg EP/L, the highest concentration tested. The EC_{50} is >94.6 mg EP/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 employed.

E. STUDY DEFICIENCIES: No major deficiencies were noted. Other deficiencies were considered minor.

F. REVIEWER'S COMMENTS: No comment.

G. CONCLUSIONS: This study is acceptable and satisfies the data requirements for an acute toxicity test on rainbow trout (DACO 9.5.2.1 and U.S. EPA guideline §72-1c). The NOEC is 94.6 mg EP/L, the highest concentration tested. The LC_{50} and EC_{50} values are estimated to be higher than 94.6 mg EP/L as no mortality or sublethal effects were observed in the control or the test concentration. Based on the results of this study, BAS 670 00 H (an end-use product containing approximately 30% a.i.) 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.