Data Evaluation Report on the acute dietary toxicity of BAS 510 F (TGAI) to avian species Mallard Duck *(Anas platyrhynchos L.)*

PMRA Submission Number 2001-1027 **EPA MRID Number: 454049-24**

Data Requirement: PMRA DATA CODE: 9.6.2.5
EPA DP Barcode: D278418
OECD Data Point: IIA 8.1.2
EPA Guideline: 71-2(b), 850.2200

Test material: BAS 510 F **Purity (%):** 95.3%
Common name: Nicobifen
Chemical name
IUPAC: 2-chloro-N-(4'-chlororobiphenyl-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 **Date:** April 25/02
{/PMRA}

Secondary Reviewer(s): John Ravenscroft **Date:** June 20,2002
{EPA}

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: Dr. S. Zok , 1999. BAS 510 F - Avian Dietary LC50 Test in Chicks of the Mallard Duck *(Anas platyrhynchos L.)* BASF Aktiengesellschaft Department of Toxicology 67056 Ludwigshafen/Rhein, Germany. Project No. 32W0179/97045.

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EXECUTIVE SUMMARY:

The acute dietary toxicity of BAS 510 F to 7-d-old Mallard Duck *(Anas platyrhynchos L.)* was assessed over 8 days in accordance with the EPA-540/9-85-008 of June 1985 and OECD 205 guidelines. BAS 510 F was administered to the birds (10/dose) in the diet at 0, 313; 625; 1,250; 2,500 and 5,000 mg a.i/kg dw of diet. The 8 day acute dietary LC_{50} was > 5000 mg a.i/kg dw of diet. The 8 day NOEC of BAS 510 F based on feed consumption was 625 mg a.i/kg dw of diet. According to the US EPA classification, BAS 510 F would be classified as practically non toxic to Bobwhite Quail on an acute dietary basis.

There was no mortality in any of the treatment groups during the 8 day study. A significantly reduced feed intake was noted in the three highest treatment groups, no other sublethal effects were noted. However, the study did not meet some important guideline requirements which are judged to be major deficiencies.

This toxicity study is classified as supplemental and does not satisfy the guideline requirement for avian acute dietary study.

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

(U.S.) Environmental Protection Agency, Washington, D.C.: "Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms"; PB 83-1 53908, Oct. 1982; !j 71-2; "Avian dietary LC,, test", EPA-SEP (= Standard Evaluation Procedure), (U.S.) EPA-540/9-85-008 of June 1985 and OECD 205, adopted April 4, 1984.

COMPLIANCE:

This study was conducted in accordance with the GLP provision of the "Chemikaliengesetz" (Chemical Act; "Bundesgesetzblatt Jahrgang 1994, Teil I, 29.07.1994"; FR Germany) and with the "OECD Principles of Good Laboratory Practice" (Paris, 1981).

A. MATERIALS:

1. Test Material BAS 510 F

Description: Solid powder
Lot No./Batch No. : N 26
Purity: 95.3%
Stability of Compound: Stable in feed for the duration of the test
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	$7x10^{-9}$ mbar @ 20 °C	not volatile
UV absorption	UV molecular extinction: $1.53x10^{3}$ at 290 nm	-
pKa	does not dissociate in water	-
Kow	2.96	Not likely to bioconcentrate

2. **Test organism**:

Species (common and scientific names): Mallard Duck *(Anas platyrhynchos L.)*
Age at study initiation: 7 days
Weight at study initiation: 90.6 ± 9.1 g
Source: John Coles, County Game Farms, Home Farm, Hatchfield, Ashford/Kent TN 261 DR, U.K.

B. STUDY DESIGN:

1. Experimental Conditions

b) Definitive Study

Table 1: Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation Period: Conditions (same as test or not): Feeding: Health (any mortality observed):	acclimation period was not specified, fed *ad lib.* Health was checked at initiation of test.	acceptable *OECD requires at least 7 days of acclimation*
Pen size and construction materials	Wire mesh cages (1.3 x 0.65 x 1.3 m; floor area 0.85 m2) with grid flooring (stainless steel; mesh size 10 x 10 mm); 10 birds per pen. These cages provide 850 cm^2 /bird which is adequate.	acceptable *EPA requires: about 35 x 100 x 24 cm; OECD requires: 300 cm^2 for bobwhite and 600 cm^2 for mallard*

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Parameter	Details	Remarks *Criteria*
Test duration	5 days of treated feed exposure followed by 3 days of observation.	acceptable *EPA/OECD requires: 5 days with treated feed and at least 3 days observation with "clean" feed.*
Test concentrations Nominal: Measured:	0 (= Control); 313; 625; 1,250; 2,500 and 5,000 mg/kg diet (corrected for test material purity = 95.3%) 92-98.5% of nominal	acceptable *Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless LC_{50} > 5000 mg ai/kg diet.* Measured conc. should be 80% of the nominal
vehicle, if used Type: Amount:	none	acceptable *EPA requires: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic. Solvent not more than 2%.*
Diet preparation and feeding	"Ssniff* experimental diet, special mixture in meal form for quails and chicks with the following composition (Weender analysis): feed was available ad libitum.	acceptable *EPA requires: Control group tested with diet containing the maximum amount of vehicle used in treated diets*
Was detailed description and nutrient analysis of the basal diet provided (Yes/No)	yes	
Indicate whether stability and homogeneity of test material in diet determined (Yes/No)	yes	
Feed withholding period	not stated	

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Parameter	Details	Remarks *Criteria*
Number of birds per replicate/groups For negative control: For treated:	 10 10 **EPA requires 20 birds per control group**	**not acceptable** *EPA (OPPTS 850.2200) requires: 10 birds minimum for each treatment group, and 20 birds minimum for the control group(s).*
Number of replicates/group (if used) For negative control: For treated:	no replicates were used	acceptable
Test conditions Temperature: Relative humidity (%): Photoperiod:	 About 21°C ± 2 in the test room; in addition, an area with a higher temperature was maintained by ceramic radiant heaters (type IOT; not emitting visible light) above the cages. Thus the chicks could find their optimum conditions themselves. The temperature in the center under the ceramic heaters was about **40°C.** 50-60% 16 hours light, 8 hours dark; light intensity about 130 Lux in the middle of the cages	acceptable *Brooder temperature:* *EPA: about 35°C (95°F)* *Room temperature:* *EPA: 22-27°C (71-81°F);* *OECD: range of 22-38 °C based on bird age and species (see OECD 205)* *Relative humidity:* *EPA: 30-80%* *OECD: 50-85% based on bird species (see OECD 205)* *Photoperiod:* *EPA: Minimum of 14 h of light* *OECD: 12-16 h of light*
Reference chemical, if used Name: Concentration tested:	-	

2. Observations:

Table 2: Observations

Parameters	Details	Remarks *Criteria*
Parameters measured (mortality/body weight/ mean feed consumption/ others)	mortality, body weight, mean feed consumption, Post-mortem examination	acceptable *OECD : the mortality in the controls should not be exceed 10% at the end of the test.*
Indicate the stability and homogeneity of test chemical in the diet	After 7 days, the concentration of test material in feed was 100.3% of the initial, homogeneity was ensured by mixing before treatment.	
Indicate if the test material was regurgitated	not stated	
Treatments on which necropsies were performed	all birds were examied microscopically	
Observation intervals	daily for mortality and feed consumption, day 0, 5 and 8 for body weight.	
Were raw data included?	Yes	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

No mortality occurred at any treatment concentration during the 8 day study period.

Table 3: Effect of BAS 510 F on mortality of Mallard Duck.

Treatment (mg a.i. kg diet) [nominal conc.]	No. of birds per treatment	Cumulative mortality				
		day 1	day 2	day 3	day 4	day 8
Negative control	10	0	0	0	0	0
313	10	0	0	0	0	0
625	10	0	0	0	0	0
1,250	10	0	0	0	0	0
2,500	10	0	0	0	0	0
5,000	10	0	0	0	0	0
LC_{50}	> 5000 mg ai/kg diet					
NOEC	5000 mg ai/kg diet					

B. SUB-LETHAL TOXICITY ENDPOINTS:

Significant reductions in feed consumption were noted at the three highest test concentrations (1250, 2500 and 5000 mg ai/kg feed). Reduced food intake was apparent from day 1-5 (exposure period) while it increased in the affected groups during the 3 day post exposure observation period.

Table 4: Sublethal effects of BAS 510 F on Mallard Duck.

Treatment (mg a.i. kg diet) [nominal conc.]	Body weight (g)		Feed Consumption (mg/kg)	
	Day 0	Day 8	Day 1-5 mean	Day 6-8 mean
Negative control	90.6	236.8	44.2	72.5
313	96.1	273.5	48.7	83.1
625	92.3	266.8	50.6	79.1
1,250	83.2	227.1	35.8	60.4
2,500	91.1	238.6	36.8	72.0
5,000	93.1	228.8	35.4	68.2
NOEC	625 mg ai/kg diet			

C. REPORTED STATISTICS:
The statistical evaluation of the body weight was performed by one-way analyses (ANOVA) followed by Dunnett's test: "A multiple comparison procedure for comparing several treatments with a control", The statistical evaluation was performed with the computer systems of the Department of Toxicology using the I NSTEM-Toxicology-data system (program TOXREP).

D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

E. STUDY DEFICIENCIES: The number of birds used in the control group (10) is lower than the EPA requirement of at least 20 birds and is not acceptable. The size of the cages would have precluded using more than 10 birds. These deficiencies are considered to be major deficiencies.

F. REVIEWER'S COMMENTS: Care was not taken to make sure that important parameters such as number of number of organisms per control meet the guideline requirements. If the reserve group had been incorporated into the control group instead of being sacrificed at the beginning of the compound feeding, the control group would have been of sufficient size.

G. CONCLUSIONS: The study failed to meet critical guideline requirements; however, the derived results (LC50 > 5000 mg ai/kg diet) indicate that the test material is practically non toxic to mallards. The applicant will not be requested to repeat this study; the avian oral toxicity test can be used for avian acute risk assessment. This study is classified as supplemental due to lack of apparent toxicity to mallards. However, poor rearing conditions and low control group sample size may have impacted the ability to detect effects, if they occurred.

III. REFERENCES:
Approved 04/01/01 C.K.