

6-18-80

8

DATA EVALUATION RECORD

1. Chemical: Formetanate ^{HCl} (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 27, 1971. Acute Oral Toxicity Study with Carzol
in Bobwhite Quail. Prepared by Industrial Bio-Test Labs,
Inc. (IBT #J259). Submitted to Nor-Am Agricultural
Products, Inc.
4. Reviewed by: Elizabeth E. Zucker
Wildlife Biologist
EEB/HED
5. Date Reviewed: June 18, 1980
6. Test Type: Avian acute oral LD₅₀
Test Species: Bobwhite quail
7. Reported Results:

Bobwhite quail showed the acute oral LD₅₀ of Carzol to be 41.50 mg/
kg of body weight (95% CL: 30.07 to 57.27 mg/kg)
8. Reviewer's Conclusions:

This study is scientifically sound but does not fulfill the guidelines requirements for an avian (upland) acute oral toxicity test. This is because the information as to the formulation of the compound and the exact age of the quail was not provided in the test report.

Materials/Methods

Test Procedures

Six groups of 10 young adult birds each (5 male; 5 female) were treated with either 0, 21.5, 31.6, 68.1, 100.0, 147.0 mg/kg of Carzol in a single gavage dosage. Birds were fasted 24 hours prior to treatment, but were given food and water ad libitum at all other times during the 21-day test period. Birds were individually weighed on Test Day 0 and before sacrifice and by groups on Test Days 3, 7 and 14. Food consumption was recorded weekly. All animals dying during the test period and all animals sacrificed at the end of the study were necropsied.

Statistical Analysis:

The Litchfield and Wilcoxon method was used to calculate the LD₅₀.

Discussion/Results:

All birds that died exhibited hyperactivity and convulsions before death. No other toxic symptoms were observed. Necropsy revealed discoloration of mucosal membranes of the gizzards of most of these birds. There were no pathological alteration in surviving birds.

Mortality data:

<u>Dosage</u>	<u># birds dead total birds</u>	<u>% Dead</u>
0	0/10	0
21.5	1/10	10
31.6	3/10	30
68.1	7/10	70
100.0	10/10	100
147.0	10/10	100

Mean body weights of surviving birds did not differ significantly from controls in all treatment groups. Food consumption was considered to be normal in all surviving treatment groups.

Reviewer's Evaluation:

Test Procedures:

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

1. The formulation of the toxicant used is unknown.
2. The age of the test quail is not reported.

3. There was no description of housing of animals in the final report.
4. It was not stated if a vehicle (water or corn oil) was used in the gavage procedure.

Statistical Analysis:

Stephan's computer program was used to verify the LD₅₀ values. An acute oral LD₅₀ value of 43.1 ppm (95% CL of 32.2 and 56.1 ppm) is accepted from Stephan's probit method.

Discussion/Results:

Mean body weights and food consumption was not significantly different from controls.

Conclusions:

1. Category: Supplemental
2. Rationale: The formulation of the compound and age of the test animals are not unknown.
3. Repairability: This study can be upgraded to Core if information as to the formulation of the product and the age of the test animals can be supplied and are found to be acceptable for fulfilling guideline requirements.

Formetanate ----- Acute Oral LD50 ----- Bobwhite Quail

```

*****
CONC.          NUMBER      NUMBER      PERCENT      BINOMIAL
                EXPOSED     DEAD        DEAD          PROB.(PERCENT)
147             10             10          100           9.76563E-2
100             10             10          100           9.76563E-2
68.1            10             7           70.           17.1875
31.6            10             3           30.           17.1875
21.5            10             1           10.           1.07422
    
```

THE BINOMIAL TEST SHOWS THAT 21.5 AND 100 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 46.3892

```

-----RESULTS CALCULATED USING THE MOVING AVERAGE METHOD
SPAN          G          LC50          95 PERCENT CONFIDENCE LIMITS
3             .148741      43.1439      32.9783      55.033
    
```

```

-----RESULTS CALCULATED USING THE PROBIT METHOD
ITERATIONS    G          H          GOODNESS OF FIT PROBABILITY
6             .182254      1           .67781
    
```

SLOPE = 4.47477
 95 PERCENT CONFIDENCE LIMITS = 2.56444 AND 6.38511

LC50 = 43.0693
 95 PERCENT CONFIDENCE LIMITS = 32.2467 AND 56.1051
