

US EPA ARCHIVE DOCUMENT

12-9-93

DATA EVALUATION RECORD

- 1. CHEMICAL: Oxyfluorfen. Shaughnessy No. 111601
- 2. TEST MATERIAL: RH-2915 Technical. 72.5% active
- 3. STUDY TYPE: Avian Reproduction Study
Species Tested: Bobwhite Quail
- 4. CITATION AND MRID NO:

Piccirillo, V.J. 1982. One Generation Reproduction Study in the Bobwhite Quail with RH-2915 Technical. Borrington Project No. 1006 (formerly 202-Y). Prepared by Borrington Laboratories, Inc., Temple Hills, Maryland. Submitted by Rohm and Haas Company, spring House, Pennsylvania.
MRID NO. 4153012-06

5. REVIEWED BY:

Richard W. Felthousen
Wildlife Biologist
EEB/EFED

Signature: *Richard W. Felthousen*
Date: 12/9/93

6. APPROVED BY:

Norm Cook
Supervisory Biologist
EEB/EFED

Signature: *Norman J. Cook*
Date: 12/9/93

7. CONCLUSIONS: The study was originally reviewed by KBN Engineering and Applied Sciences, Inc. and found to be scientifically sound and meeting the data requirement for an avian reproductive test. However, it was noted that, because body weights of 14 day-old chicks were reduced at both treatment levels (i.e., 50 and 100 ppm) the NOEC for the test could not be determined. It is also important to note that the study author failed to report this in the study. Therefore, because the NOEC cannot be determined and because the study author failed to provide any statistical analysis, relative to any of the parameters tested, the EEB has reclassified this study as "Supplemental".

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(Colinus virginianus).

71-4(a) Avian Reprod.

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5. **REVIEWED BY:**

Wayne R. Marion, Ph.D.
Wildlife Ecologist
Wildlife Resources Management

Signature: *Wayne R. Marion*
Date: 5/24/91.

6. **APPROVED BY:**

Michael L. Whitten, M.S.
Wildlife Toxicologist
KBN Engineering and
Applied Sciences, Inc.

Signature: *Michael L. Whitten*
Date: 5/24/91

Henry T. Craven, M.S.
Supervisor, EEB/HED
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*John Niles
5/14/92*

Signature: *Henry T. Craven*
Date: 12/9/93

- 7. **CONCLUSIONS:** Dietary concentrations of RH-2915 Technical were fed to adult Bobwhites at 50 ppm and 100 ppm (as active ingredient) for a 22-week exposure period. The body weight of 14 day-old chicks was reduced at 50ppm and at 100 ppm. The NOEC, therefore, could not be determined. RH-2915 Technical (as active ingredient) appeared to have no other effects on Bobwhites in terms of toxicity, behavioral abnormalities, or standard reproductive parameters. The study is scientifically sound and meets the requirements for an avian reproductive test.

*Reclassified as per discussions with
E. Fite + D. McLane*

RWJ 12/9/93

8. RECOMMENDATIONS: N/A
9. BACKGROUND:
10. DISCUSSION OF INDIVIDUAL TESTS: N/A.
11. MATERIALS AND METHODS:

A. Test Animals: The birds used in this study were unmated 6-month-old Bobwhite quail from the flock of Truslow Farms. The birds were acclimated to the reproduction facility for 15 days prior to the initiation of the study. The study included 108 Bobwhites (36 cocks, 72 hens) that were pen-reared, approaching their first breeding season, previously untreated, disease free, and phenotypically indistinguishable from wild birds. Just prior to the study, all birds were examined for injuries or abnormalities, tested for puleform-typhoid, and were randomly assigned to pens.

B. Test System: The birds were housed in wire cages (12" x 20" x 12") with 6 footcandles of light being provided. Temperatures were maintained at between 42 and 76 degrees (F) and relative humidity ranged between 36-75%. Photoperiods of 6 hours of light per day were maintained during the initial phase and then 16 hours of light per day (to induce egg laying) for the remainder of the test interval. A light meter, freezer, scales, and an incubator were available for use in the appropriate phases of the experiment.

C. Dose/Diet Preparation/Food Consumption: The basal diet used in these experiments was Agway game bird breeder ration in a diet preparation that was premixed at Truslow Farms. The test chemical, RH-2915 Technical (Lot 2-3985, TD 81-441), was incorporated into premixes that were prepared every two weeks at Borriston Laboratories. The premixes were adjusted to 100% active ingredient based upon the 72.5% active ingredient value supplied by the sponsor. The test chemical, RH-2915 Technical, and corn oil were incorporated into aliquots with a Hobart mixer and these concentrates were stored frozen until used for the weekly preparation of fresh diets. The

experimental concentrations of 0 ppm (control), 50 ppm, and 100 ppm were developed by mixing the appropriate RH-2915 Technical concentrate with the bulk basal diet mix described above. Both the control and experimental groups received the appropriate diets and water ad libitum for the duration of the study. Weekly food consumption data were recorded.

D. Design: The birds were randomly distributed into 3 groups as follows:

| Nominal Concentration | Number of Pens | Birds Per Pen | |
|-------------------------|----------------|---------------|---------|
| | | Males | Females |
| 0 ppm (Control) | 12 | 1 | 2 |
| 50 ppm RH-2915 (Tech.) | 12 | 1 | 2 |
| 100 ppm RH-2915 (Tech.) | 12 | 1 | 2 |

Adult Bobwhites were housed indoors in clean, wire reproduction cages 12" x 20" x 12" maintained over concrete floors.

E. Adult Observations/Gross Pathology: Adult birds were fed ad libitum the above diets for 12 weeks prior to egg laying and for 10 weeks during egg collection. Individual body weights for the adult birds were recorded at initiation of the experiment and on weeks 10 and 25 (termination). Body weights were not recorded during egg laying to avoid any possible adverse effects of handling during this period. Birds were observed twice daily for mortality, signs of moribundity and toxic effects. Also, all parental birds were sacrificed (by suffocation), necropsied, and examined for gross pathological changes upon the completion of the laying cycle.

F. Eggs/Eggshell Thickness: During egg laying, eggs were collected daily, marked, and stored at 65 degrees F. At weekly intervals, the stored eggs were removed from storage and placed in a Chickmaster Setter (Model 52E) incubator to be incubated at 99.9 degrees F. On day 1 of incubation, the eggs were candled for eggshell cracks, day 11 for fertility and early death of embryos, and on day 21 for embryo viability. On day 21, the eggs were transferred to a Chickmaster (Model 301) hatching machine. On Day 7 of weeks 1, 3, 5, 7, 9, and 11 of egg laying, all eggs collected were measured for eggshell thickness by opening them at the

girth, washing out the contents, and allowing the shells to dry for 48 hours. The average thickness of the dried shell plus the membrane was determined by measuring in 4 locations around the girth of the egg using a micrometer calibrated to 0.01 mm. Eggshell thickness was the mean of the four point measurements. Egg contents were saved in frozen condition for subsequent analysis.

G. Hatchlings: Hatchlings were housed in clean wire brooder batteries (measuring 28" x 32" x 11") according to the week of hatching and the treatment group. The hatchlings were color marked and toe punched according to their groups. During this time, the young birds were fed Agway Game Bird Starter Ration and water ad libitum. Hatchlings were observed twice daily for mortality, moribundity, and toxic effects. At age 14 days, individual body weights were recorded for all surviving chicks and these birds were then euthanized.

H. Statistics: The report did not indicate what type of statistical analyses were performed.

12. REPORTED RESULTS

A. Diet Analysis: No information was presented in the report regarding recovery concentrations of RH-2915 Technical, the test chemical, in the diets of treated birds.

B. Mortality and Behavioral Reactions: There were 12 mortalities reported during this study and all were among hens. Mortalities included 2, 5, and 5 hens in the Control, 50 ppm, and 100 ppm groups, respectively. These deaths followed no consistent pattern and there was no evidence in the data presented that these deaths were related to the treatment. Thus, they were considered incidental.

C. Adult Body Weight and Food Consumption: Adult body weights (Table 1) were similar among groups and there was no evidence of a treatment effect on this parameter. Similarly, food consumption data appeared to be generally similar among treatment and control groups.

D. Reproduction: There were no reproductive impairments at the dosage levels tested (Table 3, attached).

E. Eggshell Thickness: No effect on eggshell thickness was noted between the control and treatment groups.

F. Offspring Body Weight: As compared to the control group, there were no differences in the body weights of hatchlings at 14 days of age.

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

"RH-2915 Technical was evaluated for potential reproductive impairment in bobwhite quail through a one-generation reproduction study at dietary concentrations of 50 ppm and 100 ppm. Based on the results of this study, dietary levels of up to 100 ppm of RH-2915 (as active ingredient) is not expected to pose a reproductive hazard to bobwhite quail."

The report contained no Good Laboratory Practice Statement and no statements were made regarding quality assurance. The report was signed by the Quality Assurance Officer, presumably of the testing laboratory.

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

A. Test Procedures: The test procedures employed in this study were generally in compliance with the SEP, ASTM, and Subdivision E guidelines. Exceptions were:

Behavioral observations of young birds were not reported.

Body weights were not taken biweekly prior to egg laying.

No statistical methods were provided.

Some deviation from protocol was noted in temperature and humidity ranges and photoperiods. A temperature range of 42-76 degrees F (6-24 degrees C) was reported for this experiment; 21 degrees C is recommended. Humidity reportedly ranged from 36-75%; 45-70% is recommended. Photoperiods of 6 hours of light and 18 hours of darkness were reported for the quarantine period; 8 hours of light and 16 hours of darkness are recommended. In general, these deviations were thought not to have adversely affected the validity of the study.

B. Statistical Analysis: The registrant should ensure that future reports contain an adequate description of

the statistical analyses.

Statistical analyses of reproductive parameters were performed by the reviewer (attached) using ANOVA following square-root transformation of the count data and arcsine square-root transformation of the ratio data. Comparisons between control data and treatment group data were made using multiple comparison tests.

C. Discussion/Results: The mortality and behavioral data presented do not indicate any areas of major concern. In all cases, mortality was affecting the hens during egg laying and was incidental, not related to dosage levels.

The percentage of cracked eggs in this study ranged from 6.0-21.0%. This exceeds the acceptable limit of 0.6-2.0% for bobwhites (Technical Support Document to Subdivision E - Hazard Evaluation: Wildlife and Aquatic Organisms). The author briefly acknowledged these higher levels but was unable to provide an explanation for them. The values for cracked eggs do not appear to be treatment related, and the conclusion of no treatment effect for this parameter is accepted.

The analysis of 14-day survivor weights showed that the mean values for both treatment groups were significantly lower than the control values. When the analysis was conducted for individual weeks, the 50 ppm group showed reduced chick weights during weeks 5, 6, and 10, while the 100 ppm group showed reduced chick weights during weeks 3, 5, 6, 7, 8, and 10. Significant differences between groups in other parameters do not appear to be treatment-related.

The body weights of 14 day-old chicks were reduced at 50 and 100 ppm. The NOEC, therefore, could not be determined.

At dietary concentrations of RH-2915 Technical of 50 ppm and 100 ppm in diets of the bobwhite quail, there were no other treatment-related effects. The study is scientifically sound and meets the requirements for an avian reproductive test.

D. Adequacy of the Study:

- (1) Classification: ~~Core~~ *Supplemental*
- (2) Rationale: ~~N/A~~ *See Conclusions Section*
- (3) Repairability: N/A ~~Core~~

15. COMPLETION OF ONE-LINER: Yes; 21 May 1991.

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