9-5-91

MRID No. 413610-01 71-2A

DATA EVALUATION RECORD

1. **CHEMICAL:** Propanil-3,4-Dichloropropionilide. Shaughnessey No. 028201.

2. **TEST MATERIAL:** Propanil; Batch No. 01; 97.6% active ingredient; a light brown to dark purple solid.

3. **STUDY TYPE:** Avian Single Dose Oral LD_{50} Test. Species Tested: Bobwhite quail (Colinus virginianus).

4. **CITATION:** Grimes, J. and M. Jaber. 1989. Propanil: An Acute Oral Toxicity Study with the Bobwhite. Project No. 271-104. Performed by Wildlife International Ltd., Easton, MD. Submitted by Propanil Task Force, c/o John M. Wise Associates, Liberty, MO. EPA MRID No. 413610-01.

5. **REVIEWED BY:**

Louis M. Rifici, M.S.
Associate Scientist II
KBN Engineering and
Applied Sciences, Inc.

Signature:

Date:

6. **APPROVED BY:**

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

Signature:

Date:

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: Dan Barchi

Date: 9-5-91

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an avian single-dose oral acute toxicity test. The LD_{50} value of Propanil for bobwhite quail was 201 mg/kg. Therefore, Propanil is classified as moderately toxic to bobwhite quail. Sublethal effects, body weight loss, and reduced food consumption were observed at all dosage levels. Therefore, the NOEL was less than the lowest concentration tested, 62.5 mg/kg.

8. **RECOMMENDATIONS:**

9. **BACKGROUND:**

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

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5. **REVIEWED BY:**

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Date: 5/29/91

6. **APPROVED BY:**

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7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for an avian single-dose oral acute toxicity test. Addendum I, which describes the dosing regime for the individual birds, was not complete. The LD_{50} value of Propanil for bobwhite quail was 201 mg/kg. Therefore, Propanil is classified as moderately toxic to bobwhite quail. Sublethal effects, body weight loss, and reduced food consumption were observed at all dosage levels, therefore, the NOEL was less than the lowest concentration tested, 62.5 mg/kg.

8. **RECOMMENDATIONS:** See Section 14.D.(3).

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11. **MATERIALS AND METHODS:**

A. **Test Animals:** Bobwhite quail (Colinus virginianus) were obtained from a commercial quail farm in New Jersey. The birds were pen-reared, phenotypically indistinguishable from wild birds, and ranged in weight from 165 to 198 g at test initiation. All birds were acclimated to the caging and facilities for 15 days prior to test initiation. The birds were 17 weeks of age at test initiation. During acclimation, the birds were observed daily.

B. **Test System:** The birds were housed indoors in a battery of pens manufactured by GQF Manufacturing Co. The pen floor was sloped and measured 78 x 51 cm. The ceiling height was 20 to 25 cm. The external walls, ceilings, and the floor were constructed of galvanized wire and the side walls were galvanized sheeting. During the test, the average temperature was 23°C ±1° (SD), the average relative humidity was 68% ±9% (SD), and the photoperiod was 8 hours of light per day. The light intensity was approximately 130 lux.

The test material was dispersed in corn oil. The birds were individually weighed and dosed by intubation directly into the crop or proventriculus. The ratio of test material to corn oil was adjusted so that all birds received approximately the same dose volume, 6 mL per kg of body weight (Addendum I, attached). Control birds received a corresponding volume of corn oil.

The birds were offered water and feed ad libitum throughout the study except for 15 hours prior to dosing. 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:** Acute Oral LD_{50} test. Dosage levels selected for the study were 62.5, 125, 250, 500, 1000, and 2000 mg Propanil/kg of body weight, and a vehicle (corn oil) control. The dose levels were based on the total product as it was received.

D. **Design:** A total of 35 male and 35 female birds (17-weeks old) were distributed by random draw into groups of 10 (5 males, 5 females) to the treatment levels. The birds were segregated by sex for a total of 2 pens per test level. Signs of toxicity, abnormal behavior, and mortality were assessed at least twice daily. Body

weights were determined individually at test initiation and by group on days 3, 7, and 14. Average feed consumption was determined by group for days 0-3, 4-7, and 8-14 and was provided as an estimate.

The test period was 14 days.

E. **Statistics:** The LD_{50} value and its associated 95% confidence limits were calculated using a computer program developed by Stephan (1978).

12. **REPORTED RESULTS:** No mortality or abnormal behavior were observed in the control group during the study (Table 1, attached). By day 2, all birds dosed at 1000 and 2000 mg/kg and all 5 males dosed at 500 mg/kg had died. After 4 days, the remaining birds at 500 mg/kg and 80% of birds at 250 mg/kg were dead. No mortality occurred at 62.5 and 125 mg/kg. The LD_{50} was 201 mg/kg with a 95% confidence interval of 125-500 mg/kg.

At 62.5 mg/kg, lethargy and a ruffled appearance were noted approximately 2 hours after dosing. The birds had recovered by day 6. At 125 mg/kg, panting, reduced reaction to external stimuli, loss of coordination, a ruffled appearance, lower limb weakness, and lethargy were observed within 30 minutes of dosing. All the birds had recovered by day 6.

At 250 mg/kg, panting, depression, reduced reaction to external stimuli, wing droop, loss of coordination, prostrate posture, loss of righting reflex, a ruffled appearance, lower limb weakness, and lethargy were observed within 15 minutes of dosing. The survivors recovered by day 4 and remained normal until test termination. At 500 mg/kg, signs of toxicity, such as panting, depression, reduced reaction to external stimuli, loss of coordination, a ruffled appearance, lower limb weakness, and lethargy, were noted within 5 minutes of dosing. The signs of toxicity at 1000 mg/kg were similar to at 500 mg/kg and also included prostrate posture, loss of righting reflex, and lower limb rigidity. These symptoms were noted within 2 minutes of dosing. No birds in either the 500 or 1000 mg/kg group survived. At 2000 mg/kg, signs of toxicity were observed 10 minutes after dosing. These signs included panting, depression, reduced reaction to external stimuli, loss of coordination, a ruffled appearance, lower limb weakness, and lethargy. None of the birds survived.
There was a dose-related loss of average body weight and a reduction in group feed consumption encompassing all dosage levels (Table 2, attached). By the end of the test, the

remaining birds appeared normal. The no-observed-effect level (NOEL), based on sublethal effects, body weight loss, and reduction in feed consumption was lower than the lowest dosage tested, 62.5 mg/kg.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors presented no conclusions other than those above.

A Quality Assurance Unit Statement was included in the report indicating that the study conformed with Good Laboratory Practices standards published by the U.S. Environmental Protection Agency.

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

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

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.

The birds used should be from the same source and preferably the same hatch. The report does not mention whether they were from the same hatch.

Addendum I gives the dosing regime for each bird. The table includes only dosages up to 125 mg/kg and is obviously incomplete. However, the information provided is adequate to confirm that the dosing regime procedure was sound.

To provide statistically reliable results, test levels which produce at least three partial kills are recommended. In this test, only one level produced a partial kill.

B. **Statistical Analysis:** The reviewer used EPA's Toxanal computer program to determine the LD_{50} value and 95% confidence limits and obtained the same results as the authors (see attached printout).

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for an avian single-dose oral toxicity test. The LD_{50} value of Propanil for bobwhite quail was 201 mg/kg. Therefore,

Propanil is classified as moderately toxic to bobwhite quail. Sublethal effects, body weight loss, and reduced food consumption were observed at all dosage levels, therefore, the NOEL was less than the lowest concentration tested, 62.5 mg/kg.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

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

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

15. **COMPLETION OF ONE-LINER:** Yes; 05/09/91.

Page_____ is not included in this copy.

Pages 7 through 9 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product 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.

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✓ FIFRA registration data.

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LOUIS M. RIFICI PROPANIL COLINUS VIRGINIANUS 5-9-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
2000	10	10	100	9.765625E-02
1000	10	10	100	9.765625E-02
500	10	10	100	9.765625E-02
250	10	8	80	5.46875
125	10	0	0	9.765625E-02
62.5	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 125 AND 500 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 200.9977

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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Shaughnessey # 028201 Chemical Name Propanil Chemical Class _____ Page 1 of 1

Study/Species/Lab/ MRID #	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
14-Day Single Oral LD_{50}	97.6%	LD_{50} = 201.0 mg/kg* (95% C.L. Binomial 125-500) Control Mortality (%) = 0		
Species Colinus virginianus		Slope = N/A # Animals/Level = 10 Age (Days) = 17 weeks		
		Sex = 5♂, 5♀	LR 5/9/91	Supplemental.
Lab Wildlife International Ltd.		14-Day Dose Level mg/kg*/(% Mortality)		
		62.5 (0), 125 (0), 250 (80), 500 (100), 1000 (100), 2000 (100)		
MRID # 413610-01		Comments: * nominal concentrations		

8-Day Dietary LC_{50}		LC_{50} = pp (95% C.L.) Control Mortality (%) =		
Species		Slope = # Animals/Level = Age (Days) =		
		Sex =		
Lab		8-Day Dose Level pp /(% Mortality)		
		( ), ( ), ( ), ( ), ( )		
MRID #		Comments:		