8-26-86

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to Registrant's Amendment for Mallard Dietary Study on Triphenyltin Hydroxide (TPTH)

FROM: Thomas M. Armitage 8-26-86
Fisheries Biologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Raymond W. Matheny
Head - Section I
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

THRU: Michael W. Slimak
Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769-C)

Ecological Effects Branch (EEB) has received information describing the percent active ingredient in the test material used to conduct the following mallard dietary LC_{50} study:

Beavers, J. 1986. A Dietary LC_{50} Study with the Mallard, Final Report, Wildlife International Ltd. Project No. 190-108, EPA Acc. # 260995. MRID 142759

The amended study indicates that the test material had a reportd purity of 96% a.i. On the basis of this information, EEB considers this study to fulfill the guidelines requirement for an avian dietary LC_{50} determination using the technical grade of active ingredient. With a dietary LC_{50} = 533 ppm (95%) c.i. = 312-625 ppm, technical triphenyltin hydroxide can be characterized as moderately toxic to waterfowl in dietary exposure. This study does not, however, fulfill the requirement for an avian dietary LC_{50} determination using typical end use product.

8/16/85 ATTACH p.3

1

Upgrade to Core

178646
RECORD NO.

083601
SHAUGHNESSEY NO. REVIEW NO.

EEB REVIEW

DATE: IN 8-14-86 OUT SEP 3 1986

FILE OR REG. NO 47916-37

PETITION OR EXP. NO.

DATE OF SUBMISSION

DATE RECEIVED BY HED 8-14-86

RD REQUESTED COMPLETION DATE 10-13-86

EEB ESTIMATED COMPLETION DATE 10-6-86

RD ACTION CODE/TYPE OF REVIEW 660

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

DATA ACCESSION NO(S). 264186

PRODUCT MANAGER NO. Hundemann (21)

PRODUCT NAME(S) TPTH

COMPANY NAME

SUBMISSION PURPOSE W.R. Landis Associates, Inc.
Additional information for Mallard
Duck Study

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.

2

~~Formulated~~ Product Tech. Core - Rainbow 97% ai
Form Core? - Avian Dietary Mallard
Tech Core Avian Dietary - Quail

083601
SHAUGHNESSY NO.

REVIEW NO.

EE BRANCH REVIEW

DATE: IN 6-20-85 OUT 8-16-85

FILE OR REG. NO. 8340-15, 47916-37

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 6/07/85

DATE RECEIVED BY HED 6/18/85

RD REQUESTED COMPLETION DATE 8/16/85

EEB ESTIMATED COMPLETION DATE 8/09/85

RD ACTION CODE/TYPE OF REVIEW 660/Reg. Std.

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

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. H. Jacoby (21)

PRODUCT NAME(S) Brestan 47.5, TPTH

COMPANY NAME American Hoescht Corp., W. R. Landis Assoc.

SUBMISSION PURPOSE Submission of data in support of registration.

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
083601	triphenyltin hydroxide	47.5

Pesticide Name: Triphenyltin hydroxide

100 Submission Purpose and Label Information

100.1 Submission Purpose

Data in support of TPTH registrations have been submitted for review.

101.4 Adequacy of Toxicity Data

Four studies were received but only three were fully reviewed. The three reviewed studies were found to be acceptable and fulfill the specific requirements under the registration standard for TPTH. A bluegill toxicity and accumulation study submitted under EPA Accession No. 258233 was not reviewed because the submission was incomplete. No dose response data were provided with the report. A summary of the reviewed studies is as follows:

Bobwhite quail - dietary LC_{50} with technical material EPA Accession No. 258314 -- 253 (191-335) ppm -- core

Mallard duck - dietary LC_{50} with formulated product (40% active flowable) EPA Accession No. 258314 -- 533 (312-625) ppm -- core

Rainbow trout - acute LC_{50} with technical material EPA Accession No. 258233 -- 0.022 (0.020-0.024) ppm -- core

103 Conclusions

The Ecological Effects Branch has completed a review of the submitted data to support the registration of TPTH. The data partially fulfills requirements imposed by the registration standard. EEB should be contacted for an update of the standard upon receipt of the remaining outstanding data.

8/16/85
Les Touart, Fisheries Biologist
Section 1

for Ray McFarland 8/16/85
Ray Matheny, Head
Section 1

8/19/85
Michael Slimak, Chief
EEB

DATA EVALUATION RECORD

1. CHEMICAL: Triphenyltin hydroxide

2. TEST MATERIAL: 97 % active ingredient

3. TEST TYPE: Aquatic Fish Acute LC_{50}

4. STUDY IDENTIFICATION: Fischer, R. (1983) The effect of Hoe 29664 0 F AT205 on Salmo gairdneri (rainbow trout) in a static test. Unpublished report prepared by Geschaeftsbereich Landwirtschaft Pflanzenschutz Forschung Biologie Oekologisches Laboratorium for American Hoechst Corporation. [EPA Accession No. 258233] 00142885

5. REVIEWED BY:

Les Touart
Fisheries Biologist
Ecological Effects Branch/HED

Signature: Les Touart
Date: 8-14-85

6. APPROVED BY:

Raymond Matheny
Supervisory Biologist
Ecological Effects Branch/HED

Signature: Dan McLean
Date: 8-16-85

7. CONCLUSIONS:
The study is scientifically sound and fulfills the requirements for an acceptable coldwater fish acute toxicity study on the technical material. With a 96-hr LC_{50} of 0.022 ppm, triphenyltin hydroxide can be characterized as very highly toxic to coldwater finfishes.

8. RECOMMENDATIONS: N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. METHODS AND MATERIALS:

A. Test Organisms: Rainbow trout

Size: 1.48 g mean wet weight, 46.4 mm mean total length

Source: Hatchery at Moringen, Federal Republic of Germany

B. Dosage Form:

Solvents/Vehicles: DMF

C. Referenced Protocol:

Test Levels: 0.0155, 0.018, 0.021, 0.024, 0.028, 0.032, 0.037, 0.042, 0.049, 0.056, 0.065, 0.075,0.087, 0.1, 0.115, 0.135, 0.155 and 0.18 ppm nominal concentrations with appropriate controls.

Number per Level: 5 per replicate, 2 replicates per level

Temperature: 12 ± 1° C

Dissolved Oxygen: >90 % saturation throughout the test

pH: 7.4 - 7.6 ppm

Source of Dilution Water: reconstituted water

Test Vessels: 50 liter stainless steel, in a static test system

Loading: 0.15 g/l

Aeration: none

Photoperiod: not reported

Statistical Methods: LC_{50} was calculated with SAS probit.

12. REPORTED RESULTS:

EC50 and C.L.'s: 0.022 (0.020-0.024) ppm

NEL: 0.0155 ppm

Dose Response Data: See attached tables.

Observation Period: 96 hours

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
The 96-hour LC_{50} was determined to be 0.022 (0.020 - 0.024) ppm. The no-observed effect concentration was 0.0155 ppm.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY:

A. Test Procedures: The test was conducted according to acceptable methods.

B. Statistical Analysis: Appropriate.

C. Discussion/Results: The data support the conclusions drawn.

D. Adequacy of Test:

1. Validation Category: Core.

2. Rationale: N/A

3. Repairability: N/A

15. COMPLETION OF ONE-LINER FOR TEST:

16. CBI APPENDIX: N/A

DATA EVALUATION RECORD

1. CHEMICAL: Triphenyltin hydroxide ← see Correction Letter on 2a.i 9/4/86

2. TEST MATERIAL: 40 % active ingredient, flowable formulation

3. TEST TYPE: Avian dietary LC_{50}

4. STUDY IDENTIFICATION: Beavers, J. B. (1985) Triphenyltin hydroxide (TPTH) 4 lbs. per gallon flowable formulation A dietary LC_{50} study with the mallard final report. WIPN:190-108. An unpublished report prepared by Wildlife International Ltd. for W. R. Landis Associates. [Accession No. 258314] MRID 00162016

5. REVIEWED BY:

Les Touart
Fisheries Biologist
Ecological Effects Branch/HED

Signature: L. Touart
Date: 8-14-85

6. APPROVED BY:

Raymond Matheny
Supervisory Biologist
Ecological Effects Branch/HED

Signature: Dan Rieder
Date: 8-16-85

7. CONCLUSIONS:
The study is scientifically sound and fulfills the requirements for an acceptable avian dietary toxicity study on the technical material. With an LC_{50} of 533 ppm, triphenyltin hydroxide can be characterized as moderately toxic to waterfowl in dietary exposures.

8. RECOMMENDATIONS: N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. METHODS AND MATERIALS:

A. Test Organisms: mallard duck

Age/Stage of Maturity: 10 days

Body Weights: approx. 150 g at initiation, 350 g at termination

Source: Whistling Wings, Hanover, Illinois

B. Dosage Form: dietary

Solvents/Vehicles: 2 % corn oil

C. Referenced Protocol:

Test Levels: 78, 156, 312, 625, 1250, 2500 and 5000 ppm with appropriate controls.

Number per Level: 10 ducklings

Holding/Acclimation: Upon receipt, birds were acclimated for 9 days to the test conditions.

Pen/Cage Facilities: Brooding pens (Beacon Steel Products Co., Model No. B735).

Feeding: Food and water were available ad libitum

Temperature: 70 ± 3° F

Photoperiod: 17 hours of light

Observation Period: 5 days treatment, 3 days observation

Statistical Methods: An LC_{50} value was calculated using the computer program of C. E. Stephan.

12. REPORTED RESULTS:

LC50 and C.L.'s: 533 ppm (312 - 625 ppm)

NEL: 156 ppm

Food Consumption: Concentration related reduction in feed consumption at concentrations of 156 ppm and above.

Body Weight Changes: There was a marked concentration related reduction in body weight gain at 78 and 156 ppm, and a concentration related body weight loss for surviving birds at higher concentrations

Dose Response: See attached tables.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
The acute dietary LC_{50} of triphenyltin hydroxide in the bobwhite was determined to be 533 ppm, with a confidence interval of 312 ppm to 625 ppm.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY:

A. Test Procedures: The test was conducted according to acceptable methods.

B. Statistical Analysis: Appropriate.

C. Discussion/Results: The data support the conclusions drawn.

D. Adequacy of Test:

1. Validation Category: Core.

2. Rationale: N/A

3. Repairability: N/A

15. COMPLETION OF ONE-LINER FOR TEST:

16. CBI APPENDIX: N/A

TPTH

Page _____ is not included in this copy.

Pages 11 through 12 are not included in this copy.

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.

X FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

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.

DATA EVALUATION RECORD

1. CHEMICAL: Triphenyltin hydroxide

2. TEST MATERIAL: 97.1 % active ingredient

3. TEST TYPE: Avian dietary LC_{50}

4. STUDY IDENTIFICATION: Beavers, J. B. (1985) Triphenyltin hydroxide (TPTH) technical: A dietary LC_{50} study with the bobwhite final report. WIPN:190-107. An unpublished report prepared by Wildlife International Ltd. for W. R. Landis Associates. [Accession No. 258314] MRID 00142758

5. REVIEWED BY:

Les Touart
Fisheries Biologist
Ecological Effects Branch/HED

Signature: Les Touart
Date: 8-14-85

6. APPROVED BY:

Raymond Matheny
Supervisory Biologist
Ecological Effects Branch/HED

Signature: Dennis McKee
Date: 8-16-85

7. CONCLUSIONS:
The study is scientifically sound and fulfills the requirements for an acceptable avian dietary toxicity study on the technical material. With an LC_{50} of 253 ppm, triphenyltin hydroxide can be characterized as highly toxic to upland gamebirds in dietary exposures.

8. RECOMMENDATIONS: N/A

9. BACKGROUND:

10. DISCUSSION OF INDIVIDUAL TESTS: N/A

11. METHODS AND MATERIALS:

A. Test Organisms: bobwhite quail

Age/Stage of Maturity: 12 days

Body Weights: approx. 20 g at initiation, 43 g at termination

Source: Sand Prairie Quail Farm, Mequoketa, IA

B. Dosage Form: dietary

Solvents/Vehicles: 2 % corn oil

C. Referenced Protocol:

Test Levels: 78, 156, 312, 625, 1250, 2500 and 5000 ppm with appropriate controls.

Number per Level: 10 chicks

Holding/Acclimation: Upon receipt, birds were acclimated for 9 days to the test conditions.

Pen/Cage Facilities: Thermostatically controlled brooding pens (Beacon Steel Products Co., Model No. B735Q).

Feeding: Food and water were available ad libitum

Temperature: 100 ± 2° F

Photoperiod: 17 hours of light

Observation Period: 5 days treatment, 3 days observation

Statistical Methods: An LC_{50} value was calculated using the computer program of C. E. Stephan.

12. REPORTED RESULTS:

LC50 and C.L.'s: 253 ppm (191 - 335 ppm)

NEL: 78 ppm

Food Consumption: Normal for surviving birds

Body Weight Changes: Slight body weight gain at 78 and 156 ppm during treatment and weight loss at 312 ppm. Higher test levels were not assessed for weight changes due to high mortality.

Dose response: Refer to attached tables.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:
The acute dietary LC_{50} of triphenyltin hydroxide in the bobwhite was determined to be 253 ppm, with a confidence interval of 191 ppm to 335 ppm.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY:

A. Test Procedures: The test was conducted according to acceptable methods.

B. Statistical Analysis: Appropriate.

C. Discussion/Results: The data support the conclusions drawn. One of the five control groups demonstrated a high level of mortality (50%). This was attributed to toe picking and did not occur in any other control group. The lowest treatment level did not show any mortality. The mortalities in the one control group can be disregarded in evaluating the results of this test.

D. Adequacy of Test:

1. Validation Category: Core.

2. Rationale: N/A

3. Repairability: N/A

15. COMPLETION OF ONE-LINER FOR TEST:

16. CBI APPENDIX: N/A

TPTH

Page _____ is not included in this copy.

Pages 16 through 17 are not included in this copy.

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.

X FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

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.