

R.L. LD 50  
B. Swine

9-30-88

DATA EVALUATION RECORD

PAGE 1 OF

CASE: GS0058

BENEFIN

CONT-CAT: 01

GUIDELINES: 71-1

MRID: 160875

Seacat, J.; Cochran, R. (1985) The Toxicity of Benefin (Compound 54521) to Bobwhite in a Fourteen-day Acute Oral Study: Study A01085. Unpublished study prepared by Lilly Research Laboratories. 27 p.

REVIEW RESULTS:

VALID ☒

INVALID ☐

INCOMPLETE ☐

GUIDELINE:

SATISFIED ☒

PARTIALLY SATISFIED ☐ NOT SATISFIED ☐

DIRECT RVW TIME = 2 hours

START DATE: 9-30-88 END DATE: 9-30-88

REVIEWED BY: Charles R Lewis

TITLE: Agronomist

ORG: EEB/EFEB

LOC/TEL: CM II 557-7463

SIGNATURE: Charles R Lewis

DATE: 9/30/88

APPROVED BY:

TITLE:

ORG:

LOC/TEL:

SIGNATURE:

DATE:

## DATA EVALUATION REPORT

1. Chemical: N-butyl-N-ethyl-a,a,a-trifluoro-2,6-dinitro-p-toluidine
2. Test Chemical: Benefin (Compound 54521) 97.3% ai
3. Study Type: Avian Single Dose Oral LD<sub>50</sub> - Bobwhite Quail
4. Study ID: Seacat, J.; Cochrane, R. (1985) The Toxicity of Benefin (Compound 54521) to Bobwhite in a 14-Day Acute Oral Study: Study A01085. Unpublished study prepared by Lilly Research Laboratories. 27 pages. MRID No. 160875.

5. Reviewed By: Charles R. Lewis  
EEB/EFED

Signature: *Charles R. Lewis*  
Date: *Nov 14, 1988*

6. Approved By: Douglas J. Urban  
EEB/EFED

Signature: *(Douglas J. Urban)*  
Date: *11/22/88*

7. Conclusion:

The study is scientifically sound and fulfills the Guidelines requirement for an avian single dose LD<sub>50</sub>.

With an LD<sub>50</sub> > 2000 mg/kg benefin may be characterized as practically nontoxic to birds.

8. Recommendation: N/A

9. Background:

The study was reviewed for the Benefin Registration Standard.

10. Discussion of Individual Tests: N/A

*done*

## 11. Materials and Methods:

Benefin (Compound 54521) 97.3% ai was administered to 23-week-old bobwhite quail (Colinus virginianus) obtained from Barretti Quail Farm, Houston, Texas. Birds were quarantined for 15 days prior to initiation of the study. Two birds, 12 birds per concentration, were housed in stainless steel pens. Individual body weights were recorded when the study was initiated and on test days 3, 7, and 14. Food consumption was measured for test days 1 through 3, 4 through 7, and 8 through 14.

Benefin was triturated with acacia and deionized water. Doses were 125, 250, 500, 1000, and 2000 mg/kg plus a vehicle control.

Toxicity symptoms were recorded for the 14-day test period on a daily basis.

Birds had free access to Teklad diet JQ22 and Greenfield city water. A photoperiod at 8 hours light/16 hours dark was maintained during the quarantine and test period.

## 12. Reported Results:

No mortality occurred in the control or treatment groups.

"Stress-induced loose feces occurred during the initial six hours in test-day one from birds in the control group and from birds that received a dose of 125 mg/kg of benefin. Treatment-related loose feces was observed throughout test-day one from birds in the 500 mg/kg treatment group, and during test-days one and two from birds in the 250, 1000, and 2000 mg/kg treatment groups. One bird in the control 0.0 group and one bird in the 250 mg/kg group were separated from their pen mate because of pen-mate aggression. The birds that were injured because of pen-mate aggression were slightly lethargic on the day they were separated. Two birds in the 2000 mg/kg treatment group were slightly lethargic during the first five hours of test-day one. The lethargy was judged to be a result of handling stress. Yellow colored feces were observed from birds in the 250, 500 and 1000 mg/kg treatment groups during test-days one and two, and birds in the 2000 mg/kg treatment group during test days one through three. One bird in the 2000 mg/kg treatment group had a cage related injury to the right foot during test-days seven through 14.

"There were no differences in the 14-day trend of mean body weight values between the control group birds and birds

that received doses of benefin  $\leq$  2000 mg/kg. However, one bird in the 2000 mg/kg treatment group lost 22 grams of weight. This bird had a damaged right foot from test-day seven through 14. This weight loss was judged to have been a result of the injury since there were no other significant weight losses in this group.

"Food consumption was equivalent for birds in the control group and in all treated groups."

13. Study Author's Conclusions/QA Measures:

"Based on the lack of mortality in the study, the 14-day LD<sub>50</sub> value for benefin was greater than 2000 mg/kg, the highest dose administered. A dose of 125 mg/kg was the highest dose of benefin tested which did not result in treatment-related signs of toxicity."

A Quality Assurance Statement was included with the report.

14. Reviewer's Discussion and Interpretation of the Study:

- a. Test Procedures - The study was conducted according to the Guidelines.
- b. Statistical Analysis - Analysis of data was by inspection.
- c. Discussion/Results - No dose-related mortality occurred when bobwhite quail were dosed with up to 2000 mg/kg benefin.

Benefin can be characterized as practically nontoxic to bobwhite quail.

d. Adequacy of Study

- 1) Category - Core
- 2) Rationale - N/A
- 3) Repairability - N/A

15. Completion of One-Liner: Completed

16. CBI Appendix: N/A