

MRID No.: 436781-08

DATA EVALUATION RECORD
§ 71-1(A) - AVIAN SINGLE-DOSE LD₅₀ TEST

1. **CHEMICAL:** Azoxystrobin **PC Code No.:** 128810

2. **TEST MATERIAL:** ICIA5504 **Purity:** 96.2%

3. **CITATION**

Author: Barbara Hakin, Alison J. Johnson, Alan Anderson, and I. Suzanne Dawe

Title: ICIA5504: Acute Oral Toxicity (LD₅₀) to Bobwhite Quail

Study Completion Date: November 25, 1992

Laboratory: Huntingdon Research Centre Ltd.,
Cambridgeshire, England

Laboratory Report ID: ISN 287/921070

Sponsor: Zeneca AG Products, Zeneca Inc.,
Wilmington, DE

MRID No.: 436781-08

4. **REVIEWED BY:**

William Erickson
Biologist
EEB/EFED/EPA

Signature: *W. Erickson*

Date: 4/01/96

5. **APPROVED BY:**

Harry Craven
Section Head 4
EEB/EFED/EPA

Signature: *Harry T. Craven*

Date: 6/21/96

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Colinus virginianus*

Test Organisms Age/Size: 12 months/172-217 g

Definitive Study Duration: 14 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirement for an acute oral toxicity test using bobwhite quail. The LD₅₀ was greater than 2000 mg/kg, which classifies azoxystrobin as practically nontoxic to the bobwhite quail.

Results Synopsis

LD₅₀: >2000 mg/kg
NOEL: 2000 mg/kg

95% C.I.: N/A
Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:** Core.

(1)

DP Barcode:

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4. **REVIEWED BY:** Barbara H. Herbert, B.S., Associate Scientist, KBN Engineering and Applied Sciences, Inc.

Signature: *Barbara H. Herbert* **Date:** Oct. 19, 1995

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist, KBN Engineering and Applied Sciences, Inc.

Signature: *P. Kosalwat* **Date:** 10/19/95

5. **APPROVED BY:** , EEB, EFED

Signature: **Date:**

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Colinus virginianus*
Test Organisms Age/Size: 12 months/172-217 g
Definitive Study Duration: 14 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test using bobwhite quail. The LD₅₀ was greater than 2000 mg/kg, which classifies sulfentrazone as practically non-toxic to the bobwhite quail. The NOEL was 2000 mg/kg.

Results Synopsis

LD₅₀: >2000 mg/kg
NOEL: 2000 mg/kg

95% C.I.: N/A
Probit Slope: N/A

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9. **GUIDELINE DEVIATIONS:** None.
10. **SUBMISSION PURPOSE:** New Chemical.
11. **MATERIALS AND METHODS:**

A. Test Organisms

Guideline Criteria	Reported Information
Species: A wild waterfowl species, preferably the mallard (<i>Anas platyrhynchos</i>), or an upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	<i>Colinus virginianus</i>
Age at beginning of test: At least 16 weeks old.	12 months
Supplier	Mr. B. Potter, Rosedean, Woodhurst, Cambridgeshire, England
Acclimation period: At least 15 days.	15 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes
Photoperiod: 10-h light, 14-h dark is recommended.	10-h light; 14-h dark
Diet was nutritious and appropriate for species?	Yes
Feed withheld at least 15 hours prior to dosing?	Yes

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes, two birds utilized
<u>Definitive Test</u> Nominal concentrations: At least five, in a geometric scale, unless LD ₅₀ > 2000 mg ai/kg.	0, 500, 1000, and 2000 mg/kg, uncorrected for purity
Controls: Water control or vehicle control (if vehicle is used)	Corn oil control
Number of birds per group: 10 (strongly recommended)	10, 5 male and 5 female
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	1ml/100g
Observations period: At least 14 days.	14 days

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Individual body weights measured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	Yes

Guideline Criteria	Reported Information
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Yes
Control Mortality: Not more than 10%	0%
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes, no clinical signs were observed.

Mortality

Dosage (mg/kg)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6-8	9-11	12-14
Control	10	0	0	0	0	0	0	0	0
500	10	0	0	0	0	0	0	0	0
1000	10	0	0	0	0	0	0	0	0
2000	10	0	0	0	0	0	0	0	0

Other Significant Results: Post-mortem examination showed no abnormalities in the ten birds from the highest dosage group. Body weights and feed consumption values in the treatment groups were generally similar or slightly greater than control values.

Reported Statistical Results

Statistical Method: None

LD₅₀: >2000 mg/kg 95% C.I.: N/A

NOEL: 2000 mg/kg Probit Slope: N/A

13. Verification of Statistical Results

Statistical Method: visual inspection of data

LD₅₀: >2000 mg/kg

95% C.I.: N/A

NOEL: 2000 mg/kg

Probit Slope: N/A

14. **REVIEWER'S COMMENTS:** All birds were given Aureomycin in water (120 mg/L) for 10 days after obtaining from the supplier. However, the treatment probably did not affect the test results. This study is scientifically sound and fulfills the guideline requirement for an acute oral toxicity test using bobwhite quail. The LD₅₀ was greater than 2000 mg/kg, which classifies azoxystrobin as practically non-toxic to the bobwhite quail.