# DATA EVALUATION RECORD § 71-1(A) - AVIAN SINGLE-DOSE LD<sub>50</sub> TEST

CHEMICAL: Azoxystrobin PC Code No.: 128810

TEST MATERIAL: ICIA5504 2. Purity: 96.2%

3. CITATION

Author: Barbara Hakin, Alison J. Johnson, Alan

Anderson, and I. Suzanne Dawe

ICIA5504: Acute Oral Toxicity (LDso) to Title:

Mallard Duck

November 24, 1992 Study Completion Date:

Huntingdon Research Centre Ltd., Laboratory:

Huntingdon, Cambridgeshire, England

Laboratory Report ID: ISN 288/921094

> Zeneca AG Products, Zeneca Inc., Sponsor:

Wilmington, DE

436781-09 MRID No.:

REVIEWED BY:

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6/21/96

6. STUDY PARAMETERS

Scientific Name of Test Organism: Anas platyrhynchos Test Organisms Age/Size: 26 weeks/900-1280 g Definitive Study Duration: 14 days

7. CONCLUSIONS: This study does not fulfill the guideline requirement for an avian acute oral toxicity test. Several test birds in the three highest treatment groups vomited within an hour of dosing. An accurate LD50 could not be determined. An LD<sub>50</sub> of >250 mg/kg (i.e., the lowest test dose) classifies azoxystrobin as no more than moderately toxic to mallard ducks.

128810

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

1.	CHEMICAL: PROVECTOR	PC Code No.:
2.	TEST MATERIAL: ICIA5504	<u>Purity</u> : 96.2%

CITATION

Barbara Hakin, Alison J. Johnson, Alan Anderson, and I. Suzame Dawe <u>Author:</u>

ICIA5504: Acute Oral/Toxicity (LD50) to Title:

Mallard Duck

November 24, 1992 Study Completion Date:

Huntingdon Research Centre Ltd., Laboratory:

Huntingdon, Cambridgeshire, England

Laboratory Report ID: ISN 288/921094

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Signature: Balan & What

Date: /0-19-95

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

signature: P. Kosalwa

Date: 10/19/95

5. APPROVED BY: EEB, EFED

Signature:

Date:

STUDY PARAMETERS

Scientific Name of Test Organism: Anas platyrhynchos Test Organisms Age/Size: 26 weeks/900-1280 g Definitive Study Duration: 14 days

CONCLUSIONS: This study does not fulfill the quideline requirements for an avian acute oral toxicity test. Several 7. test birds in the three highest treatment groups vomited within an hour of dosing. An accurate LD50 could not be determined. An LDsn of >250 mg/kg (i.e., the lowest test dose) classifies Sulfentrazone as no more than moderately toxic to mallard ducks. The NOEL for Sulfentrazone was 250 mg/kg.

# Results Synopsis

LD<sub>50</sub>: >250 mg/kg NOEL: 250 mg/kg

95% C.I.: N/A

Probit Slope: N/A

# 8. ADEQUACY OF THE STUDY

A. Classification: Supplemental.

B. Rationale: Actual dosage each bird received above 250 mg/kg is unknown due to vomiting.

C. Repairability: No.

9. **GUIDELINE DEVIATIONS:** None noted.

10. SUBMISSION PURPOSE: New Chemical.

#### 11. MATERIALS AND METHODS:

#### A. Test Organisms

Guideline Criteria	Reported Information				
Species: A wild waterfowl species, preferably the mallard (Anas platy-rhynchos), or an upland game bird species, preferably the bobwhite (Colinus virginianus).	Anas platyrhnchos				
Age at beginning of test: At least 16 weeks old.	26 weeks				
Supplier	The Country Game Farms, Ashford, Kent, England				
Acclimation period: At least 15 days.	15 days				

#### B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes

Guideline Criteria	Reported Information
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, a range finding test was conducted using 6 birds.				
Definitive Test Nominal concentrations: At least five, in a geometric scale, unless LD <sub>50</sub> > 2000 mg ai/kg.	0, 250, 500, 1000, and 2000 mg/kg, uncorrected for purity				
Controls: Water control or vehicle control (if vehicle is used)	Corn oil control  10, 5 male and 5 female				
Number of birds per group: 10 (strongly recommended)					
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxy- methylcellulose, or gum arabic.	Corn oil				
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1ml/100g).	0.5ml/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				
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, vomiting at 500 mg/kg and above, one mortality at 2000 g/kg				

# Mortality

		Cumulative Number of Dead								
Dosage	No. of		Day of Study							
(mg/kg)	Birds	1	2	3	4	5	6-8	9-11	12-14	
Control	10	0	0	0	0	0	0	· 0	0	
250	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	1	1	1	1	1	1	1	1	

Other Significant Results: There was no clear evidence that the variations in body weights and food consumption among the control and the treatment groups were dose related. Vomiting following

5

treatment increased with increased ICIA5504 concentration from three of ten at 500 mg/kg to seven of ten birds at 2000 mg/kg.

#### Reported Statistical Results

Statistical Method: None

 $LD_{50}$ : >2000 mg/kg

95% C.I.: N/A

NOEL: 250 mg/kg

Probit Slope: N/A

#### 13. Verification of Statistical Results:

Statistical Method: visual inspection of data

 $LD_{50}$ : >250 mg/kg

95% C.I.: N/A

NOEL: 250 mg/kg

Probit Slope: N/A

14. REVIEWER'S COMMENTS: This study does not fulfill the guideline requirement for an acute oral toxicity test using mallard duck. Several birds in the three highest treatment groups vomited within an hour of dosing. Therefore, an accurate LD<sub>50</sub> could not be determined. An LD<sub>50</sub> of >250 mg/kg classifies azoxystrobin as no more than moderately toxic to mallard ducks.