060101

STUDY VALIDATION

DATA REVIEW NO: ES-C-2

TEST: Avian Acute Oral LD_{50}

SPECIES: Bobwhite quail

RESULTS: Avian Acute oral LD_{50} = 4640 mg/kg

Fourteen day old birds were tested on a period of 8 days. Five dosage levels were used 215, 464, 1000, 2150 and 4640 mg/kg. Birds at the 2150 and 4640 dosage level showed symptoms of toxicity. The thiabendazole treated group as a whole showed a reduction in body weight gain over the 8 day test period. No mortalities were observed during the test period with the exception of the dieldrin controls

CHEMICAL: Thiabendazole technical, 98.5% a.i.

TITLE: Final Report Acute Oral LD_{50} - Bobwhite Quail Project No. 105-119, July 28, 1977

ACCESSION NO.: 232421 Reg. No. 618-88

STUDY DATE: July 28, 1977

RESEARCHER: Robert Fink - Wildlife International Ltd.

REGISTRANT: Merck Chemical Division

VALIDATION CATEGORY: ~~Supplemental~~ CORE (ATTACHMENT)

CATEGORY Repairability: ~~No~~. The study used 14 day old birds instead of 16 week old birds and was conducted for only 8 days instead of 14 days. Since the treated group (especially the three highest dosages) showed a statistically significant reduction in body weight gain, the study should have run to its full term. (14 days).

ES-C-2 Signif. diff.

Betw weigh loss

Treatmt gp.

20.
17.
14.
14.
12.

5.4
7.84

Neg controls.

20.
19.
20.
22.
21.

21.6
2.24

15.25396825 F
1. Num DF.
8. Den. DF.

50.4 Error SS.
96.1 Treat SS.
146.5 Total SS

no Sig. diff. betwn Neg. contrl + treatmt gp.

30.
29.
28.
31.
28.

29.4
1.04

29.
29.
31.
28.
29.

28.8
1.56

0.4 F Stat.
1. df
8. df.

18.
0.9
18.9

2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: 5/10/79

SUBJECT: Registration of Mertect LSP (Thiabendazole)-618 IU

FROM: Arthur D. Riel, Biologist, EEB
Hazard Evaluation Division

TO: Product Manager 21 (Wilson)

Thru: Douglas Urban, Acting Section Head (#1), ESS-EEB
Hazard Evaluation Division

Thru: Clayton Bushong, Chief, EEB
Hazard Evaluation Division

Letter from registrant, Merck and Co. (R.R. Buck) dated 1-17-79 regarding registration of product (Mertect LSP) for wheat seed treatment is hereby acknowledged.

Area of contention involves an avian acute oral LD50 test conducted on 7-28-77 by Robert Fink of Wildlife International for Merck and Co. using technical thiabendazole. Several reviewers placed the test in a supplementary category because present protocol requirements were not followed i.e. use of 16-week-old birds and test duration time of 14 days. Fink used 14 day-old birds during an 8-day test.

A memo by Akerman (3-13-78) accepts studies using 14-day old birds during an interim period of 2-10-76 to 3-13-78. Disucssion with Akerman also suggests acceptance of the eight day test duration during this interim.

In this instance, the Environmental Safety Section will therefore accept this protocol and validate the study as core for registration purposes.

Mr. Buck also referred to the avian reproductive studies requested previously and stated that they were submitted on 11-16-78. Due to our backlog, these studies have not been reviewed yet but will be handled through standard procedure when reached.

Arthur D Riel 5-10-79
Arthur D. Riel, Biologist
Env. Safety Section #1, EEB
Hazard Evaluation Division

Clayton Bushong 5/10/79
Clayton Bushong, Chief
Ecological Effects Branch
Hazard Evaluation Division

Douglas Urban 5/10/79
Douglas Urban, Acting Head
Env. Safety Section #1, EEB
Hazard Evaluation Division

3

A FORM 1320-6 (REV. 3-76)

060101

STUDY VALIDATION*

DATA REVIEW No: ES-C-3

TEST: Avian Acute Oral LD_{50}- Mallard Duck

SPECIES: Mallard Duck

RESULTS: Acute Oral LD_{50}= >4640 mg/kg

Study deviated from accepted protocol by using 14 day old birds instead of 16 week old birds and by conducting the test over an 8 day period instead of 14 days. Five dosage levels (215, 464, 1000, 2150 and 4640 mg/kg) were used. Within 4 hours after dosing, birds at the highest level exhibited signs of lethargy, lower limb weakness, and loss of coordination, with one duck showing depression and reduced reaction to stimuli. By day 6 surviving birds were asymptomatic. Two deaths occurred one on day 4 at the 215 mg/kg level and 1 on day 2 at the 4640 mg/kg level. The treated group as a whole showed a reduction in body weight gain over the 8 day test period.

CHEMICAL: Thiabendazole Technical, 98.5% a.i.

TITLE: Final Report - Acute Oral LD_{50}- Mallard Duck
Project No. 105-118.

ACCESSION NO.: 232421 Registration No. 618-88

STUDY DATE: October 4, 1977

RESEARCHER: Robert Fink, Wildlife International Ltd.

REGISTRANT: Merck Chemical Division

VALIDATION CATEGORY: Supplemental

CATEGORY REPAIRABILITY: No. The study used 14 day old birds instead of 16 week old birds and was conducted for 8 days instead of 14 days. Since the treated group showed a statistically significant reduction in body weight gain, the study should have run to full term (14 days) to see if other deaths or problems occurred.

---

* (From review of 5/12/78 by J. Tice)