5-28-91

MRID No. 413607-01

DATA EVALUATION RECORD

1. **CHEMICAL:** Propanil-3, 4-Dichloropropionilide. Shaughnessey Number: 028201.

2. **TEST MATERIAL:** Propanil. Batch No. 01; Aliquot No. 27; Code Blue; 97.6% purity; a light brown to dark purple solid.

3. **STUDY TYPE:** Avian dietary LC_{50} Test. Species Tested: Mallard duck (Anas platyrhynchos).

4. **CITATION:** Grimes, J. and M. Jaber. 1989. Propanil: A Dietary LC_{50} Study with the Mallard. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory Study No. 271-102. Submitted by Propanil Task Force, Liberty, Missouri. MRID No. 413607-01.

5. **REVIEWED BY:**

Rosemary Graham Mora, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Rosemary G. Mora
Date: 5/28/91

6. **APPROVED BY:**

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

Signature: Michael L. Whitten
Date: 5/28/91

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

Signature:
Date:

7. **CONCLUSIONS:** The study is scientifically sound but does not meet the requirements for an avian dietary LC_{50} test. With an LC_{50} of 5627 ppm (based on nominal concentrations) the test material is considered to be practically non-toxic to mallard ducklings. The NOEC could not be determined.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

6 hrs

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The test birds were mallard ducks (Anas platyrhynchos) obtained as one day old ducklings from Whistling Wings, Hanover, Illinois. At the time of test initiation the ducklings were 10 days old. The ducklings were immature, and therefore could not be differentiated by sex. All birds were acclimated to the caging and facilities for 9 days prior to initiation of the test.

B. **Test System:** All birds were housed indoors in pens constructed of galvanized wire and sheeting. Pen dimensions were 72 cm x 90 cm x 24 cm high. Fluorescent lights provided 16 hours of light per day. The average brooder compartment temperature was 33°±3°C (SD). The average ambient temperature was 26°±1°C (SD). The relative humidity was 72% ±11% (SD).

C. **Dosage:** Avian Dietary LC_{50} Test. Based upon known toxicity data, nominal concentrations selected for the study were 562, 1000, 1780, 3160, and 5620 parts per million (ppm). Concentrations were not adjusted for purity of the test substance (Propanil, 97.6% purity).

D. **Design:** Groups of ten birds were randomly assigned to each of five treatment groups and four control groups. Each concentration was assigned one pen. All treatment birds were fed Wildlife International Ltd.'s game bird ration with the appropriate amount of test substance. Food and water were supplied ad libitum during acclimation and during the test.

Appropriate amounts of the test substance were mixed into the ration with an industrial mixer (Addendum II, attached). Chemical analysis of the test diet was performed for samples collected at test initiation and at the end of the exposure period (Day 5) (Addendum III, partial attached).

All birds were observed at least twice daily for mortalities, signs of toxicity, and abnormal behavior. Each group of control and treatment birds was weighed at test initiation, on Day 5, Day 8, and Day 11. Group food consumption was determined for days 0-5, 6-8 and 9-11.

E. **Statistics:** The LC_{50} and 95% confidence limits were calculated by the probit test method using the computer program of C.E. Stephan (1978).

12. **REPORTED RESULTS:** "Samples of the test diet were analyzed by Midwest Research Institute for concentrations of Propanil. The results of the verification samples ranged from 91% to 95% of the nominal. Homogeneity samples ranged from 88% to 89% of nominal at 562 ppm and 92% to 99% of nominal at 5620 ppm. At ambient room temperature, analysis of the diets at nominal concentrations of 562 ppm and 5620 ppm showed a reduction of 45% and 26%, respectively, over a 5 day period."

"There were no mortalities in the control groups. All birds appeared and behaved normally throughout the test period."

No mortality was observed in the 562 ppm and 1000 ppm groups (Table 2, attached). Signs of intoxication in the 562 ppm concentration were noted on the afternoon of Day 3 and included lethargy in three birds. All birds in this concentration appeared normal from Day 4 to test termination. Lethargy was observed in three birds exposed to the 1000 ppm diet. The signs were first noted on Day 5 and ceased from the morning of Day 6 to test termination.

Ten percent, 20%, and 50% mortality was observed in the 1780, 3160, and 5620 ppm groups, respectively (Table 2, attached). Signs of toxicosis in the 1780 ppm group began on the morning of Day 3 and continued until the afternoon of Day 6; signs of toxicosis included lethargy, a ruffled appearance and reduced reaction to external stimuli. In the 3160 ppm group, a ruffled appearance, reduced reaction to external stimuli, lethargy, lower wing weakness, depression, and head bobbing were observed from Day 3 to the afternoon of Day 7, at which time all survivors appeared normal. Beginning the morning of Day 3, the birds in the 5620 ppm concentration illustrated signs of toxicosis including ruffled appearance, lethargy, wing droop, reduced reaction to external stimuli, depression, loss of coordination and lower limb weakness. The survivors appeared normal by the afternoon of Day 7, except for one bird which demonstrated signs of intoxication intermittently until it was found dead on the afternoon of Day 10.

"When compared to the controls, there was a reduction in body weight gain or body weight loss at all concentrations tested during the exposure period (Days 0 - 5) (Tables 3 and

interpretation of the study results. If the test had been continued for 72 hours after the mortality on day 10, it is probable that no further mortalities would have occurred. No other birds were demonstrating signs of intoxication, and the birds had not been exposed to test diets since day 5.

However, the results of analysis of test feed exposed at room temperature for 5 days indicate that the mean measured concentration to which the mallards were exposed was 74.1% of nominal in the 5620 ppm = 4164 ppm concentration and 55.3% of nominal at 520 ppm (Addendum III, partial attached). Since the stability of the test substance in the diet was variable and only two concentrations were analyzed (520 ppm and 5620 ppm), it is difficult to determine levels of test substance to which the test birds were exposed. Consequently, an accurate LC_{50} value based on the measured concentrations could not be determined.

The study is scientifically and meets the requirements for an avian dietary LC_{50} test. With an LC_{50} of 5627 ppm (based upon nominal concentrations) the test material is considered to be practically non-toxic to the mallard ducklings. The NOEC could not be determined, due to reduced body weight gains at all concentrations tested.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** However, these results should be viewed with caution because the stability of this compound under test conditions is in question (An average of 64.7% of theoretical concentrations were measured in 5-day stability analysis samples). The aerobic metabolism half-life of the technical product is 0.5 - 2 days).

(3) **Repairability:**

15. **COMPLETION OF ONE-LINER:** Yes; May 16, 1991.

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PROPANIL EEB REVIEW

Page_____ is not included in this copy.

Pages 5 through 10 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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ROSEMARY GRAHAM MORA PROPANIL ANAS PLATYRHYNCHOS 05-16-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
5620	10	5	50	62.30469
3160	10	2	20	5.46875
1780	10	1	10	1.074219
1000	10	0	0	9.765625E-02
562	10	0	0	9.765625E-02

THE BINOMIAL TEST SHOWS THAT 0 AND +INFINITY 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 5619.999

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	2.169066	5619.999	0	+INFINITY

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.508155	1	.9472666

SLOPE = 3.03382

95 PERCENT CONFIDENCE LIMITS = .8711619 AND 5.196479

LC50 = 5627.115

95 PERCENT CONFIDENCE LIMITS = 3801.339 AND 23891.13

LC10 = 2146.207

95 PERCENT CONFIDENCE LIMITS = 570.8973 AND 3157.886

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