

DP Barcode: D240854

MRID No.: 443874-07

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

1. **CHEMICAL:** Cloquintocet-mexyl

PC Code No.: 999999

2. **TEST MATERIAL:** CGA-185072

Purity: 91.6%

3. **CITATION**

Authors: B.Hakin, A.J.Norman, A.Anderson, and I.S.Dawe

Title: Acute Oral Toxicity of CGA-185072 to the Mallard Duck

Study Completion Date: March 2, 1989

Laboratory: Huntington Research Centre, Ltd.

P.O. Box 2

Huntington, Cambridgeshire, PE18 6ES, England

Sponsor: Novartis Crop Protection, Inc.

P.O. Box 18300

Greensboro, NC 27419

Laboratory Report ID: CBG 472/89311

MRID No.: 443874-07

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

Signature: *Stephen Carey*

Date:

11/19/98

5. **APPROVED BY:** Harry Craven, ERBIII, EFED

Signature:

Harry Craven

Date:

11/19/98

6. **STUDY PARAMETERS**

Scientific Name of Test Organism: *Anas platyrhynchos*

Test Organisms Age/Size: ~16 week of age

Definitive Study Duration: 14 days

7. **CONCLUSIONS:**

Results Synopsis

LD₅₀: >2000 mg ai/kg

95% C.I.: N/A

NOEL: 2000 mg ai/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

1. N/A

2. N/A

10. SUBMISSION PURPOSE:

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>Anas platyrhynchos</i>
Age at beginning of test: At least 16 weeks old.	~16 weeks old
Supplier	Mr. J. Coles The County Game Farms Ashford, Kent, England
Acclimation period: At least 15 days.	14 days

B. Test System

Guideline Criteria	Reported Information
Pen facilities adequate?	Yes
Photoperiod: 10-h light, 14-h dark is recommended.	7-h light, 17-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
Definitive Test Nominal concentrations: At least five, in a geometric scale, unless $LD_{50} > 2000$ mg ai / kg.	Three dose levels of 500, 1000, and 2000 were used. The resulting LD_{50} was greater than 2000 mg ai/kg.
Controls: Water control or vehicle control (if vehicle is used)	Vehicle control
Number of birds per group: 10 (strongly recommended)	10
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).	5 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
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?	No

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

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Other Significant Results: None

Reported Statistical Results

Statistical Method:

LD₅₀: >2000 mg ai/kg 95% C.I.: N/A

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

13. Verification of Statistical Results

Statistical Method: visual estimation

LD₅₀: >2000 mg ai/kg 95% C.I.: N/A

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

15. REVIEWER'S COMMENTS: This study is scientifically sound and fulfills the guideline requirements for an acute oral LD50 test using Mallard duck. Based on mean measured concentrations, the 14-day LD50 was determined to be greater than 2000 mg ai/kg, which classifies CGA-185072 as practically non-toxic to the mallard. The NOEC was determined to be 2000 mg ai/kg. This study is classified as **Core**.