10-5-92

EEB f. loc

MRID No. 416041-03

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: Mallard duck (Anas platyrhyncos).

4. **CITATION:** Driscoll, C., J. Foster, K.A. Hoxter, G.J. Smith, M. Jaber. 1990. Iprodione Technical: A dietary LC_{50} Study with the Mallard. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory project #171-119. Submitted by Rhone-Poulenc Ag Company, Research Triangle Park, NC. EPA MRID No. 416041-03.

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:**

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

Signature: Michael L. Whitten
Date: 4-12-91

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

Signature: Henry T. Craven
Date: Dennis J. McLane 10-5-92

7. **CONCLUSIONS:** Based upon nominal concentrations, the dietary LC_{50} of Iprodione was greater than 5620 ppm a.i., the highest concentration tested. This value classifies the test material as practically non-toxic to mallard ducklings. The no-observed-effect-concentration was 1780 ppm a.i. The study is scientifically sound and meets the requirements for an avian dietary LC_{50} test.

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 mallard ducklings (Anas platyrhyncos) obtained from Whistling Wings, Hanover, Illinois. All birds were from the same hatch, pen-reared and phenotypically indistinguishable from wild birds. The birds used in this study were immature and could not be differentiated by sex. All test birds were acclimated to the caging and facilities for 8 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 vinyl coated wire mesh. Each pen's floor space measured approximately 62 cm X 92 cm. Ceiling height was approximately 25.5 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 average temperature in the brooding compartment of the pens was 32°C ± 2°C (SD). Average ambient room temperature for this study was 24°C ± 13°C (SD) with an average relative humidity of 46% ± 10% (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.

D. **Design:** Each treatment or control group contained ten ducklings. 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 three control groups. Throughout acclimation and testing all birds were fed a game bird ration formulated to Wildlife International Ltd.'s specifications. Water, from the town of Easton public water supply, on the Wildlife International Ltd. site, 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 LD_{50} value.

Therefore, an estimation of the LD_{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 any of the test concentrations (Table 2, attached). All birds were normal in appearance and behavior throughout the test period. When compared to the controls, there was a reduction in feed consumption and body weight gain at the 5620 ppm a.i. concentration for days 0-5 however, this group showed recovery during the observation period Days 6 to 8, when compared to controls" (Tables 3 and 4, attached).

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, 2 and 4 (attached).

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: "In conclusion, the mallard dietary LC_{50} value of Iprodione Technical for this study was determined to be greater than 5620 ppm a.i., the highest concentration tested. The no mortality level was 5620 ppm a.i. The no-observed-effect-level was 3160 ppm a.i. based on a reduction in body weight and a corresponding reduction in feed consumption at the 5620 ppm a.i. concentration during the exposure period (Days 0-5)".

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:

Average ambient room temperature for this study was somewhat low [24°C ± 13°C (SD)]. Guidelines state that the temperatures outside the brooder may range from 22-27°C.

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

B. **Statistical Analysis:** Since no birds died in the test, the LC_{50} cannot be calculated and is assumed by the reviewer to be greater than 5620 ppm a.i., the highest concentration tested.

C. **Discussion/Results:** No mortality occurred during the test. The LC_{50}, therefore, was greater than 5620 ppm (based on nominal concentrations). This value classifies Iprodione Technical as practically non-toxic to mallard ducklings. Treatment related effects on body weight and food consumption did occur, however, as discussed below.

The authors concluded that no treatment-related effects on body weight and food consumption occurred at 3160 ppm a.i. This conclusion was apparently based upon the fact that body weight and food consumption values at 3160 ppm a.i. were within the range of control values. However, values in one of the control groups were abnormally low. The body weight gain during days 1-5 in the lowest control group was 89 g (54% increase); food consumption during this period was 44 g/bird/day (Table 3, attached). These values are extremely low for 10-day old mallards. In order to determine whether treatment-related effects occurred, it is not sufficient to compare treatment group values merely with the range of control values; a determination must also be made regarding whether the control values are normal. In this case, the values in one control group, being abnormally low, should not be used to determine the concentrations in which groups treatment-related effects occurred. With this in mind, the reduced body weight gain at 3160 ppm a.i. (93 g, 60% increase) is considered to be treatment-related. Therefore, the NOEC is 1780 ppm a.i.

The lower range of the reported average ambient temperature is below the recommended range for LC_{50} studies. The registrant should ensure that environmental conditions are within the recommended ranges.

With minor deviations, the study followed recommended guidelines. The study is scientifically sound and

meets the requirements for an avian single-dose oral LD_{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.

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.

____ 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.

Shaughnessy No. _____ Chemical Name _____ Chemical Class _____ Page _____ of _____

Study/Species/Lab/ Accession	Chemical % a.i.	Results	Reviewer/ Date	Validation Status
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg (95% C.L.) Contr. Mort.(%)=		
Species	____	Slope= # Animals/Level= Age(Days)= Sex =	____	____
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L) Contr. Mort.(%)=		
Species	____	Slope= # Animals/Level= Age(Days)= Sex =	____	____
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 > 5620 ppm (95% C.L. —) Contr. Mort.(%) = 0	M. Rabbin 4/12/91	CORE
Species Mallard duck Anas platyrhyncos 96.2%		Slope= — # Animals/Level= 10 Age(Days)= 10 Sex = NA		
Lab Wildlife International		8-Day Dose Level ppm/(%Mortality) 5621 0 1. 1000 1 0 1. 1780 1 0 1. 3160 1 0 1. 5620 1 0		
Acc. 416041-04		Comments: NOEC = 1780 ppm a.i.		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab	____	8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
48-Hour LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Temperature =		
Lab	____	48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp__ (95% C.L.) Con. Mor(%)= Sol. Con. Mor.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		
96-Hour LC_{50}		LC50 = pp__ (95% C.L) Con. Mort.(%)= Sol. Con. Mort.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab	____	96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( )	____	____
Acc.		Comments:		