10-16-92 EEB files

MRID No. 416041-02

DATA EVALUATION RECORD

1. **CHEMICAL:** Iprodione
Shaughnessey Number: 109801

2. **TEST MATERIAL:** Iprodione; 96.2% purity; EPA Est No. 264-NC-01; Reference #8906201; Wildlife International Ltd. Identification No. WIL-1478; off-white granular solid.

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

4. **CITATION:** Driscoll, C.P., J. Foster, K.A. Hoxter, G.J. Smith, and M. Jaber. 1990. Iprodione: A dietary LC_{50} study with the Northern Bobwhite. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory project #171-118A. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-02.

5. **REVIEWED BY:**

Marise H. Robbins, M.S.E.S., M.A.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Marise H. Robbins
Date: 4/12/91

6. **APPROVED BY:**

James R. Newman, Ph.D.
Project Manager/
Principal Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: James R Newman
Date: 4/12/91

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

Signature: Henry T. Craven
Date: 10/16/92

Dennis J. McLane 10-5-92

7. **CONCLUSIONS:** Based upon nominal concentrations, the dietary LC_{50} of Iprodione was greater than 5620 ppm, the highest concentration tested. This value classifies Iprodione as practically non-toxic to bobwhite quail chicks. Based on effects on body weights at all test levels, the no-observed-effect-concentration could not be determined.

The study is scientifically sound and meets the requirements for an avian dietary LC_{50} study.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

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

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study were 10-day-old bobwhite quail (Colinus virginianus) obtained from the Wildlife International Ltd. Production Flock, Easton, Maryland. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. All test birds were acclimated to the caging and facilities for 10 days prior to the initiation of the study. During acclimation all birds were observed daily. Birds exhibiting abnormal behavior or physical injury were not used.

B. **Test System:** All birds were housed indoors in brooding pens. External walls, ceilings and floors were constructed of galvanized steel wire and sheeting. Each pen's floor space measured approximately 72 cm X 90 cm. Ceiling height was approximately 23 cm. The photoperiod was sixteen hours of light per day during acclimation and throughout the study. The light source was Chroma 50 fluorescent lights which closely approximate noon-day sunlight. The birds received approximately 130 lux of illumination. During the test, the temperature in the brooding compartment of the pens was 38°C ± 2°C (SD). Average ambient room temperature for this study was 22°C ± 1°C (SD) with an average relative humidity of 32% ± 7% (SD).

C. **Dosage:** 8-day dietary LC_{50} study. The dosages were established based on "known toxicity data". Nominal dosages used in this study were 562, 1000, 1780, 3160, and 5620 parts per million (ppm) active ingredient (a.i.). All dietary test concentrations were adjusted to 100% active ingredient based upon the reported purity of the test substance. Therefore all dietary concentrations and the LC_{50} value are reported as parts per million of the active ingredient in the diet.

2

D. **Design:** Each treatment or control group contained ten chicks. The birds used in this study were immature and could not be differentiated by sex. Birds were assigned by random draw to five test groups and five control groups. Throughout acclimation and testing all birds were fed a game bird ration formulated to Wildlife International Ltd.'s specifications. The chicks were given a vitamin supplement in their water from the day they were hatched until the initiation of the test. Water, from the town of Easton public water supply, and feed were supplied ad libitum during acclimation and the test. The birds received no form of antibiotic medication during the study.

The test substance was dispersed in corn oil. The concentration of corn oil in the treated and control diets was 2%. A Hobart mixer was used to mix the test diet. Diets were prepared on the day of test initiation. An amount of diet sufficient to last the five day exposure period was presented to the birds at initiation of the test.

Each group was fed the appropriate test or control diet for five days. During the exposure period, the control group received an amount of corn oil in their diet equivalent to the greatest amount used in the treated diets. Following the five-day exposure period all groups were given untreated feed for three days.

Body weights by group were measured at initiation of the test, on Day 5, and at termination of the test on Day 8. Average estimated feed consumption was determined for each test concentration group and control group for the exposure period, Days 0-5, and for the observation period Days 6-8. 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, feed consumption is presented as an estimate due to the unavoidable wastage by the birds.

All birds were observed at least twice daily during the test. Observations of mortality, signs of toxicity, and behavior were recorded.

Samples of the test diets were taken to verify the test concentrations administered and to confirm the stability and homogeneity of the test substance in the diets.

E. **Statistics:** The pattern of mortality in this study did not facilitate the calculation of an LC_{50} value. Therefore, an estimation of the LC_{50} value was made by a visual inspection of the mortality data.

12. **REPORTED RESULTS:** "There were no mortalities in the control group (Table 1, attached). All birds were normal in appearance and behavior throughout the test period."

"There were no mortalities at the 562 through 3160 ppm a.i. concentrations (Table 2, attached). One bird in the 562 ppm a.i. level was toe-picked (a cannibalistic form of aggression) from Day 5 until test termination, however, this was not considered treatment related. All other birds at the 562 through 3160 ppm a.i. concentrations were normal in appearance and behavior throughout the test period".

"There were two mortalities in the 5620 ppm a.i. concentration, one on Day 3 and one on Day 5. No signs of toxicity were observed in these birds prior to the mortalities. All other birds were normal in appearance and behavior throughout the study".

"When compared to the controls, there was a dose response effect on body weights for all test concentrations during the exposure period (Day 0-5). A decrease in body weight gain was evident at the 562 ppm a.i. through 3160 ppm a.i. levels. Birds lost weight at the 5620 ppm a.i. test concentration during the exposure period; however, body weights increased in the treatment groups during the observation period similar to controls. There was no apparent effect at any level on feed consumption (Tables 3 and 4, attached) during either exposure or post-exposure periods".

The results of studies conducted to determine the homogeneity, stability and concentration of the test substance in the diet are shown in Appendix III, Tables 1-3 (attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** "In conclusion, the dietary LC_{50} value for northern bobwhite exposed to Iprodione Technical was determined to be greater than 5620 ppm a.i., the highest concentration tested. The no mortality level was 3160 ppm a.i. The no-observed-effect-concentration was determined to be lower than 562 ppm a.i., based on effects on body weights at all test levels".

The report stated that the study was conducted in conformance with Good Laboratory Practice regulations. Quality assurance audits were conducted and the final report was signed by the Quality Assurance Officer of Wildlife International Ltd.

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

A. Test Procedure: The test procedures were in accordance with Subdivision E - Hazard Evaluation: Wildlife and Aquatic Organisms, ASTM and SEP guidelines except for the following deviations:

Body weights were measured by group. Individual body weights should have been measured at test initiation and termination.

The SEP states that gross necropsies are preferred, yet none were performed.

B. Statistical Analysis: Since only two birds died in the test, the LC_{50} cannot be calculated and is assumed to be greater than 5620 ppm a.i., the highest concentration tested.

C. Discussion/Results: No treatment effects on feed consumption were observed. Exposure to Iprodione resulted in 2 mortalities at the highest dosage level. When compared to the controls, there appeared to be a dose related response effect on body weight gain for all test concentrations during the exposure period (Day 0-5). The birds in the four lowest treatment levels (562 ppm a.i. through 3160 ppm a.i.) showed reduced body weight gains in comparison to the control birds. The birds in the 5620 ppm a.i. group actually lost weight during days 0-5. These effects should be considered in any risk assessment of this chemical. Altered growth or development of birds caused by exposure to these concentrations in the wild might result in reduced survival rates.

With an LC_{50} greater than 5620 ppm, Iprodione is considered to be practically non-toxic to bobwhite quail chicks. Based on effects on body weights at all test levels, the no-observed-effect-concentration could not be determined.

With minor deviations, the study followed recommended guidelines. The study is scientifically sound and meets the requirements for an avian dietary LC_{50} study.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

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

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

15. **COMPLETION OF ONE-LINER:** Yes; April 12, 1991.

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IPRODIONE

Page_____ is not included in this copy.

Pages 7 through 11 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.

____ Information about a pending registration action.

X FIFRA registration data.

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Shaughnessey # 109801 Chemical Name Iprodione Chemical Class Technical Page 1 of 1

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				
		14-Day Dose Level mg/kg/(% Mortality)		
MRID #		( ), ( ), ( ), ( ), ( )		
		Comments:		
8-Day Dietary LC_{50}	96.2%	LC_{50} >5620 ppm (95% C.L. —) Control Mortality (%) = 0		
Species Bobwhite quail Colinus virginianus		Slope = NA # Animals/Level = 10 Age (Days) = 10	M. Robbins 3/20/91	CORE
		Sex = M/F		
Lab Wildlife International				
		8-Day Dose Level pp /(% Mortality)		
MRID # 416041-02		562(0), 1000(0), 1780(0), 3160(0), 5620(20)		
		Comments: NOEC could not be determined based on effects on body weights at all levels.		

2