

## STUDY VALIDATION

DATA REVIEW NO: ES-C-3

TEST: Avian Acute Oral LD<sub>50</sub> - Mallard Duck

SPECIES: Mallard Duck

RESULTS: Acute oral LD<sub>50</sub> = > 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, ~~on~~ 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<sub>50</sub> - Mallard Duck  
Project No. 105-118,ACCESSION NO: 232421 Reg. No. 618-88

STUDY DATE: October 4, 1977

RESEARCHER: Robert Fink, Wildlife International Ltd.

REGISTRANT: Merck Chemical Division

VALIDATION CATEGORY: ~~Supplemental~~ CORE (SEE 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 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.

Body weight gain

ES-C-3

98.  
105.  
96.  
94.  
88.

196.2  
30.56

120.  
124.  
121.  
142.  
145.

230.4  
117.04

$P < .001$

31.69751098

1.  
6.

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F statistic

438.  
2924.1  
3662.1

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. Discussion 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  
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