United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
Washington, DC 20460

EPA Pesticide Fact Sheet

Name of Chemical: TPTH
Reason for Issuance:
Date Issued: Sept. 30, 1984
Fact Sheet Number: 39

1. Description of chemical:

Generic Name: triphenyltin hydroxide
Common name: fentin hydroxide (BSI, ISO), triphenyltin hydroxide (USA, S. Africa)
Trade name: Du-ter®, Duter®, Haitin, TPTH, TPTOH, Suzu H®, Supertin, Tubotin®
EPA Shaughnessy Code: 083601
Chemical Abstracts Service (CAS) Number: 76-87-9
Year of Initial Registration: 1971
Pesticide Type: Fungicide
Chemical family: Organotin
U.S. and Foreign Producers: M & T Chemicals (U.S.A.), Philips-Duphar (Netherlands), Nitto-Kasei Co. (Japan)

2. Use patterns and formulations:

Application sites: To control early and late blight on potatoes, leaf spot on sugar beets and peanuts, scab and several other diseases on pecans, leaf spot and alternaria blight on carrots, and to suppress spider mites on peanuts.
Types of formulations: Wettable powders and flowable suspensions
Types and Methods of Application: Aerial and ground sprays, application through irrigation systems.
Application Rates: 1.5 to 12 ounces a.i./acre
Usual carriers: Water, Surfactants, spreaders, or stickers should not be used because excessive phytotoxicity can result. Not to be used with oil sprays.

3. Science Findings:

Summary science statement:

TPTH is very highly toxic (Category I) when it reaches the eyes, or when inhaled or absorbed through the skin. Because the major routes of human

exposure are skin contact and inhalation, this high toxicity is cause for concern. TPTH produces birth defects in laboratory animals, can damage the immunological systems of exposed animals, produces lesions in the uteruses of female rats and has very high subacute inhalation toxicity. It is not a mutagen.

Chemical characteristics:

Physical state:	solid, fine powder
Color:	white to off-white
Odor:	none
Vapor pressure	non-volatile
Melting point:	118-120° C (technical)
Flammability:	400° C
Octanol/water partition coefficient:	R=1270 and 1370
Stability:	decomposes at about 300°C to bis-triphenyltin oxide
	stable at pH values of 5, 7, and 9 for >30 days

Solubility:			
	water -	8 ppm	Benzene - 41 g/l
	ether -	28 g/l	Ethanol - 10 g/l
	1,2-Dichloromethane -	74 g/l	Acetone - 70 g/l
	Methylene chloride -	171 g/l	

Unusual handling characteristics: None reported (No data on explodability or corrosion characteristics)

Toxicological characteristics:

Acute Effects:

Acute Oral LD_{50} - 165 mg/kg (male rats), 156 mg/kg (female rats) (Category II)
Acute Dermal LD_{50} - 127 mg/kg (male rabbits) (Category I)
Dermal Irritation - Primary Skin Irritation (PSI) = 2.8 (Category III)
Acute Inhalation Toxicity - 60.3 ug/l (Category I)
Primary Eye Irritation - Corrosive (Category I)

Major Routes of Exposure: Dermal, inhalation

Chronic Effects:

Oncogenicity - Caused pathological lesions on the uteruses of female rats at lowest dose tested (LDT). Controversy as to whether this is an oncogenic effect has not yet been resolved.

Teratology - Caused hydrocephalus and hydronephrosis at $\leq$ 1.25 mg/kg (lowest level tested). Other effects: abortions, decreased body weight gain, decreased % live fetuses, decreased fetal weight, increased resorptions.

Mutagenicity - Not a mutagen

Immunotoxicity - Effects spleen weight and IgM AFC spleen cells and spleen cell response to mitogens at 2.5 mg/kg/day (LDT). Decreased leukocyte counts were observed at most dose levels, including LDT. Study does not show a No Observed Effects Level (NOEL).

Subacute Inhalation - Effects were noted at 0.0011 mg/liter (LDT), including alopecia, nasal discharge, red ears, ptosis, piloerection, and epithelial hyperplasia of the skin. The histopathology report has not been completed: the effects at lower dose levels have not been evaluated.

Physiological and Biochemical Behavioral Characteristics:

Translocation: Does not translocate

Environmental Characteristics:

Absorbtion and leaching characteristics: Relatively immobile in sandy loam, clay loam, and silty clay loam soils.

Loss from photodegradation and/or volatilization: No information is available on photodegradation or volatilization. TPTH has low vapor pressure, so little volatilization is expected.

Resultant average persistance: Half-life of 1 to 3 months in sandy and silt loam soils, 126 days in flooded silt loam.

Half-life in Water: Stable to hydrolysis for 30 days at 21° C, loss of approx. 16% at 32°C

Ecological characteristics:

Hazards to Birds: Cannot be estimated without more data

Hazards to Fish and Aquatic Invertebrates: Any use pattern that would result in contamination of aquatic systems through spray drift or runoff could result in high risk to populations of fish and aquatic invertebrates, because of the very high toxicity of TPTH to aquatic organisms. More data on persistance and chronic effects are needed to complete the hazard evaluation.

Potential Problems with Endangered Species: Cannot be estimated without more data. Aquatic species would presumably be at high risk if exposed.

Tolerance Reassessment:

List of crops and tolerances: (CFR 180.236)

	(PPM)		(PPM)
Beets, sugar, roots	0.1N*	Carrots	0.1N
Cattle, kidney	0.05N	Cattle, liver	0.05N
Goats, kidney	0.05N	Goats, liver	0.05N
Hogs, kidney	0.05N	Hogs, liver	0.05N
Horses, kidney	0.05N	Horses, liver	0.05N
Peanuts	0.05N	Peanuts, hulls	0.4
Pecans	0.05N	Potatoes	0.05N
Sheep, kidney	0.05N	Sheep, liver	0.05N

*"N" stands for "Negligible Residues".

List of food contact uses: Pecans, peanuts, potatoes, carrots

Results of tolerance assessment: No ADI can be set at this time

Problems known to have occured from use: PIMS file contains eight entries, according to its index. We cannot retrieve the data at this time (Sept 1984).

4. Summary of Regulatory Position and Rationale:

Use Classification: Reclassified (by the Registration Standard) as a Restricted Use chemical because of toxicity and teratogenic effects.
Use, Formulation or Geographic Restrictions: Manufacturing use products may only be formulated into end-use products intended for use as a fungicide on pecan trees, peanuts, carrots, potatoes, sugar beets, and tobacco, or as anti-fouling paint, or spider mite suppressants on peanuts."

Unique Label warning statements:

a. Hazards to Humans Statements

Labels of manufacturing-use and formulated end-use products (EUPs) must bear the statements:

"DANGER - Fatal if inhaled. Corrosive, causes irreversible eye damage. May be harmful or fatal if swallowed or absorbed through the skin. Do not get in eyes, or on skin. Do not breathe dust, vapor, or spray mist. When handling either products containing TPTH or spray-diluted mixtures, wear protective clothing (long pants, long sleeve shirt, impermeable gloves, hat, boots, and a pesticide respirator jointly approved by the Mining Enforcement and Safety Administration and the National Institute for Occupational Safety and Health.) When handling concentrated products, wear a face shield. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse. Do not enter treated areas for at least 24 hours after treatment."; and

"The United States Environmental Protection Agency has determined that triphenyltin hydroxide causes birth defects in laboratory animals. Exposure to triphenyltin hydroxide during pregnancy should be avoided."

The word "POISON" (in red letters) and a skull and crossbones must appear in close proximity to the word "DANGER".

b. Statements of Practical Treatment

Labels of manufacturing-use and end-use products must bear the statements:

"If on skin: Wash with plenty of soap and water."

"If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

"If in eyes: Flush with plenty of water. Call a physician."

"If swallowed: Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Call a physician or Poison Control Center."

c. Environmental Hazard Statement

The following specific statements must appear on the labels of all manufacturing use products:

"This pesticide is toxic to fish and wildlife. Do not discharge into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All labels of EUPs intended for outdoor use must bear this statement:

"This pesticide is toxic to fish and wildlife. Do not apply directly to water or wetlands. Drift or runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Cover or incorporate spills. Do not contaminate water by cleaning of equipment or disposal of wastes."

d. Disposal Statements

All labels of manufacturing use or formulated end-use products (EUPs) must bear this statement, under the heading "STORAGE AND DISPOSAL":

"Do not contaminate water, food, or feed by storage or disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The statements required by this standard must appear on the labels of all MUPs and EUPs released for shipment after March 30, 1984. After review of data to be submitted under this standard, the Agency may impose additional label requirements.

Summary of risk/benefit analysis: No risk/benefit analysis per se has been done. The Agency has determined that TPTH meets the risk criteria in 40 CFR §162.11(a), primarily because TPTH has produced teratogenic effects in laboratory animals. TPTH will be placed in the Special Review process, during which there will be an analysis of its risks and benefits.

5. Summary of major data gaps

Dates when major data gaps are due to be filled.

Data Requested	Due date
Description of manufacturing process	April 1, 1985*
Discussion of formation of unintentional ingredients	April 1, 1985*
Preliminary analysis	April 1, 1985*
Certification of limits	April 1, 1985*
Analytical methods and data for enforcement of limits	April 1, 1985*
Vapor pressure	April 1, 1985
Plant residues	April 1, 1985
Animal residues	April 1, 1985

Data Requested (continued)	Due Date
Storage stability data	April 1, 1985*
Magnitude of the residue for each food use	April 1, 1985
Photodegradation	April 1, 1985
Metabolism studies in lab	November 1, 1986
Mobility studies	April 1, 1985
Dissipation studies in field	November 1, 1986
Accumulation studies in rotational crops	November 1, 1986
Accumulation studies in fish	April 1, 1985
Reentry protection	November 1, 1986
90-day feeding (rodent)	January 1, 1986
90-day feeding (non-rodent)	January 1, 1986
21-day dermal	April 1, 1985
90-day inhalation	April 1, 1985**
Chronic toxicity	April 1, 1985***
Oncogenicity	April 1, 1985***
Teratogenicity	April 1, 1985****
Reproduction (2-generation)	September 1, 1986
Chromosomal aberration	September 1, 1986
Other genotoxic effects	September 1, 1986
General metabolism	February 1, 1986
Avian dietary toxicity	April 1, 1985
Avian Reproduction	April 1, 1986
Coldwater fish acute toxicity	April 1, 1985
Density, bulk density, or specific gravity	April 1, 1985*
Oxidizing/reducing action	April 1, 1985*
Explodability	April 1, 1985*
Corrosion	April 1, 1985*

*Product-specific data required for manufacturing use products containing TPTH.

**If the registrant commits to conducting new studies, the deadline is January 1, 1986.

***If the registrant commits to conducting new studies, the deadline is
vember 1, 1988.

****If the registrant commits to conducting new studies, the deadline is
November 1, 1985.

6. Contact person at EPA: Henry Jacoby, U.S. Environmental Protection Agency, TS-767-C, 401 M Street SW, Washington, DC 20460 (703) 557-1900

DISCLAIMER: The information presented in this Chemical Information Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration and reregistration.