

P. (LD 50 11/22/88
B. S. ...

DATA EVALUATION RECORD

PAGE 1 OF

CASE: GS0058

BENEFIN

CONT-CAT: 01

GUIDELINES: 71-1

MRID: 160875

Seacat, J.; Cochrane, 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 Unpublished study prepared by Lilly Research Laboratories. 27 p.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 557-71163

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 Technical
3. Study Type: Avian Single Dose Oral LD50 - Mallard Duck and Bobwhite Quail
4. Study ID: Broddle, W.D.; Kehr, C.C.; West, H.C.; et al. (1973) The Safety of Balan® to the Mallard and Quail. (Unpublished study received December 3, 1973, under 6735-201; prepared by Elanco Products Co., Div. of Eli Lilly and Co., submitted by Tide Products, Inc., Edinburg, TX; CDL:010110-A.) MRID No. 24273.

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

Signature:

Date:

Charles R. Lewis
Nov. 11, 1988

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

Signature:

Date:

Douglas J. Urban
11/22/88

7. Conclusion:

The study appears to be scientifically sound but does not satisfy the Guidelines requirement for an avian single dose oral LD50. Insufficient information has been provided. Missing data include: percent active ingredient not provided; age of birds not provided; acclimation period not adequately described; use of controls not reported; pen facilities not described; photoperiod and temperature not included; amount of feed or description not reported.

Benefin may be characterized as practically nontoxic to the mallard duck and bobwhite quail with an LC50 > 2000 mg/kg.

8. Recommendation: N/A

9. Background:

The study was reviewed for the Benefin Registration Standard.

10. Discussion of Individual Tests: N/A

11. Materials and Methods:

Technical benefin (percent ai not provided) was placed in gelatin capsules for oral administration to adult mallard ducks (Anas platyrhynchos) and bobwhite quail (Colinus virginianus). Birds were acclimated to laboratory conditions for several days. Birds were obtained from Whistling Wings, Hanover, IL (mallards) and Cedar Grove Quail Farm, Rock Hill, SC (quail).

Ten birds, five male and five female, were dosed with 2 g/kg and observed for 14 days. Food and water were available at all times during the observation period. Body weight and changes in behavior were recorded.

12. Reported Results:

The LD₅₀ was > 2 g/kg and no gross treatment-related changes were noted.

Mallard Mean Body Weight (kg)

	<u>Start</u>	<u>Finish</u>
Male	1.1926	1.2018
Female	1.1812	1.1840

Quail Mean Body Weight (g)

	<u>Start</u>	<u>Finish</u>
Male	201.0	203.8
Female	198.8	200.0

13. Study Author's Conclusions:

"The probability that avian species will be injured by ingesting benefin is remote."

No Quality Assurance Statement was included.

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

- a. Test Procedures - Insufficient information has been provided to determine if the test procedures recommended in the Guidelines have been followed.
- b. Statistical Analysis - No mortality was reported and insufficient data are provided on weight changes to evaluate the results statistically.

c. Discussion/Results - No mortality occurred when birds were dosed with 2.0 g/kg benefin. However, insufficient information has been provided on the test procedures. Among the inadequacies are: percent active ingredient not provided; age of birds not provided (other than adult); acclimation period not adequately described; use of controls not reported; pen facilities not described; photoperiod and temperature not provided; feed consumption not reported.

d. Adequacy of Study

- 1) Category - Supplemental
- 2) Rationale - Refer to 14.c.
- 3) Repairability - Submission of complete study conditions and results may result in upgrading the study.

15. Completion of One-Liner: Completed

16. CBI Appendix: N/A