

12-16-96

Date Out:

DP Barcode: D196902
Chemical Code: 083601

ENVIRONMENTAL FATE AND GROUND WATER BRANCH

To: Walt Waldrop, PM #71
Special Review and Reregistration Division (7508W)

From: Mah T. Shamim, Ph.D., Section Chief
Chemistry Review Section 2
Environmental Fate & Ground Water Branch/EFED (7507C)

M. Shamim

Thru: Pauline Wagner, Acting Chief
Environmental Fate & Ground Water Branch/EFED (7507C)

Pauline Wagner 12/16/96

Attached, please find the EFGWB review of...

Common Name:	TPTH	Trade name:	
Company Name:	Hoechst Celanese Corporation		
ID #:	083601		
Purpose:	Review Accumulation in Fish study.		

Type Product:	Action Code:	Review Time:
fungicide	627	5 days

STATUS OF STUDIES IN THIS PACKAGE:

**STATUS OF DATA REQUIREMENTS
ADDRESSED IN THIS PACKAGE:**

Guideline #	MRID	Status ¹
165-4	42995601	A

Guideline #	Status ²
165-4	S

¹Study Status Codes: A=Acceptable U=Upgradeable C=Ancillary I=Invalid.
²Data Requirement Status Codes: S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved W=Waived.

1. CHEMICAL:

chemical name: Triphenyltin Hydroxide

common name: TPTH

physical/chemical properties:

molecular formula	C ₁₈ H ₁₆ OSn
molecular weight	367 g/Mol
physical state	crystalline
melting point	118-120°C
aqueous solubility	4.3 mg/l at 22°C and pH 5

2. TEST MATERIAL:

¹⁴C-phenyl-labeled TPTH, specific activity 128.5 mCi/g.

3. STUDY/ACTION TYPE:

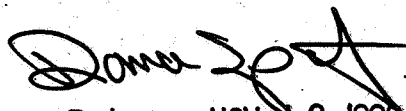
Review of an Accumulation in Fish study.

4. STUDY IDENTIFICATION:

Dionne, E. 1993. Triphenyltin Hydroxide (TPTH) - Bioconcentration and Elimination of ¹⁴C-Residues by Bluegill Sunfish (*Lepomis macrochirus*). Unpublished study performed by Springborn Laboratories, Inc., Wareham, MA; and submitted by Hoechst Celanese Corporation, Somerville, NJ. MRID: 42995601.

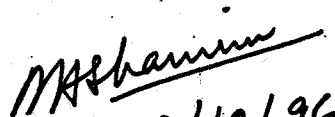
5. REVIEWED BY:

Dana Spatz
Chemist, CRS #2
EFGWB/EFED/OPP


Date: NOV 12 1996

6. APPROVED BY:

Mah T. Shamim, Ph.D.
Section Head, CRS #2
EFGWB/EFED/OPP


Date: 12/12/96

7. CONCLUSIONS:

Accumulation in Fish

This study is acceptable and can be used to fulfill the Accumulation in Fish data requirement.

TPTH (triphenyltin hydroxide) accumulated in bluegill sunfish that were exposed to a nominal concentration of 0.50 µg/L [¹⁴C]TPTH for 170 days. Bioconcentration factors were 2900x in edible tissues (fillet), 4900x in nonedible tissues (viscera and carcass), and 3700x in whole fish. Maximum mean concentrations of total [¹⁴C]residues were 1.5 mg/kg in the edible tissues, 2.5 mg/kg in the nonedible tissues, and 1.9 mg/kg in the whole fish. Greater than 90% of the accumulated residues in the fish were extractable, and all of the extracted radioactivity was identified as TPTH. Depuration was slow; approximately 50% of the accumulated [¹⁴C]residues were eliminated from the fish tissues after 56 days of depuration.

8. RECOMMENDATIONS:

The Accumulation in Fish (165-4) data requirement is now satisfied.

The remaining data requirements to be fulfilled are:

- | | |
|-------|--|
| 164-1 | Soil Field Dissipation- <i>Reserved pending results of pecan harvester monitoring study (as per MEMO dated 3/26/93 from Margaret Rice, SRB/SRRD to OPP Docket-30000/42).</i> |
| 201-1 | Droplet Size Spectrum |
| 202-1 | Field Drift Evaluation |

An environmental fate assessment will be completed during Phase V of reregistration.

9. BACKGROUND:

Triphenyltin Hydroxide is a nonsystemic, protectant, foliar fungicide registered for use on pecans, carrots, potatoes and sugar beets. Of the total usage, 85% is applied to pecans. TPTH is a Restricted Use Pesticide. The TPTH Registration Standard was issued in September 1984. On December 17, 1984 TPTH was placed into Special Review with the issuance of a PD 1. The trigger for initiation of a Special Review was data indicating that TPTH produces teratogenic effects in laboratory animals.

DATA EVALUATION RECORD

STUDY 1

CHEM 083601

Triphenyltin hydroxide

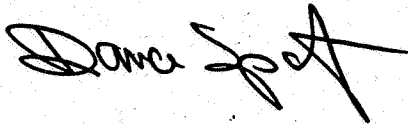
§165-4

STUDY ID 42995601

Dionne, E. 1993. Triphenyltin Hydroxide (TPTH) - Bioconcentration and Elimination of ¹⁴C-Residues by Bluegill Sunfish (*Lepomis macrochirus*). HRAVC Project ID No. 91-0010. SLI Study No. 1719.0391.6172.140; SLI Report No. 93-3-4667. Unpublished study performed by Springborn Laboratories, Inc., Wareham, MA; and submitted by Hoechst Celanese Corporation, Somerville, NJ.

REVIEWED BY: Dana Spatz
TITLE: Chemist
ORG: EFGWB/EFED/OPP

SIGNATURE:



CONCLUSIONS:

Laboratory Accumulation - Fish

1. This study is acceptable and can be used to fulfill the Accumulation in Fish data requirement.
2. TPTH (triphenyltin hydroxide) accumulated in bluegill sunfish that were exposed to a nominal concentration of 0.50 µg/L [¹⁴C]TPTH for 170 days. Bioconcentration factors were 2900x in edible tissues (fillet), 4900x in nonedible tissues (viscera and carcass), and 3700x in whole fish. Maximum mean concentrations of total [¹⁴C]residues were 1.5 mg/kg in the edible tissues, 2.5 mg/kg in the nonedible tissues, and 1.9 mg/kg in the whole fish. Greater than 90% of the accumulated residues in the fish were extractable, and all of the extracted radioactivity was identified as TPTH. Depuration was slow; approximately 50% of the accumulated [¹⁴C]residues were eliminated from the fish tissues after 56 days of depuration.

METHODOLOGY:

Juvenile bluegill sunfish (*Lepomis macrochirus*; mean length and weight 50 mm and 1.74 g, respectively) were held in a laboratory aquarium containing aerated well water at 18°C and irradiated with fluorescent light for 16 hours/day for ≥14 days prior to the initiation of the study. Flow-through aquatic exposure systems were

prepared using three 73-L glass aquaria (75 x 39 x 30 cm), which were supplied with aerated well water (pH 6.5-7.2, total hardness 23-26 mg/L as CaCO₃, alkalinity 18-34 mg/L as CaCO₃) at a rate of 8.3 turnovers per day (90% replacement in 7 hours). The water supplied to two of the aquaria was continuously treated at 0.50 mg/L with phenyl ring-labeled [U-¹⁴C]TPTH (triphenyltin hydroxide; radiochemical purity >98%, specific activity 4754.9 MBq/g, Hoechst Aktiengesellschaft) dissolved in acetone. To serve as the control, the water supplied to the third aquarium was treated with an equivalent amount of pesticide-free acetone. The flow-through systems were allowed to equilibrate for 1 week prior to the introduction of the fish; the treated water was sampled on five occasions during the equilibration period.

After the test systems had equilibrated, 150 bluegill sunfish were transferred into each aquarium. The fish were fed a dry commercial pelleted food twice daily at a rate of approximately 2% of their total biomass per feeding, except during each 24-hour period prior to each sampling. During the 170-day exposure, water samples (5 mL) were collected from both of the treated aquaria at approximately 7-day intervals and from the control aquarium at approximately 28-day intervals. Fish (5/aquarium) were collected from one of the treated aquaria (designated the "exposure" or "treatment" aquarium) and from the control aquarium on days 14, 28, 56, 84, 112, 126, 140, 154, and 168 of the exposure period. For [¹⁴C]residue identification, an additional 1000 mL of water were collected at approximately monthly intervals. All fish in the "metabolite" aquarium were collected only on day 170 of the exposure period. Following the exposure period, 50 fish from the "exposure" and "control" aquaria were transferred into flowing, pesticide-free water for a 63-day depuration period. During depuration, water samples (5 mL) and fish (5) were collected from the aquarium containing the treated fish at 7-day intervals; water and fish samples were collected from the aquarium containing the control fish on days 28 and 56.

Aliquots of all water samples were analyzed for total radioactivity using LSC. Aliquots of the water samples collected from the "metabolite" aquarium were also analyzed by HPLC and TLC. The water samples were extracted three times with methylene chloride. The methylene chloride extracts were combined and concentrated to dryness by rotary evaporation, and the resulting [¹⁴C]residues were redissolved in acetonitrile. The extracts were analyzed by HPLC using a C-18 column eluted with acetonitrile: water:85% phosphoric acid (80:20:1, v:v:v); the column was equipped with radioactive flow detection. Additional aliquots were analyzed by two-dimensional TLC on silica gel plates developed with methanol:ammonium hydroxide (100:1, v:v) and toluene:ethyl acetate:acetic acid:water (75:25:1:0.5, v:v:v:v). Following development, radioactive zones on the plates were located using a TLC scanner.

The fish were dissected into edible (fillet) and nonedible (viscera and carcass) tissues. The tissues were weighed, mixed with cellulose

powder, and air-dried at ambient temperature for ≥ 24 hours. The dried samples were analyzed for total radioactivity by LSC following combustion. Recoveries for the oxidizer determined prior to sample analyses were 99.5%.

Triplicate subsamples (10 g) of the edible tissues from fish sampled on day 170 of the exposure period were homogenized by milling with dry ice. The homogenate was mixed with hexane and vortexed, then the mixture was centrifuged and the supernatant decanted. The hexane-extracted tissue was homogenized with methanol, then filtered. The hexane and methanol extracts were concentrated under a stream of nitrogen, and aliquots of both concentrates were analyzed for total radioactivity by LSC. The extracted tissues were analyzed by LSC following combustion.

Additional subsamples of the edible and nonedible tissues from fish sampled after 170 days of exposure were extracted and analyzed according to the scheme presented in Figure 6. Duplicate subsamples of the edible (5 g) and visceral tissues (3 g) were homogenized three times with acetone:water:methanol:hydrobromic acid (53:27:13:7, v:v:v:v) for 2 minutes/extraction. Between extractions, the samples were centrifuged and the extracts were decanted. Aliquots of the extracts and the extracted tissues were analyzed for total radioactivity using LSC and LSC following combustion, respectively. The three acidic extracts from each sample were combined, diluted with a saturated NaCl solution, and partitioned twice with hexane and once with ethyl acetate. The hexane and ethyl acetates were dried over sodium sulfate, then combined and concentrated using rotary evaporation and a nitrogen stream. The resulting liquid layer was decanted, and the solids that formed during concentration were rinsed three times by vortexing with acetonitrile. The liquid concentrate and the acetonitrile rinses were combined and concentrated under a nitrogen stream; aliquots of the solution were analyzed for total radioactivity using LSC. Due to "phase separation" in the nonedible tissue extracts, these extracts were evaporated to dryness, and the resulting residues were redissolved in acetone prior to analyses. Aliquots of the concentrated tissue extracts were analyzed by HPLC and TLC as described for the water samples. Recoveries from fish tissues fortified with [^{14}C]TPTH at 4.51-8341 $\mu\text{g}/\text{kg}$ ranged from 88.3 to 125.2%.

DATA SUMMARY:

[^{14}C]TPTH (triphenyltin hydroxide) residues accumulated in bluegill sunfish that were continuously exposed to phenyl ring-labeled [^{14}C]TPTH (radiochemical purity >98%) at a nominal concentration of 0.50 $\mu\text{g}/\text{L}$ for 170 days under flow-through conditions. The bioconcentration factors were 2900x for edible tissues (fillet), 4900x for nonedible tissues (viscera and carcass), and 3700x for whole fish. Maximum mean concentrations of total [^{14}C]residues were

1.5 ppm for edible tissues, 2.5 ppm for nonedible tissues, and 1.9 ppm for whole fish. Greater than 90% of the [¹⁴C]residues in the fish tissues could be extracted, and all of the [¹⁴C]residues extracted from the tissues were parent TPTH.

Depuration was slow; only approximately 50% of the accumulated [¹⁴C]residues were eliminated from the fish tissues by day 56 of the depuration period.

Throughout the study, the temperature of the treated and untreated water was 17°C, the pH ranged from 6.2-7.6, and the dissolved oxygen content ranged from 7.9-9.3 mg/L. During the study period, total [¹⁴C]residues were <0.16 ppb in the control water, ≤4.5 ppb in the edible control fish tissues, and ≤3.8 ppb in the nonedible control fish tissues.

COMMENTS:

1. Residues in whole fish were not determined directly; the concentration of [¹⁴C]residues in the edible and nonedible fish tissues and their respective weights were used to determine the total [¹⁴C]residues on a whole fish basis.
2. No fish died during the 48 hours prior to testing. During the exposure period, eight fish died in the metabolite aquarium and seven control fish died; no fish died in the exposure aquarium. The study author stated that the fish generally appeared healthy, behaved normally, and grew continuously throughout the study.
3. Twenty-one fish were removed from the metabolite aquarium on day 126 of the exposure period to maintain the biomass at 605 g.
4. Aqueous solubility of TPTH is reported to be 4.3 mg/L.

TPTH

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Pages 8 through 25 are not included in this copy.

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_____ 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.

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