4-13-93 EEB files

MRID No. 000 ~~250~~-50066

DATA EVALUATION RECORD

1. **CHEMICAL:** Bayleton (Triadimefon).
Shaughnessey Number: Not available.

2. **TEST MATERIAL:** Bay Meb 6447; 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4 triazol-1-yl)-2-butanone; 93% purity; Bayer batch # 5030047; a white granular material with a distinct odor.

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

4. **CITATION:** Fink, R. 1977. Final report, eight-day dietary LC_{50} - bobwhite quail. Study performed by Wildlife International Ltd., Easton, Maryland. Laboratory study # 149-105. Submitted by Chemagro Agricultural Division, Mobay Chemical Corporation (Address not given). MRID No. ~~250-~~ 000 50066.

5. **REVIEWED BY:**

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

Signature: Michael L. Whitten
Date: 2/14/91 Dem 3-11-93

6. **APPROVED BY:**

Pim Kosalwat, Ph.D.
Senior Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: P. Kosalwat
Date: 2/14/91

Allen W. Vaughan 7.5.91

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

Signature:
Date: Henry T. Craven 4/13/93

7. **CONCLUSIONS:** The study is scientifically sound and fulfills the requirements for an avian dietary LC_{50} test. Under the conditions of this study, and based upon nominal concentrations, the dietary LC_{50} of Bayleton was 8392 ppm. This value classifies Bayleton as practically non-toxic to bobwhite chicks. The NOEC was 1000 ppm, based upon reduced body weight gain and reduced food consumption at all higher concentrations.

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 14-day old bobwhite quail (Colinus virginianus) hatched from eggs obtained from Wildlife International's own production flock.

B. **Test System:** The pen facilities in which the birds were housed during the study, and the photoperiod to which the birds were exposed, were not described. The brooder temperature was maintained at 99.0°F.

C. **Dosage:** 8-day dietary LC_{50} test. Nominal concentrations were 464, 1000, 2150, 4640, and 10,000 parts per million (ppm). "For the purposes of diet preparation, the experimental material was assumed to be 100 percent active material."

D. **Design:** Groups of ten birds were randomly assigned, without regard to sex, to each of five control groups, five laboratory standard (dieldrin) groups, and five treatment groups. All birds were fed a commercial game bird starter ration. Food and water were supplied ad libitum throughout the test.

The test substance and dieldrin were dissolved in corn oil and added to the basal feed. The concentration of the solutions in the treatment and dieldrin diets was 2% (by weight). The birds were fed the appropriate dietary concentrations for five days, and then given untreated food for three days. The control birds received the basal diet throughout the study.

Mortality and symptoms of toxicity were recorded daily throughout the study. Birds were weighed by pen at initiation and termination of the study. Food consumption was recorded by pen during the five-day exposure period.

E. **Statistics:** Mortality in the dieldrin group was analyzed by the probit method of Litchfield and Wilcoxon. Due to the mortality pattern in the experimental material treatment group, the LC_{50} was merely estimated.

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12. **REPORTED RESULTS:** There was no mortality in the control groups, and the birds appeared normal throughout the study. "However, there was some evidence of toe-picking in Control group 3, which appears to have affected weight gain" (Table 1, attached).

There was 70% mortality at 10,000 ppm; no birds died in any other treatment groups (Table 2, attached).

Beginning on day 3, birds in the 4640- and 10,000-ppm groups displayed a ruffled appearance, wing droop, reduced activity, and reduced reaction to external stimuli. The birds that died displayed loss of coordination, lower limb weakness, loss of righting reflex, and lower limb rigidity.

The report provided results on mortality and symptoms of toxicity in the dieldrin group.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The author presented no conclusions, but included the following statement as a summary: "The acute LC_{50} of Bayleton Technical in the Bobwhite quail is estimated to be greater than 4640 ppm."

The report included no statements regarding quality assurance. One quality assurance measure was the inclusion of a laboratory standard treatment, commonly known as a positive, or reference control.

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

A. **Test Procedure:** This study was conducted in 1977, before the current SEP, ASTM, and Subdivision E Guidelines were published. However, the test procedures were in accordance with current guidelines except for the following deviations:

The LC_{50} was estimated to be greater than 4640 ppm; Subdivision E guidelines state that, in lieu of a statistically calculated LC_{50}, the data should show that the LC_{50} is greater than 5000 ppm.

The average ambient relative humidity was not reported.

A full description of the test facilities (construction material, dimensions) was not reported.

The photoperiod was not reported.

The concentration of test substance in the diet was not confirmed by chemical analysis. This is recommended, but not required.

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

The vehicle (corn oil) was not added to untreated diets. The control birds received only the basal diet throughout the study.

Body weights were measured by group. Individual body weights should have been measured.

Food consumption was recorded at the end of test day 5. Food consumption should also have been recorded at the end of the 3-day observation period.

B. **Statistical Analysis:** The LC_{50} value calculated (attached) by the binomial test using EPA's Toxanal computer program was 8392 ppm, with 95% confidence limits of 0 to +∞.

C. **Discussion/Results:** In order to provide statistically reliable results, a toxicity test should produce at least three partial kills (i.e., mortality between 0 and 100%). Apparently, range finding tests were not employed to choose the treatment concentrations used in this test. Mortality was limited to the highest concentration group. Therefore, neither the probit nor moving average methods could calculate an LC_{50}, and the 95% confidence interval (0 to +∞) obtained by the binomial test using EPA's Toxanal computer program is infinitely large. The observed mortality and treatment concentrations would seem to indicate a more practical confidence interval of 4640 to 10,000 ppm. The LC_{50} value derived using the Toxanal program (8392 ppm) classifies the test material as practically non-toxic to bobwhite chicks. Although this value is not statistically reliable, any test material with an LC_{50} value > 5000 ppm is considered to be practically non-toxic. Therefore, this LC_{50} value, although imprecise, is acceptable.

Other discrepancies noted in Section 14.A (above) probably did not affect the validity of the study.

Since historical dieldrin values were not given, the reviewer could not assess the results reported from the laboratory standard (dieldrin) group.

The author did not discuss possible treatment effects on food consumption or body weight gain, and the report did not mention an NOEC. The author did state that weight gain in control group 3 appeared to have been affected by "toe-picking" in that group. Table 1 (attached) shows what appears to be a trend of decreased body weight gain with increased concentrations of test material. Food consumption also appears to have been affected at concentrations $\geq$ 2150 ppm. The NOEC, therefore, was 1000 ppm, based upon reduced body weight gain and reduced food consumption at all higher concentrations.

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

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** The study followed recommended guidelines except for minor deviations.

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

15. **COMPLETION OF ONE-LINER:** Yes; February 5, 1991.

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RIN 5710-93

TRIADIMEFON EFB REVIEW

Page_____ is not included in this copy.

Pages 6 through 7 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.

✓ FIFRA registration data.

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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.

Available

Chemical Name: Bayleton (Triadimefon) Chemical Class: ____ Page 1 of 1

/ Chemical % a.i.	Results	Reviewer/ Date	Validatic Status
se. Oral LD_{50} ____	LD50 = mg/kg (95% C.L.) Contr. Mort.(%)= Slope= # Animals/Level= Age(Days)= Sex = 14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
le Dose Oral LD_{50} ____	LD50 = mg/kg. (95% C.L.) Contr. Mort.(%)= Slope= # Animals/Level= Age(Days)= Sex = 14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
8-Day Dietary LC_{50} Bobwhite Species (Colinus virginianus) 93% Lab Wildlife International Acc MRID# 000.50066	LC50 = 8392 ppm (95% C.L. 0 to too) Contr. Mort.(%) = 0 Slope = N/A (Binomial test) # Animals/Level = 10 Age(Days) = 14 Sex = unknown 8-Day Dose Level ppm*/(%Mortality) 464 (0), 1000 (0), 2150 (0), 4640 (0), 10,000 (70) Comments: * Nominal Concentrations NOEC = 1000 ppm	M.L. Whitten 2-5-91 CORE	____
8-Day Dietary LC_{50} Species Lab Acc. ____	LC50 = ppm (95% C.L.) Contr. Mort.(%)= Slope= # Animals/Level= Age(Days)= Sex = 8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
48-Hour LC_{50} Species Lab Acc. ____	LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)= Slope= # Animals/Level= Temperature = 48-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
96-Hour LC_{50} Species Lab Acc. ____	LC50 = pp__ (95% C.L.) Con. Mor(%)= Sol. Con. Mor.(%)= Slope= # Animals/Level= Temp.= 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____
96-Hour LC_{50} Species Lab Acc. ____	LC50 = pp__ (95% C.L.) Con. Mort.(%)= Sol. Con. Mort.(%)= Slope= # Animals/Level= Temp.= 96-Hour Dose Level pp /(%Mortality) ( ), ( ), ( ), ( ), ( ) Comments:	____	____

WHITTEN BAYLETON COLINUS VIRGINIANUS 1-31-91

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
10000	10	7	70	17.1875
4640	10	0	0	9.765625E-02
2150	10	0	0	9.765625E-02
1000	10	0	0	9.765625E-02
464	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 8392.17

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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