Reviewer Mike Davy

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MRID No. 417320-01

DATA EVALUATION RECORD

1. **CHEMICAL:** Proxel.
Shaughnessey No. 098901.

2. **TEST MATERIAL:** Proxel press paste (benzisothiazolin); BX228; 72.2% purity; a brown powder.

3. **STUDY TYPE:** Avian Dietary LC_{50} Test. Species Tested: Bobwhite quail (*Colinus virginianus*).

4. **CITATION:** Long, R.D., J. Foster, K. Hoxter, and G.J. Smith. 1990. Proxel Press Paste: A Dietary LC50 Study with the Northern Bobwhite. Project No. 123-162. Performed by Wildlife International Ltd., Easton, MD. Submitted by ICI Americas, Inc., Wilmington, DE. EPA MRID No. 417320-01.

5. **REVIEWED BY:**

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Signature: Mark A. Mossler
Date: 7/22/92

6. **APPROVED BY:**

Michael Whitten, M.S.
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Signature: Michael L. Whitten
Date: 7/22/92

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Signature: Brian Montague
Date: 12/20/02

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an avian dietary LC_{50} toxicity test using a total test material. Based on nominal concentrations, the LC_{50} of proxel press paste for bobwhite quail was >5620 ppm. Therefore, this test material is classified as practically non-toxic to bobwhite quail. The NOEC was 5620 ppm.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

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10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bobwhite quail (*Colinus virginianus*) were obtained from an in-house production flock. The birds were from the same hatch, pen-reared and were phenotypically indistinguishable from wild birds. All birds were acclimated to the caging and facilities from the day of hatch. The birds were 10 days of age at test initiation. During acclimation, the birds were observed daily.

B. **Test System:** The birds were housed indoors in thermostatically-controlled brooding pens. The pen floors measured 72 x 90 cm. The ceiling height was 23 cm. The external walls, ceilings, and the floors were constructed of galvanized wire and sheeting. During the test, the average temperature in the brooding pens was 37 ±3°C and the ambient room temperature was 25 ±1°C. The average relative humidity was 39 ±1%. A 16-hour photoperiod was used throughout the study. The light intensity was approximately 130 lux.

The test diets were prepared by mixing the test substance in corn oil and blending into the diet. The concentration of corn oil in the treated and control diets was 2%. The diets were prepared at test initiation with a blender and enough was presented to the birds to last throughout the exposure period.

The birds were offered water and feed *ad libitum* throughout the study. A list of the ingredients in the feed was given in the report and it appeared to be free of unfamiliar ingredients and medications.

C. **Dosage:** Eight-day dietary LC_{50} test. Dosage levels selected for the study were 562, 1000, 1780, 3160, and 5620 ppm. The dose levels were not corrected for the percent active ingredient of the test material.

D. **Design:** Ten chicks per test level and in each of four controls were randomly assigned to pens. Signs of toxicity, abnormal behavior, and mortality were assessed at least twice daily. Body weights by group were measured at initiation, day 5, and day 8 (termination) of the test. Average feed consumption was determined by group for days 0-5 (the exposure period) and 6-8 (the observation period). Feed consumption was determined by

measuring the change in the weight of the feed presented to the birds over a given period of time. However, this is an estimate due to wastage by birds.

E. **Statistics:** The LC_{50} value was estimated by visual assessment of the data due to the mortality pattern in this study.

12. **REPORTED RESULTS:** There was one mortality in the control group on day 7. This mortality was attributed to nostril picking. All other birds were normal in appearance and behavior throughout the test.

No mortality, abnormal effects, or reductions in body weight gain or feed consumption were observed in the treatment groups (Tables 3 & 4, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The dietary LC_{50} for bobwhite exposed to proxel press paste was greater than 5620 ppm, the highest concentration tested. The no mortality and no-observed-effect concentration (NOEC) was 5620 ppm.

Statements of adherence to Quality Assurance resulting in conformance to EPA Good Laboratory Practice standards (40 CFR Part 160) were included in the report. However, samples were not taken for confirmation of test material concentration, stability, or homogeneity.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedures were in accordance with Subdivision E, ASTM, and SEP guidelines with the following exceptions:

The temperature (up to 40°) was occasionally greater than recommended (35°C).

Group weights were used during the study. Individual body weights of the birds are recommended for monitoring weight gain or loss.

Necropsies were not conducted. These are recommended, but not required, by the guidelines.

Chemical analyses were not conducted to confirm the test material concentration. These measurements are recommended by the guidelines.

It was not stated if the test material was technical or a formulated product.

B. **Statistical Analysis:** Since a dose response was not evident by the end of the testing period, an LC_{50} value and 95% confidence limits could not be obtained. Upon review of the data, the LC_{50} reported by the authors (>5620 ppm) appears correct.

C. **Discussion/Results:** The report stated that the test material was added to the diet with corn oil. However, Appendix II stated that 100 ml of acetone was used in the diet preparation. If acetone was used, it should have been noted in the report.

This study is scientifically sound and meets the guideline requirements for an avian dietary LC_{50} toxicity test. Based on nominal concentrations of the total test material, the LC_{50} value of proxel press paste for bobwhite quail was >5620 ppm. Therefore, this material is classified as practically non-toxic to bobwhite quail. The NOEC was 5620 ppm (nominal concentration), based on the lack of mortality or sublethal effects.

D. **Adequacy of the Study:**

(1) **Classification:** Core for the total product.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 7-7-92.

TABLE 3

BODY WEIGHT AND ESTIMATED FEED CONSUMPTION OF CONTROL BOBWHITE

Concentration	Average Body Weight (Grams)						Feed Consumption Grams Per Bird Per Day	
	Exposure			Observation		Total	Exposure	Observation
ppm	Day 0	Change	Day 5	Change	Day 8	Change	Days 0-5	Days 6-8
0	20	10	30	10	40	20	6	13
0	20	11	31	8	39	19	8	13
0	20	12	32	8	40	20	7	10
0	19	9	28	8	36	17	7	11

TABLE 4

BODY WEIGHT AND ESTIMATED FEED CONSUMPTION OF BOBWHITE
EXPOSED TO PROXEL PRESS PASTE FOR FIVE DAYS

Concentration	Average Body Weight (Grams)						Feed Consumption Grams Per Bird Per Day	
	Exposure			Observation		Total	Exposure	Observation
ppm	Day 0	Change	Day 5	Change	Day 8	Change	Days 0-5	Days 6-8
562	22	11	33	9	42	20	7	10
1000	21	12	33	10	43	22	8	13
1780	20	11	31	10	41	21	9	10
3160	21	10	31	10	41	20	11	9
5620	21	8	29	8	37	16	9	10

Shaughnessey # 078901 Chemical Name Proxel Chemical Class ______

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
14-Day Single Oral LD_{50}		LD_{50} = mg/kg ( ) 95% C.L. Control Mortality (%) =		
Species		Slope = # Animals/Level = Age (Days) = Sex =		
Lab				
MRID #		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:		
8-Day Dietary LC_{50}	72.2	LC_{50} = >5620 ppm* (N/A) 95% C.L. Control Mortality (%) = 2.5%		
Species Japanese quail		Slope = N/A # Animals/Level = 10/test, 40/control Age (Days) = 10 Sex = N/A	7/9/92	Core / total product
Lab Wildlife International				
MRID # [illegible]		8-Day Dose Level ppm*/(% Mortality) [illegible] (0), 1000 (0), 1780 (0), 3160 (0), 5620 (0)		
		Comments: * Based on nominal concentrations of total product. NOEC: 5620 ppm		

6