5-4-93

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Acute Fish Toxicity Data Requirement for Dow Corning 5700 Antimicrobial Agent (107401).

Acute fish toxicity data submitted to the Agency by Industrial Bio-Test Laboratories, INC. to support an indoor microbiocide use registration was categorized as "Invalid". The Ecological Effects Branch does not accept any toxicity test data from the above laboratory. The acute fish toxicity data requirement has not been satisfied.

Tom A. Bailey
5/4/93

Page_____ is not included in this copy.

Pages 2 through 16 are not included.

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____ Description of the product manufacturing process.

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____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

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DATA EVALUATION RECORD

1. **CHEMICAL:** Trimethoxysilyl (PDOA).
Shaughnessey No. ~~169160~~. 107401

2. **TEST MATERIAL:** Dow Corning 5700 antimicrobial agent (TX-81-9411-03); 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; EPA Reg. No. 34292-1; Lot No. TX-81-9411-03; EPA Est. No. 34292-M1; 42% purity; a light amber liquid.

3. **STUDY TYPE:** 71-2. Avian Dietary LC_{50} Test. Species Tested: Mallard duck (*Anas platyrhynchos*).

4. **CITATION:** Beavers, J.B. and R. Fink. 1981. Eight-day Dietary LC_{50} - Mallard Duck. Project No. 103-205. Performed by Wildlife International Ltd., St. Michaels, MD. Submitted by Dow Corning Corporation, Midland, MI. EPA MRID No. 403852-17.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Mark A. Mossler
Date: 4/20/93

6. **APPROVED BY:**

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

Signature: Michael L. Whitten
Date: 4-20-93

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

Signature: Henry T. Craven 5/3/93
Date: Tom A. Bailey 5/4/93

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for an avian dietary LC_{50} toxicity test. The birds were older than the recommended age. The LC_{50} of TX-81-9411-03 was >5620 ppm ai, which classifies this compound as practically non-toxic to the mallard duck. The NOEC was 562 ppm ai.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

5hrs

7

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Mallard ducklings (*Anas platyrhynchos*) were hatched from eggs obtained from an in-house production flock. The birds were placed in brooders which maintained the temperature at 38°C for the first seven days after hatching, and 24°C thereafter. The birds were 14 days of age at test initiation.

B. **Test System:** The birds were housed in brooding pens which measured 72 x 90 x 24 cm. During the test, a 14-hour photoperiod was used.

The test diets were prepared by mixing the test substance in corn oil and blending into the diet. The concentration of corn oil in the treated diet was 2%.

The birds were offered water and feed *ad libitum* throughout the study. A list of the ingredients in the feed was given in the report.

C. **Dosage:** Eight-day acute dietary LC_{50} test. Dosage levels selected for the study were 562, 1000, 1780, 3160, and 5620 ppm active ingredient (ai). The dose levels were corrected for the percent active ingredient of the test material (42%).

D. **Design:** Ten ducklings per test level and in each of five controls were randomly assigned to pens. The birds were fed treated diet for 5 days and untreated diet for 3 days. Signs of toxicity and mortality were assessed daily. Body weights by group were measured at initiation and day 8 (termination) of the test. Average feed consumption was determined by group for days 0-5 (the exposure period). 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, this is an estimate due to wastage by the birds.

E. **Statistics:** The LC_{50} of the laboratory standard was estimated by probit analysis using the mortality data.

12. **REPORTED RESULTS:** No mortality or abnormal effects were observed in the control or treatment groups during the study with the exception of a few birds at the 1000 ppm ai level which were noted as lethargic on day 4 of the study.

A slight reduction in feed consumption and body weight gain was noted at the three highest treatment levels (attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The acute LC_{50} of TX-81-9411-03 in the mallard duck is estimated to be greater than 5620 ppm ai.

The LC_{50} of a concurrent group of birds exposed to dieldrin was 122 ppm.

A Quality Assurance statement indicating conformance to Good Laboratory Practices (CFR Vol. 43, No. 247, 1978) was included in the report.

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

A. **Test Procedure:** The test procedures were in accordance with Subdivision E, ASTM, and SEP guidelines with the following exceptions:

The test birds were 14 days of age, rather than the recommended 5 days of age.

Group weights were used during the study. Individual body weights of the birds are recommended for monitoring weight gain or loss.

Food consumption was not monitored during the 3-day recovery period.

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

A description of test pen construction was not included in the report.

Corn oil was not added to the control diet.

Analytical verification of test concentrations was not conducted.

B. **Statistical Analysis:** Since a dose response was not evident by the end of the testing period, an LC_{50} value and 95% confidence limits could not be obtained. Upon review of the data, the LC_{50} appears to be greater than 5620 ppm ai.

C. **Discussion/Results:** Review of the feed consumption and body weight data indicated that the no-observed-effect

concentration (NOEC) was 562 ppm ai, based on a reduction in feed consumption during the exposure period in the four highest treatment groups. However, the birds were 14 days of age at the initiation of the study. It is important to realize that 50% of ten-day old mallards can survive for 5 days without eating. Feed consumption values demonstrated that less diet was eaten by the birds in the four highest concentration groups. The lack of mortality or other effects may have resulted from partial avoidance of the test chemical rather than from ingestion of a "non-toxic" test material. Therefore, mortality may have been witnessed for birds of a younger age.

This study is scientifically sound but does not meet the guideline requirements for an avian dietary LC_{50} toxicity test. The LC_{50} of TX-81-9411-03 for mallard ducklings was >5620 ppm ai. Therefore, this compound is classified as practically non-toxic to the mallard duck. The NOEC was 562 ppm ai, based on a reduction in feed consumption and body weight gain.

D. **Adequacy of the Study:**

(1) **Classification:** Supplemental.

(2) **Rationale:** The birds were older (and potentially more resistant to the test chemical) than the recommended age.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER:** Yes, 3-28-93.

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Ecological Effects Branch One-Liner Data Entry Form

Chemical Trimethoxysilyl (PHOA) **Shaughnessy No.** 169160 **Pesticide Use** Antimicrobial agent

AVIAN ORAL TOX SPECIES (AGE)	% AI	LD_{50} (95%CL)	SLOPE	NOEL	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1.								
2.								
3.								
4.								
5.								
AVIAN DIETARY SPECIES (AGE)	**% AI**	**LC_{50} (95%CL)**	**SLOPE**	**NOEL**	**STUDY/REVIEW DATES**	**MRID/ CATEGORY**	**LAB**	**RC**
1. Anas platyrhynchos - 14 days	42	>5620 ppm ai (NA*)	NA*	562 ppm ai	1981/1993	403852-17 Supplemental	WIL	NM
2.								
3.								
4.								
5.								

COMMENTS: * - not Applicable

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DATA EVALUATION RECORD

1. **CHEMICAL:** Trimethoxysilyl (PDOA).
Shaughnessey No. ~~169160.~~ 107401

2. **TEST MATERIAL:** Dow Corning 5700 antimicrobial agent (TX-81-9411-03); 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; EPA Reg. No. 34292-1; Lot No. TX-81-9411-03; EPA Est. No. 34292-M1; 42% purity; a light amber liquid.

3. **STUDY TYPE:** 71-1A. Avian Single Dose Oral LD_{50} Test.
Species Tested: Mallard duck (*Anas platyrhynchos*).

4. **CITATION:** Beavers, J. and R. Fink. 1981. Acute Oral LD_{50}-Mallard Duck. Project No. 103-206. Performed by Wildlife International Ltd., St Michaels, MD. Submitted by The Dow Corning Company, Midland, MI. EPA MRID No. 403852-18.

5. **REVIEWED BY:**

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Date: 4-20-93

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

Signature: Henry T. Craven
Date: 5/3/93

Tom C. Bailey 5/4/93

7. **CONCLUSIONS:** This study is ~~not~~ scientifically sound ~~and~~ does not meet the requirements for an acute oral toxicity test. The ducks in the highest dosage group regurgitated the dosage. Under the conditions of the test, the LD_{50} for ducks dosed with TX-81-9411-03 was greater than ~~2510~~ 1590 mg ai/kg. The NOEL could not be determined.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

5.5 MS

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10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Animals:** The birds used in the study (Anas platyrhynchos) were hatched from eggs obtained from an in-house flock. They were acclimated to the laboratory for two weeks prior to testing. Except for a 15-hour fasting period immediately prior to dosing, water and a game bird ration were offered ad libitum during acclimation and testing. No antibiotics were administered during the test. The birds were 24 weeks of age at test initiation.

B. **Test System:** All birds were housed indoors in pens measuring 72 x 90 x 33 cm. Fluorescent lights provided 14 hours of illumination per day. The temperature was maintained at 18-24°C and the relative humidity was 30-80%.

C. **Dosage:** Fourteen-day single dose oral LD_{50} test. Five nominal dosages [398, 631, 1000, 1590, and 2510 mg active ingredient (ai)/kg of body weight] and a diluent (distilled water) control were used in the test. The dosages were corrected for the percent active ingredient of the test substance (42%).

D. **Design:** Groups of ten birds (five males and five females) were randomly assigned to each treatment and control group.

The test substance was dispersed in distilled water and intubated directly into the crop of each bird using a stainless steel catheter. Each bird was individually weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. The control birds received a corresponding volume of distilled water only. Each bird received a constant dosage volume per kilogram of body weight.

All birds were observed once a day during testing for mortality and signs of toxicity. The birds were individually weighed at test initiation and by group on days 3, 7, and 14. Group food consumption was determined for days 1-7 and 8-14 by measuring the change in feed presented to the birds over a period of time. However, this is an estimate due to wastage by the birds.

E. **Statistics:** The LD_{50} was determined by visual inspection of the data due to the pattern of mortality in this study.

12. **REPORTED RESULTS:** There was no mortality of the control birds. The birds in the control group were normal in appearance and behavior.

There was no mortality or signs of toxicity in the three lowest dosage groups. Ten percent mortality was observed in the 1590 mg ai/kg group and 0% mortality was witnessed in the highest dosage group.

In the 1590 mg ai/kg group, some salivation and rapid respiration were observed after dosing, and a few birds exhibited lethargy during the remainder of day 1. All birds were normal by day 2. The female found dead on day 5 had not demonstrated signs of toxicity prior to death.

In the 2510 mg ai/kg group, salivation and regurgitation were observed after dosing, and birds exhibited signs of toxicity from within one hour after dosing throughout day 2. By day 3, all birds were normal. Signs of toxicity included lethargy, reduced reaction to external stimuli, loss of coordination, and lower limb weakness.

There was a reduction in body weight in the four highest treatment groups in comparison to the control for the test period (attached). Reduced feed consumption was also noted for all groups during the study.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The acute oral LD_{50} value for mallard ducks exposed to TX-81-9411-03 was determined to be greater than 2510 mg ai/kg.

A Quality Assurance statement was included in the report indicating compliance with Good Laboratory Practice regulations set forth by the U.S. EPA (CFR Vol. 43, No. 247, 1978).

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

A. **Test Procedure:** The test procedures were in accordance with Subdivision E and SEP guidelines with the following exceptions:

It was not stated if the birds were from the same hatch.

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

Group body weights, rather than individual body weights, were taken at the end of the test.

B. **Statistical Analysis:** Upon review of the body weight and feed consumption data, the reviewer determined that the no-observed-effect level (NOEL) was not reached.

C. **Discussion/Results:** Because regurgitation occurred in the highest dosage group, the results from this test are not valid. Since one bird died at the 1590 mg ai/kg level, it is plausible that increased mortality could have occurred at the next higher level if the doses were not rejected. Perhaps administration of the test substance by gelatin capsule would alleviate this problem.

This study is scientifically sound but does not meet the requirements for an acute oral toxicity test.

D. **Adequacy of the Study:**

(1) **Classification:** Supplemental.

(2) **Rationale:** The ducks in the highest dosage group regurgitated the dosage.

(3) **Repairability:** No.

15. **COMPLETION OF ONE-LINER:** Yes, 3-28-93.

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Chemical Trimethoxysilil (000A) **Shaughnessy No.** 169160 **Pesticide Use** Antimicrobial Agent

AVIAN ORAL TOX SPECIES (AGE)	% AI	LD_{50} (95%CL)	SLOPE	NOEL	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1. Anas platyrhynchos (24 weeks)	4/2	>2510 mg ai/kg (NA*)	NA*	CNO**	1981/1993	40385218 Invalid	WIL	MM
2.								
3.								
4.								
5.								

AVIAN DIETARY SPECIES (AGE)	% AI	LC_{50} (95%CL)	SLOPE	NOEL	STUDY/REVIEW DATES	MRID/ CATEGORY	LAB	RC
1.								
2.								
3.								
4.								
5.								

COMMENTS: *-NA = not applicable, **CNO = could not determine

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