UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 25, 1999

This document supercedes the previous chapter dated April 12, 1999 (DP Barcode D255118). It incorporates new information on percent crop-treated, processing factors, and anticipated residues.

MEMORANDUM:

SUBJECT: **Revised Triphenyltin Hydroxide: Product and Residue Chemistry Chapters of the RED** PC Code No. 083601. Case No. 0099. DP Barcode D258541.

FROM: Catherine Eiden, Chemist
and
Sarah Levy, Chemist
Risk Characterization & Analysis Branch
Health Effects Division (7509C)

THRU: Steve Knizner, Branch Senior Scientist
Risk Characterization & Analysis Branch
Health Effects Division (7509C)

TO: Loan Phan, Chemical Review Manager
Special Review Branch
Special Review and Reregistration Division (7508C)

Attached please find the revised product and residue chemistry chapter of the triphenyltin (TPTH) RED. This chapter has been prepared by Dynamac Corp. under contract to the Agency and has undergone secondary review to reflect HED policies.

cc: C. Eiden, S. Levy, RCAB files
CAE 08/25/99, SJL 08/25/99, SAK 08/25/99
RDI: CM#2, 824B, 305-7887, CAE

TRIPHENYLTIN HYDROXIDE
PC Code 083601; Case 0099

Reregistration Eligibility Decision

December 9, 1998

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
1910 Sedwick Road
Building 100, Suite B
Durham, NC 27713

TRIPHENYLTIN HYDROXIDE (TPTH)

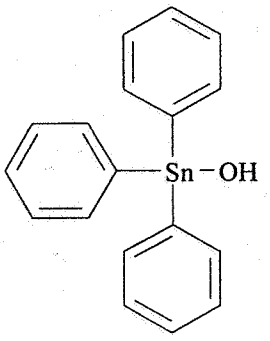
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 083601; Case No. 0099

DESCRIPTION OF CHEMICAL

Triphenyltin hydroxide (TPTH) is a fungicide registered for use on pecans, potatoes, and sugar beets.



Empirical Formula:	$C_{18}H_{16}OSn$
Molecular Weight:	366.7
CAS Registry No.:	76-87-9
PC Code:	083601

IDENTIFICATION OF ACTIVE INGREDIENT

TPTH is a fine white powder with a melting point of 118-120 C, bulk density of 0.2758 g/mL at 25 C, octanol/water partition coefficient (log K_{ow}) of 3.268, and vapor pressure of $<1 \times 10^{-7}$ torr at 25 C. TPTH is practically insoluble in water (8 ppm), and is moderately soluble in most organic solvents (acetone 70 g/L; benzene 41 g/L; 1,2-dichloromethane 74 g/L; ether 28 g/L; ethanol 10 g/L; and methylene chloride 171 g/L).

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 10/19/98 identified four TPTH manufacturing-use products (MPs) registered under PC Code 083601. A list of the registered MPs subject to a reregistration eligibility decision is presented below.

Formulation	EPA Reg. No.	Registrant
96% T	1812-279 [1]	Griffin L.L.C.
96% T	5204-86 [2]	Elf Atochem N.A. Incorporated
96% T	45639-171 [3]	AgrEvo USA Company
96% T	55146-71	Agtrol International

[1] Transferred 2/26/85 from Uniroyal Chemical Company Incorporated, EPA Reg. No. 400-391.
[2] Transferred 12/18/86 from Hoechst Celanese (Clariant Corporation per REFS), EPA Reg. No. 8340-19, which was transferred 8/14/85 from Solvay Duphar B.V., EPA Reg. No. 37100-13.
[3] Transferred 9/17/94 from Hoechst Celanese (Clariant Corporation per REFS), EPA Reg. No. 8340-17.

REGULATORY BACKGROUND

The TPTH Guidance Document dated 9/84 required that updated generic and product-specific product chemistry data be submitted for TPTH. The TPTH Reregistration Standard Update dated 3/18/92 summarized and reviewed product chemistry data submitted in support of reregistration of TPTH. We note that the Agtrol International 96% T was registered subsequent to issuance of the TPTH Update.

The current status of the product chemistry data requirements for TPTH technical products is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

Pertinent product chemistry data requirements remain unfulfilled for all of the registered 96% T/TGAIs. The following additional data are required: (i) OPPTS 830.7050 for the Griffin 96% T; (ii) OPPTS 830.1550, 1700, 1750, 1800, 6314, 6316, 7050, and 7370 for the Elf Atochem 96% T; (iii) OPPTS 830.1550 and 7050 for the AgrEvo 96% T; and (iv) OPPTS 830.1550, 1750, 6314, 6316, 6317, 6320, and 7050 for the Agtrol 96% T. Provided that the registrants submit the data required in the attached data summary tables for the 96% Ts, and either certify that the suppliers of beginning materials and the manufacturing processes for the TPTH technical products have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, HED has no objections to the reregistration of TPTH with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s):	1151
Subject:	EPA Reg. No. 352-279. Griffin TPTH. Product Chemistry Data for Registration Standard.
From:	A. Reiter
To:	H. Jacoby
Dated:	7/15/85
MRID(s):	00142930

CBRS No(s):	1135
Subject:	#8340-15. Evaluation of TPTH Analytical Methods.
From:	A. Reiter
To:	H. Jacoby
Dated:	9/24/85
MRID(s):	00142876

CBRS No(s):	1136
Subject:	EPA No. 8340-15, TPTH (Hoechst). Product Chemistry Data for Registration Standard.
From:	A. Reiter
To:	H. Jacoby
Dated:	8/30/85
MRID(s):	00147329

CBRS No(s):	1278
Subject:	Triphenyl Tin Hydroxide (TPTH; Fentin Hydroxide). Response to Registration Standard: Hoechst Triphenyltin Hydroxide Technical, EPA Reg. No. 8340-17 and 8340-15.
From:	S. Hummel
To:	L. Rossi
Dated:	2/3/87
MRID(s):	00161669 and 00161670

CBRS No(s):	9790
DP Barcode(s):	D176344
Subject:	Reregistration of TPTH. Case No. 0099. Chemical No. 083601. Hoechst Celanese Corporation. 96% T (EPA Reg. No. 8340-17).
From:	P. Deschamp
To:	L. Rossi/E. Ferris
Dated:	8/26/92
MRID(s):	42049501

CBRS No(s):	11133
DP Barcode(s):	D186296
Subject:	Triphenyltin hydroxide (TPTH) Reregistration: List A Chemical. Hoechst Celanese Corp. Response to TPTH Reregistration Update (3/18/92) Product Chemistry Data Requirements Regarding Certified Limits and Enforcement Analytical Methods (Guideline Nos. 62-2 and 62-3). (Case No. 0099, Chemical No. 083601).
From:	F. Toghrol
To:	L. Rossi/W. Waldrop
Dated:	3/26/93
MRID(s):	42585401

CBRS No(s):	11131 and 11381
DP Barcode(s):	D186293 and D188185
Subject:	Triphenyltin hydroxide (TPTH). Case No. 0099. Griffin's Response to Reregistration Standard Update of 3/92.
From:	L. Cheng
To:	W. Waldrop
Dated:	4/30/93
MRID(s):	42578901-42578905 and 42640901

CBRS No(s):	11740
DP Barcode(s):	D190288
Subject:	Triphenyltin Hydroxide (TPTH). Case No. 0099. Product Chemistry 62-1 and 63.
From:	L. Cheng
To:	E. Ferris/W. Waldrop
Dated:	5/5/93
MRID(s):	42725201

CBRS No(s):	11918
DP Barcode(s):	D191624
Subject:	Triphenyltin Hydroxide (TPTH)/Fentin Hydroxide. Case No. 0099. Hoechst Product Chemistry Data.
From:	L. Cheng
To:	W. Waldrop
Dated:	6/7/93
MRID(s):	42756601

CBRS No(s):	11380
DP Barcode(s):	D188184
Subject:	Fentin Hydroxide/TPTH. Case No. 0099. Elf Atochem's Response to Product Chemistry Data Requirements.
From:	L. Cheng
To:	W. Waldrop
Dated:	6/15/93
MRID(s):	42642201

CBRS No(s):	12338
DP Barcode(s):	D193850
Subject:	Triphenyltin Hydroxide (TPTH). Case No. 0099. Griffin's Response to CBRS 4/30/93 Review (No. 11131 and 11381).
From:	L. Cheng
To:	E. Ferris
Dated:	10/28/93
MRID(s):	42365503 (reassessed) and 42852201

CBRS No(s):	12746
DP Barcode(s):	D196286
Subject:	Triphenyltin Hydroxide (TPTH). Case No. 0099. Response to Product and Residue Chemistry Reviews.
From:	L. Cheng
To:	E. Ferris
Dated:	7/12/94
MRID(s):	42965601

CBRS No(s):	13442
DP Barcode(s):	D200790
Subject:	Triphenyltin Hydroxide (TPTH) Reregistration: List A Chemical No. 083601; Case No. 0099. Griffin Response to Product Chemistry Data Requirements (GLN No. 6201, 63-17, and 63-20).
From:	F. Toghrol
To:	J. Ellenberger/K. Davis
Dated:	7/14/94
MRID(s):	43125201

CBRS No(s):	13686
DP Barcode(s):	D203201
Subject:	Triphenyltin hydroxide (TPTH) Reregistration: List A Chemical No. 083601; Case No. 0099. Elf Atochem Response to Product Chemistry Data Requirements (GLN No. 63-17 and 63-20).
From:	F. Toghrol
To:	W. Waldrop
Dated:	9/26/94
MRID(s):	43187801

CBRS No(s):	13732
DP Barcode(s):	D203509
Subject:	Triphenyltin hydroxide (TPTH) Reregistration: List A Chemical No. 083601; Case No. 0099. Hoechst Celanese Response to Product Chemistry Data Requirements (GLN Nos. 63-17 and 63-20).
From:	F. Toghrol
To:	W. Waldrop
Dated:	9/27/94
MRID(s):	43218701

CBRS No(s):	15100
DP Barcode(s):	D211116
Subject:	Triphenyltin Hydroxide (TPTH.) Case No. 0099. Registrant's Response to 7/14/94 CBRS Review (GLN 63-20).
From:	L. Cheng
To:	J. Andreasen
Dated:	4/18/95
MRID(s):	None

CBRS No(s):	15097
DP Barcode(s):	D211111
Subject:	Triphenyltin Hydroxide (TPTH). Case No. 0099. Additional Information on GLN 62-1 for Elf Atochem and 171-4(e).
From:	L. Cheng
To:	J. Andreasen
Dated:	4/18/95
MRID(s):	None

CBRS No(s):	None; RD Memorandum
DP Barcode(s):	D241037
Subject:	Product Chemistry Review of a Technical Grade of Active Ingredient; EPA Reg./File Symbol No. 55146-TR; Product Name: Agtrol TPTH Technical 96% AI; Action Code 165; Company Name: Agtrol Chemical Products.
From:	S. Malak
To:	C. Giles-Parker/M. Rodriguez
Dated:	1/29/98
MRID(s):	44413201 and 44413202

CBRS No(s):	None; RD Memorandum
DP Barcode(s):	D242876
Subject:	Product Chemistry Review of a Technical Grade of Active Ingredient; EPA Reg./File Symbol No. 55146-TR; Product Name: Agtrol TPTH Technical 96% AI; Action Code 166; Company Name: Agtrol Chemical Products.
From:	S. Malak
To:	C. Giles-Parker/M. Rodriguez
Dated:	2/7/98
MRID(s):	None

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00083551 Thompson-Hayward Chemical Company (1979) General Chemistry: [Du-ter Fungicide]. (Unpublished study received Oct 18, 1979 under 148-689; CDL:099046-A)

00093704 Corbin, H.B. (1976) The Partitioning of bis(Tributyltin) Oxide (TBTO), Tributyltin Fluoride (TBTF), Triphenyltin Hydroxide (TPTH), Triphenyltin Fluoride (TPTF), and Tricyclohexyltin Hydroxide (TCTH) between n-Octanol and Water: R-1150-M. (Unpublished study received Jan 15, 1982 under 46197-1; prepared by M & T Chemicals, Inc., submitted by Kansai Paint Co., Ltd., Rahway, N.J.; CDL:246589-A)

00142876 Hommel, K.; Puschmann, H. (1976) Determination of Triphenyltin Compounds in Formulations and in the Technical Grade Active Principle. Unpublished study prepared by Hoechst. 5 p.

00142930 Griffin Corp. (1985) Product Chemistry: Griffin Triphenyltin Hydroxide Technical. Unpublished study. 18 p.

00147329 American Hoechst Corp. (19??) Product Chemistry Data for Triphenyltin Hydroxide . Unpublished compilation. 32 p.

00161669 Hoechst AG (1986) Product Chemistry Data: Triphenyltinhydroxide. Unpublished compilation. 16 p.

40802501 Goerlitz, G. (1988) Response to TPTH Product Chemistry Data Review (RCB No. 1278) dated May 29, 1987. Unpublished compilation prepared by Analytisches Laboratorium. 50 p.

42049501 Schollmeier, M. (1991) Hoe 029664, Substance Pure Determination of Solubility in Water with the Column Elution Method According to OECD-Guideline #105 (...): Lab Project Number: A 45991: CP91/018 . Unpublished study prepared by Hoechst Celanese Corp. 20 p.

42365503 Harris, M. (1992) Griffin Analytical Method TM1045: Determination of Triphenyltin Hydroxide in Super Tin 80 WSP: Lab Project Number: 92-003. Unpublished study prepared by Griffin Corp. 37 p.

42578901 Hand, O. (1992) Griffin Corporation Test Methods: Physical and Chemical Characteristics of Pesticide Products: TPTH. Unpublished study prepared by Griffin Corp. 47 p.

42578902 Hand, O. (1992) Griffin Analytical Method TM-1054: Triphenyltin Hydroxide Impurities Assay Method: Lab Project Number: 92-007. Unpublished study prepared by Griffin Corp. 44 p.

42578903 Hand, O. (1992) Griffin Analytical Method TM-1055: Triphenyltin Hydroxide UV Spectrophotometric Method: Lab Project Number:92-007. Unpublished study prepared by Griffin Corp. 25 p.

42578904 Hand, O. (1992) Griffin Analytical Method TM-1059: Determination of Triphenyltin Hydroxide by Titration: Lab Project Number: 92-007. Unpublished study prepared by Griffin Corp. 12 p.

42578905 Hand, O. (1992) Griffin Analytical Method TM-1060: Trace Triphenyltin Hydroxide ICP Method: Lab Project Number: 92-007.Unpublished study prepared by Griffin Corp. 13 p.

42585401 Gorlitz, G. (1992) Registrant's Response to EPA's TPTH Product Chemistry Review Regarding Data Requirement Ref. No. 62-3 (Enforcement Analytical Methods): Lab Project Number: OE92/204. Unpublished study prepared by Hoechst AG. 28 p.

42640901 Hand, O. (1992) General Chemistry Data Development for Triphenyltin Hydroxide Technical: Lab Project Number: 92-007. Unpublished study prepared by Griffin Corp. 27 p.

42642201 Gitlitz, M. (1992) Triphenyltin Hydroxide Technical Product Chemistry: Lab Project Number: PC-TPTH. Unpublished study prepared by Elf Atochem North America Inc. 125 p.

42725201 Anthony, C. (1993) Triphenyltin Hydroxide (TPTH) Physical and Chemical Properties: Lab Project Number: 00415-001. Unpublished study prepared by Case Consulting Labs, Inc. 36 p.

42756601 Wells, D. (1993) TPTH--Product Chemistry Physical and Chemical Tests for a Manufacturing Use Product: Lab Project Number: 10934-0792-6136-880: 93-2-4648. Unpublished study prepared by Springborn Laboratories, Inc. 44 p.

42852201 Hand, O. (1993) Response to Review of TPTH General Chemistry Data: DP Barcodes D186293 and D188185: Lab Project Number: 92-007: 92-008. Unpublished study prepared by Griffin Corp. 17 p.

42965601 Anthony, C. (1993) Registrant Response for Additional TPTH Product Chemistry Data: Addendum to MRID 42725201: Lab Project Number: 00415-001-AD1. Unpublished study prepared by Case Consulting Labs, Inc. 12 p.

43125101 Hand, O. (1993) General Chemistry Data Development for Triphenyltin Hydroxide Technical: One Year Storage Stability: Lab Project Number: P92-008. Unpublished study prepared by Griffin Corp. 25 p.

43125201 Hand, O. (1994) Addendum to Griffin Analytical Method TM-1045: Response to Review of TPTH General Chemistry Data: DP Barcode D193850: Lab Project Number: 92-007: 92-008. Unpublished study prepared by Griffin Corp. 14 p.

43187801 Ellison, F. (1994) Triphenyltin Hydroxide (TPTH): Storage Stability and Corrosion Characteristics: 1 Year at Room Temperature: Final Report: Lab Project Number: 00415-001. Unpublished study prepared by Case Consulting Laboratories, Inc. 25 p.

43218701 Wells, D. (1994) Storage Stability of TPTH: Lab Project Number: 10934.0792.6137.840: 94-2-5174. Unpublished study prepared by Springborn Laboratories, Inc. 48 p.

44413201 Jacobson, S. (1997) Agtrol TPTH Technical--Product Chemistry Volume I: Product Identity and Composition, Description of the Production Process, Description of the Formulation Process and Discussion of Formation of Impurities: Lab Project Number: 97722. Unpublished study prepared by Compliance Services International. 45 p.

44413202 Jacobson, S. (1997) Agtrol TPTH Technical--Product Chemistry Volume II: Preliminary Analysis, Certified Limits and Enforcement Analytical Method: Lab Project Number: 97723: 01-8359-162: 01-8359. Unpublished study prepared by Compliance Services

International. 78 p.

44641101 Richardson, W. (1998) Final Report: Preliminary Analysis of Triphenyltin Hydroxide Technical Grade Active Ingredient (TGAI): Lab Project Number: CHB-EX-004: CHB-EX-004-011-P-1. Unpublished study prepared by Phibro-Tech, Inc. 88 p.

Case No. 0099
Chemical No. 083601

Case Name: TPTH
Registrant: Griffin L.L.C.
Product(s): 96% T (EPA Reg. No. 1812-279)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	Y	CSF 7/6/93 [3]
830.1600	Description of materials used to produce the product	Y	00142930 [4]
830.1620	Description of production process	Y	00142930 [4]
830.1670	Discussion of formation of impurities	Y	00142930 [4]
830.1700	Preliminary analysis	Y	00142930 [4], 42640901 [5], 42365503 [6], 42852201 [6], 43125201 [7]
830.1750	Certified limits	Y	CSF 7/6/93 [3], 43125201 [7]
830.1800	Enforcement analytical method	Y	00142930 [4], 42578902 [5], 42365503 [6], 42578904 [5]
830.6302	Color	Y	**00083551**, 42640901 [5]
830.6303	Physical state	Y	**00083551**, 42640901 [5]
830.6304	Odor	Y	**00083551**, 42640901 [5]
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	**00083551**, 42640901 [5]
830.6314	Oxidation/reduction: chemical incompatability	Y	42640901 [5]
830.6315	Flammability	N/A [8]	**00083551**
830.6316	Explodability	Y	42640901 [5]
830.6317	Storage stability	Y	42640901 [5], 43125101 [7]
830.6319	Miscibility	N/A [8]	
830.6320	Corrosion characteristics	Y	42640901 [5], 43125101 [7], Letter 12/21/94 [9]
830.7000	pH	Y	**00083551**, 42640901 [5]
830.7050	UV/Visible absorption	N [10]	
830.7100	Viscosity	N/A [8]	
830.7200	Melting point/melting range	Y	**00083551**, 42578901 [5], 42640901 [5]
830.7220	Boiling point/boiling range	N/A [8]	
830.7300	Density/relative density/bulk density	Y	00142930 [4], 42640901 [5]
830.7370	Dissociation constants in water	Y	42578901 [5], 42578904 [5] 42640901 [5], 42852201 [6]
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	**00093704**, 42578901 [5], 42578903 [5], 42640901 [5]
830.7840	Water solubility: column elution method; shake flask method	Y	**00083551**, 42578901 [5], 42578903 [5], 42640901 [5]
830.7950	Vapor pressure	Y	00142930 [4], 42578901 [5], 42640901 [5]

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] **Bolded** references were reviewed in the Product Chemistry Chapter of the TPTH Reregistration Standard dated 4/11/84, and the remaining references were reviewed as noted.

[3] CSF dated 7/6/93 was originally evaluated under CBRS No. 12338, D193850, 10/28/93, L. Cheng, and accepted upon submission of chromatograms for OPPTS 830.1700 under CBRS No. 13442, D200790, 7/14/94, F. Toghrol.

[4] CBRS No. 1151, 7/15/85, A. Reiter.

[5] CBRS Nos. 11131 and 11381, D186293 and D188185, 4/30/93, L. Cheng.

[6] CBRS No. 12338, D193850, 10/28/93, L. Cheng.

[7] CBRS No. 13442, D200790, 7/14/94, F. Toghrol.

[8] Data are not required because the T/TGAI is a solid at room temperature.

[9] CBRS No. 15100, D211116, 4/18/95, L. Cheng.

[10] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

Case No. 0099
Chemical No. 083601

Case Name: TPTH
Registrant: Elf Atochem N.A. Incorporated
Product(s): 96% T (EPA Reg. No. 5204-86)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N	
830.1600	Description of materials used to produce the product	Y	42642201 [3]
830.1620	Description of production process	Y	42642201 [3]
830.1670	Discussion of formation of impurities	Y	42642201 [3]
830.1700	Preliminary analysis	N [4]	42725201 [5], 42965601 [6], Letter 3/30/95 [7]
830.1750	Certified limits	N	
830.1800	Enforcement analytical method	N [8]	42725201 [5]
830.6302	Color	Y	**00083551**
830.6303	Physical state	Y	**00083551**
830.6304	Odor	Y	**00083551**
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	**00083551**
830.6314	Oxidation/reduction: chemical incompatability	N	
830.6315	Flammability	N/A [9]	
830.6316	Explodability	N	
830.6317	Storage stability	Y	43187801 [10]
830.6319	Miscibility	N/A [9]	
830.6320	Corrosion characteristics	Y	43187801 [10]
830.7000	pH	Y	**00083551**
830.7050	UV/Visible absorption	N [11]	
830.7100	Viscosity	N/A [9]	
830.7200	Melting point/melting range	Y	**00083551**
830.7220	Boiling point/boiling range	N/A [9]	
830.7300	Density/relative density/bulk density	Y	42725201 [5]
830.7370	Dissociation constants in water	N	
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	**00093704**
830.7840	Water solubility: column elution method; shake flask method	Y	**00083551**, 42725201 [5]
830.7950	Vapor pressure	Y	42725201 [5]

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] **Bolded** references were reviewed in the Product Chemistry Chapter of the TPTH Reregistration Standard dated 4/11/84, and the remaining references were reviewed as noted.

[3] CBRS No. 11380, D188184, 6/15/93, L. Cheng.

[4] Preliminary analysis data submitted by Griffin will satisfy data requirements for this product, provided both products are produced by the same manufacturer; otherwise, preliminary analysis data are required for the impurities of the Elf Atochem TGAI.

[5] CBRS No. 11740, D190288, 5/5/93, L. Cheng.

[6] CBRS No. 12746, D196286, 7/12/94, L. Cheng.

[7] CBRS No. 15097, D211111, 4/18/95, L. Cheng.

[8] Enforcement analytical methods are required for the impurities related to the active ingredient and present at ≥0.1% in the technical product.

[9] Data are not required because the T/TGAI is a solid at room temperature.

[10] CBRS No. 13686, D203201, 9/26/94, F. Toghrol.

[11] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

Case No. 0099
Chemical No. 083601

Case Name: TPTH
Registrant: AgrEvo USA Company
Product(s): 96% T (EPA Reg. No. 45639-171)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N	
830.1600	Description of materials used to produce the product	Y	00147329 [3]
830.1620	Description of production process	Y	00147329 [3]
830.1670	Discussion of formation of impurities	Y	00147329 [3]
830.1700	Preliminary analysis	Y	00147329 [3], 00161669 [4], 40802501
830.1750	Certified limits	Y	00147329 [3], 00161669 [4], 42585401 [5]
830.1800	Enforcement analytical method	Y	00142876 [6], 00147329 [3], 00161669 [4], 40802501, 42595401 [5]
830.6302	Color	Y	**00083551**
830.6303	Physical state	Y	**00083551**
830.6304	Odor	Y	**00083551**
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	**00083551**
830.6314	Oxidation/reduction: chemical incompatability	Y	42756601 [7]
830.6315	Flammability	N/A [8]	
830.6316	Explodability	Y	42756601 [7]
830.6317	Storage stability	Y	43218701 [9]
830.6319	Miscibility	N/A [8]	
830.6320	Corrosion characteristics	Y	42756601 [7], 43218701 [9]
830.7000	pH	Y	**00083551**
830.7050	UV/Visible absorption	N [10]	
830.7100	Viscosity	N/A [8]	
830.7200	Melting point/melting range	Y	**00083551**
830.7220	Boiling point/boiling range	N/A [8]	
830.7300	Density/relative density/bulk density	Y	00147329 [3]
830.7370	Dissociation constants in water	Y	00147329 [3]
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	**00093704**
830.7840	Water solubility: column elution method; shake flask method	Y	**00083551**, 42049501 [11]
830.7950	Vapor pressure	Y	00147329 [3]

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] **Bolded** references were reviewed in the Product Chemistry Chapter of the TPTH Reregistration Standard dated 4/11/84; underlined references were reviewed in the TPTH Reregistration Standard Update dated 3/18/92; and the remaining references were reviewed as noted.

[3] CBRS No. 1136, 8/30/85, A. Reiter.

[4] CBRS No. 1278, 2/3/87, S. Hummel.

[5] CBRS No. 11133, D186296, 3/26/93, F. Toghrol.

[6] CBRS No. 1135, 9/24/85, A. Reiter.

[7] CBRS No. 11918, D191624, 6/7/93, L. Cheng.

[8] Data are not required because the T/TGAI is a solid at room temperature.

[9] CBRS No. 13732, D203509, 9/27/94, F. Toghrol.

[10] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[11] CBRS No. 9790, D176344, 8/26/92, P. Deschamp.

Case No. 0099
Chemical No. 083601

Case Name: TPTH
Registrant: Agtrol International
Product(s): 96% T (EPA Reg. No. 55146-71)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	44413201
830.1600	Description of materials used to produce the product	Y	44413201
830.1620	Description of production process	Y	44413201
830.1670	Discussion of formation of impurities	Y	44413201
830.1700	Preliminary analysis	Y	44413202, 44641101 [4]
830.1750	Certified limits	N [3]	44413202
830.1800	Enforcement analytical method	Y	44413202
830.6302	Color	Y	**00083551, 42640901,** 44413201
830.6303	Physical state	Y	**00083551, 42640901,** 44413201
830.6304	Odor	Y	**00083551, 42640901,** 44413201
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	**00083551, 42640901**
830.6314	Oxidation/reduction: chemical incompatability	N [5]	
830.6315	Flammability	N/A [6]	
830.6316	Explodability	N [5]	
830.6317	Storage stability	N [5]	
830.6319	Miscibility	N/A [6]	
830.6320	Corrosion characteristics	N [5]	
830.7000	pH	Y	**42640901**
830.7050	UV/Visible absorption	N [7]	
830.7100	Viscosity	N/A [6]	
830.7200	Melting point/melting range	Y	**00083551, 42640901,** 44413201
830.7220	Boiling point/boiling range	N/A [6]	
830.7300	Density/relative density/bulk density	Y	**42640901,** 44413201
830.7370	Dissociation constants in water	Y	**42578904**
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	**42640901**
830.7840	Water solubility: column elution method; shake flask method	Y	**42640901**
830.7950	Vapor pressure	Y	**42640901**

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] **Bolded** references are reviewed under the TPTH Reregistration Standard dated 4/11/84 or under CBRS Nos. 11131 and 11381, D186293 and D188185, 4/29/93, L. Cheng (for Griffin L.L.C.) and have been determined to be applicable to the Agtrol TGAI (RD Memorandum, D242876, 2/7/98, S. Malak); underlined references were reviewed by the Registration Division (D241037, 1/29/98, S. Malak); remaining references were reviewed as noted.

[3] A revised CSF must be submitted including modified nominal concentrations and certified limits reflecting the results of the current preliminary analysis (D252337, S. Law, 1/25/99.).

[4]D252337, S. Law, 1/25/99.

[5] The registrant has stated that data are not required for technical product registration; however, because the technical product is also a manufacturing-use product, these data are required.

[6] Data are not required because the T/TGAI is a solid at room temperature.

[7] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

TRIPHENYLTIN HYDROXIDE

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 083601; Case 0099

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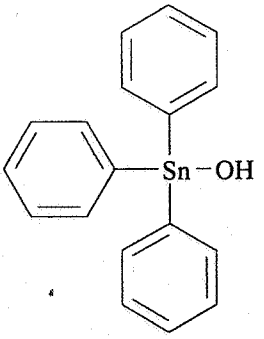
TRIPHENYLTIN HYDROXIDE



REREGISTRATION ELIGIBILITY DOCUMENT

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 083601; Case 0099

INTRODUCTION

Triphenyltin hydroxide (TPTH) is a fungicide registered for use on pecans, potatoes, and sugar beets. TPTH is manufactured by members of the TPTH Task-Force (AgrEvo, Elf Atochem and Griffin) under the trade names Super Tin®, Pro-Tex®, Brestan®, and Photon®. TPTH formulations registered for use on food/feed crops include two wettable powders (WPs), two flowable liquid concentrates (FlCs), and one emulsifiable concentrate (EC) formulation. These products may be applied as broadcast foliar applications using ground or aerial equipment and by chemigation (potatoes only).

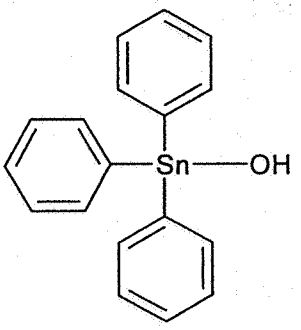
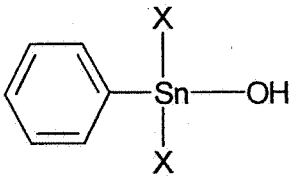
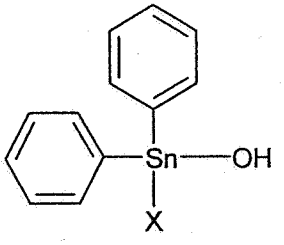
REGULATORY BACKGROUND

TPTH is a List A reregistration chemical and was the subject of a Registration Standard dated 4/11/84, its associated Guidance Document dated 9/84, and a Reregistration Standard Update dated 3/18/92. These documents summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Several submissions of data have been received since the Update was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of TPTH.

Tolerances have been established at 0.05 ppm for residues of TPTH *per se* in/on pecans, potatoes, sugar beet roots, and kidney and liver of cattle, goats, hogs, horses, and sheep [40 CFR §180.236]. No tolerances for residues of TPTH have been established for processed food/feed commodities.

The qualitative nature of the residue of TPTH in plants and animals is adequately understood. Based on the results of plant and animal metabolism studies and a TOX Branch memorandum (J. Doherty, PP#3F2823/FAB#3H5384, 10/28/83), the Residue Chemistry Chapter of the TPTH Update concluded that the residues to be regulated in plants and animals include TPTH and the di- and monophenyltin hydroxide (DPTH and MPTH) or oxide metabolites. The chemical names and structures of TPTH and its metabolites of concern are depicted in Figure A.

Figure A. Chemical name and structure of triphenyltin hydroxide and its residues of concern in plant and animal commodities (X = oxides or hydroxides).

Common Name/Chemical Name	Chemical Structure
Triphenyltin hydroxide (TPTH)	
Monophenyltin hydroxide (MPTH)	
Diphenyltin hydroxide (DPTH)	

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 10/14/98 indicates that there are five TPTH end-use products (EPs) with uses on food/feed crops registered to the TPTH Task Force members. These EPs are presented below in Tbale 1.

Table 1. Triphenyltin Hydroxide End-Use Products with Food/Feed Uses Registered to Griffin and AgrEvo.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
1812-244	10/93	4 lb/gal FlC	SUPER TIN® 4L
1812-350 [a]	2/96	80% WP	SUPER TIN® 80WP
1812-351 [b]	9/94	0.5 lb/gal EC	PRO-TEX®
45639-170	10/92	47.5% WP	BRESTAN® H 47.5WP FUNGICIDE
45639-186	2/93	4 lb/gal FlC	PHOTON® FUNGICIDE

[a] Includes SLN Nos. ME970001, MI970001, MN970003, ND970004, OR970021, WA970035, and WI970005.
[b] This product is a MAI that also includes maneb (3.5 lb/gal EC) in addition to the 0.5 lb/gal of TPTH.

The REFS product data report for EPA Reg. No. 45639-170 should be updated to delete cucumbers, summer squash, tomatoes, and tobacco from the list of sites on which this product can be used; the registrants are not supporting uses on these commodities. For EPA Reg No. 1812-351, sugar beets should be added to the list of acceptable use sites.

A review of the labels cited above and supporting residue data indicate that the following label amendments are required:

Use directions for potatoes on the 4 lb/gal FlC labels (EPA Reg No. 1812-244 and 45639-186) do not indicate a minimum retreatment interval (RTI). The labels should be amended to specify a RTI of 7 days.

Use directions for potatoes on all labels except the 47.5% WP currently specify a 21-day PHI. The registrants have recently submitted adequate residue data supporting a 7-day PHI together with amended labels for three of the five EPs registered for use on potatoes. The registrants may amend use directions on potatoes to specify a 7-day PHI.

Use directions for sugar beets on all labels should be amended to remove grazing/feeding restrictions. The labels should also be amended to prohibit use of TPTH on sugar beets grown in CA.

Use directions for sugar beets on the 47.5% WP (EPA Reg No. 45639-170) label should be amended to specify a 21-day PHI; the label currently specifies a 14-day PHI. In addition, the label states that the product "contains 15.2 ounces per bag." This statement should be amended to clarify that the product contains 15.2 ounces of *active ingredient* per 32.0 ounce bag.

The registrants should amend all labels to include a 30-day rotational crop restriction.

A comprehensive summary of the registered food/feed use patterns of TPTH, based on the product labels registered to the TPTH Task Force, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of TPTH is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of TPTH food/feed uses are based on the use patterns registered by the basic producers, AgrEvo and Griffin. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer's labels.

OPPTS GLN 860.1300: Nature of the Residue in Plants and Livestock

The qualitative nature of the residue in plants and animals is adequately understood based on potato, soybean, and rice metabolism studies, and acceptable ruminant and poultry metabolism studies. The residues of concern in plant and animal commodities include TPTH and its metabolites DPTH and MPTH (See Figure A).

OPPTS GLN 860.1340: Residue Analytical Methods

The available methods for tolerance enforcement, listed in the Pesticide Analytical Manual (PAM), Vol. II, as Methods I-IV, are colorimetric methods that measure TPTH *per se*. A new tolerance enforcement method was required for TPTH residues as the Agency no longer considers colorimetric methods to be adequate for enforcing tolerances and because the tolerance expression for TPTH is being revised to include DPTH and MPTH.

A proposed GC/flame photometric detection (FPD) enforcement method (Method AL007/91-0), which determines TPTH and its metabolites, DPTH and MPTH, has undergone successful independent laboratory validation using sugarbeet and potato matrices, and has been submitted for an Agency method tryout.

Briefly, residues are extracted from crop matrices with acidified methanol, partitioned into toluene, and evaporated to dryness. The residues are redissolved in tetrahydrofuran, and derivatized using butyl magnesium chloride. The residues are partitioned into hexane, dried over sodium sulfate, and concentrated. Residues in the hexane concentrate are cleaned-up on a silica gel column, and analyzed by GC/FPD with a tin filter (610 nm). Residues of the butyl derivative

of each analyte are reported as TPTH equivalents. The limit of quantitation (LOQ) for residues of each analyte in sugar beet and potato matrices is 0.01 ppm.

Residue data on crop plants and processed commodities have been collected using methods which sequentially screen for total extractable organotin using graphite furnace atomic absorption spectroscopy and analyze for individual phenyltin analytes by GC/FPD or HPLC. These methods are similar to the method described above with minor modifications involving changes in solvents and cleanup procedures.

In conjunction with the ruminant feeding study (DP Barcode D239451, J. Punzi, 4/2/98), the registrants provided data validating a GC/FPD method for determining residues of TPTH and its metabolites DPTH and MPTH in animal commodities. The method is similar to the proposed enforcement for plant commodities described above. The LOQ for each analyte is 0.02 ppm in milk, cream, and muscle, and 0.1 ppm in kidney, liver, and fat.

An independent laboratory validation (ILV) of this method has also been conducted and the method is currently undergoing an Agency Tolerance Method Validation (TMV) by the Biological and Economic Analysis Division (BEAD) Laboratory.

The Agency's review of the registrant's response to the Reregistrations Standard Update (L. Cheng, 11/23/93) required that, "... representative samples from the plant and animal metabolism studies be analyzed using the proposed enforcement method in order to ascertain that these methods are capable of recovering all residues of concern. If analysis of samples from previously accepted metabolism studies is impractical, the registrant must provide data from other sources to demonstrate the adequate recovery of the total toxic residue." These data remain outstanding, but are considered confirmatory.

OPPTS GLN 860.1360: Multiresidue Method Testing

The registrants have not provided recovery data for TPTH and its metabolites using FDA multiresidue methods. This represents a data-gap. The registrants are referred to OPPTS GLN 860.1360 for details concerning multiresidue method testing.

OPPTS GLN 860.1380: Storage Stability Data

The requirements for supporting storage stability data are satisfied for the purposes of reregistration. To support the residue field trial data for pecans, data depicting the storage stability of TPTH and its metabolites in pecans held in frozen storage for up to 261 days (~9 months). Currently available data indicate regulable residues of TPTH are stable in sugar beet leaf tops from zero to 7 months and from 2 to 4 years. The registrants have advised the Agency that the required 2-year storage stability study on sugar beets is continuing. The Agency considers these data confirmatory.

The available storage stability data indicate that residues of TPTH, MPTH and DPTH are stable at -20 C for 14-16 weeks in potatoes, sugar beet roots, refined sugar and sugar beet molasses.

Samples of cow tissue and milk were analyzed within 30 days of collection in the ruminant feeding study. Therefore, storage stability data on regulable residues of TPTH in animal commodities are not required.

OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

For purposes of reregistration, the requirements for magnitude of the residue data in/on plants are fulfilled for the following crops pending adequate resolution of storage stability issues: pecans, potatoes, and sugar beets. Adequate field trial data depicting TPTH residues of concern in/on these crops following applications made according to the maximum or proposed use patterns have been submitted. Geographical representation is adequate and a sufficient number of trials reflecting representative formulation classes were conducted.

Existing tolerances for pecans (0.05 ppm), potatoes (0.05 ppm), and sugar beets (0.05 ppm) are adequate. These tolerances are based on non-detectable residues in field trial samples and limits of quantitation (LOQ) of 0.01 ppm for each metabolite: MPTH, DPTH, and TPTH.

A tolerance for residues of TPTH and its regulable metabolites in/on sugar beet tops at 10 ppm is required. Residue field trial data are available indicating that the combined residues of TPTH and its metabolites in/on sugar beet tops were 2.5-9.7 ppm harvested 21 days following treatment at 1x. These data are supported by the available storage stability data. Additional storage stability data are being collected and considered confirmatory.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

Tolerance Reassessment

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for potatoes and sugarbeets.

Data from an acceptable cooking study are available (MRID 41785204) pertaining to TPTH regulable residues of TPTH in/on fortified potato commodities prepared by domestic and commercial processes. Results for fried potatoes and chips were not reported. For boiled potatoes without a peel, a reduction factor of 0.004 X was calculated, for boiled potatoes with a peel, a reduction factor of 0.17 X, for baked potatoes with a peel a reduction factor of 0.12 X was calculated, and for potato granules a reduction factor of 0.004 X was calculated. The established tolerance of 0.05 ppm for regulable residues of TPTH will cover residues in potato processed commodities from potatoes treated with TPTH. (based on current residue data [S. Law,1/14/99, MRID 44667001, D250912-17] showing 28 potato samples with non-detectable residues and a LOQ of 0.01 ppm for each compound of toxicological concern [MPTH, DPTH and TPTH]).

Upon re-evaluation of the data, the sugar beet processing study (MRID# 41785203) was deemed unacceptable (1991 Reregistration Standard Update) and a new study was required. Nonetheless, the data on phenyltins indicate that residues reduce 0.14X for molasses and reduce by 0.20X for refined sugar beet sugar during processing. A new confirmatory study will be required. Data from sugar beet processing studies (MRID 41785203) indicate that TPTH regulable residues do not concentrate in refined sugar, dehydrated pulp or molasses. The established tolerance for regulable residues of TPTH in/on sugar beet root (0.05 ppm) will cover residues in molasses and dehydrated pulp derived from processing sugar beets treated with TPTH.

Anticipated Residues for Dietary Risk Assessment

For the purposes of dietary risk assessment, anticipated residues (ARs)for TPTH regulable residues have been calculated for pecans, sugar beet roots and potatoes. They are provided below in Table 2. Note that these ARs have not incorporated percent of crop treated data or processing factors. These refinements should be incorporated into the DEEM™ analysis and will be given in the DEEM™ memo (S. Levy, DP258010 and DP257154, August 1999).

Table 2. Anticipated Residues (AR) for Dietary Risk Assessment (Does not Include % CT or Processing Factors).

Commodity	Acute AR (ppm)[1]	Chronic AR (ppm)[2]
Sugar beets	0.004	0.004
Sugar beet, refined sugar	0.004	0.004
Molasses	0.004	0.004
Pecan	0.005	0.005
Potato	0.015	0.015
Potato, chips	0.015	0.015
Potato, baked	0.015	0.015
Potato, boiled	0.015	0.015
Potato, granules	0.015	0.015

[1] AR calculated based on the addition of ½ the sum of LOQs (0.01 ppm) for each metabolite (TPTH, DPTH, and MPTH) for samples with non-detectable residues or based on the highest measured field trial result (value for pecans is based on total tin method - i.e., TPTH and its regulable metaboites plus any other form(s) of tin). If field trials were conducted at an exaggerated rate, the residue values were corrected for a 1x rate of application. For sugar beets, the rate of treatment was 2.9 lbs ai/A or 3.86x of the maximum labeled rate (0.75 lbs ai/A). For potatoes the treatment rate was the maximum labeled rate of 0.75 lbs ai/A (1x). For pecans the rate of treatment was 4.125 lbs ai/A or approximately 1x; the maximum labeled rate is 3.8 lbs ai/A (See Table A). Field trial data obtained from MRID #41267101 (reviewed by R. Perfetti, 1/10/90).

[2] AR calculated based on the addition of ½ the LOQ of 0.01 ppm for each metabolite or average of field trial results If field trials were conducted at an exaggerated rate, the residue values were corrected for a 1x rate of application. For sugar beets, the rate of treatment was 2.9 lbs ai/A or 3.86x of the maximum labeled rate (0.75 lbs ai/A). For potatoes the treatment rate was the maximum labeled rate of 0.75 lbs ai/A (1x). For pecans the rate of treatment was 4.125

lbs ai/A or approximately 1x; the maximum labeled rate is 3.8 lbs ai/A (See Table A). Field trial data obtained from MRID #41267101 (reviewed by R. Perfetti, 1/10/90).
%CT information: Acute Estimated Maximum: 44% for sugar beets, 23% for potatoes and 56% for pecans. Chronic Weighted Average: 35% for sugar beets, 13% for potatoes and 35% for pecans. Processing factors are given above.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Tolerance Reassessment

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs are fulfilled. A tolerance of 0.05 ppm has been established for residues of TPTH *per se* in liver and kidney of cattle, goats, sheep, hogs and horses. Currently, there are no TPTH uses on poultry feed items. For the purposes of tolerance reassessment only, a tolerance-based dietary burden for livestock has been calculated below. Based upon the established or reassessed tolerances for TPTH residues in/on animal feed items, the calculated tolerance-based theoretical dietary burdens for livestock are as follows in Table 3. Note that this is a worst case livestock dietary burden and is therefore used to reassess tolerances. Refined livestock diets used to calculate meat/milk anticipated residues are found later in this document.

Table 3. Calculation of tolerance-based dietary burdens of livestock animals for TPTH (this "worst-case" diet is used for reassessing livestock tolerances).

Feed Commodity	% Dry Matter [a]	% Diet [a]	Tolerance (ppm) [b]	Dietary Contribution (ppm) [c]
Beef Cattle				
Beet, sugar, tops	23	20	10	8.7
Beet, sugar, pulp, dried	88	5	0.05	0.003
Processed potato waste	15	75	0.1	0.5
TOTAL BURDEN		100		**9.20**
Dairy Cattle				
Beet, sugar, pulp, dried	88	20	0.05	0.01
Beet, sugar, molasses	75	10	0.05	0.007
Processed potato waste	15	40	0.1	0.26
Potato culls	20	20	0.05	0.05
TOTAL BURDEN		100		**0.4**
Swine				
Potato culls	20	50	0.05	0.03
TOTAL BURDEN				**0.03**

[a] Table 1, OPPTS 860 Guidelines (August 1996).
[b] Reassessed tolerance from Table C.
[c] Contribution = [tolerance / % DM (if cattle)] X % diet).

An adequate ruminant feeding study has been submitted in which cows were dosed orally for 28-30 days with TPTH at levels equivalent to 7, 21, and 70 ppm in the diet (approximately 0.76x,

2.3x, and 7.6x the tolerance-based dietary burden for beef cattle). The results are summarized below in Table 4.

Table 4. Results of Ruminant Feeding study.

Matrix	Feeding Levels		
	7 ppm	21 ppm	70 ppm
Milk	<0.02 (all samples all sampling times)	0.04 (all samples at 21-day plateau)	0.13(2), 0.15(2), 0.18 (at 14-day plateau)
Skimmed milk	<0.02 (all samples all sampling times)	<0.02 (all samples all sampling times)	Sampling discontinued due to toxicity problems
Cream	0.07(2),0.09 (at 28-day plateau)	0.19, 0.27, 0.37 (at 14-day plateau)	
Muscle	0.23, 0.24,0.31	0.63, 0.70, 0.75	
Kidney	0.68, 0.81,1.15	2.10, 2.79, 2.94	
Liver	2.52, 2.64, 3.20	7.13, 7.24, 7.93	
Subcutaneous fat	<0.10, <0.10, 0.11	0.22, 0.29, 0.31	
Peritoneal fat	<0.10, 0.11, 0.16	0.24, 0.24, 0.33	

The reassessed tolerances based on the beef and dairy cattle and swine diets using feed items with tolerance level residues and using average tissue residue levels, are given in Tables 5 and 6 below.

Table 5. Reassesed Tolerances - meat.

Matrix	Tolerances (ppm)			
	7 ppm (0.76x)[1]	21 ppm (2.3x)[1]	70 ppm (7.6x)[1]	Tolerance
Muscle	0.26 ÷ 0.76 = 0.34	0.69 ÷ 2.3 = 0.3	Sampling discontinued due to toxicity problems	0.50
Kidney	0.88 ÷ 0.76 = 1.15	2.61 ÷2.3 = 1.13		2.0
Liver	2.79 ÷ 0.76 = 3.7	7.43 ÷ 2.3 = 3.23		4.0
Peritoneal & Subcutaneous fat	0.11 ÷ 0.76 = 0.14	0.27 ÷ 2.3 = 0.11		0.2

[1] These extrapolated feeding levels are based on the beef cattle diet.

Table 6. Reassessed tolerances - milk.

Matrix	Tolerances (ppm)			
	7 ppm (17.5x)[1]	21 ppm (52.5x)[1]	70 ppm (175x)[1]	Tolerances
Milk	0.02 ÷ 17.5 = 0.001	0.04 ÷ 52.5 = 0.0008	0.15 ÷ 175 = 0.0009	0.06
Cream	0.076 ÷ 17.5 = 0.004	0.27 ÷ 52.5 = 0.005	NA	0.06
Skim Milk	0.02 ÷ 17.5 = 0.001	0.02 ÷ 52.5 = 0.0004	NA	0.06

[1] These extrapolated feeding levels are based on the dairy cattle diet.

The available data indicate that the established tolerances for residues of TPTH in the kidney and liver of cattle, goats, horses, and sheep (0.05 ppm each) are too low. These tolerances should be reassessed, in terms of the combined regulable residues of TPTH, to 4.0 ppm in liver and 2.0 ppm in kidney of cattle, goats, horses, and sheep.

Residue data from the feeding study also indicate that tolerances for the combined regulable residues of TPTH should be established in cattle, goats, horses, and sheep as follows: 0.5 ppm in meat; 0.2 ppm in fat; and 0.06 ppm in milk based on non-detectable levels (0.02 ppm) for each metabolite.

The low-dose group from the feeding study (7 ppm) is approximately 233.3x the theoretical dietary burden for swine. Using the results of the feeding study to reassess tolerances for swine, the data indicate that tolerances for regulable residues of TPTH in hog kidney and liver should be revoked concomitant with establishing a separate tolerance of 0.3 ppm for residues in hog meat byproducts (the combined LOQ for TPTH residues in kidney, liver and fat). In addition, tolerances should also be established for regulable residues of TPTH in hog fat at 0.3 ppm and in hog meat at 0.06 ppm (the combined LOQ for TPTH residues in meat).

Anticipated Residues for Dietary Risk Assessment

Chronic

For the purposes of chronic dietary risk assessment, average theoretical dietary burdens have been calculated. The average dietary burden for livestock is based on anticipated residues calculated from field trial data and ½ limit of detection (1/2 LOD) for samples with non-detectable residues with correction for exaggerated application rates. Sugar beet tops and processed potato waste are the two feed items with the highest regulable residues of TPTH and are included in the diet. However, of all feed items, residues on sugar beet tops dominate the cattle dietary burden of TPTH. Because sugar beet tops are not commonly fed to dairy cattle (sources include various USDA Extension Agents in cooperation with USDA-IR-4, literature searches, industry, academia and sugar beet equipment dealers), sugar beet tops are not included in the calculation of the dairy cattle theoretical average dietary burden for TPTH ARs (7/21/99

and 8/18/99, ChemSAC decisions). For TPTH residues in/on animal feed items, the calculated (average) theoretical dietary burdens for livestock are as follows in Table 7.

Table 7. Calculation of theoretical average dietary burdens of livestock animals for TPTH.

Feed Commodity	% Dry Matter [a]	% Diet [a]	Anticipated Residue (ppm) [b]	Dietary Contribution (ppm) [c]
Beef Cattle				
Beet, sugar, tops	23	20	5.0	4.35
Processed potato waste	15	50 [d]	0.015	0.05
TOTAL BURDEN				**4.4**
Dairy Cattle				
Beet, sugar, dehydrated pulp	88	20	0.004	0.001
Potato culls	20	20	0.0032	0.003
TOTAL BURDEN				**0.004**
Swine				
Potato culls	20	50	0.0032	0.008
TOTAL BURDEN				**0.008**

[a] Table 1, OPPTS 860 Guidelines (August 1996).

[b] Anticipated residue for **sugar beet tops** calculated from the average of field trial data at a 21-day PHI (5.0 ppm) (L. Cheung memo, 2/23/96, MRID 43836601, D221156).
Anticipated residue for **wet potato peels** calculated from the average of field trial data at a 7-day PHI for potatoes. All 28 samples had non-detectable residues. One-half the limit of detection (0.005 ppm) added for all 3 compounds of toxic concern (0.015 ppm) (S. Law memo, 1/14/99, MRID 44667001, D250912-17).

[c] Contribution = [anticipated residue/ % DM (if cattle)] X % diet).

[d] It is not realistic for beef cattle to eat a diet consisting of 75% processed potato waste and 20% sugar beet tops (as is listed in Table 1, OPPTS 860 Guidelines (August 1996)). Therefore, to reflect a more realistic beef cattle diet, 50% of processed potato waste in the beef diet is used instead of 75%, for purposes of this assessment only.

An adequate ruminant feeding study has been submitted in which cows were dosed orally for 28-30 days with TPTH at levels equivalent to 7, 21, and 70 ppm in the diet (approximately 1.6x, 4.8x, and 16x the average theoretical dietary burden for beef cattle of 1.35 ppm). The combined residues of TPTH, DPTH and MPTH, expressed as TPTH equivalents, in dairy cattle matrices are summarized below in Table 8.

Table 8. Results of Dairy Feeding Study.

Matrix	Feeding Levels		
	7 ppm	21 ppm	70 ppm
Milk	<0.02 (all samples all sampling times)	0.04 (all samples at 21-day plateau)	0.13(2), 0.15(2), 0.18 (at 14-day plateau)
Skimmed milk	<0.02 (all samples all sampling times)	<0.02 (all samples all sampling times)	Sampling discontinued due to toxicity problems
Cream	0.07(2),0.09 (at 28-day plateau)	0.19, 0.27, 0.37 (at 14-day plateau)	
Muscle	0.23, 0.24,0.31	0.63, 0.70, 0.75	
Kidney	0.68, 0.81,1.15	2.10, 2.79, 2.94	
Liver	2.52, 2.64, 3.20	7.13, 7.24, 7.93	
Subcutaneous fat	<0.10, <0.10, 0.11	0.22, 0.29, 0.31	
Peritoneal fat	<0.10, 0.11, 0.16	0.24, 0.24, 0.33	

The calculated anticipated residues for use in the chronic dietary risk assessment are given in the Tables 9, 10 and 11 below:

Table 9. Chronic Anticipated Residues - Meat.

Matrix	**Chronic Anticipated Residues (AR) @ Feeding Levels (ppm)**			
	7 ppm (1.6x)[1]	21 ppm (4.8x)[1]	70 ppm (16x)[1]	Average AR
Muscle	0.26 ÷ 1.6 = 0.16	0.69 ÷ 4.8 = 0.14	Sampling discontinued due to toxicity problems	0.15
Kidney	0.88 ÷ 1.6 = 0.55	2.61 ÷ 4.8 = 0.54		0.55
Liver	2.79 ÷ 1.6 = 1.74	7.43 ÷ 4.8 = 1.55		1.65
Peritoneal & Subcutaneous fat	0.11 ÷ 1.6 =0.07	0.27 ÷ 4.8 = 0.06		0.07

[1] These extrapolated feeding levels are based on the beef cattle diet (4.4 ppm = 1X level).

Table 10. Chronic Anticipated Residues - swine meat.

Matrix	Tolerances (ppm)			
	7 ppm (875x)[1]	21 ppm (2625x)[1]	70 ppm (8750x)[1]	Average AR
Muscle	0.26 ÷ 875 = 0.0003	0.69 ÷ 2625 = 0.0003	Sampling discontinued due to toxicity problems	0.0003
Kidney	0.88 ÷ 875 = 0.001	2.61 ÷ 2625 = 0.001		0.001
Liver	2.79 ÷ 875 = 0.003	7.43 ÷ 2625 = 0.003		0.003
Peritoneal & Subcutaneous fat	0.11 ÷ 875 = 0.0001	0.27 ÷ 2625= 0.0001		0.0001

[1] These extrapolated feeding levels are based on the swine diet (0.008 ppm = 1X level).

Table 11. Chronic Anticipated Residues - Milk.

Matrix	Chronic Anticipated Residues (AR) @ Feeding Levels (ppm)			
	7 ppm (1750x)[1]	21 ppm (5250x)[1]	70 ppm (17,500x)[1]	Average AR
Milk	0.02 ÷ 1750 = 0.000011	0.04 ÷ 5250 = 0.000008	0.15 ÷ 17,500 = 0.000009	0.00003
Cream	0.076 ÷ 1750 = 0.000043	0.27 ÷ 5250 = 0.00005	NA	0.00005
Skim Milk	0.02 ÷ 1750 = 0.000011	0.02 ÷ 5250 = 0.000004	NA	0.000008

[1] These extrapolated feeding levels are based on the dairy cattle diet (0.004 ppm = 1X level).

Acute

For the purposes of acute dietary risk assessment, reasonable maximum theoretical dietary burdens have been calculated. The reasonable maximum dietary burden for livestock is based on the highest average field trial residue (HAFT) calculated from field trial data for sugar beet tops (beef cattle only, see page 10 for rationale). Sugar beet tops contain the highest residues of any of several feed items and is included here as the only beef cattle feed item because its residues will dominate any diet. For TPTH residues in/on livestock feed items, the calculated reasonable maximum theoretical dietary burdens for livestock are as follows in Table 12:

Table 12. Calculation of reasonable maximum dietary burdens of livestock animals for TPTH.

Feed Commodity	% Dry Matter [a]	% Diet [a]	Anticipated Residue (ppm) [b]	Dietary Contribution (ppm) [c]
Beef Cattle				
Beet, sugar, tops	23	20	9.67	8.4
TOTAL BURDEN				**8.4**
Dairy Cattle				
Beet, sugar, dehydrated pulp	88	20	0.004	0.001
Potato culls	20	20	0.0032	0.003
TOTAL BURDEN				**0.004**
Swine				
Potato Culls	20	50	0.0032	0.008
TOTAL BURDEN				**0.008**

[a] Table 1, OPPTS 860 Guidelines (August 1996).

[b] For beef cattle, anticipated residue for **sugar beet tops** calculated from the highest average field trial value of 2 samples from the field trial with the highest residues at a 21-day PHI (9.67 ppm). For dairy cattle, the average residue was used (5.05 ppm). (L. Cheung memo, 2/23/96, MRID 43836601, D221156).

[c] Contribution = [anticipated residue/ % DM (if cattle)] X % diet).

For the purposes of acute dietary risk assessment, the calculated anticipated residues for use in the acute dietary risk assessment are given in the Tables 13, 14 and 15 below. For the purposes of extrapolation, 8.4 ppm is considered to be the 1x feeding level for acute dietary risk assessment for livestock tissues. The feeding levels from the feeding study correspond approximately 0.83x, 2.5x, and 8.3x the reasonable maximum dietary burden for beef cattle of 8.4 ppm).

Table 13. Acute Anticipated Residues - Meat.

Matrix	Acute Anticipated Residues (AR) @ Feeding Levels (ppm)			
	7 ppm (0.83x)[1]	21 ppm (2.5x)[1]	70 ppm (8.3x)[1]	Anticipated Residue
Muscle	0.26 ÷ 0.83 = 0.31	0.69 ÷ 2.5 = 0.28	Sampling discontinued due to toxicity problems	0.30
Kidney	0.88 ÷ 0.83 = 1.06	2.61 ÷ 2.5 = 1.04		1.0
Liver	2.79 ÷ 0.83 = 3.36	7.43 ÷ 2.5 = 2.97		3.16
Peritoneal & Subcutaneous fat	0.11 ÷ 0.83 = 0.13	0.27 ÷ 2.5 = 0.108		0.12

[1] These extrapolated feeding levels are based on the beef cattle diet (8.4 ppm = 1X)

Table 14. Reassesed Tolerances - swine meat.

Matrix	Tolerances (ppm)			
	7 ppm (875x)[1]	21 ppm (2625x)[1]	70 ppm (8750x)[1]	Average AR
Muscle	0.26 ÷ 875 = 0.0003	0.69 ÷ 2625 = 0.0003	Sampling discontinued due to toxicity problems	0.0003
Kidney	0.88 ÷ 875 = 0.001	2.61 ÷ 2625 = 0.001		0.001
Liver	2.79 ÷ 875 = 0.003	7.43 ÷ 2625 = 0.003		0.003
Peritoneal & Subcutaneous fat	0.11 ÷ 875 = 0.0001	0.27 ÷ 2625= 0.0001		0.0001

[1] These extrapolated feeding levels are based on the swine diet (0.008 ppm = 1X level).

For the purposes of extrapolation, 0.004 ppm is considered to be the 1x feeding level for acute dietary risk assessment for milk. The feeding levels from the feeding study correspond to approximately 1750x, 5250x, and 17,5006x the reasonable maximum dietary burden for dairy cattle of 0.004 ppm.

Table 15. Acute Anticipated Residues - Milk.

Matrix	Acute Anticipated Residues (AR) @ Feeding Levels (ppm)			
	7 ppm (1750x)[1]	21 ppm (5250x)[1]	70 ppm (17,500x)[1]	Average AR
Milk	0.02 ÷ 1750 = 0.000011	0.04 ÷ 5250 = 0.000008	0.15 ÷ 17,500 = 0.000009	0.00003
Cream	0.076 ÷ 1750 = 0.000043	0.27 ÷ 5250 = 0.00005	NA	0.00005
Skim Milk	0.02 ÷ 1750 = 0.000011	0.02 ÷ 5250 = 0.000004	NA	0.000008

[1] These extrapolated feeding levels are based on the dairy cattle diet (0.004 ppm = 1X level).

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, Irrigated Crops

TPTH is not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

TPTH is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under these guideline topics.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

A confined rotational crop study is available and was previously reviewed and deemed adequate by EFED (E. Regelman, 2/22/91). Total radioactive residues (TRR) were 0.011-0.096 ppm in/on RACs of spinach, radish, carrots, and wheat planted 30 days following the last of six soil applications of ^{14}C-TPTH at 0.25 lb ai/A/application (totaling 1.5 lb ai/A/season; **2x**). TRRs in rotational crop RACs were 0.024-0.066 ppm from the 120-day plant-back interval (PBI) and <0.008-0.017 ppm from the 365-day PBI. Analyses of spinach leaves, radish and carrot roots, and wheat grain from the 30- and 120-day PBIs indicated that total organotin compounds accounted for ≤0.005 ppm in each commodity and were comprised mainly of TPTH. These data indicate that accumulation of TPTH residues in rotational crops is limited. As TPTH residues of concern were <0.01 ppm at the 30-day PBI, limited field rotational crops studies are not required, and the registrants should amended all labels to include a 30-day rotational crop restriction.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

Based on the results from the confined rotational study, limited field studies on TPTH residues in rotational crops are not required.

Table A. Food/Feed Use Patterns Subject To Reregistration for Triphenyltin Hydroxide (Case 0099).

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations [b]
Sugar beets					
Broadcast foliar applications Aerial or ground equipment	4 lb/gal FlC [1812-244] [45639-186] 80% WP [1812-350] 0.5 lb/gal EC [1812-351] 47.5% WP [45639-170]	0.25	3	10	The labels specify a maximum rate of 0.75 lb ai/A/season. The minimum volume for aerial and ground applications is 5 and 15 gal/A, respectively. The label prohibits the grazing or feeding of sugar beet tops to livestock. A 21-day PHI is specified except on the 47.5% WP label which specifies a 14-day PHI.
Potatoes					
Broadcast foliar application Aerial, ground or chemigation equipment	4 lb/gal FlC [1812-244] [45639-186] 80% WP [1812-350] 0.5 lb/gal EC [1812-351]	0.19	4	7 [c]	The label specifies a maximum rate of 0.75 lb ai/A/season. The minimum volume for aerial applications is 3 gal/A. A 21-day PHI is specified.
	47.5% WP [45639-170]	0.24	3	7	The label allows a maximum rate of 0.71 lb ai/A/season. The minimum volume for aerial applications is 3 gal/A. A 7-day PHI is specified.

(continued; footnotes follow)

Table A. Continued.

Site Application Type Application Timing Application Equipment [a]	Formulation [EPA Reg. No.]	Max. Single Application Rate (lb ai/A)	Max. # Apps./season	Minimum Retreatment Interval (Days)	Use Limitations [b]
Pecans					
Broadcast foliar applications Aerial or ground equipment	4 lb/gal FlC [1812-244] 80% WP [1812-350] 47.5% WP [45639-170]	0.38	10	14	The label allows a maximum of 3.8 lb ai/A/season. The minimum volume for aerial applications is 20 gal/A. The label prohibits applications after shucks have started to open; a PHI is not specified.

[a] The labels prohibit application through any type of irrigation system except on potatoes. Chemigation of potatoes through any irrigation system other than the following is prohibited: sprinkler including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set, or hand move irrigation systems.

[b] The labels specify a 48-hour restricted entry interval (REI) for all crops with the exception of labels for the 47.5% WP (EPA Reg. No. 45639-170) and a 4 lb/gal FlC (EPA Reg. No. 45639-186) which specify a 24-hour REI.

[c] Use directions for potatoes on the 4 lb/gal FlC labels (EPA Reg Nos. 1812-244 and 45639-186) do not indicate a RTI. These labels state that applications to potatoes "should begin with the appearance of blight weather conditions and continue as needed."

Table B. Residue Chemistry Science Assessments for Reregistration of Triphenyltin Hydroxide.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1200: Directions for Use	N/A	Yes[2]	See Table A.
860.1300: Plant Metabolism	N/A	No	**00030252 00030253 00030254 00030309 00030310 00030311 00086459 00086493 00086494 00124220**
860.1300: Animal Metabolism	N/A	No	**00030250 00030251 00030313 00030315 00030316 00080381 00086552 00086553 00086554 00124220**
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	Yes[3]	**00029834 00029835 00030259 00030272 00036021 00036027 00036029 00080387 00086450 00086452 00086472 00086473 00086534 00086545 00086561 00086569 00086571 00086601 00086603 00124220** *00156382 00160465 00160466 00160467 00160468 00160469 00165010 00165025 40149301 40149302 40149303 40149304 40149305 40149401 40149402 41556601 41556602 41785201 41785202 41785203 41785204* 42806101[4] 43617901[5] 43635501[6] 43838801[7] 43838802[7] 43855301[8] 43855302[8] 43855303[8] 43874701[9] 43874702[9] 44066301[10] 44066302[10]
- Animal commodities	N/A	Yes [11]	43808101[12] 43808102 [12] 44334401[13] 44334402 [13]
860.1360: Multiresidue Methods	N/A	Yes [14]	

(continued; footnotes follow)

Table B. Continued.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [1]
860.1380: Storage Stability Data	N/A	Yes [15]	*41556601 41556602 41785201 41785202* 42564801[16] 42806101[4] 42965101[17]
860.1500: Crop Field Trials			
Root and Tuber Vegetables Group			
- Potatoes	0.05 [§180.236]	No	**00086492 00086494** *00160466 40149401 40149304 41556602* 44667001[18]
- Sugar beets, roots	0.05 [§180.236]	No	**00086560** *00160468 40149302 40149401 41556601*
Leaves of Root and Tuber Vegetables Group			
- Sugar beets, tops	0.05 [§180.236]	No	43836601[19]
Tree Nuts Group			
- Pecans	0.05 [§180.236]	No	**00086600** *00165025 40149303 41267101*[20]
860.1520: Processed Food/Feed			
- Sugar beet	None	No	*41785201 41785203*
- Potatoes	None	No	*41785202 41785204*
860.1480: Meat, Milk, Poultry, and Eggs			
- Liver and kidney of cattle, goats, hogs, horses, and sheep	0.05 [§180.236]	No	**00053415 00080381** 44334401[13] 44334402[13]
860.1400: Water Fish and Irrigated Crops	None	N/A	
860.1460: Food Handling	None	N/A	
860.1850: Confined Rotational Crops	None	No	41512701[21]
860.1900: Field Rotational Crops	None	No	

(continued; footnotes follow)

1. **Bolded** references were reviewed in the Residue Chemistry Chapter of the Triphenyltin Hydroxide Reregistration Standard dated 4/11/84, and *italicized* references were reviewed in the Residue Chemistry Chapter of the Triphenyltin Hydroxide Reregistration Standard Update dated 3/18/92. All other references were reviewed as noted.

2. Based upon the available residue data and/or changes in data requirements, the Agency is recommending changes to use directions. The recommended label amendments are listed in the SUMMARY OF SCIENCE FINDINGS, under Directions for Use.

3. The proposed enforcement method for plants must be validated by the Agency prior to publication in the Pesticide Analytical Manual, Volume II. The method has been submitted for an Agency method tryout.

4. DP Barcode D192579, L Cheng, 11/23/93.

5. DP Barcode D215273, L. Cheng, 6/27/95.

6. DP Bårcode D216970, L. Cheng, 7/25/95.

7. DP Barcode D221155, L Cheng, 2/23/96.

8. DP Barcode D222076, L Cheng, 1/24/97.

9. DP Barcode D222078, L Cheng, 2/23/96.

10. DP Barcode D228535, L Cheng, 1/24/97.

11. The GC/FPD method used to determine TPTH residues in the ruminant feeding study is adequate for data collection. However, HED has previously concluded that the method must be modfied to include a base hydrolysis step to release conjugated residues. Alternatively, the registrants must provide data indicating that base hydrolysis is unnecessary for adequate reovery of the total toxic residue, i.e. radiovalidation of htemethod. An ILV of the method has been conducted in accordance with PR Notice 96-1, TMV is currently underway.

12. DP Barcode D220557, L. Cheng, 2/23/96.

13. DP Barcode D239451, J. Punzi, 4/2/98.

14. The registrants need to provide recovery data for TPTH and its metabolites using FDA multiresidue methods. The registrants are referred to OPPTS GLN 860.1360 for details concerning multiresidue method testing.

15. Data are required depicting the storage stability of TPTH and its metabolites in pecans held in frozen storage for up to 9 months. Data are also required depicting the storage stability of TPTH residues in sugar beet tops stored frozen for up to 2 years. The registrants have informed the Agency that the required 2-year study on sugar beets is underway.

16. DP Barcode D185360, L. Cheng, 3/10/93.

17. DP Barcode D196286 and D211111, L. Cheng, 7/12/94 and 4/18/95.

(continued; footnotes follow)

18. DP Barcodes D250912 and D250917, S.Law

19. DP Barcode D221156, D226002, and D234680, L. Cheng, 2/23/96, 1/24/97 and 7/28/97.

20. No DP Barcode, R. Perfetti, 5/6/94.

21. EFGWB, E. Regelman, 2/22/91.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of TPTH are currently expressed in terms of TPTH *per se* (40 CFR §180.236). For purposes of tolerance enforcement, TPTH residues of concern in plant and animal commodities have been determined to include TPTH and its metabolites, MPTH and DPTH. Accordingly, the tolerance definition for TPTH residues should also be changed to read as follows:

> Tolerances are established for the combined residues of the fungicide triphenyltin hydroxide and its monophenyltin (MPTH) and diphenyltin (DPTH) hydroxide and oxide metabolites, expressed in terms of parent TPTH, in/on the following raw agricultural commodities:

A summary of the TPTH tolerance reassessment for the animal and crop commodities and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.236:

Sufficient data are available to reassess tolerances for the residues of TPTH, DPTH, and MPTH in/on pecans, potatoes, sugar beets, and livestock commodities.

The available residue data indicate that the established tolerances for TPTH regulable residues in/on pecans, potatoes and sugar beet roots are adequate provided that use directions are amended as required, and storage stability data are provided for residues in pecans. Existing tolerance for sugar beet root is adequate to cover residues in refined sugar, molasses, and dehydrated pulp from sugar beet processing. The existing tolerance for potato is adequate to cover residues in potato processed commodities.

The available data indicate that the established tolerances for regulable residues of TPTH in the kidney and liver of cattle, goats, horses, and sheep (0.05 ppm each) are too low. These tolerances should be reassessed, in terms of the combined regulable residues of TPTH, to 4.0 ppm in liver and 2.0 ppm in kidney of cattle, goats, horses, and sheep.

Residue data indicate that tolerances for residues of TPTH in hog kidney and liver should be revoked concomitant with establishing a separate tolerance of 0.3 ppm for residues in hog meat byproducts.

Tolerances Needed Under 40 CFR §180.236:

Based on the available residue data, a tolerance of 10.0 ppm should be established for regulable TPTH residues in/on sugar beet tops.

For livestock commodities, new tolerances for the combined residues of TPTH in cattle, goat, horse, and sheep commodities should be established at 0.5 ppm in meat, 0.2 ppm in fat, and 0.06 ppm in milk. New tolerances are needed for residues in hog meat and fat (at 0.06 and 0.3 ppm, respectively). In addition, the separate tolerances for residues in hog kidney and liver should be revoked concomitant to establishing a separate tolerance for residues in hog meat byproducts at 0.3 ppm.

Table C. Tolerance Reassessment Summary for Triphenyltin Hydroxide.

Commodity	Current Tolerance (ppm) [a]	Tolerance Reassessment (ppm) [b]	Comment/*Correct Commodity Definition*
Tolerances listed under 40 CFR §180.236:			
Pecans	0.05	0.05	*Pecan*
Potatoes	0.05	0.05	*Potato*
Sugar beet, roots	0.05	0.05	*Beets, sugar, roots*
Liver and kidney of cattle, goats, horses, and sheep	0.05	4.0	The available data from the ruminant feeding study support increasing the tolerance on liver.
		2.0	The available data from the ruminant feeding study support increasing the tolerance on kidney.
Liver and kidney of hogs		Revoke	The tolerance should be revoked concomitant with establishing a separate 0.3 ppm tolerance for residues in *meat byproducts* of hogs.
Tolerances needed under 40 CFR §180.236:			
Beets, sugar, tops (leaves)	None	10.0	Based on the available field trial data on sugar beet tops.
Meat of cattle, goats, horses, and sheep	None	0.5	Based on data from the ruminant feeding study.
Fat of cattle, goats, horses, and sheep	None	0.2	
Hog, fat	None	0.3	
Hog, meat	None	0.06	
Hog, meat byproducts	None	0.3	A tolerance of 0.3 ppm for residues in mbyp should be established to replace separate tolerances for residues in kidney and liver
Milk	None	0.06	Based on non-detectable residues and a LOQ of 0.02 ppm for each metabolite.

[a] Expressed in terms of TPTH *per se*.

[b] Expressed in terms of the combined residues of TPTH, and its metabolites MPTH and DPTH.

CODEX HARMONIZATION

There are currently no Codex Maximum Residue Limits (MRLs) established for residues of TPTH in/on plant or animal commodities (electronic correspondence from S. Funk, 10/15/98).

AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode: D185360
Subject: Triphenyltin Hydroxide. Case # 0099. Storage Stability in Potato, Sugar Beet, Sugar and Molasses.
From: L. Cheng, HED
To: E. Feris, SRRD
Dated: 3/10/93
MRID(s): 42564801

DP Barcode: D192579
Subject: Triphenyltin Hydroxide (TPTH). Case No. 0099. Registrants' Response to Reregistration Standard Update of 3/92.
From: L. Cheng, HED
To: W. Waldrop, SRRD
Dated: 11/22/93
MRID(s): 42806101

DP Barcode: None
Subject: Response to the TPTH Reregistration Standard: Residue Chemistry
From: R.B. Perfetti, HED
To: L. Rossi, SRRD
Dated: 5/6/94
MRID(s): None

DP Barcode: D196286
Subject: Triphenyltin Hydroxide (TPTH). Case No. 0099. Response to Product and Residue Chemistry Reviews.
From: L. Cheng, HED
To: E. Ferris, SRRD
Dated: 7/12/94
MRID(s): 42065601 & 42965101

DP Barcode: D211111
Subject: Triphenyltin Hydroxide (TPTH). Case No. 0099. Additional Information on GLN 62-1 for Elf Atochem & 171-4(e).
From: L. Cheng, HED
To: J. Andreasen, SRRD
Dated: 4/18/95
MRID(s): None

DP Barcode: D215273
Subject: TPTH. Case No. 0099. Data to Satisfy GLN 171-4(c) and 4(d)/
From: L. Cheng, HED
To: J. Andreasen, SRRD
Dated: 6/27/95
MRID(s): 43617901

DP Barcode: D216970
Subject: TPTH. Case 0099. Validation of Analytical Method. GLN 171-4(c).
From: L. Cheng, HED
To: J. Andreasen, SRRD
Dated: 7/25/95
MRID(s): 43635501

DP Barcode: D222078
Subject: TPTH/Fentin Hydroxide. Case 0099. Additional Data for Analytical Method (171-4c).
From: L. Cheng, HED
To: J. Andreasen, SRRD
Dated: 2/23/96
MRID(s): 43874701 & 43874702

DP Barcode: D221155
Subject: TPTH/Fentin Hydroxide. Case 0099. Method Validation in Sugarbeet and Potato.
From: L. Cheng, HED
To: J. Andreasen, SRRD
Dated: 2/23/96
MRID(s): 43838801 & 43838802

DP Barcode: D220557
Subject: TPTH/Fentin Hydroxide. Case 0099. Residue Method In Meat and Milk.
From: L. Cheng, HED
To: J. Andreasen, SRRD
Dated: 2/23/96
MRID(s): 43808101 & 43808102

DP Barcode: D221156
Subject: TPTH/Fentin Hydroxide. Case 0099. Magnitude of Residue in Sugarbeet Leaves.
From: L. Cheng, HED
To: J. Andreasen, SRRD
Dated: 2/23/96

MRID(s): 43836601

DP Barcode: D226002
Subject: Triphenyltin Hydroxide (TPTH). Case 0099. Calculation of Maximum Residue in Sugar Beet.
From: L. Cheng, HED
To: C. Scheltema, HED
Dated: 1/24/97
MRID(s): None

DP Barcode: D222076
Subject: TPTH/Fentin Hydroxide. Case 0099. Method Validation in Sugarbeet and Potato Processed Commodities.
From: L. Cheng, HED
To: C. Scheltema, HED
Dated: 1/24/97
MRID(s): 43855301, 43855302 & 43855303

DP Barcode: D228535
Subject: TPTH/Fentin Hydroxide. Case 0099. Method Validation in Potato Processed Commodity - Chips.
From: L. Cheng, HED
To: C. Scheltema, HED
Dated: 1/24/97
MRID(s): 44066301 & 44066302

DP Barcode: D234680
Subject: TPTH/Fentin Hydroxide. Case 0099. Landis Letter Dated 3/24/97.
From: L. Cheng, HED
To: K. Boyle, HED
Dated: 7/28/97
MRID(s): None

DP Barcode: D239451
Subject: Triphenyltin Hydroxide Reregistraton. Dairy Cattle Feeding Study and Analytical Method Validation.
From: J.S. Punzi, HED
To: R. McNally, SRRD
Dated: 4/2/98
MRID(s): 44334401 & 44334402

DP Barcode: D250912-17
Subject: TPTH/Fentin Hydroxide. Case 0099. Magnitude of Residue in Potatoes.
From: S. Law
To: A. Chiri
Dated: 1/14/99
MRID(s): 44667001

DP Barcode: D257154
Subject: TPTH/Fentin Hydroxide. Case 0099. Review of Registrant Submitted Monte Carlo (Probabilistic) Acute and Chronic (Non-Cancer and Cancer) Dietary Exposure Analyses for TPTH Residues in Pecans, Potatoes, Sugar Beets, Meat and Milk.
From: S. Levy
To: L. Phan
Dated: 8/20/99
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