Data Evaluation Report on the acute oral toxicity of BAS 510 F (TGAI) to avian species Bobwhite Quail *(Colinus virginianus)*

PMRA Submission Number: 2001-1027 **EPA MRID Number: 454049-22**

Data Requirement: PMRA DATA CODE: 9.6.2.1
EPA DP Barcode: D278418
OECD Data Point: II A 8.1.1
EPA Guideline: 71-1(a), 850.2100

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 19/02
{PMRA}

Secondary Reviewer(s): John Ravenscroft **Date:** June 21, 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 Single-Dose Oral LDS0 On the Bobwhite Quail *(Colinus virginianus)* BASF Aktiengesellschaft Department of Toxicology 67056 Ludwigshafen/Rhein, Germany. Project No. 1 1 W0179/97043.

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EXECUTIVE SUMMARY:

The acute oral toxicity of BAS 510 F to 4.5 month-old Bobwhite Quail *(Colinus virginianus)* was assessed over14 days in accordance with the EPA-540/9-85-007 guideline. BAS 510 F was administered to the birds (10/group) by gavage at 0, 500, 1000, and 2000 mg ai/kg bw. No mortality was observed in any treatment group during the 14 day observation period. The 14 day-acute oral LD_{50} was > 2000 mg a.i/kg bw. Sublethal toxic effects were also not observed at any test concentration. The 14 day NOEL of BAS 510 F to Bobwhite Quail, based on survival and sublethal effects, was 2000 mg a.i/kg bw. According to the US EPA classification, BAS 510 F would be classified as practically non toxic to Bobwhite Quail on an acute oral basis.

This toxicity study is classified as acceptable and satisfies the guideline requirement for an acute oral study.

Results Synopsis

Test Organism Size/Age (mean weight): 4.5 months old

LD_{50}: >2000 mg a..i./kg bw
NOEL:2000 mg a.i./kg bw
Endpoint(s): 14 day survival and sublethal effects

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED:

The test design followed the requirements of the (U.S.) EPA "Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation Wildlife and Aquatic Organisms": PB 83-153908, October 1982, § 71-1, "Avian single-dose oral LDso" and EPA SEP (Standard Evaluation Procedure); (U.S.) EPA-540/9-85-007 of June 1985.

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 storage
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): Bobwhite Quail *(Colinus virginianus)*
Age at study initiation: 4.5 months
Weight at study initiation : not stated
Source: Morris Hatchery Tnc.Goulds Florida 33170-5399 USA

(EPA recommends that either bobwhite quail or mallard duck be used. Birds should be at least 16 weeks old at test initiation and should be uniform in size and weight as well as phenotypically indistinguishable from wild birds).

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study: Not used.
b) Definitive Study

Table 1. Experimental Parameters

Parameter	Details	Remarks *Criteria*
Acclimation Period: Conditions (same as test or not): Feeding: Health (any mortality observed):	Birds were kept in a steel wire pen for two weeks and were kept in the test cages for an additional week before dosing. The birds were offered a commercial quail diet ad libitum throughout maintenance before the study and during the test with the exception of a fasting period of about 15 to 20 hours prior to dosing.	Acceptable *EPA recommends that birds be pre-conditioned to the test facilities for at least 15 days.* *OECD recommends that birds be pre-conditioned to the test facilities for at least 7 days.*

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Parameter	Details	Remarks *Criteria*
Pen size and construction materials	Stainless steel wire mesh cages (0.59 x 0.45 x 0.26 m) with wire mesh floors, mesh size 10 x 15 mm; floor area about 0.26 m2 for 5 birds each; males and females were caged separately.	*acceptable* *EPA requires: pens must conform to good husbandry practices and should not create crowding stress.* *OECD lists no criteria for pen construction other than stating that pens should be suitable for the captive rearing of that species.*
Test duration	14 days	*acceptable* *EPA requires a day for dosing and at least 14 days observation.*
Dose preparation [Indicate method of confirmation of dose]	technical compound was mixed with CMC carrier and homogenized	
Mode of dose administration	gavage	*Gavage or gelatin capsule.*
Dose levels Nominal: Measured:	500, 1000 and 2000 mg ai/kg b.w. (Treatments were adjusted for the purity of the technical, 95.8%) Measured concentrations in the carrier were 98-102.5% of the nominal.	*Acceptable* *EPA requires a minimum of 5 treatment levels unless LD_{50} is demonstrated to be greater than 2000 mg ai/kg bw*

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Parameter	Details	Remarks *Criteria*
Solvent/vehicle, if used Type: Amount/bw:	Carboxymethyl cellulose not stated	Acceptable *EPA recommends that the test material be administered without a vehicle if possible. Maximum vehicle concentration should not exceed 0.1 to 1.0% of body weight.*
Number of birds per groups/treatment For solvent/vehicle control: For treated:	10 10	Acceptable *EPA recommends 10 birds per treatment group and 10 birds for each control and vehicle group.*
No. of feed withholding days before dosing	15-20 hrs	Acceptable *EPA recommends that food should be withheld for at least 15 hours prior to dosing.*
Test conditions Temperature: Relative humidity: Photoperiod:	20±2 C 50-60% 10 hours light, fluorescent lamps	Acceptable *EPA recommends that a 10 hr light/14 hr dark photo-period.*
Reference chemical, if used Name: Concentrations tested:	-	

2. Observations:

Table 2: Observations

Parameters	Details	Remarks *Criteria*
Parameters measured (mortality/individual body weight at test initiation and termination/ mean feed consumption/ others)	Mortality: twice on day zero, daily thereafter Clinical signs: twice on day zero, daily at least on workdays thereafter Feed consumption and Body weight.	*EPA recommends:* *Body weight measured at test initiation, on Day 14 and at end of the test if the test is extended beyond 14 days.* *Calculation of mortality. Mortality must NOT be more than 10% in controls.* *Feed consumption may be measured as average daily food consumption.*
Indicate if the test material was regurgitated	not stated	*Regurgitation is an indication that the does was rejected. The test may have to be repeated if the problem persists.*
Groups on which necropsies were performed	-	*EPA recommends that gross necropsies be performed with inspections of the GI tract, liver, kidneys, heart, and spleen.*
Observation intervals	birds were observed twice on day 1 and daily after that	
Were raw data included?	Yes	

H. RESULTS AND DISCUSSION:

A. MORTALITY:

No mortality occurred in any of the groups during the 14 day. Therefore the test chemical can be classified as practically non toxic to bobwhite quail.

Table 3: Effect of BAS 510 F on mortality of Bobwhite Quail.

Treatment (mg a.i./kg bw)	No. of birds	Cumulative mortality				
		day 1	day 2	day 3	day 4	day 14
vehicle control	10	0	0	0	0	0
500	10	0	0	0	0	0
1000	10	0	0	0	0	0
2000	10	0	0	0	0	0
LD_{50}	> 2000 mg ai/kg bw					
NOEL	2000 mg ai/kg bw					

B. SUBLETHAL TOXICITY ENDPOINTS:

The only sublethal response noted was soft stools, however, this was noted in all groups including the control during the first two days of the study but not there-after. The test material had no effect on the body weight gain or food consumption of bobwhite quail.

Table 3. Effect of BAS 510 F on food consumption and body weight of Bobwhite Quail

Treatment (mg a.i./kg bw)	Observation			
	body weight in males (g)		food consumption in males (g/bird/day)	
	day 0	day 14	day 7	day 14
vehicle control	194	210	15.8	17.6
500	194.8	207.2	16.2	17.7
1000	195.7	210.2	15.5	17.7
2000	193.8	206.4	15.4	16.7

C. REPORTED STATISTICS:

For body weight data a parametric one-way analysis of variance was done via the F-test (ANOVA). If the resulting p-value was equal or less than 0.05, a comparison of each dose group with the control group was carried out. These comparisons were performed simultaneously via Dunnett's test. The statistical evaluation was performed with the computer systems of the Department of Toxicology using the INSTEM-Toxicology-data system (program TOXREP).

D. VERIFICATION OF STATISTICAL RESULTS BY THE REVIEWER:

Not necessary due to general lack of effects.

E. STUDY DEFICIENCIES: None noted.

F. REVIEWER'S COMMENTS: No further comments.

G. CONCLUSIONS: This study is acceptable and classified as core. The $LD_{50} > 2000$ mg ai/kg bw and the NOEL is 2000 mg ai/kg bw.

III. REFERENCES:

Approved 04/01/01 C.K.