

9/5/1996

MRID No. 440331-02

DATA EVALUATION RECORD
§ 71-2(A) -- UPLAND GAME BIRD DIETARY LC₅₀ TEST

1. **CHEMICAL:** Benzyl Benzoate PC Code No.: 009501

2. **TEST MATERIAL:** Benzyl Benzoate Purity: 99.4%

3. **CITATION:**

Author: I.F. van Dreumel and J.B.J. Reijnders
Title: 5-Day Dietary Toxicity Study in Bobwhite Quail with Benzyl Benzoate

Study Completion Date: February 26, 1996

Laboratory: NOTOX, Hertogenbosch, The Netherlands

Laboratory Report ID: 160234

Sponsor: Allergopharma J. Ganzer KG, Reinbek, Germany

DP Barcode: D227329

MRID No.: 440331-02

4. **REVIEWED BY:** Curtis E. Laird, Fishery Biologist
Ecological Effects Branch
Environmental Fate and Effects Division
(7507C)

Signature: *Curtis E. Laird*

Date: 9-4-96

5. **APPROVED BY:** Norman J. Cook, Head-Section #2
Ecological Effects Branch
Environmental Fate and Effects Division
(7507C)

Signature: *Norman J. Cook*

Date: 09-05-96

6. **STUDY PARAMETERS:**

Scientific Name of Test Organism: *Colinus virginianus*

Age of Test Organisms at Test Initiation: 14 days

Definitive Study Duration: 8 days

7. **CONCLUSIONS:** This study is scientifically sound and fulfills the guideline requirements for an acute dietary toxicity test using bobwhite quail. The LC₅₀ was greater than 5000 ppm, which classifies Benzyl Benzoate as practically non-toxic to the bobwhite quail. The NOEC was determined to be 488 ppm. There appeared to be some pesticide related problems at the 1563 ppm dosage level (pale discoloration of the kidney, liver, spleen and spleen reduced in size, reduction in body weight, etc.).

Results Synopsis

LC₅₀: >5000 ppm

95% C.I.: N/A

NOEL: 5000 ppm

Probit Slope: N/A

8. ADEQUACY OF THE STUDY:

A. Classification: Core

B. Rationale: N/A

C. Repairability: N/A

9. GUIDELINE DEVIATIONS:

10. SUBMISSION PURPOSE:

11. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: An upland game bird species, preferably the bobwhite (<i>Colinus virginianus</i>).	<i>Colinus virginianus</i>
Age at beginning of test: 10-14 days old.	14 days old
Supplier	Purchased from H. and E. Küberich, Germany
Chicks appeared healthy and did not have excessive mortality before the test?	Yes
Acclimation period: As long as possible.	3 days

B. Test System

Guideline Criteria	Reported Information
Pen size: about 35 x 100 x 24 cm	72 x 90 x 23 cm

23

Guideline Criteria	Reported Information
Brooder temperature: about 35°C (95°F)	Range: 25-31°C
Room temperature: 22-27°C (71-81°F)	Not reported
Relative humidity: 30-80%	Range: 40-68%
Adequate ventilation?	Yes
Photoperiod Minimum of 14 h of light.	14 h of light per day
Diet: A commercial diet for game birds.	Quail chick diet manufactured by Special Diet Services, Witham, Essex, UK

C. Test Design

Guideline Criteria	Reported Information
Range finding test?	Yes, at 50, 500, 2000, and 5000 ppm. No mortalities or treatment related effects at any level.
<u>Definitive Test</u> Nominal concentrations: Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless $LC_{50} > 5000$ ppm.	48, 153, 488, 1563, and 5000 ppm
Controls: Control group tested with diet containing the maximum amount of vehicle used in treated diets?	Yes
Number of birds per group: 10 (strongly recommended)	10 birds per treatment group and 20 for the control
Vehicle: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic.	Acetone in the test diet was allowed to evaporate for approximately 24 hours.

34

Guideline Criteria	Reported Information
Vehicle amount (% of diet by weight): Not more than 2%	N/A
Test durations: 5 days with treated feed and at least 3 days observation with "clean" feed.	Yes
No mortality during last 72 hr of observations?	One bird at 1563 ppm

12. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes
Body weights measured at beginning and end of study?	Yes
Estimated consumption per pen reported for pretreatment, treatment, and observation periods?	Yes
Control Mortality: Not more than 10%	No mortality
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

45

Mortality

Nominal Concentration (ppm)	No. of Birds	Cumulative Number of Dead							
		Day of Study							
		1	2	3	4	5	6	7	8
Control	20	0	0	0	0	0	0	0	0
48	10	0	0	0	0	0	0	0	0
153	10	0	0	0	0	0	0	0	0
488	10	0	0	0	0	0	0	0	0
1563	10	0	0	0	0	0	0	0	1*
5000	10	0	0	0	0	0	0	0	0

* Actually occurred on day 9 of the study

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Other Significant Results: Signs of excessive aggression were evident in birds at the 1563 ppm level. Signs included lethargy, ptosis, swelling, scabs, abnormal gait, and hunched posture. No adverse effects were observed in birds at the highest treatment level (5000 ppm). There was a significant decrease in body weight gain in birds at the 1563 ppm level. However, this was contributed to the aggressive behavior of the birds and was not considered treatment related.

Statistical Results

Statistical Method: Visual inspection and Dunnett's test for comparing means (body weight and food consumption)

LC₅₀: >5000 ppm

95% C.I.: N/A

NOEC: ⁵⁰⁰⁰ 488 ppm

Probit Slope: N/A

13. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: By visual inspection

LC₅₀: >5000 ppm

95% C.I.: N/A

NOEC: 488 ppm

Probit Slope: N/A

14. REVIEWER'S COMMENTS: This study is scientifically sound and fulfills the guideline requirements for an acute dietary toxicity test using bobwhite quail. The LC₅₀ was greater than

5 to

5000 ppm, which classifies Benzyl Benzoate as practically non-toxic to the bobwhite quail. The NOEC was determined to be 488 ppm (see section 7 above for information). The study is classified as **Core**.

67