

3-5-201
10-11-88

DATA EVALUATION RECORD

PAGE 1 OF

CASE: GS0103

PHORATE FRSTR

CONT-CAT: 01 GUIDELINES: 71-4

MRID: 158333

Beavers, J. (1986) Phorate Technical: A One-generation Reproduction Study with the Bobwhite (Colinus virginianus): Final Report: Project No. 130-141. Unpublished study prepared by Wildlife International Ltd. 102 p.

REVIEW RESULTS:

VALID _____ INVALID ☒ INCOMPLETE _____

GUIDELINE: SATISFIED _____ PARTIALLY SATISFIED _____ NOT SATISFIED ☒

DIRECT RVW TIME = 8 START DATE: 7/7/88 END DATE: 7/8/88

REVIEWED BY: Ann Stavola
TITLE: Aquatic Biologist
ORG: HED/EEB

LOC/TEL: CM2 Ford 557 1354

SIGNATURE: Anne Stavola DATE: 7/8/88

APPROVED BY:

TITLE:

ORG:

LOC/TEL:

SIGNATURE:

DATE: 10/11/88

1/15

1. Chemical: Phorate
2. Test Material: Technical 92.1%
3. Study/Action Type: Avian reproduction
Bobwhite quail (Colinus virginianus)
4. Study ID: MRID 158333. Beavers, J. (1986) Phorate
technical: A one-generation reproduction study
with the bobwhite (Colinus virginianus). Final
report: Project No. 130-141. Unpublished study
prepared by Wildlife International, Ltd. 158333

5. Reviewed By: Ann Stavola
Aquatic Biologist
HED/EEB

Signature: *Ann Stavola*

Date: 7/25/88

6. Approved By: Douglas Urban
Supervisory Biologist
HED/EEB

Signature: *Douglas J. Urban*

Date: 10/11/88

7. Conclusions:

The study is not scientifically sound and does not meet EPA guideline requirements for an avian reproduction study with bobwhite since 25 percent of the control pens did not reproduce normally.

8. Recommendations:

A new study is needed.

9. Background:

Avian reproduction studies were required in the Phorate Registration Standard, 1983.

10. Materials and Methods:

- a. Test Animals - Bobwhite quail (*Colinus virginianus*). Pen-reared, healthy, phenotypically indistinguishable from wild birds. Purchased from Barrett's Quail Farm, Houston, Texas. All were from the same hatch and approximately 25 weeks old and approaching their first breeding season at the start of the study.
- b. Test System-Adults - There were one male and one female quail in each pen, 30 x 51 cm with sloping floors so the height ranged from 21 to 26 cm. Every week a 7-day supply of food was placed in each pen. Water was provided ad libitum. The average temperature and relative humidity in the study room were 69 ± 4 °F and 67 percent, respectively. The air system in the room constantly replaced the room's air with fresh air. For the first 8 weeks of the study, the photoperiod was 8L:16D. During week 9 it was adjusted to 17L:7D and stayed at this photoperiod until the adult birds were sacrificed. The strength of the light was 12 footcandles.

The test diets were prepared by mixing phorate technical, (92.1% a), corn oil, and acetone with the basal diet. The final concentrations of phorate fed to the adults were 5, 20 and 60 ppm in addition to control pens. The adults were not fed any medication in their food.
- c. Egg Collection and Incubation - Eggs were collected daily, fumigated with formaldehyde gas to prevent pathogen contamination and stored in a cold room at 55 ± 2 °F and 76% RH until they were placed in incubators. Incubation was done on a weekly basis. The incubator had a temperature of 99.2 ± 0.2 °F and RH of 55%. The incubator rotated the eggs every hour in a 100 ° arc for 21 days to prevent adhesion of the embryos.
- d. Hatching - On day 21, the eggs were transferred to hatching where the temperature and RH were respectively, 98.9 ± 0.4 °F and 77%. All hatchlings, unhatched eggs and egg shells were removed on day 25 or 26.
- e. Chicks - The chicks were fed untreated diet and received no medication. They were housed in pens, 72 x 90 x 23 cm high. Temperature was 100 °F from the time of hatching until 14 days old. The photoperiod was 17L:7D.
- f. Study Design - The phases of the study were:
 - 1) Acclimation - Approximately 7 weeks.
 - 2) Pre-photostimulation - Approximately 9 weeks.

- 3) Pre-egg laying (with photostimulation) - Approximately 3 weeks.
- 4) Egg-laying - Approximately 10 weeks.
- 5) Post-adult sacrifice (final incubations, hatching, 14-day offspring rearing periods) - Approximately 6 weeks.

The treatment groups were: control, 5 ppm, 20 ppm, and 60 ppm. The test material was phorate technical grade, 92.1% ai.

- g. Observations-Adult Bird Observations - Daily for signs of toxicity or abnormal behavior; weekly for food consumption for each pen; body weights at initiation, weeks 2, 4, 6, and 8 and at terminal sacrifice; post-mortem necropsy at death or at end of adult phase of study.

Eggs

- Eggs laid.
- Egg shell thickness: Weekly throughout egg-laying period one egg was collected from each of the odd numbered pens in odd weeks and even numbered pens in even weeks. The eggs were opened at the mid-section, washed out and air-dried for 1 week at ambient temperature. The shell plus membrane were measured at 5 points with a micrometer to the nearest 0.005 mm.
- Eggs cracked: Determined by candling eggs before placing into incubators.
- Eggs set: The number laid minus the numbers cracked for each pen and studied for egg shell thickness.
- Viable embryos: Determined by candling on day 11 of incubation.
- Live 3-week embryos - determined by candling on day 21 of incubation.
- Hatchlings: The number that hatched per pen and the average body weight of the hatchlings by pen was determined.
- Chicks: On day 14 after hatching, the average body weight by parental pen was determined.

Statistical Analysis:

Dunnett's method was used to determine statistically significant differences between the control group and each treatment group. Sample units were the individual pens for each group. If an adult quail died during the study, the pen was not used in the analyses. The following parameters were analyzed with statistics:

- Adult body weight
- Adult feed consumption
- Eggs laid of the maximum laid (64 was the maximum by one hen)
- Eggs cracked of eggs laid
- Viable embryos of eggs set
- Live 3-week embryos of viable embryos
- 14-day old survivors of hatchlings
- 14-day old survivors of eggs set
- Hatchlings of maximum set (58 eggs was the maximum set by one hen)
- Offspring's body weight
- Egg shell thickness

12. Reported Results:

Five adults died during the study. They were a male at 5 ppm during week 12, 2 hens at 20 ppm during week 8, a male at 60 ppm during week 10 and a male at 60 ppm during week 16. Necropsies indicated a varied number of external lesions such as on the feet, legs, nostrils, and head. Internal changes included weight loss, lung lesions and fluid accumulation.

Other adults exhibited lesions or abnormal behavior associated with pen wear and tear or cannibalism.

When gross necropsies were done on all birds still alive at the end of the study, foot and head lesions were evident in control quail as well as treated quail. In addition, changes such as yolk peritonitis, egg in abdominal cavity, and juvenile ovary were more common in control quail than in any treatment group. Regressed ovaries were observed in quail fed 20 and 60 ppm phorate.

There were no treatment-related effects on body weight at any concentration of phorate. There were no treatment-related effects on food consumption at 5 ppm or 20 ppm. There were statistically significant increases in consumption at these levels during 2 to 3 weeks. The birds fed 60 ppm had significant decreases in consumption during weeks 1 and 5 and significant increases during weeks 3, 4, 6, and 8.

There were no apparent treatment-related effects at any tested concentration on any of the reproductive parameters. There were no treatment-related reductions in egg shell thickness at any concentration. Eggs from the 20 ppm group had a slight, but statistically significant increase in egg shell thickness, but the authors did not believe it was treatment-related. The body weights of the hatchlings and 14-day-old chicks were similar for all 4 groups.

13. Study Author's Conclusions/QA Statement:

"Dietary concentrations of phorate technical up to 60 ppm did not result in mortality, overt signs of toxicity, or effects upon reproductive parameters among bobwhite during an exposure of 21 weeks. When compared with the control, there was a reduction in feed consumption at 60 ppm during the first week of the study. However, there were no apparent treatment-related effects upon body weights of adults or body weights of hatchlings at any of the concentrations tested."

QA Statement: "This study was conducted so as to conform with Good Laboratory Practices as published by U.S. Environmental Protection Agency"

14. Reviewer's Evaluation and Interpretation of the Study

- a. Test Procedure - The test procedures used follow those in EPA's Pesticide Assessment Guidelines Subdivision E, EPA-540/9-82-024, October 1982. However a review of the data for numbers of eggs laid by pen for each group (Appendix VII) indicate that there was a problem with the control quail. According to Rick Bennett of EPA's ERL of Corvallis, OR (pers. comm., 7-7-88), who conducts avian reproduction studies for EPA, a pair of penned quail normally produces approximately one egg per day. At times 5 percent to 10 percent of the quail do not reproduce, and they have determined that the most likely cause is incompatibility between mates which can be caused by differences in body sizes, aggression, or poor husbandry. However, this incompatibility is normally evident prior to egg production so those pens can be culled from the study.

In this study, control pens 4, 6, 14, and 15 produced 12 or fewer eggs; in fact, pen 15 produced none. These numbers were compared with those from other bobwhite quail studies done by WIL. In these comparison studies, control quail produced approximately 20 to 50 eggs per pen. Something happened to the control birds in this phorate study. Some of the control females had head and foot lesions. Also, as indicated above, one control

female had a juvenile ovary, and one had an egg lodged in the abdominal cavity. There were also signs of yolk peritonitis. These data indicate that the control quail were stressed and not reproducing normally. For these reasons, the study is not acceptable.

b. Statistical Analysis - None were done due to problems with the controls which mask any treatment - caused effects.

c. Conclusions

- 1) Category - Invalid - Supplemental (see attached memo)
- 2) Rationale - Failure of 25 percent of control pens to reproduce normally.
- 3) Reparability - A new study is needed.

Summary of Phorate Effects on Bobwhite Quail
Reproduction Parameters

Parameter	Nominal Concentration of Phorate			
	0	5	20	60
Eggs laid				
Total number	517	600	500	450
Number/hen	32 $\pm$ 18	40 $\pm$ 14	36 $\pm$ 20	32 $\pm$ 15
Eggs cracked				
Total number	30	37	26	24
Number/hen	2	2	2	2
% of eggs laid	5	7	5	4
Eggs set				
Total number	417	483	412	365
% of eggs laid	81	81	82	81
Viable embryos (11-day)				
Total number	364	421	277	333
% of eggs laid	70	70	55	74
% of eggs set	85	86	73	90
Live embryos (21-day)				
Total Number	361	420	275	332
% of viable embryos	97	100	99	99
Hatchlings				
Total number	329	396	265	322
% of eggs laid	64	66	53	72
% of eggs set	79	82	64	88
% of viable embryos	90	94	96	97
% of live embryos	93	94	97	96
14-Day Old Chicks				
Total number	307	356	250	298
Number/hen	19	24	18	21
% of normal hatchlings	94	89	94	87
Average hatchling weight (g)	7	7	7	7
Average 14-Day Old chick weight (g)	29	29	28	30
Mean Adult Weight				
At study termination				
Females (g/bird)	234	239	239	240
Males (g/bird)	223	229	226	218

Summary of Phorate Effects on Bobwhite Quail
Reproduction Parameters (Cont'd)

Parameter	Nominal Concentration of Phorate			
	0	5	20	60
Mean change from study initiation				
Females (g/bird)	+30	+32	+26	+31
Males (g/bird)	+14	+15	+16	+14
Mean eggshell thickness (mm)	0.219 <u>+ 0.019</u>	0.227 <u>+ 0.015</u>	0.235 <u>+ 0.020</u>	0.220 <u>+ 0.011</u>
Average feed Consumption (g/bird/day)				
Pre-egg production	192	207	208	207
Egg production	253	273	279	270
Mean total	445	480	487	477

Pharmaceutical FFD Review

Page _____ is not included in this copy.

Pages 10 through 15 are not included in this copy.

The material not included contains the following type of information:

- _____ Identity of product inert ingredients.
 - _____ Identity of product inert impurities.
 - _____ Description of the product manufacturing process.
 - _____ Description of quality control procedures.
 - _____ Identity of the source of product ingredients.
 - _____ Sales or other commercial/financial information.
 - _____ A draft product label.
 - _____ The product confidential statement of formula.
 - _____ Information about a pending registration action.
 - ☒ FIFRA registration data.
 - _____ The document is a duplicate of page(s) _____.
 - _____ The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
