

Data Evaluation Report on the acute toxicity of BAS 510 F to the saltwater Mysid, *Americamysis bahia*

PMRA Submission Number 2001-1027

EPA MRID Number {454050-02}

Data Requirement: PMRA DATA CODE: 9.4.2
EPA DP Barcode: D278418
OECD Data Point:
EPA Guideline: 72-3(b)

Test material: BAS 510 F

Purity (%): 96.9%

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: not stated

Primary Reviewer: Peter Takacs, Hemendra Mulye
{PMRA}

Date: February 12/2002

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

Date: April 1, 2002

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 (0.78 lbs a.i./Acre/application).

EPA PC Code: 128008

CITATION: Robert L. Boeri, Derek C. Wyskiel, Timothy J. Ward and Catherine M. Holmes September, 2000. Flow-Through Acute Toxicity of BAS 510 F to the Mysid, *Americamysis bahia*. T.R. Wilbury Laboratories, Inc. 40 Doaks Lane Marblehead, Massachusetts 01945. Study number 1916-BA.



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EXECUTIVE SUMMARY:

The 96-hr acute toxicity of BAS 510 F to *Americamysis bahia* was studied under flow-through conditions. Mysids were exposed to saltwater control, solvent (acetone) control, and, test chemical at nominal concentration of 0.52, 0.88, 1.4, 2.4, 4.0 mg ai/L. Mortality was observed daily. The highest test concentration (3.81 mg ai/L, mean measured) resulted in 10% mortality, the same response was observed at the lowest test concentration of 0.41 mg ai/L (mean measured).

The 96 hour LC_{50} was >3.81 mg ai/L. The 96 hour NOEC based on mortality is less than 0.41 mg ai/L. Mean measured concentrations were used in calculating these endpoints.

This study is classified as acceptable and satisfies the guideline requirements for an acute toxicity study with marine invertebrates. Based on the results, a classification to the level of toxicity of the test material can not be assigned.

Results Synopsis

Test Organism Age: < 24 hrs
Test Type: Flow-through
 LC_{50} : >3.81 mg ai/L
NOEL: < 0.41 mg ai/L
Endpoint(s) Effected: Mortality

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

The definitive toxicity test was performed according to T.R. Wilbury Study Protocol 1916-BA (BASF Study Number 46669, Flow-Through Acute Toxicity of BAS 510 F to the Mysid, *Americamysis bahia*), which was signed by the study director on September 1, 2000. It was based on procedures of the U.S. Environmental Protection Agency (1985, 1988) and OPPTS (1996).

COMPLIANCE:

This study was conducted according to EPA Good Laboratory Practice Regulations (40 CFR 160).

A. MATERIALS:

1. Test Material

BAS 510 F

Description: white powder
Lot No./Batch No. : N75
Purity: 96.9%
Stability of Compound
Under Test Conditions: expires August 29/2002.
Storage conditions of test chemicals: stored in the dark at room temperature

Physicochemical properties of BAS 510 F

Parameter	Values	Comments
Water solubility at 20°C	4.69 mg/L	very insoluble
Vapour pressure	7×10^{-9} mbar @ 20 °C	non-volatile
UV absorption	UV molecular extinction: 1.53×10^3 at 290 nm	-
pKa	does not dissociate in water	not affected by pH
Kow	910	moderately lipophilic but not likely to bioconcentrate (borderline)

2. Test organism:

Species: *Americamysis bahia*,
Age at test initiation: less than 24 hours old
Source: collected from in house culture

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B. STUDY DESIGN:

1. Experimental Conditions

a) Range Finding Test:

A range-finding test with the test substance was conducted under static conditions from November 8 to 12, 2000. Nominal concentrations of BAS 510 F were 0 (control and solvent control), 0.10, 0.50, 1.0, 5.0, and 8.0 mg ai/L. After 96 hours there was 100% survival in the control and solvent control, and at 0.10, 0.50, 1.0, and 5.0 mg ai/L, and 90% survival at 8.0 mg ai/L. Insoluble material was observed floating on the surface of the test vessel with a nominal concentration of 8.0 mg ai/L at 24, 48, 72, and 96 hours. No other insoluble material was observed at any tested concentration.

b) Definitive Study

Table 1. Experimental Parameters

Parameter	Details	Remarks
		Criteria
<u>Acclimation:</u> Period: Conditions: Feeding: Health:	14 days same as test fed live nauplii good, no mortality during 48 hr prior to test	 (Mysids should be fed during study)
Duration of the test	96 hr	 (EPA requires 96 hours)
<u>Test condition:</u> Flow through	During the test the diluter was activated 819 times, resulting in an average of 6.8 volume additions per 24 hours in each test vessel.	 (EPA requires consistent flow rate of 5 - 10 volumes/24 hours, meter systems calibrated before study and checked twice daily during test period)

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Parameter	Details	Remarks
		Criteria
Aeration	Not required to maintain adequate oxygen levels	
Test vessel:		
Material:	Glass aquaria	Loading should not exceed 30 mysids per L for a static test, therefore, this configuration is considered acceptable.
Size:	20L	
Fill volume:	15L	(EPA requires: size 20 mL or 3.9 L fill 200 mL)
Source of dilution water	Water used for acclimation of test organisms and for all toxicity testing was carbon filtered, natural seawater collected at T.R. Wilbury Laboratories in Marblehead, Massachusetts. Water was adjusted to a salinity of 11 to 17 parts per thousand with deionized water and stored in polyethylene tanks where it was aerated and reticulated through particle filters, activated carbon, and an ultraviolet sterilizer.	(EPA requires soft reconstituted water or water from a natural source, not dechlorinated tap water)
Water parameters:		
Salinity:	16-17 ppt	
pH:	7.7-8.1	
Dissolved oxygen:	7.0-8.2 mg/L	
Temperature:	21.5 - 22.3 °C (measured continuously)	
Pesticides:	See last page	
Intervals of water quality measurement	daily	pH: not specified Salinity: EPA requires 20 ± 3 ppt Temperature: EPA requires 25°C (measured continuously or if water baths are used, every 6 hr, may not vary > 2°C; OECD requires range of 18-22°C ($\pm 1^\circ\text{C}$)) Dissolved oxygen: EPA requires Static: 60% during 1st 48 hr and 40% during 2nd 48 hr Flow-through: 60%)
Number of replicates:		
Control (dilution water):	2	
Solvent control:	2	
Treatments:	2	

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Parameter	Details	Remarks
		Criteria
<u>Number of organisms per replicate:</u>		
Control	10	
Solvent control:	10	
Treatments:	10	(EPA/OECD require 5 treatment levels plus control EPA requires a minimum of 20mysid per treatment. Biomass loading rate for static 0.8 g/L at 17oC, 0.5 g/L at > 17oC; flow-through: 1 g/L/day).
<u>Treatment concentrations:</u>	Nominal: 0, 0.52, 0.88, 1.4, 2.4, 4.0 mg/L mean measured: 0.419, 0.827, 1.38, 2.31, 3.81 mg/L	
		(EPA requires a geometric series with each concentration being at least 60% of the next higher one)
Solvent (type, percentage, if used)	acetone(0.5 mL/L)	See footnote 1.
		(EPA requires solvents not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-though tests)
Lighting	A 16 hour light and 8 hour dark photo period was automatically maintained with cool-white fluorescent lights that provided a light intensity of approximately 32 foot candles. A 15 minute transition period was provided between dark and light.	This lighting is bright by comparison to the acute Mysid test with NI-25 (EPA requires 14 hours light, 10 hours dark; OECD : optional light-dark cycle or complete darkness)
<u>Recovery of chemical:</u>		
Frequency of determination:	beginning and end of study (0 and 96 hours)	
Level of Quantitation:	0.10 mg/L;	
Level of Detection:	0.00209 mg/L	Samples filtered through 0.22 m filter upon collection.

¹Based on observations of insoluble material in test vessels with nominal concentrations of 3.0 and 5.0-mg/L (solvent concentration was 0.1 ml/L acetone) during an oyster shell deposition test (T.R. Wilbury study number 1917-BA), the maximum concentration used during the test with mysids was the reported water solubility of the test substance (4.0 mg/L). The concentration of solvent was increased to 0.5 mg/L in an attempt to maximize the test substance solubility.

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2. Observations:

Table 2: Observations

Parameters	Details	Remarks
		Criteria
Parameters measured including the sublethal effects	Survival at termination of test	
Observation intervals	0, 24, 48, 72 and 96 hours	
Water quality was acceptable (Yes/No)	Yes	although water salinity was below the recommended range
Were raw data included?	Yes	

II. RESULTS AND DISCUSSION

A. MORTALITY:

Table 3: Effect of BAS 510 F on mortality of *Americamysis bahia*

Treatment (mg a.i./L) [mean measured]	No. of organisms	Observation period	
		96 hr	
		No Dead	% mortality
Control	20	0	0
Solvent control	20	0	0
0.419	20	2	10
0.827	20	3	15
1.38	20	2	10
2.31	20	1	5
3.81	20	2	10
NOEC	3.81 mg ai/L		
LC ₅₀	> 3.81 mg ai/L		

C. REPORTED STATISTICS:

Results of the toxicity test could not be interpreted by standard statistical techniques (Stephan, 1983) at 24, 48, 72, or 96 hours because there was greater than 50% survival at all tested concentrations. The no observed effect concentration is the highest concentration of test substance that does not cause toxicant-related mortality or sublethal effects.

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D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

Not applicable

E. STUDY DEFICIENCIES: No deficiencies were noted.

F. REVIEWER'S COMMENTS: The NOEC has been revised to reflect that mortality was observed in each of the groups treated with BAS 510F while no mortality was observed in either the control or solvent blank.

G. CONCLUSIONS: This study is acceptable. Based on the LC_{50} of > 3.81 mg ai/L, the test chemical is not considered acutely toxic to the Mysid shrimp *Americamysis bahia*. Since mortality was observed in all of the treatments except controls, the NOEC is empirically determined to be less than the lowest dose tested, *i.e.*, 0.419 mg ai/L.

III. REFERENCES:

Approved 04/01/01 C. K.

Chemical characterization of a representative sample of natural seawater used to formulate the dilution water for the toxicity test with BAS 510 F and the Mysid, *Americamysis bahia*.

Aluminum mg/L 0.077 ND₂
Arsenic mg/L 0.0050 ND
Boron mg/L 0.013 4.99
Cadmium mg/L 0.00021 ND
Calcium mg/L 0.044 393
Chromium mg/L 0.0017 ND
Cobalt mg/L 0.0017 ND
Copper mg/L 0.0029 ND
Iron mg/L 0.011 ND
Lead mg/L 0.00078 ND
Magnesium mg/L 0.40 982
Mercury mg/L 0.00010 ND
Nickel mg/L 0.0016 ND
Potassium mg/L 20 378
Silver mg/L 0.0017 ND
Sodium mg/L 55 9,900
Zinc mg/L 0.0030 ND
Chloride mg/L 3,000 18,300
Fluoride mg/L 0.030 0.59
Total Phosphorus mg/L 0.040 ND
Total Organic Carbon mg/L 0.40 1.23
Organochlorine
Pesticides ug/L 0.0055 ND
Methoxychlor ug/L 0.019 ND

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Chlordane ug/L 0.048 ND

Toxaphene ug/L 0.29 ND

Organophosphorus

Pesticides ug/L 0.2 ND

Naled ug/L 0.38 ND

PCBs ug/L 0.096 ND

¹ Parameters were measured in unfiltered natural seawater that was collected on December 20, 1999 and analyzed by Lancaster Laboratories, Inc., as part of routine water quality testing conducted twice per year.

² ND = not detected at or above the method detection limit.

³ TOC of salinity adjusted seawater (adjusted with deionized water).