

Data Evaluation Report on the acute toxicity of BAS 510 F (TGAI) to bluegill, (Lepomis macrochirus RAF)

PMRA Submission Number 2001-1027

EPA MRID Number {454049-28}

Data Requirement: PMRA DATA CODE: 9.5.2.2
EPA DP Barcode: D278418
OECD Data Point: IIA 8.2.1 and IIA 8.2.1.2
EPA Guideline: 72-1a

Test material: BAS 510 F

Purity (%): 95.3%

Common name: Nicobifen

Chemical name

IUPAC: 2-chloro-N-(4'-chlorobiphenyl-2-yl) nicotinamide

CAS name: 3-Pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl)

CAS No.: 188425-85-6

Synonyms:

Primary Reviewer: Peter Takacs and Hemendra Mulye
{PMRA}

Date: May 1/02

Secondary Reviewer(s): Thomas M. Steeger, Ph.D
{EPA}

Date: June 18, 2002

Thomas M. Steeger

Company Code: BAZ

Active Code: CHH-BAZ-4

Use Site Category: In Canada, this fungicide is proposed for use on USC 13, 14 and 30; agricultural feed, food and turf uses. BAS 510 F is to be used 2-6 times per growing season depending on the crop, at a maximum recommended application rate of 875 g a.i./ha/application.

EPA PC Code: 128008

CITATION: Sabine Zok, January 2001. BAS 510 F, Acute toxicity Study on the bluegill, (Lepomis macrochirus RAF) in a static system (96 hours). Experimental Toxicology and Ecology BASF Aktiengesellschaft; 67056 Ludwigshafen, Germany, project #: 14F0179/975132.



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EXECUTIVE SUMMARY:

In a 96-h acute toxicity study, bluegill, (*Lepomis macrochirus*) were exposed to BAS 510 F at nominal concentrations of 0, 0.6, 1.0, 1.6, 2.5 and 4.0 mg a.i./L under static conditions. The 96-h LC_{50} was > 4.0 mg a.i./L (3.7 mg/L, measured). Sublethal effects were not observed. Based on the results of this study, BAS 510 F would be classified as moderately toxic to bluegill in accordance with the classification system of the U.S. EPA.

This toxicity study is classified as supplemental and does not satisfy the guideline requirement for acute fishy toxicity study. The study can be upgraded to core if the registrant demonstrates that neither pH nor water hardness affect the toxicity and/or solubility of BAS 510F. Also, the registrant must provide greater detail on the quality of water used in the study. The Environmental Fate and Effects Division (EFED) is not requiring that the study be repeated.

Results Synopsis

Test Organism Size/Age(mean wet weight or length): 0.9 g, 7 months old.

Test Type: Static

LC_{50} : > 3.7 mg a.i./L (solubility limit of test chemical)

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

EPA guideline "Pesticide Assessment Guidelines, subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms (U.S.) Environmental Protection Agency, Washington DC, para. 72-1a, P. 66, October 1982 and the (U.S.) EPA- SEP (Standard Evaluation Procedure) No. 540/g-85-006, June 1985. EEC directive 92169, Annex V, Cl. OECD guideline No. 203 "Fish Acute Toxicity Test" July 1992.

COMPLIANCE:

GLP Provisions of the Chemicals Act 29.07.94, FR Germany and OECD Principles of Good Laboratory Practice (Paris 1981).

A. MATERIALS:

1. Test Material

BAS 510 F

Description: Solid with white appearance
Lot No./Batch No. : N26
Purity: 95.3%
Stability of Compound
Under Test Conditions: stable
Storage conditions of
test chemicals: ambient conditions

Physicochemical properties of BAS 510 F.

Parameter	Values	Comments
Water solubility at 20°C	4.69 mg/L	low solubility
Vapour pressure	7×10^{-9} mbar @ 20 °C	not volatile
UV absorption	UV molecular extinction: 1.53×10^3 at 290 nm	-
pKa	does not dissociate in water	-
Log Kow	2.96	Some potential for bioaccumulation
photolysis	does not undergo photolysis	-
DT50 (water/sediment system)	342 day	Very persistent in the aquatic environment, partitions into sediment

2. Test organism:

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Species: bluegill, (*Lepomis macrochirus* RAF)

Age at test initiation: About 7 months

Weight at study initiation: 0.9 (0.6 - 1.4) g

(EPA requires: mean 0.5 - 5 g)

Length at study initiation: 4.3 (3.9 - 4.8) cm

(EPA requires: Longest not > 2x shortest; OECD requires 2.0 ± 1.0 cm for bluegill and 5.0 ± 1.0 cm for rainbow trout)

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

B. STUDY DESIGN:

1. Experimental Conditions

b) Definitive Study

Table 1 . Experimental Parameters

Parameter	Details	Remarks
		Criteria
<u>Acclimation:</u> Period: Conditions: (same as test or not) Feeding: Health: (any mortality observed)	14 days similar to test conditions but in flow through tanks ad lib food healthy	acceptable <i>(EPA requires minimum 14 days; no feeding during test; OECD requires minimum of 12 days)</i>
Duration of the test	96 hr	acceptable <i>(EPA/OECD require 96 hour)</i>
<u>Test condition:</u> Static Type of dilution system- for flow through method Flow rate Renewal rate for static renewal	static	acceptable <i>(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)</i>

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Parameter	Details	Remarks
		Criteria
Aeration, if any	None	acceptable <i>(EPA requires: no aeration; OECD permits aeration)</i>
<u>Test vessel</u> Material: (glass/stainless steel) Size: Fill volume:	Glass aquaria (58.5 x 28 x 29.5 cm); two aquaria for each test group 40-liter fill volume (water depth 23 cm)	acceptable <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.	It is unclear whether the water is dechlorinated or whether they use some other means of treating water in Ludwigshafen, Germany. <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	Total hardness: about 2.5 mmol/L (= about 250 mg/L CaCO ₃) Acid capacity : about 5.5 mmol/L Ca content : about 90 mg/L Mg content : about 10 mg/L pH : about 8.0 - 8.6 The 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.	Water hardness of 250 mg/L as exceeds EPA recommended range of 40 - 48 mg/L ; pH range of 8.0 - 8.6 exceeds EPA recommended range of 7.2 - 7.6.
Temperature	22 - 23 °C	<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 <u>Salinity</u> EPA: 30-34 ‰ (parts per thousand) salinity, weekly range < 6 ‰ (EPA water quality: measured at beginning of test and every 48 hours)
Intervals of water quality measurement	Water parameter (pH value, oxygen content and water temperature) were measured at start of exposure (1 hour) and 24,48,72 and 96 hours after start of exposure.	
<u>Number of replicates/groups:</u> Control (dilution water): Treatments:	 2 2	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)
<u>Number of organisms per replicate /groups:</u> Control (dilution water): Treatments:	 10 10	acceptable (EPA: ≥ 10/concentration); OECD requires at least 7 fish/concentration)

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Parameter	Details	Remarks
		Criteria
Biomass loading rate	0.2 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: Measured:	0, 0.6, 1.0, 1.6, 2.5 and 4.0 mg/l 0.58, 0.92, 1.47, 2.35, 3.7 mg/L (mean of 1 hr and 96 hr samples) 90-95.8% of nominal	acceptable
Solvent (type, percentage, if used)	not 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	16hrs light; 8 hrs dark	acceptable <i>(EPA requires: 16 hours light/8 hours dark); OECD requires 12 -16 hours photoperiod)</i>
Feeding	none during study and 24 hrs prior to 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	 at start and at finish of test not stated	
Positive control {if used, indicate the chemical and concentrations}	none	
Other parameters, if any	-	

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2. Observations:

Table 2: Observations

Parameter	Details	Remarks Criteria
Parameters measured including the sublethal effects/toxicity symptoms	mortality and behavioural effects	
Observation intervals	1, 4, 24, 48, 72 and 96 hours after start of exposure.	acceptable <i>(EPA/OECD requires: minimally every 24 hours)</i>
Water quality was acceptable (Yes/No)	yes	
Were raw data included?	Yes	
Other observations, if any	-	

II. RESULTS and DISCUSSION:

A. MORTALITY:

Mortality observed was not considered to be treatment related as only one fish died in each of two test concentrations and there was no dose response. Mortality of a single fish was observed in the 1.6 and 2.5 mg ai/L treatments.

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Table 2: Effect of BAS 510 F on acute mortality of bluegill.

Treatment (mg a.i./L) [mean measured]	No. of fish at start of study	Observation period					
		24 hr		48 hr		96 hr	
		No Dead	% mortality	No Dead	% mortality	No Dead	% mortality
Control (dilution water only), if used	20	0	0	0	0	0	0
0.58	20	0	0	0	0	0	0
0.92	20	0	0	0	0	0	0
1.47	20	1	5	1	5	1	5
2.35	20	0	0	0	0	0	0
3.7	20	1	5	1	5	1	5
NOEC	3.7 mg ai/L						
LC ₅₀	>3.7 mg ai/L						

B. NON-LETHAL TOXICITY ENDPOINTS:

Sublethal effects were not noted at any treatment level.

C. REPORTED STATISTICS:

If possible, the median lethal concentration (LC₅₀) after 1, 4, 24, 48, 72 and 96 hours, based on the nominal concentrations and based on the mean of the analytically determined concentrations is calculated using probit analysis*. If possible the LC₅ and LC₉₅ are given as well. Symbols of the model of the dose response relationship $F(P) = A + B * LN(K)$ K = concentration P = relative frequency of dead animals after exposure with K F = inverse function of the cumulative standard normal distribution LN = natural logarithm A, B = model parameters. In case that the data obtained are inadequate for the use of statistical methods for LC₅₀ calculation an approximate LC₅₀ is calculated as geometric mean of LC₀ and LC₁₀₀.

D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

Not required due to lack of mortality.

E. STUDY DEFICIENCIES: The sunfish used were somewhat larger than the required length of 2 ± 1 cm. Water hardness (250 mg/L as CaCO₃) and pH (8.0 - 8.6) exceeded the EPA-recommended ranges of 40 - 48 mg/L as CaCO₃ and 7.2 - 7.6, respectively. The study failed to provide sufficient

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documentation on the quality of dilution water.

F. REVIEWER'S COMMENTS: The study utilized an unusual method for solubilizing the test material: 5.46 g of BAS 510F were placed on cellulose filter paper and 180 L of test water was circulated through the filter until a concentration of 4 mg/L was obtained in the stock solution. Similar to some of the aquatic plant studies (e.g., *Pseudokirchneriella* MRID 454050-17), the study did not rely on a co-solvent. However, many of the aquatic exposure studies have relied on co-solvents and at concentrations greater than 1 mg/L, a white precipitate was observed in the exposure tanks. This study does not report any precipitate however, after 96 hours, exposure concentrations in the highest treatment (3.7 mg a.i./L) had declined to 89% of nominal. It is unclear how studies requiring a co-solvent had more a problem with solubility than studies that did not use a co-solvent. Additionally, the relatively hard water used in the study may have further limited the solubility of BAS 510F; EFED is uncertain how the solubility and/or toxicity of the compound may have been affected in softer water.

Fish died in the 1.47 and 3.7 mg a.i./L treatment groups; the report concludes that these mortalities are not treatment-related since the percent mortality falls below the 10% control (historical) mortality. Study results should not be interpreted relative to historical controls. Rather, the study conclusions should be gauged relative to controls run concurrently with the study. Therefore, the NOEC, based on mortality is 0.92 mg a.i./L.

G. CONCLUSIONS: The study is classified as supplemental. It can be upgraded to core if the registrant demonstrates that neither water hardness or pH affect the solubility and/or toxicity of BAS 510F. Also the registrant must provide greater details on the quality of water (trace elements and pesticides) used in the study. The 96 hr LC50 was estimated to be greater than the highest concentration tested, i.e., 3.7 mg a.i./L, which was also the water solubility limit for the test chemical. EFED is not requiring that the study be repeated.

III. REFERENCES:

Approved 04/01/01 C.K.