



04 / OPP # 34211

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

(TOPP)

January 14, 1998

MEMORANDUM:

SUBJECT: Triphenyltin Hydroxide: Registrants' Response to Residue Chemistry Data Requirements. PC Code No. 083601. Case No. 0099. MRID # 44667001. DP Barcodes D250912, D250915 and D250917.

FROM: Sarah Law, Chemist *Sarah Law*
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THRU: Steve Knizner, Branch Senior Scientist *Steve Knizner*
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TO: Angel Chiri, Chemical Review Manager
Special Review and Reregistration Division (7508W)

The TPTH Reregistration Standard Update dated 3/18/92 required that the registrants amend TPTH labels to specify a 21-day postharvest interval (PHI) to reflect the potato residue data submitted for reregistration. Since then, the TPTH Task Force has submitted a new magnitude of the residue study (MRID 44667001) to support a reduced PHI of 7 days on potatoes. The submission was reviewed by the Dynamac Corporation under the supervision of HED and has undergone secondary review in HED to reflect Agency policies.

Conclusions:

1. Potato samples from the crop field trials were analyzed for residues of TPTH and its metabolites, DPTH and MPTH, using a GC/FPD method adequate for data collection purposes. The limit of quantitation (LOQ) for each analyte in/on potatoes is 0.01 ppm. The method (HRC PWT 117/951733) has previously undergone a successful ILV trial, and a later version (Method AL007/91-0) has been submitted for an Agency method tryout.



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2. The submitted residue data from 14 trials on potatoes are adequate. The combined residues of TPTH were <0.03 ppm (< the combined LOQ of TPTH, DPTH and MPTH) in/on 28 samples of potatoes harvested 7 days following the last four foliar applications of TPTH (70% WP or 4 lb/gal FIC) at approximately 0.19 lb ai/A/application (approximately 0.75 lb I/A/season; 1x the registered seasonal rate). These data support a reassessed tolerance of 0.05 ppm for combined residues of TPTH and its metabolites DPTH and MPTH in/on potatoes.
3. The residue data submitted adequately support the proposed reduction in the labeled PHI from 21 to 7 days for TPTH uses on potatoes. The registrants have submitted labels for the 4 lb/gal FIC and 80% WP (EPA Reg. Nos. 1812-244 and -350), sold as SUPER TIN® 4L and 80 WP, which have been amended to specify a 7-day PHI. In addition, the registrants have submitted an amended label for the 0.5 lb/gal EC (EPA Reg. No. 18120351), a multiple active ingredient (MAI) formulation, sold as PRO-TEX®, which includes maneb. The label has been amended to allow a 7-day PHI in CT, DE, FL, ME, MI, NH, NY, OH, PA, RI, VT, and WI, and a 14-day PHI in all other states.
4. HED notes that the registrants have provided amended labels for only three of the five EPs with registered TPTH uses on potatoes, EPA Reg. Nos. 1812-244, -350, and -351. The registrants may amend use directions on all TPTH EPs with uses on potatoes to specify a 7-day PHI.
5. The registrants could also amend use directions for potatoes on the 4 lb/gal FIC (EPA Reg. Nos. 1812-244 and 45639-186) to indicate a minimum retreatment interval (RTI) or 7 days.

If additional input is needed, please advise.

Attachment 1: Registrant's Response to Residue Chemistry Data Requirement (MRID 44667001).

cc: RF, S. Law (RCAB), S. Knizner (RCAB), List A File, Circulation
RDI: CM2, Room 821I, 305-0783, SJL 01/14/99, SAK 01/14/99

TRIPHENYL TIN HYDROXIDE
PC Code 083601; Case 0099
(DP Barcodes D250912, D250915 and D250917)

Registrants' Response to Residue Chemistry Data Requirements

December 4, 1998

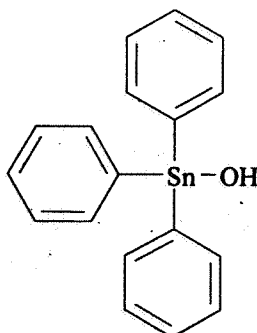
Contract No. 68-D4-0010

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Arlington, VA

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3910

TRIPHENYLTIN HYDROXIDE



(PC Code 083601, Case No. 0099)

DP Barcodes D250912 and D250917

REGISTRANTS' RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The TPTH Reregistration Standard Update dated 3/18/92 required that the registrants amend TPTH labels for potatoes to specify a 21-day postharvest interval (PHI) to reflect the potato residue data submitted for reregistration. The TPTH Task Force submitted a new magnitude of the residue study (1997; MRID 44667001) to support a reduced PHI of 7 days on potatoes. The data from this submission are evaluated herein for adequacy in fulfilling residue chemistry data requirements for the reregistration of TPTH. The conclusions and recommendations stated below pertain only to the magnitude of the residue and analytical methodology.

The qualitative nature of TPTH residues 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 TPTH Update concluded that the residues to be regulated in plants and animals are TPTH and the di- and monophenyltin hydroxide (DPTH and MPTH) or oxide metabolites.

Tolerances of 0.5 ppm have been established for residues of TPTH *per se* in/on pecans, potatoes, and sugar beet roots, and in kidney and liver of cattle, goats, hogs, horses, and sheep [40 CFR §180.236]. The available methods for tolerance enforcement (PAM, Volume II, Methods I through 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 enforcement method (GC/flame photometric detection (FPD) Method AL007/91-0), which quantifies TPTH and its metabolites, DPTH and MPTH, has undergone successful independent laboratory validation (ILV) using sugarbeet and potato matrices, and has been submitted for an Agency method tryout (DP Barcode D228535, 1/24/97, L. Cheng).

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

CONCLUSIONS AND RECOMMENDATIONS

Residue Analytical Methods

1. Potato samples from the crop field trials were analyzed for residues of TPTH and its metabolites, DPTH and MPTH, using a GC/FPD method adequate for data collection purposes. The limit of quantitation (LOQ) for each analyte in/on potatoes is 0.01 ppm. The method (HRC PWT 117/951733) has previously undergone a successful ILV trial, and a later version (Method AL007/91-0) has been submitted for an Agency method tryout.

Magnitude of the Residue in Plants

- 2a. The submitted residue data from 14 trials on potatoes are adequate. The combined residues of TPTH were <0.03 ppm (< the combined LOQ) in/on 28 samples of potatoes harvested 7 days following the last of four foliar applications of TPTH (70% WP or 4 lb/gal FIC) at ~0.19 lb ai/A/application (~0.75 lb ai/A/season; 1x the registered seasonal rate). These data indicate that the combined residues of TPTH and its metabolites will not exceed the established tolerance of 0.05 ppm for TPTH residues in/on potatoes.
- 2b. The residue data submitted adequately support the proposed reduction in the labeled PHI from 21 to 7 days for TPTH uses on potatoes. The registrants have submitted labels for the 4 lb/gal FIC and 80% WP (EPA Reg. Nos. 1812-244 and -350), sold as SUPER TIN® 4L and 80WP, which have been amended to specify a 7-day PHI. In addition, the registrants have submitted an amended label for the 0.5 lb/gal EC (EPA Reg. No. 1812-351), a multiple active ingredient (MAI) formulation, sold as PRO-TEX®, which includes

maneb. The label has been amended to allow a 7-day PHI in CT, DE, FL, ME, MI, NH, NY, OH, PA, RI, VT, and WI, and a 14-day PHI in all other states.

- 2c. HED notes that the registrants have provided amended labels for only three of the five EPs with registered TPTH uses on potatoes, EPA Reg. Nos. 1812-244, -350, and -351. The registrants may amend use directions on all TPTH EPs with uses on potatoes to specify a 7-day PHI.
- 2d. The registrants could also amend use directions for potatoes on the 4 lb/gal FIC (EPA Reg Nos. 1812-244 and 45639-186) to indicate a minimum retreatment interval (RTI) of 7 days.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Potato tuber samples were analyzed for residues of TPTH and its metabolites (DPTH and MPTH) using a GC/FPD method. The method, identified as HRC PWT 117/951733 and also as AgrEvo Residue Method AL007/91-0 in previous Agency reviews, has undergone a successful ILV trial and has been submitted for an Agency method validation (DP Barcodes D221155 and D228535, L. Cheng, 2/23/96 and 1/24/97). Analyses were performed by Huntingdon Life Sciences, Ltd., Huntingdon, England. The method is summarized below.

Briefly, residues are extracted from potatoes with acidified methanol, diluted with 6% saline, partitioned into toluene, centrifuged, and evaporated to dryness. The residues are redissolved in tetrahydrofuran, derivatized using butyl magnesium chloride, and any excess Grignard reagent is hydrolyzed using sulfuric acid. The residues are partitioned into hexane, washed with water, dried over sodium sulfate, and concentrated. Residues in the hexane concentrate are cleaned-up on a column of silica gel using hexane as the eluent, and analyzed by GC/FPD with a tin filter (610 nm). For reporting purposes, residues of the butyl derivative of each analyte are converted to TPTH equivalents. The LOQ for residues of each analyte in/on potatoes is 0.01 ppm; the limit of detection (LOD) is 0.0013-0.0017 ppm for each analyte. Adequate sample calculations and chromatograms were submitted.

In conjunction with the potato residue study (1997; MRID 44667001), the registrants submitted a method description together with procedural recovery data. For procedural recoveries, control samples of potato tuber were fortified simultaneously with TPTH, DPTH, and MPTH at 0.03 or 0.30 ppm (0.01 or 0.1 ppm of each analyte in TPTH equivalents) and analyzed using the GC/FPD method described above.

Method recovery data are presented in Table 1. Method recoveries of the combined residues of TPTH were 59-85% and 53-77% from potatoes fortified with TPTH residues at the combined LOQ (0.03 ppm) and 0.30 ppm, respectively. The average method recovery for the combined residues of TPTH in/on potatoes for both fortification levels was 67% (± 10.4). Apparent residues of TPTH, DPTH, and MPTH, determined as TPTH equivalents, were each <0.01 ppm ($<LOQ$) in/on 12 untreated potato samples.

These data indicate that the GC/FPD method is adequate for collecting data on the residues of TPTH, DPTH, and MPTH in/on potatoes.

Table 1. Concurrent method recoveries from untreated potato samples simultaneously fortified with TPTH, DPTH, and MPTH at 0.01 ppm each (TPTH equivalents) and analyzed using a GC/FPD method.

Commodity	Fortification Level (ppm)	% Recovery, total TPTH equivalents	Average % Recovery (SD)
Potato tubers	0.03	59, 59, 74, 65, 85	68.4 (± 11.1)
	0.30	57, 53, 77, 70, 75	66.4 (± 10.8)

Storage Stability Data

Storage stability data are available indicating that residues of TPTH, MPTH and DPTH are stable at -20 C for up to 16 weeks in/on potatoes (DP Barcode D185360, L. Cheng, 3/10/93). Potato samples from the residue study were stored frozen for 59-111 days (8-16 weeks) with the exception of samples from the NC trial which were stored for 165 days (24 weeks). The available storage stability data adequately support the residue data on potatoes.

Magnitude of the Residue in Plants

Potatoes. Residue field trial data on potatoes were reviewed in the TPTH Reregistration Standard Update (3/18/92), and the Agency concluded that the labeled use pattern for TPTH on potatoes needed to be amended to specify a 21-day postharvest interval (PHI) and a maximum seasonal rate of 0.75 lb ai/A. To support a reduced PHI of 7 days, the TPTH Task Force has submitted a new magnitude of the residue study (1997; MRID 44667001) on potatoes

Tolerances have been established for residues of TPTH *per se* in/on potatoes at 0.05 ppm [40 CFR §180.236]. No tolerances have been established for residues of TPTH in processed potato commodities; however, adequate potato processing studies were submitted and reviewed. The studies show that TPTH residues do not concentrate in chips or granules, but concentrate by 3x in wet peel. Tolerances for TPTH residues in processed potato commodities will be further addressed in the TPTH RED.

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A REFS search dated 10/14/98 listed five TPTH end-use products registered to Griffin and AgrEvo for use on potatoes. These products include two 4 lb/gal FICs (EPA Reg. Nos. 1812-244 and 45639-186), 47.5% and 80% WPs (EPA Reg. Nos. 45639-170 and 1812-350), and a 0.5 lb/gal EC (EPA Reg. No. 1812-351) which is a MAI formulation including maneb at 3.5 lb/gal. These labels allow 3-4 foliar applications to potatoes at a maximum of 0.19-0.24 lb ai/A/application for a maximum seasonal application rate of 0.71-0.75 lb/ai/A. The labels specify a 7-day RTI with the exception of the 4 lb/gal FIC labels which do not specify a RTI. The labels allow application of TPTH using ground or aerial equipment, and specify a minimum of 3 gal water/A for aerial applications.

All of the labels indicate a 21-day PHI with the exception of the 47.5% WP which allows a 7-day PHI. In addition, the 80% WP SLN labels (ME970001, MI970001, MN970003, ND970004, OR970021, WA970035, and WI970005) all allow a 7-day PHI.

The registrants have submitted labels for a 4 lb/gal FIC and 80% WP (EPA Reg. Nos. 1812-244 and -350), sold as SUPER TIN® 4L and 80WP, which have been amended to specify a 7-day PHI. In addition, the registrants have submitted an amended label for the 0.5 lb/gal EC (EPA Reg. No. 1812-351), a MAI formulation, sold as PRO-TEX®, which includes maneb at 3.5 lb/gal. The label has been amended to allow a 7-day PHI in CT, DE, FL, ME, MI, NH, NY, OH, PA, RI, VT, and WI, and a 14-day PHI in all other states.

To support these proposed label changes, the registrants have submitted data (1997; MRID 44667001) from 14 tests conducted during 1996 in CO, FL, ID (3), ME, NY (2), NC, ND, WI, and WA (3) depicting residues of TPTH and its metabolites DPTH, and MPTH in/on potatoes. TPTH (80% WP or 4 lb/gal FIC) was applied foliarly four times to potatoes at ~0.19 lb ai/A at 7-day RTIs for a maximum seasonal application rate of 0.75 lb ai/A (1x rate). At two test sites (NY and WA) side-by-side trials were conducted using the WP and FIC; the remaining ten trials were conducted using the WP. Applications were made using ground equipment in 15-32 gal of water per acre.

A single control and two treated samples of potatoes were harvested from each test site 7 days following the last foliar application, and were frozen within 2 hours of harvest. Samples were shipped frozen to the analytical laboratory, Huntingdon Life Sciences, Ltd., Huntingdon, England, where they were stored frozen (~ -20 C) prior to analysis. The maximum storage time from sampling to analysis was 59-111 days with the exception of samples from the NC trial which were stored for 165 days. The available storage stability data adequately support the submitted potato residue data.

Residues of TPTH, DPTH and MPTH were determined using the GC/FPD method described above. The validated LOQ for each analyte in/on potatoes is 0.01 ppm; the LOD is 0.0013-0.0017 ppm for each analyte. Combined residues of TPTH, DPTH and MPTH were <0.03 ppm (<LOQ) in/on 28 treated samples of potatoes. Residue values were not corrected for procedural recoveries. Apparent residues of TPTH were <0.03 ppm in/on 12 control potato samples.

Geographic representation of the residue data is adequate and a sufficient number of tests have been conducted to support the proposed 7-day PHI. Because the combined residues of TPTH were <LOQ in/on all potato samples from each test site, 25% fewer trials are required as stated in the Agency guidelines (OPPTS GLN 860.1500). The registrants provided data on potatoes from Region 1 (3 tests), Regions 2, 3, and 9 (one test each), Region 5 (2 tests), and Region 11 (6 tests). Data from Region 10 were not provided as required by the guidance, however, this region accounts for only 4% of potato production, and the registrants provided data from areas accounting for >90% of U.S. potato production.

Conclusions: The available residue data on potatoes are adequate and indicate a supported reassessed tolerance of 0.05 ppm for combined regulable residues of TPTH and its metabolites DPTH and MPTH.

The residue data submitted adequately support the proposed reductions in the labeled PHI for TPTH uses on potatoes. The registrants provided amended labels for only three of the five EPs with registered TPTH uses on potatoes, EPA Reg. Nos. 1812-244, -350, and -351. The registrants may amend use directions on all TPTH EPs with uses on potatoes to specify a 7-day PHI.

The registrants should also amend use directions for potatoes on the 4 lb/gal FICs (EPA Reg Nos. 1812-244 and 45639-186) to indicate a minimum RTI. The labels state that applications to potatoes "should begin with the appearance of blight weather conditions and *continue as needed.*" The labels should be amended to specify a minimum RTI of 7 days.

AGENCY MEMORANDA CITED IN THIS REVIEW

DP Barcodes: D171632
Subject: Triphenyltin Hydroxide (TPTH) Product and Residue Chemistry Reregistration Standard Updates.
From: E. Zager
To: L. Rossi and W. Burnam
Dated: 3/18/92
MRID(s): None

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

MASTER RECORD IDENTIFICATION NUMBER

The citation for the MRID document referred to in this review is presented below.

44667001 Waggoner, T. (1998) Raw Agricultural Commodity (RAC) Residue Evaluation of Triphenyltin Hydroxide Applied to Potatoes: Lab Project Number: 02708A003:1714-96-027-0108D-12:1714-96-027-0108D-09. Unpublished study prepared by Huntingdon Life Sciences, Ltd.