

Shaughnessy # 900497
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DATA EVALUATION RECORD

1. CHEMICAL: Dichlormid = Acetamide, 2,2-dichloro-N,N-di-2-propenyl
2. TEST MATERIAL: 97%
3. TEST TYPE: Acute Oral Toxicity
4. STUDY IDENTIFICATION:
Hakin, B., A.J. Norman, and M. Rodgers, 1986. " The Acute Oral Toxicity (LD₅₀) of Dichlormid to the Bobwhite Quail." Prepared by Huntingdon Research Centre Ltd.
Study For: Stauffer Chemical Company
MRID No.: 4156101
5. REVIEWED BY: Carol J. Belew, Biologist *Carol J. Belew 7/30/91*
EFED/EEB
6. APPROVED BY: Les Touart, Section Head *L T 7/30/91*
EFED/EEB
7. CONCLUSIONS: This study is scientifically sound and meets the guideline requirements for an acute oral toxicity test. Based on the nominal concentrations, Huntingdon Laboratories determined the LD₅₀ to be 1,545 mg/kg with 95% confidence limits of 1,319 to 1,830 mg/kg. This study indicates the Dichlorid is practically non-toxic to bobwhite quail.
8. RECOMMENDATIONS: N/A
9. BACKGROUND:
An initial range-finding test was conducted using six adult Bobwhite quail (three males and three females). Three dose levels of 2000, 1000 and 500 ppm were used in the initial test. Both birds died at the 2000 ppm dose level. No birds died at the lower dose levels. Dose levels for the main study were based on the results of this range-finding test.
10. DISCUSSION OF INDIVIDUAL TESTS: N/A
11. METHODS AND MATERIALS:
 - A. Test Organisms:
Age/stage of maturity- The birds were young adults over 16 weeks of age.
Size- 166-239 grams
Sex- 30 females and 30 males
Source- D.R. and R.E. Wise, Cambridgeshire, England



B. Dosage Form:

Solvents/vehicles- Corn oil was used as the vehicle for dosing.
Route of administration- The birds were dosed using oral gavage with a syringe and a Ch 10 or 20 Nelaton plastic catheter.

C. Referenced Protocol

Test levels- 521 mg/kg, 729 mg/kg, 1020 mg/kg, 1429 mg/kg, and 2000 mg/kg.

Number per level- Five females and 5 males per treatment were used.

Holding/acclimation- The birds were held for 14 days prior to treatment.

Pen/cage facilities- The birds were housed in groups of 2 or 3 (males and females separately) according to treatment in tiered cages. Each cage was constructed from polytene coated stainless steel wire and contained an automatic drinker and food hopper.

Feeding- The birds were fed standard HRC layer diet in pellet form through automatic feeders. All food was withheld for 15 hours prior to treatment.

Physical condition- All birds were in good health at the beginning of the test. However, prior to the test, three birds were replaced with spare birds for the following reasons: one bird was found dead, 1 bird had a large cut on its head and one bird was very light in weight.

Temperature- 21-25°C

Humidity- 83%

Photoperiod- Seven hours of light and 17 hours of dark were provided.

Controls- Controls were dosed with corn oil.

Measured test levels- 521, 729, 1020, 1429, and 200 mg/kg

Observation period- Birds were held for a period of 14 days prior to treatment and 14 days after treatment.

Statistical methods- The LD₅₀ value was determined by a method of probit analysis using MLP. Sources for information on the statistical analysis method used are "Statistical Method in Biological Assay" by D.J. Finney (1978) and "Maximum Likelihood Programme" by G.J.S. Rose (1978).

12. REPORTED RESULTS:

LD50- 1,545 mg/kg with 95% confidence limits of 1,319 to 1,830 mg/kg.

Dose response data- Birds in all dose levels showed some effect; however, birds in group 5 and 6 (dose level 1429-2000 mg/kg) displayed the most severe stress symptoms with ruffled feathers and unsteady gaits. On Day 2, all males from groups 5 and 6 and 3 females from group 6 died. All surviving birds recovered by Day 6. During days 0-7, males in group 4 and females in group 5 and 6 had large decreases in bodyweight.

Observation period- Fourteen days

Food consumption- After dosing, food consumption of males in Groups 5 and 6 much reduced prior to their death on Day 2.

Food consumption was variable in other groups, with no clear

evidence of any treatment-related effect.

Body weight changes- Males Group 4 and females in Group 5 and 6 showed a large body weight decrease compared with control values over Days 0 to 7 following dosing. Over Days 7 and 14, the female in Groups 5 and 6 showed a large compensatory increase in bodyweight. Bodyweight changes in other groups were variable, with no clear evidence of any treatment related effect.

Necropsy results- One bird from Group 4 was observed to be thin. Otherwise, no abnormalities were detected in any bird examined.

Test conditions

Temperature- 21-25° C

Humidity- 83%

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

Under the conditions of this study, the LD₅₀ of Dichlormid to the Bobwhite Quail was 1545 mg/kg with 95% confidence limits of 1319 mg/kg to 1830 mg/kg. The Compliance With Good Laboratory Practice Standards statement for HRC Report No. 202/891262 was signed by Barbara Hakins, Study Director on June 26, 1990. The compliance information states:

To the best of our knowledge and belief the study described in this report was conducted in compliance with the following Good Laboratory Practice Standards:

United States Environmental Protection Agency,
(FIRFRA), Title 40 Code of Federal Regulations Part
160, Federal Register, 29 November 1983 and
subsequent amendment Federal Register 17 August
1989.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY:

- A. Test Procedures: This study is scientifically sound and generally followed the recommended protocols outlined in the SEP.
- B. Statistical Analysis: Statistical analysis of the data set indicates that the LD₅₀ is 1545 mg/kg. with 95% Confidence limits of 1327 and 1843 mg/kg.
- C. Discussion/Results: The study was generally sound and thorough. However, no information was given about the size of the cages used.
- D. Adequacy of Test:
 1. Validation Category: This study is scientifically sound and is in accordance with the recommended protocols outlined in the SEP. This study meets the criteria for a core study.
 2. Rationale: The study indicates that Dichlormid is practically non-toxic to Bobwhite quail.

15. COMPLETION OF ONE-LINER FOR TEST:

16. CBI APPENDIX: