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MRID No. 443735-06

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

CHEMICAL: Mesotrione PC Code No.: 122990

TEST MATERIAL: Purity: 96.8% ZA1296

3. CITATION:

> M. Rodgers, D. Cameron, and K. Maltby Authors:

Title: ZA1296: Acute Oral Toxicity (LD₅₀) to

Bobwhite Quail

November 29, 1995 Study Completion Date:

Huntingdon Life Sciences Ltd., Laboratory:

Huntingdon, Cambridgeshire, England

Laboratory Report ID: ISN 347/951557

> ZENECA Ag Products, Wilmington, DE Sponsor:

MRID No.: 443735-06 DP Barcode: D245475

Max Feken, M.S., Environmental Toxicologist, REVIEWED BY:

Golder Associates Inc.

Date: 8/25/98

Pim Kosalwat, Ph.D., Senior Scientist, APPROVED BY:

Golder Associates Inc.

signature: P. Kosalwat

Date: 8/25/98

APPROVED BY:

Godgen Signature:

Date: 1/12/00

STUDY PARAMETERS: 6.

Signature: /

Scientific Name of Test Organism: Colinus virginianus Test Organisms Age/Size: ≈21 weeks/175-214 q

Definitive Study Duration: 14 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test. The LD_{50} was >2000 mg/kg, which classifies ZA1296 as practically non-toxic to the bobwhite quail.

Results Synopsis:

 LD_{50} : >2000 mg/kg 95% C.I.: N/A

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

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8. ADEQUACY OF THE STUDY:

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. **GUIDELINE DEVIATIONS:** No deviations of consequence were noted.

10. SUBMISSION PURPOSE:

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).	Colinus virginianus				
Age at beginning of test: At least 16 weeks old.	Reported as "approximately 21 weeks of age"				
Supplier	D.R. and R.E. Wise, Monkfield, Bourn, Cambridgeshire				
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

Guideline Criteria	Reported Information				
Feed withheld at least 15 hours prior to dosing?	Overnight fasting period of 21 hours				

C. Test Design

Guideline Criteria	Reported Information				
Range finding test?	Yes, two birds dosed at 2000 mg/kg survived.				
Definitive Test Nominal concentrations: At least five, in a geometric scale, unless $LD_{50} > 2000$ mg ai/kg.	500, 1000, and 2000 mg/kg, not corrected for purity				
Controls: Water control or vehicle control (if vehicle is used)	Vehicle control				
Number of birds per group: 10 (strongly recommended)	10, 5 male and 5 female				
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxy- methylcellulose, or gum arabic.	1% methylcellulose				
Amount of vehicle per body weight: Constant volume/weight % of body weight, not to exceed 1% (1 ml/100 g).	Vehicle control birds received a corresponding volume of 1% methylcellulose (10 mL/kg)				
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

Guideline Criteria	Reported Information				
Individual body weights mea- sured at beginning of test, on day 14 and at end of test if extended beyond 14 days?	Individual body weights measured on days 0, 7, and 14 of the study				
Mean feed consumption measured at beginning of test, on day 14, and at end of test if extended beyond 14 days?	Average group food consumption determined for days 1-7, and 8-14				
Control Mortality: Not more than 10%	0%				
Raw data included?	Yes				
Signs of toxicity (if any) were described?	Yes				

Mortality

				Cum	ılat	ive Nu	umber o	f Dead	
Dosage	No.	Day of Study							
(mg/kg)	of Birds	1	2	3	4	5	6-8	9-11	12-14
Control	10	0	0	0	0	0	0	0	o
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: There were no treatment-related signs of toxicity observed in the control or the dosage groups. The body weight gain and feed consumption values for all dosage groups were similar to those of the control group. Necropsy results of twenty birds (10 from the control group and 10 from the 2000 mg/kg group) were unremarkable.

Reported Statistical Results

Statistical Method: visual interpretation

LD₅₀: >2000 mg/kg 95% C.I.: N/A

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

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Methods: visual interpretation

LD₅₀: >2000 mg/kg 95% C.I.: N/A

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

14. REVIEWER'S COMMENTS: The analytical report attached to the study was reviewed and it was determined that the dosing solutions contained the test material at the proper concentration and that the material was stable over a two hour period. This study is scientifically sound and fulfills the guideline requirements for an acute oral toxicity test using bobwhite quail. The LD₅₀ was >2000 mg/kg, which classifies ZA1296 as practically non-toxic to the bobwhite quail. The NOEL was determined to be 2000 mg/kg based on the lack of effects at any dosage tested. The study is classified as Core.