

US EPA ARCHIVE DOCUMENT

formulated Core
MALLARD 12-28-87

196113
RECORD NO.

08 36 01
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 05-26-87 OUT 28 DEC 1987

FILE OR REG. NO. 47916-35
PETITION OR EXP. NO. _____
DATE OF SUBMISSION 04-14-87
DATE RECEIVED BY HED 05-20-87
RD REQUESTED COMPLETION DATE 07-17-87
EEB ESTIMATED COMPLETION DATE 07-17-87
RD ACTION CODE/TYPE OF REVIEW 660

TYPE PRODUCT(S) : I, D, H, F, N, R, S Fungicide
DATA ACCESSION NO(S). 401733-00
PRODUCT MANAGER NO. L. Rossi (21)
PRODUCT NAME(S) TPTH

COMPANY NAME Wesley Industries, Inc.

SUBMISSION PURPOSE Submission of mallard dietary study with
formulated product, in response to
registration standard

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>08 36 01</u>	<u>Triphenyltin hydroxide</u>	<u>40%</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

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

A mallard dietary study with formulated product was received and reviewed. The study was found to be acceptable and fulfills the specific requirement under the registration standard for TPTH. Study ID is as follows:

Wesley Triple Tin 4L: A Dietary LC₅₀ Study with the Mallard. Wildlife International Ltd. Project No. 190-116A. 1986. Unpublished study submitted by W.R. Landis Associates, Inc., Valdosta, GA. EPA Reg. No. 47916-35. EPA Acc. No. 401733-00.

103 Conclusions

The Ecological Effects Branch has completed a review of the submitted data to support the registration of TPTH. The data partially fulfill requirements imposed under the registration standard. EEB will update the standard when review of all the submitted data is completed.

Allen W. Vaughan 12.21.87
Allen W. Vaughan, Entomologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

Norman Cook 12.22.87
Norman Cook, Section Head
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

Henry T. Crazen 12.23.87
Henry T. Crazen, Acting Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

DATA EVALUATION RECORD

1. Chemical: TPTH
2. Test Material: Wesley Triple Tin 4L; (40% ai)
3. Study/Action Type: Dietary LC₅₀ Study - Mallard Duck
(Anas platyrhynchos)
4. Study ID: Grimes, 1987
Wesley Triple Tin 4L: A Dietary LC₅₀ Study with the Mallard. Wildlife International Ltd. Project No. 190-116A. 1986. Unpublished study submitted by W.R. Landis Associates, Inc., Valdosta, GA. EPA Reg. No. 47916-35. EPA Acc. No. 401733-00.
5. Reviewed By: Allen W. Vaughan
Entomologist
EEB/HED
Signature: *Allen W. Vaughan*
Date: 12.21.87
6. Approved By: Norman Cook
Section Head
EEB/HED
Signature: *Norman Cook*
Date: 12.22.87
7. Conclusions:

The study is scientifically sound and fulfills the guideline requirement for a dietary study on a waterfowl species using a TPTH formulated product. With an LC₅₀ = 421 ppm, TPTH (Wesley Triple Tin 4L) may be characterized as highly toxic to mallard duck. (On a 100% ai basis, the LC₅₀ = 168.4 ppm.)
8. Recommendations: N/A.
9. Background:

This study was submitted in support of registration standard.
10. Discussion of Individual Tests or Studies: N/A
11. Materials and Methods (Protocols):

Ten mallard ducklings, 10 days of age, were dosed at each treatment and control group. Birds were immature and no determination of sex was made. Concentrations tested were 100, 178, 316, 562, and 1000 ppm test substance. Birds were fed the appropriate test or control diet for 5 days followed by untreated feed for 3 days. Dietary test concentrations were not adjusted for purity of the test substance.

During acclimation and testing, all birds were housed indoors in thermostatically controlled brooding pens. Each pen contained 10 birds. Ambient room temperature for this study was approx. 17°C. Photoperiod was 16 hours of light during acclimation and the course of the study.

During acclimation birds were observed daily. Birds which exhibited abnormal behavior or physical injury were not used. After starting the test, birds were observed at least twice daily until the termination of the study. Signs of toxicity, abnormal behavior and mortality were recorded.

Body weights by group were measured at the initiation of the study and on days 5 and 8. Average estimated feed consumption for each test concentration group was determined for days 0 to 8.

An LC₅₀ value along with a 95% confidence interval was calculated using the computer program of C.E. Stephan.

12. Reported Results:

There were no mortalities in the control group. All birds were normal in appearance and behavior throughout the test period.

There were no mortalities at the 100 and 178 ppm concentrations. There was 20% mortality at the 316 ppm level, 80% mortality at the 562 ppm level, and 100% mortality at the 1000 ppm level.

At the 100 ppm level, all birds were normal in appearance and behavior throughout the study.

At the 178 ppm level, signs of toxicity were first noted on Day 5 and continued through Day 6. By Day 7, all birds were normal in appearance and behavior and remained so until study termination.

Signs of toxicity at the 316 ppm concentration were first observed on Day 2. Mortalities were noted on Days 4 and 5. Surviving birds continued to exhibit signs of toxicity until study termination.

At the 562 ppm level, signs of toxicity were first noted on Day 2. Mortalities occurred on Days 3 through 7. On Day 7, one survivor was normal in appearance and behavior and continued so until study termination. One exhibited slight signs of toxicity until study termination.

Signs of toxicity at the 1000 ppm level were first observed on Day 1. Mortalities were first noted on Day 2. By the afternoon observation of Day 5, all birds were dead.

Overt signs of toxicity included depression, reduced reaction to external stimuli, loss of coordination, lower limb weakness, wing droop, lethargy, and a ruffled appearance.

When compared to the controls, there was a concentration related reduction in body weight gain or loss in body weight at levels of 100, 178, 316, and 562 ppm during the exposure phase. A reduction in feed consumption was noted for this same period at all but the lowest concentration.

13. Study Author's Conclusions/Quality Assurance:

The mallard dietary LC₅₀ value of TPTH (Wesley Triple Tin 4L, 40% ai) for this study was determined to be 421 ppm, with a 95% confidence interval of 332 to 535 ppm. The no mortality concentration was 178 ppm. The no-observed-effect concentration was less than 100 ppm due to a reduction in body weight gain at the 100 ppm concentration. On a 100% ai basis, the LC₅₀ = 168.4 PPM.

A quality assurance statement was included by Lee F. Doggett.

14. Reviewer's Discussion and Interpretation:

- a. Test Procedures - Test procedures complied with those outlined in the HED Standard Evaluation Procedure for the avian dietary study using a formulated product. There were no problems in this regard.
- b. Statistical Analysis - Analysis of data was by the same program as that used by EEB. See attached print-out.
- c. Discussion/Results - The LC₅₀ for the mallard duck is 421 ppm for 40% ai formulated product, equivalent to 168.4 ppm ai. This chemical may be characterized as highly toxic to mallard duck on a dietary basis.
- d. Adequacy of the Study
 - 1) Classification - Core for formulated product
 - 2) Rationale - SEP protocol; no major deviations noted
 - 3) Reparability - N/A.

15. Completion of One-Liner for Study:

One-liner form completed.

16. CBI Appendix: N/A.

Vaughan IPIH Mallard duck 12-04-87

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CONC.      NUMBER      NUMBER      PERCENT      BINOMIAL
          EXPOSED      DEAD        DEAD        PROB. (PERCENT)
1000      10              10          100         9.765625E-02
562       10              8           80          5.46875
316       10              2           20          5.46875
178       10              0           0           9.765625E-02
100       10              0           0           9.765625E-02

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THE BINOMIAL TEST SHOWS THAT 178 AND 1000 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS. BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 421.4165

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RESULTS CALCULATED USING THE MOVING AVERAGE METHOD
SPAN      G          LC50      95 PERCENT CONFIDENCE LIMITS
4         .1144044    421.6586  325.646   587.767

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RESULTS CALCULATED USING THE PROBIT METHOD
ITERATIONS  G          H          GOODNESS OF FIT PROBABILITY
5          .3148741    1          .9909694

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SLOPE = 7.234619
95 PERCENT CONFIDENCE LIMITS = 3.175011 AND 11.29423

LC50 = 421.4449
95 PERCENT CONFIDENCE LIMITS = 332.1975 AND 534.9096

LC10 = 281.317
95 PERCENT CONFIDENCE LIMITS = 155.4662 AND 351.233



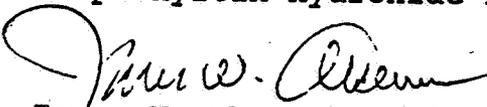
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 15 1980

MEMORANDUM

SUBJECT: Triphenyltin hydroxide EEC Modeling Analysis Report.


FROM: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Lois Rossi, PM-21
Registration Division (H7505C)

Information submitted by the registrant in Accession number 407982-01 does not directly address any 40 CFR Part 158.145 data requirements. The registrant has provided an exposure model which estimates expected exposures from the proposed soybean use of TPTH. After review of the report entitled, "Analysis of the Environmental Fate of Triphenyltin Hydroxide (TPTH) Applied to Soybeans in a Standard Farm Pond Setting," by DiToro, Paquin and Wu, EEB is not dissuaded that TPTH use on soybeans may result in hazardous exposures to aquatic organisms.

EEB does not accept several of the assumptions made in the model analysis. Specifically,

- 1) assessment of the results based on 96-hr average concentrations achieved once every three years -- EEB evaluates risk by assessing maximum peak concentrations and estimated environmental 1/2-life;
- 2) probabilities of occurrence based on crop rotation (treatments every other year) -- EEB assesses risk when the product is used and must consider that unless prohibited by the label use in repetitive years is possible; and

