

6-19-80

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DATA EVALUATION RECORD

1. Chemical: Formetanate<sup>HU</sup> (Carzol) SP
2. Formulation: Unknown 92.6% a.i. (letter dated 9/5/80)
3. Citation: Fletcher, D., D. H. Jenkins and M.L. Keplinger.  
September 24, 1971. Acute Oral Toxicity Study with Carzol in Mallard Ducks. Prepared by Industrial Bio-Test Labs, Inc. (Report # J260). Submitted to Nor-Am Agricultural Products, Inc.
4. Reviewed by: Elizabeth E. Zucker  
Wildlife Biologist  
EEB/HED
5. Date Reviewed: June 19, 1980
6. Test Type: Acute Oral LD<sub>50</sub>  
Test Organism: Mallard duck
7. Reported Results: The acute oral LD<sub>50</sub> for Carzol was found to be 11.50 mg/kg (95% C.L.-9.53 to 13.46 mg/kg) in mallard duck.
8. Reviewer's Conclusions:

This study is scientifically sound, however, it cannot fulfill the guidelines requirement for an avian (waterfowl) acute oral toxicity test. This is because information as to the formulation of the toxicant used and the exact age of the test animals was not provided in the final study report.

## Materials/Methods

### Test Procedures

Ten young adult ducks (5 males and 5 females each) were assigned to one of six dosage groups (0, 4.64, 6.81, 10.00, 14.70, 21.60 mg/kg). Birds were fasted 24 hours prior to gavage of toxicant (1% solution in distilled H<sub>2</sub>O) then allowed to take food and water ab libitum for the rest of the study period. Ducks were weighed individually on Test Day 0 and at sacrifice (Test Day 21) and weighed by groups on Test Days 3, 7, and 14. Food consumption was recorded weekly during the 21-day test period. Necropsy was performed on all birds.

### Statistical Analysis:

The Litchfield and Wilcoxon method was used to calculate the LD<sub>50</sub>.

### Discussion/Results:

#### Mortality:

<u>Group</u>	<u>Number Dead/ Number Tested</u>	<u>% Dead</u>
Control	0/10	0
4.64	0/10	0
6.81	0/10	0
10.00	2/10	20
14.70	9/10	90
21.60	10/10	100

Body weights and food consumption were found to be normal for all test groups as compared to controls. Animals dying during the test period exhibited evidence of lacrimation, diarrhea, tracheal congestion, ataxia and convulsions before death. Postmortem examination revealed flaccid cardiac musculature and dilation of the intestinal vessels in a majority of birds. Autopsy of survivors revealed flaccid cardiac musculature and dilation of intestinal vessels in a majority of the specimens.

### Reviewer's Evaluation:

#### Test Procedures:

The following deviations from EPA guidelines for avian acute oral testing are noted:

1. The formulation of the compound tested is not reported.

2. The age of the birds is not clearly designated.
3. There was not an adequate description as to the housing and husbandry procedures used for maintaining test animals.

The following discrepancy was noted by the auditor for the Nor-Am Agricultural Products, Inc:

1. The raw data, when calculated for food consumption, showed a difference of 1470 grams offered each week to most of the groups as compared to what was recorded in the final report. However, this should not have affected the results of the study.

Statistical Analysis:

Stephan's computer program was used to calculate the  $LD_{50}$ . Results of the probit method are accepted:  $LD_{50} = 11.66$  (95% CL 10.05-13.56).

Discussion/Results:

Even though there was a major discrepancy as to recorded food consumption, this should not have affected the results of this acute oral test, unless the birds did not obtain enough food required for normal maintenance. Control birds appeared to be handled satisfactorily.

Conclusions:

1. Category: Supplemental
2. Rationale: The formulation of the product and the exact age of the test animals are not identified.
3. Repairability: If the above information is provided and found to be acceptable, the study can be upgraded to Core.

Formetanate ----- Acute Oral LD50 ----- Mallard Duck

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
21.6	10	10	100	9.76563E-2
14.7	10	9	90.	1.07422
10	10	2	20.	5.46875
6.81	10	0	0	9.76563E-2
4.64	10	0	0	9.76563E-2

THE BINOMIAL TEST SHOWS THAT 6.81 AND 14.7 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS SINCE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 11.7267

-----RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS
4	.114107	11.6861	9.83903 14.4479

-----RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	.349888	1	.999332

SLOPE = 12.915  
 95 PERCENT CONFIDENCE LIMITS = 5.27561 AND 20.5544

LC50 = 11.6592  
 95 PERCENT CONFIDENCE LIMITS = 10.0478 AND 13.557

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