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DP Barcode: D240854 MRID No.: 443874-09

DATA EVALUATION RECORD § 71-2(A) -- UPLAND GAME BIRD DIETARY LC₅₀ TEST

1. CHEMICAL: Cloquintocet-mexyl PC Code No.: 999999

2. TEST MATERIAL: CGA-185072 Purity: 91.6 %

3. CITATION

Authors: B.Hakin, M.Rodgers, A.J.Norman, A.Anderson, and

I.S.Dawe

<u>Title</u>: Dietary Toxicity of CGA-185072 to the bobwhite quail

Study Completion Date: February 2, 1989

Laboratory: Huntingdon Research Centre, Ltd.

PO Box 2

Huntingdon, Cambridgeshire, PE18 6ES, England

Date: 10/23/98

Sponsor: Novartis Crop Protection, Inc.

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Laboratory Report ID: CBG 469/89703

MRID No.: 443874-09

4. **REVIEWED BY:** Stephen Carey, Biologist, EFED, ERBIII

Signature: Harry Craven, EFED, ERBIII

Signature: Henry T. Craven

6. STUDY PARAMETERS

Scientific Name of Test Organism: Colinus virginianus Age of Test Organisms at Test Initiation: 13 days old Definitive Study Duration: 3-day pre-treatment period

5-day treatment period 3-day post-treatment period

3-day post-treatment period

7. CONCLUSIONS:



Results Synopsis

LC₅₀: >4890 ppm ai NOEL: 4890 ppm ai

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

8. ADEQUACY OF THE STUDY

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. **GUIDELINE DEVIATIONS**

1. N/A

10. <u>SUBMISSION PURPOSE</u>:

11. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information				
Species: An upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	Colinus virginianus				
Age at beginning of test: 10-14 days old.	13 days				
Supplier	D.R. and R.E. Wise, Monkfield, Bourn, Cambridgeshire				
Chicks appeared healthy and did not have excessive mortality before the test?	Yes				
Acclimation period: As long as possible.	9 days				

B. Test System

Guideline Criteria	Reported Information			
Pen size: about 35 x 100 x 24 cm	wooden boxes 83 x 52 x 51 cm			
Brooder temperature: about 35°C (95°F)	Not Reported			
Room temperature: 22-27°C (71-81°F)	23-25°C			
Relative humidity: 30-80%	46 %			
Adequate ventilation?	Yes			
Photoperiod Minimum of 14 h of light.	Not Reported			
Diet: A commercial diet for game birds.	Basal diet (batch no. 4083)			

C. Test Design

Guideline Criteria	Reported Information				
Range finding test?	No				
Definitive Test Nominal concentrations: Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless $LC_{50} > 5000$ ppm.	LC50 > 5200 ppm				
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets?	Not Reported				

Guideline Criteria	Reported Information
Number of birds per group: 10 (strongly recommended)	10
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Corn oil
Vehicle amount (% of diet by weight): Not more than 2%	Not Reported
Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed.	5-day treatment period, 3-day post-treatment period.
No mortality during last 72 hr of observations?	No

12. REPORTED RESULTS

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Body weights measured at beginning and end of study?	Yes
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Yes
Control Mortality: Not more than 10%	0 %
Raw data included?	Yes
Signs of toxicity (if any) were described?	No

Mortality

	Conc. (ppm)		Cumulative Number of Dead					
		Mean	No. of Birds		Day of Study			
Group Nominal Measur	Measured		1	2	3	4	5	
Control	0	ND	10	0	0	0	0	0
4	163	163	10	0	0	0	0	0
5	325	315	10	0	0	0	0	0
6	650	618	10	Ó	0	0	0	0
7	1300	1260	10	0	0	0	0	0
8	2600	2600	10	0	0	1	1	1
9	5200	4890	10	0	0	0	0	0

Other Significant Results: One bird was found dead in group 8 (at 2600 ppm) on Day 3. No further moralities occurred. All control and test groups showed continued bodyweight increases throughtout the study, and there was no evidence of any differences between treatments. Food consumption was similar in all groups throughtout the study, and there was no evidence of any differences between treatments. No abnormalities were detected in any bird examined. No attempt was made to determine the sex of the birds because of their size and age. Group mean bodyweights were in the range 14 to 15 grams at the beginning of the pre-treamtnet period. All mean results are within 6 % of nominal concentrations.

Statistical Results

Statistical Method: visual estimation

LC₅₀: >5200 ppm 95% C.I.: N/A

NOEL: 5200 ppm Probit Slope: N/A

13. Verification of Statistical Results

Statistical Method: visual estimation

LC₅₀: >4890 ppm

95% C.I.: N/A

NOEL: 4890 ppm

Probit Slope: N/A

14. <u>REVIEWER'S COMMENTS</u>: This study is scientifically sound and fulfills the guideline requirements for an upland game bird dietary LC50 test using bobwhite quail. Based on mean measured concentrations, the 5-day LC50 was determined to be >4890 ppm which classifies CGA-185072 as practically non-toxic to the bobwhite quail. The NOEC was determined to be 4890 ppm. Data on the test organism's brooder temperature, photoperiod, test with diet containing the maximum amount of vehicle used in treated diets, vehicle amount are not reported in the study. One bird in group 8 perished at the second highest dose (2600 ppm). This study is classified as **core**.