5-5-86

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

To: Henry Jacoby PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767)

Thru: Henry T. Craven
Section Head IV
Ecological Effects Branch/HED (TS-769)

Michael Slimak
Branch Chief
Ecological Effects Branch/HED (TS-769)

Subject: Data Evaluation and Review of Single Dose Avian Acute Oral LD_{50}.

EEB has recieved and reviewed the following study:

1. Wildlife International, Ltd. 1982. Acute Oral LD_{50} - Bobwhite Quail TELONE II Soil Fumigant Final Report. Submitted by Dow Chemical Company, Midland, Michigan. EPA Reg. No. 464-511. Assigned under EPA Accession Number 261149.

   The study does fulfill the guideline requirement for avian acute oral LD_{50}. The study is classified as CORE guideline.

John Noles, Biologist
Ecological Effects Branch

John Noles
5/5/86

029001
SHAUGHNESSEY NUMBER

11
REVIEW NO.

EEB REVIEW

DATE: IN 2-11-86 OUT

FILE OR REG. NO. 464-511

PETITION OR EXP. NO.

DATE OR SUBMISSION 1-22-86

DATE RECIEVED BY HED 2-7-86

RD REQUESTED COMPLETION DATE 5-28-86

EEB ESTIMATED COMPLETION DATE 5-21-86

RD ACTION CODE/TYPE OF REVIEW 400

TYPE PRODUCT(S): I, D, H, F, N, R, S Fumigant

DATA ACCESSION NO(S). 261149

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) TELONE II

COMPANY NAME Dow Chemical U.S.A.

SUBMISSION PURPOSE Submission of avian acute oral LD_{50} study for review

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
029001	1,3-Dichlorpropene	94%

DATA EVALUATION RECORD

1. Chemical: 1,3-Dichloropropene

2. Test material: 92.0 % a.i.

3. Study Type: Avian Single-Dose Oral LD_{50}

   Species tested: Colinus virginanus

4. Study Identification: Wildlife International LTD. 1982 Acute Oral LD_{50} - Bobwhite Quail Telone II Soil Fumigant Final Report. Prepared by by Wildlife International LTD. St. Michaels, Maryland. Submitted by Dow Chemical Company, Midland, Michigan. EPA Reg. No. 464-511. EPA Accession # 261149. = MRID# 00118938 =

5. Review by:

   John Noles
   Biologist
   Ecological Effects Branch/HED

   Signature: John Noles 10-16-
   Date: 5/5/86

6. Approved by:

   Harry Craven
   Section Head IV
   Ecological Effects Branch/HED

   Signature: Henry T. Craven
   Date: 5/6/86

7. Conclusions:

   This study is scientifically sound and meets guideline requi rements. The avian acute oral LD_{50} indciates that 92% 1,3-Dichloropropene is moderately toxic to the bobwhite quail, Colinus virginanus.

8. Recommendations:

   N/A

9. Background: The study was voluntarily submitted by the company to update the files on TELONE II.

10. Discussion of Individual Test:

    N/A

11. Materials and Methods:

    A. Test animals: Bobwhite Quail, Colinus virginanus from commercial stock, Wildlife International, LTD.,

St. Michaels, Maryland; age at initiation of study - seven (7) months; test system: grouped by treatment indoors in Beacon battery brooders (model no. B735) measuring 72 x 90 x 24 cm high; temperture 18^0 - 24^0C; Photoperiod 14 hours light/10 hours dark; fresh air exchange clocked at 6 hour intervals; average weight at beginning and end of study - 201.8 g and 209.3 g, respectively.

B. Dose: Variable dosages with corn oil solvent delivery system; 0 mg/kg (control group), 68.1 mg/kg, 100.0 mg/kg, 147 mg/kg, 215 mg/kg, and 316 mg/kg.

C. Design: 10 birds per pen/treatment group; 1 pen for control group and 5 pens for each experimental dosage group.

D. Statistics: Probit, moving average, and binomial methods used for the estimation of LD_{50} and its 95% confidence limits for data set [Finey (1971), Stephan (1977), Thompson (1947), and Weil (1952).

12. Reported Results: The study found the acute oral LD_{50} was estimated to be 152 mg/kg for the 92% a.i. level with confidence limits 134 mg/kg to 172 mg/kg. The summary of the study is as follows:

0 mg/kg (Control group) - Behavior: normal during study.
Mortalities: 0.
Food consumption: 30g (day 1-7)/34g (day 8-14) per day.
Weight: 199g (day 1), 216g (day 3), 207 (day 7), 216 (day 14).

68 mg/kg - Behavior: some huddling and hyperexcitability after dosing. Normalcy after day 2 until completion of study.
Mortalities: 0.
Food consumption: 27g (days 1-7)/31g (days 8-14).
Weight: 200g (day 1), 206g (day 3), 204g (day 7), 218g (day 14).

100 mg/kg - Behavior: some huddling, lethargy, and ruffled appearances until day 7, execpt for one bird. Asymptomatic until day 7 when some birds displayed lethargy, ruffled appearances, reduced reaction, and lower limb weakness. Normalcy returned after day 12 until completion of study.
Mortalities: 0.
Food consumption: 19g (days 1-7)/32g (days 8-14).
Weight: 203g (day 1), 199g (day 3), 193g (day 7), 214g (day 14).

147 mg/kg - Behavior: variable, regurgitation after dosing, lethargy, ruffled appearances, and lower limb weakness. Normalcy returned after day 8 until completion of study.
Mortalities: Total = 4 (2 on day 2, 1 on day 3, and 1 on day 4).
Food consumption: 18g (days 1-7)/37g (days 8-14).
Weight: 207g (day 1), 189g (day 3), 182g (day 7), 196g (day 14).

215 mg/kg - Behavior: variable, some dosage regurgitation, rapid respiration, reduced reaction, lethargy, loss of coordination, and lower limb weakness.
Mortalities: Total = 10 (8 on day 2, 1 on day 3, and 1 on day 5).
Food consumption: 3g (days 1-7).
Weight: 201g (day 1), 156g (day 3).

316 mg/kg - Behavior: variable, some dosage regurgitation, lethargy, and reduced reaction.
Mortalities: Total = 10 (10 on day 2).
Food consumption: 2g (days 1-7).
Weight: 198g (day 1).

13. Study author(s) Conclusions/QA Measures:

LD_{50} = 152 mg/kg, confidence limits 134 mg/kg to 172 mg/kg.

Wildlife International, Ltd. certifies that the study was conducted according to their own developed standard operating procedures and in accordance with the "Good Laboratory Practices" as described in the Federal Register Vol. 43, No. 247 - Friday, December 22, 1978. Inspection during the operational phase was conducted to ensure compliance with the above. The data report (Project No. 103-207) was presented to Dow Chemical Company by Wildlife International, Ltd. with the original copy placed in Wildlife International, LTD, files. A duplicate report copy was submitted to the Agency by Dow Chemical Company.

14. Reviewer's Discussion and Interpretation of the Study:

A. Test procedures: The procedures were in accordance with the protocols recommended by the guidelines. It as noted that the test material was 92% a.i. and the applicable product label claim a 94% a.i. level. The small difference does not present any problems because the levels are indicative of technical grades.

B. Statistical Analysis: The data submitted provided a detailed statistical analysis of the data derived from the study. The probit, moving average, and the binomial test methods [Stephan (1977), Thompson (1947), and Weil (1952)] were utilized in the data analysis. As previously indicated, the LD_{50} for the submitted study was 152 mg/kg. EEB's "Toxanal" program was used, separately, to analyze the data. The binomial tests shows that 100 mg/kg and 215 mg/kg can be used as statistically sound conservative 95% confidence limits, because the actual confidence level associated with these limits is greater than 95%. An approximate LC_{50} for this set of data is 154.261 mg/kg. 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.

C. Discussion/Results: The single dose avian oral LD_{50} is estimated to be 152 mg/kg for the 92% test material with confidence limits of 134 mg/kg to 172 mg/kg. Therefore, the chemical is moderately toxic to bobwhite quail.

D. Adequacy of Study:

1. Classification: Core

2. Rationale: Followed guideline; TGAI test material.

3. Repair: N/A

15. Completion of One-Liner for Study:

One liner form completed 4/28/86 .

16. CBI Appendix:

N/A.

(TDR:3B) DATA EVALUATION RECORD PAGE 1 OF

CASE GS0328 TELONE PM PM# 05/18/84

CHEM 029001 1,3-Dichloropropene

BRANCH EEB DISC 40 TOPIC 05050542

FORMULATION 90 = FORMULATION NOT IDENTIFIED

FICHE/MASTER ID 00118938 CONTENT CAT 01

Fink, P.; Beavers, J.; Joiner, G.; et al. (1982) Acute Oral LD50--Bobwhite Quail: Telone II Soil Fumigant: Project No. 103-207. Final rept. (Unpublished study received Sep 22, 1982 under 464-EX-63; prepared by Wildlife International Ltd., submitted by Dow Chemical U.S.A., Midland, MI; CDL:248415-C) = 261149 D 10-6-84

SUBST. CLASS = S.

DIRECT RVW TIME = (MH) START-DATE END DATE

REVIEWED BY: RICHARD M. LEE
TITLE: ENTOMOLOGIST
ORG: EEB/HED
LOC/TEL:

SIGNATURE: [signature] DATE: 8/5/85

APPROVED BY:
TITLE:
ORG:
LOC/TEL:

SIGNATURE: [signature] DATE: 8/[illegible]/85

Data Evaluation Record

1. Chemical: Telone II (Dichloropropene)

2. Formulation: Formulated product 92.0% a.i.

3. Citation: Acute oral LD_{50} - Bobwhite quail Telone® II soil fumigant (1982), Wildlife International Ltd. submitted to Dow Chemical Co. (ES-512, Acc. No. 248415).

4. Reviewed by: Richard M. Lee
Entomologist
EEB/HED

5. Date Reviewed: 12/10/82

6. Test Type: Avian acute oral LD_{50}

A. Test Species: Bobwhite quail Colinus virginianus

7. Reported Results: The acute oral LD_{50} of Telone II for bobwhite quail was 152 mg/kg with 95% C.I. of 134-172 mg/kg.

8. Reviewer's Conclusions: The study is scientifically sound and with an LD_{50} of 152 mg/kg dichloropropene is moderately toxic to bobwhite quail. The study does fulfill the guideline requirement for an avian acute oral LD_{50}.

Material/Methods

Test Procedure

General procedures followed EPA protocol. Bobwhite quails of seven months old were quarantined and acclimated for 15 days with 16 hours fast prior to the initiation of the study. Five males and five female birds were randomly assigned to each treatment. Five doses of Telone, 68.1, 100.0, 147.0, 215.0, and 316.0 mg/kg with a vehicle (corn oil) control were tested. Observations for signs of toxicity and mortality were recorded daily. Body weight measurements were also recorded on day 1, 3, 7, and 14. Food consumption for each pen was measured for test-days 1-7 and 8-14 inclusively and were used to calculate an interval mean-daily per bird feed consumption. The study was terminated on day 14.

Statistical Analysis

The LD_{50} and its 95% C.I. were calculated using a moving average method.

Discussion/Results

The mix-sexed A.O. LD_{50} was 152 mg/kg with a 95% C.I. of 134-172 mg/kg. All mortality occurred during first seven days of the experiment and no mortalities observed in control and two low-dosage (i.e. 68.1 and 100.0 mg/kg) groups. At lower dosage levels (i.e. 68.1 & 100 mg/kg), some huddling, hyperexcitability, and ruffled appearance were observed on day 1 but soon recovered. At the 147 mg/kg dosage level, some regurgitation, lethargy, rufflea appearance, and lower limb weakness were observed but all surviving birds appeared normal from day 8 on. There was a dose related reduction in feed consumption for the first seven day of the study, and a dose related loss of body weight of surviving birds at the 100 mg/kg through 215 mg/kg dosage levels for the first three days of the study.

Reviewer's Conclusion

A. Test Procedure

The procedures used generally followed EPA's established guidelines and are scientifically sound.

B. Statistical Analysis

The statistical procedure used are appropriate

C. Discussion/Results

The A.O. LD_{50} for bobwhite quail was estimated as 152 mg/kg. However actual LD_{50} value may be slightly lower, because older (and more resistant quails (7 months old) were used.

D. Conclusion

1. Category: Core
2. Rationale: N/A
3. Repairability: N/A