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

MAR 18 1992
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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Triphenyltin Hydroxide (TPTH) Product and Residue Chemistry Reregistration Standard Updates. CBRS No. 8985; DP BARCODE No. D171632.

FROM: E. Zager, Chief
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Lois Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508C)

and

William Burnam, Ph.D., Acting Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Attached are the updates to the Product and Residue Chemistry Chapters of the Triphenyltin Hydroxide (TPTH) Reregistration Standard. These updates were prepared by Acurex Corporation under supervision of CBRS, HED. They have undergone secondary review in the branch and have been revised to reflect Agency policies.

Revised product and residue chemistry data requirement tables are included.

Please note that several of the outstanding reregistration data requirements involve tolerance revisions and/or proposals, and amendments to existing product labels. These actions will require input from Registration Division.

If you need additional input from CBRS, please advise.

Attachment 1: Triphenyltin Hydroxide (TPTH) Product Chemistry Reregistration Standard Update.

Attachment 2: Triphenyltin Hydroxide (TPTH) Residue Chemistry Reregistration Standard Update.

Attachment 3: Confidential Appendix (3 pages)

cc (With Attachments 1, 2, and 3): P. Deschamp, Triphenyltin Hydroxide (TPTH) Reregistration Standard File, Triphenyltin Hydroxide (TPTH) Subject File, C. Furlow (PIB/FOD), and Acurex.

cc (With Attachments 1 and 2): Circulation (7).
cc (Without Attachments): RF.

ATTACHMENT 1

TRIPHENYLTIN HYDROXIDE (TPTH)
(Chemical Code 083601)

TASK 3

Reregistration Standard Update

Product Chemistry

August 16, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
4915 Prospectus Drive
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Research Triangle Park, NC 27709

TRIPHENYLTIN HYDROXIDE (TPTH)

(Chemical Code 083601)

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

INTRODUCTION

A Product Search Listing conducted on December 5, 1990 identified four registered technical (T) products of triphenyltin hydroxide (TPTH): Griffin Corp. 96% Ts (EPA Reg. Nos. 1812-279 and 1812-337); Hoechst Celanese Corp. 96% T (EPA Reg. No. 8340-17), and Atochem North America, Inc. 96% T (EPA Reg. No. 5204-86). The Griffin Corp. 96% T (EPA Reg. No. 1812-337) was transferred from Wesley Industries (EPA Reg. No. 47916-37) on 2/19/90.

The Guidance Document dated 9/84 requires updated generic and product-specific product chemistry data for the manufacturing-use products.

Griffin Corp. submitted data (1985; MRID 00142930) in response to the Guidance Document regarding the 96% T (EPA Reg. No. 1812-279) that were reviewed by the Agency (CBRS No. 1151 dated 7/15/85 by A. Reiter). Wesley Industries submitted data (19??; MRID 00142951 and 1985; 00150573) in response to the Guidance Document regarding the 96% T (EPA Reg. No. 47916-37) which were reviewed by the Agency (CBRS No. 1152 dated 7/15/85 by A. Reiter; and CBRS No. 98 dated 2/24/86 by S. Hummel). These data are considered in this update document for their adequacy in fulfilling the requirements for the Griffin 96% T (EPA Reg. No. 1812-337).

Hoechst Celanese submitted data (MRIDs 00142876, 00147329, and 00161669) in response to the Guidance Document for the 96% T (EPA Reg. No. 8340-17) which were reviewed by the Agency (CBRS No. 1136 dated 8/30/85 by A. Reiter; CBRS No. 1135 dated 9/24/95 by A. Reiter; and CBRS No. 1278 dated 2/3/87 by S. Hummel). Hoechst's response (1988; MRID 40802501) to CBRS No. 1278 is reviewed in this document.

Atochem has not submitted data regarding the 96% T (EPA Reg. No. 5204-86). All product chemistry data remains outstanding for this product.

Each of the Topical Discussions listed below have corresponding Guideline Reference Numbers from "Pesticide Assessment Guidelines - Subdivision D - Product Chemistry," referred to in Title 40 of the Code of Federal Regulations (40 CFR), Part 158, "Data Requirements for Registration," Subpart C, "Product Chemistry Data Requirements." These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of TPTH.

Guideline Reference No.
from 40 CFR §158.155-190

SUMMARY

The following product chemistry data remain outstanding:

- Data remain outstanding for the Griffin 96% T (EPA Reg. No. 1812-279) regarding product identity, enforcement analytical methods, density, vapor pressure, dissociation constant, oxidizing/reducing action, explodability, and corrosiveness.

- Data remain outstanding for the Griffin 96% T (EPA Reg. No. 1812-337) regarding product identity, starting materials and manufacturing process, preliminary analysis, certification of ingredient limits, enforcement analytical methods, dissociation constant, oxidizing/reducing action, explodability, storage stability, and corrosiveness. If the manufacturing process has changed since the product transfer then all product chemisty data will be required.

- Data remain outstanding for the Hoechst Celanese 96% T (EPA Reg. No. 8340-17) regarding product identity, certification of ingredient limits, enforcement analytical methods, oxidizing/reducing action, explodability, storage stability, and corrosiveness.

- All product chemistry data specified in the TPTH Guidance Document remain outstanding for the Atochem North America, Inc. 96% T (EPA Reg. No. 5204-86).

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

The TPTH Guidance Document dated 9/84 does not require additional product-specific data for manufacturing-use products; however, current criteria for the evaluation of product composition have become more stringent since the issuance of the TPTH Guidance Document and all registrants must submit updated information.

61-2. Starting Materials and Manufacturing Process

The TPTH Guidance Document dated 9/84 requires submission of updated generic and product-specific data concerning the starting materials and manufacturing process. In response, the registrants have submitted the following data:

Griffin Corp. submitted data (1985; MRID 00142930) that the Agency (CBRS No. 1151 dated 7/15/85 by A. Reiter) determined do satisfy the requirements of 40 CFR §158.160-165 regarding the starting materials and manufacturing process for the Griffin Corp. 96% T (EPA Reg. No. 1812-279).

Wesley Industries submitted data (19??; MRID 00142951) for their 96% T (EPA Reg. No. 47196-37) that the Agency (CBRS No. 1152 dated 7/15/85 by A. Reiter) determined did not satisfy the requirements of 40 CFR §158.160-165 regarding the starting materials and manufacturing process. The equipment used and the physical conditions maintained during the reaction were not described; the sequence of reagent addition was not given. W.R. Landis Associates submitted additional data (1985; MRID 00150573) on behalf of Wesley Industries that the Agency (CBRS No. 98 dated 2/24/86 by S. Hummel) determined did not satisfy these requirements. The names and addresses of the producers or suppliers of each starting material, purity, and other data regarding the starting materials were not provided. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

In response to the Guidance Document, Hoechst Celanese submitted data (19??; MRID 00147329) that the Agency (CBRS No. 1136 dated 8/30/85 by A. Reiter) determined do satisfy the requirements for 40 CFR §158.160-165 for the Hoechst Celanese 96% T (EPA Reg. No. 8340-17).

Atochem North America, Inc. has not submitted data regarding the starting materials and manufacturing process for their 96% T (EPA Reg. No. 5204-86). All data pertaining to these topics are required for this product.

61-3. Discussion of Formation of Impurities

The TPTH Guidance Document dated 9/84 specifies that updated generic and product-specific data regarding a detailed discussion of the formation of impurities must be submitted. In response, the registrants have submitted the following data:

Griffin Corp. submitted data (1985; MRID 00142930) that the Agency (CBRS No. 1151 dated 7/15/85 by A. Reiter) determined satisfy the requirements of 40 CFR §158.167 regarding the formation of impurities for the 96% T (EPA Reg. No. 1812-279).

Wesley Industries submitted data (19??; MRID 00142951) for their 96% T (EPA Reg. No. 47196-37) that the Agency (CBRS 1152 dated 7/15/85 by A. Reiter) determined do satisfy the requirements of 40 CFR §158.167 regarding the formation of impurities. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337).

MRID 6/3/85

Hoechst Celanese submitted data (19??; MRID 00147329) that the Agency (CBRS No. 1136 dated 8/30/85 by A. Reiter) determined do satisfy the requirements of 40 CFR §158.167 for the 96% T (EPA Reg. No. 8340-17). No additional data are required.

Atochem North America, Inc. has not submitted data regarding the formation of impurities for their 96% T (EPA Reg. No. 5204-86). All data pertaining to this topic are required for this product.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The TPTH Guidance Document dated 9/84 specifies that updated generic and product specific data must be submitted regarding the preliminary analysis. In response, the registrants have submitted the following data:

Griffin Corp. submitted data (1985; MRID 00142930) that the Agency (CBRS No. 1151 dated 7/15/85 by A. Reiter) determined do satisfy the requirements of 40 CFR §158.170 regarding the preliminary analysis for the 96% T (EPA Reg. No. 1812-279).

Wesley Industries submitted data (19??; MRID 00142951) for their 96% T (EPA Reg. No. 47196-37) that the Agency (CBRS No. 1152 dated 7/15/85 by A. Reiter) determined do not satisfy the requirements of 40 CFR §158.170 regarding preliminary analysis. Only three batches of technical were analyzed, and there were no analyses for any of the impurities. W.R. Landis submitted additional data (1985; MRID 00150573) on behalf of Wesley Industries that the Agency (CBRS No. 98 dated 2/24/86 by S. Hummel) determined did not

satisfy the requirements of 40 CFR §158.170. Analyses were not performed for some of the impurities. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

Hoechst Celanese submitted data (19??; MRID 00147329) that the Agency (A. Reiter; August 30, 1985; CBRS No. 1136) determined did not satisfy the requirements of 40 CFR §158.170 regarding the preliminary analysis because analyses were not performed for the impurities. In response to CBRS No. 1136, Hoechst Celanese submitted additional data (1986; MRID 00161669) that the Agency (CBRS No. 1278 dated 2/2/87 by S. Hummel) determined did not satisfy the requirements of 40 CFR §158.170 because analyses for some of the impurities present at >0.1% were not included. In response to CBRS No. 1278, Hoechst Celanese submitted additional data (1988; MRID 40802501) which are summarized in the Confidential Appendix. These data satisfy the requirements of 40 CFR §158.170 regarding preliminary analysis. Five batches were tested, and all of the impurities have been included.

Atochem North America, Inc. has not submitted product chemistry data regarding the preliminary analysis for their 96% T (EPA Reg. No. 5204-86). All data pertaining to this topic are required for this product.

62-2. Certified Limits

The TPTH Guidance Document dated 9/84 specifies that updated generic and product-specific data must be submitted regarding certification of ingredient limits. In response, the registrants have submitted the following data:

Griffin Corp. submitted data (1985; MRID 00142930) that the Agency (CBRS No. 1151 dated 7/15/85 by A. Reiter) determined do satisfy the requirements for 40 CFR §158.175 regarding the establishment of certified limits for the Griffin 96% T (EPA Reg. No. 1812-279).

Wesley Industries submitted data (19??; MRID 00142951) for their 96% T (EPA Reg. No. 47196-37) that the Agency (CBRS No. 1152 dated 7/15/85 by A. Reiter) determined do not satisfy the requirements of 40 CFR §158.175 regarding the establishment of ingredient limits. Some of the impurities were not included. W. R. Landis submitted additional data (1985; MRID 00150573) on behalf of Wesley Industries that the Agency (CBRS No. 98 dated 2/24/86 by S. Hummel) determined do not satisfy the requirements of 40 CFR §158.175. The data included only a partial list of the impurities. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

In response to the Guidance Document, Hoechst Celanese submitted data (19??; MRID 00147329) that the Agency (A. Reiter; August 30, 1985; CBRS No. 1136) determined did not satisfy the requirements of 40 CFR §158.175 regarding the establishment of certified limits. The upper limit for the active ingredient was not given, and some of the impurities were not identified. In response to CBRS No. 1136, Hoechst Celanese submitted data (1986; MRID 00161669) that the Agency (S. Hummel; February 3, 1987; CBRS No. 1278) determined did not satisfy the requirements for the certified limits. The results were not submitted on EPA Form 8570-4 Rev. 2/85, the limits for the active ingredient were not given to one decimal place, and one of the impurities was not sufficiently defined. Additional data are required.

Atochem North America, Inc. has not submitted data regarding the establishment of certified limits for their 96% T (EPA Reg. No. 5204-86). All data pertaining to this topic are required for this product.

62-3. Enforcement Analytical Methods

The TPTH Guidance Document dated 9/84 specifies that analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity for which a certified limit is required. In response, the registrants have submitted the following data:

Griffin Corp. submitted data (1985; MRID 00142930) that the Agency (CBRS No. 1151 dated 7/15/85 by A. Reiter) determined do not satisfy this topic for 40 CFR §158.180 regarding enforcement analytical methods for the 96% T (EPA Reg. No. 1812-279). Validation data were not included, and the reviewer stated that the procedures were not written clearly enough to evaluate the method. Additional data are required.

Wesley Industries submitted data (19??; MRID 00142951) for their 96% T (EPA Reg. No. 47196-37) that the Agency (CBRS No. 1152 dated 7/15/85 by A. Reiter) determined do not satisfy the requirements of 40 CFR §158.180 regarding enforcement analytical methods. The analysis procedures for two impurities and validation data were not given. W.R. Landis submitted additional data (1985; MRID 00150573) on behalf of Wesley Industries that the Agency (CBRS No. 98 dated 2/24/86 by S. Hummel) determined do not satisfy the requirements. Validation data were not given, and it was not clear that the method was specific for TPTH and one impurity. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

In response to the Guidance Document, Hoechst Celanese submitted data (1976; MRID 00142876; 19??; MRID 00147329) that the Agency (A. Reiter; September 24, 1985; CBRS No. 1135) determined do not satisfy the requirements of 40 CFR §158.180 regarding the enforcement analytical methods for the 96% T (EPA Reg. No. 8340-17). Validation data

were not submitted for the method used to analyze the active ingredient; detailed, validated procedures were not submitted for the impurities. In response to CBRS No. 1135, Hoechst Celanese submitted data (1986; MRID 00161669) that the Agency (S. Hummel; February 3, 1987; CBRS No. 1278) determined do not satisfy the requirements of 40 CFR §158.180. The Agency stated that the methods were not sufficiently specific for the active ingredient and impurities, and that additional identification of some of the impurities were needed. In response to CBRS No. 1278, Hoechst Celanese submitted data (1988; MRID 40802501) which are presented in the Confidential Appendix. These data do not meet the requirements of 40 CFR §158.180. Although the registrant claims that these methods are the best that can be found, some of the impurities can be analyzed by more specific methods. Additional data are required.

Atochem North America, Inc. has not submitted data regarding enforcement analytical methods for their 96% T (EPA Reg. No. 5204-86). All data pertaining to this topic are required for this product.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The TPTH Guidance Document dated 9/84 specifies additional generic and product-specific data for certain physical and chemical characteristics to satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-7, 63-9, 63-10, 63-14, 63-16, 63-17, 63-20).

Griffin submitted data (1985; MRID 00142930) for their 96% T (EPA Reg. No. 1812-279). These data were reviewed by the Agency (CBRS No. 1151 dated 7/15/85 by A. Reiter) and found insufficient to satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-7 and 63-9). These deficiencies and the additional data requirements identified in the TPTH Guidance Document remain outstanding for this product.

Wesley Industries submitted data (19??; MRID 00142951 and 1985; 00150573) for their 96% T (EPA Reg. No. 47196-37). These data were reviewed by the Agency (CBRS No. 1152 dated 7/15/85 by A. Reiter; CBRS No. 98 dated 2/24/86 by S. Hummel) and found to satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-7 and 63-9); however, additional verification regarding the reported value for dissociation constant (§63-10) in water was required. Upon notification from Griffin that the manufacturing process has not changed since the transfer of ownership from Wesley, these data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Also, additional data are required concerning the following physicochemical characteristics of the 96% T (EPA Reg. No. 1812-337) as a manufacturing-use product: §63-10, 63-14, 63-16, 63-17, and 63-20.

Hoechst Celanese submitted data (19??; MRID 00147329) for their 96% T (EPA Reg. No. 8340-17). These data were reviewed by the Agency (CBRS No. 1136 dated 8/30/85 by A. Reiter) and found to satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos.

63-7, 63-9, and 63-10). Additional data requirements identified in the TPTH Guidance Document remain outstanding for this product.

No data pertaining to the physicochemical characteristics of the Atochem North American 96% T (EPA Reg. No. 5204-86) have been submitted. All data requirements specified in the TPTH Guidance Document remain outstanding for this product.

MASTER RECORD IDENTIFICATION NUMBERS:

MRID Documents containing data that have been previously reviewed by the Agency are designated in bold print in the following bibliographic listing of the Product Chemistry Citations (used). A summary of the MRID documents and their associated Agency Memoranda is presented below.

Product Chemistry Citations (used):

00142876 Hommel, K., Puschmann, H. (1976) Determination of Triphenyltin Compounds in Formulations and 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.

00142951 Wesley Ind. (19??) Chemistry and Product Manufacturing Process of TPTH. Unpublished Compilation. 9 p.

00147329 Amer. Hoechst (19??) Product Chemistry Data for Triphenyltin Hydroxide. Unpublished Compilation. 32 p.

00150573 Wesley Industries Inc. (1985) Wesley Technical Triphenyltin Hydroxide; Product Chemistry Data: Addendum I. Unpublished Study. 13 p.

00161669 Hoechst Ag. (1986) Product Chemistry Data: Triphenyltin Hydroxide. Unpublished Compilation. 16 p.

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

Agency Memoranda:

CBRS No.	98
Subject:	Triphenyl Tin Hydroxide, Response to Registration Standard: Wesley Triphenyl Tin Hydroxide.
From:	S. Hummel
To:	H. Jacoby
Dated:	February 24, 1986
MRID:	00150573

CBRS No.	1135
Subject:	Hoechst TPTH. Evaluation of TPTH Analytical Methods
From:	A. Reiter
To:	H. Jacoby
Dated:	September 24, 1985
MRID(s):	00142876 and 128877

CBRS No.	1136
Subject:	Hoechst TPTH. Product Chemistry Data for Registration Standard
From:	A. Reiter
To:	H. Jacoby
Dated:	August 30, 1985
MRID:	00147329

CBRS No.	1151
Subject:	Griffin TPTH. Product Chemistry Data for Registration Standard
From:	A. Reiter
To:	H. Jacoby
Dated:	July 15, 1985
MRID:	00142930

CBRS No.	1152
Subject:	Wesley Triphenyl Tin Hydroxide Product Chemistry data for Registration Standard.
From:	A. Reiter
To:	H. Jacoby
Dated:	July 15, 1985
MRID:	00142951

CBRS No. 1278
Subject: TPTH Response to Registration Standard: Hoechst TPTH Technical
From: S. Hummel
To: L. Rossi
Dated: February 3, 1987
MRID(s): 00161669 and 00161670

TABLE A. GENERIC DATA REQUIREMENTS FOR THE ATOCHEM TPTH TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	No		Yes[4]
61-3. Formation of Impurities	TGAI	No		Yes[4]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	No		Yes[4]
Physical and Chemical Characteristics[5]				
63-2. Color	TGAI	Yes		No
63-3. Physical State	TGAI	Yes		No
63-4. Odor	TGAI	Yes		No
63-5. Melting Point	TGAI	Yes		No
63-6. Boiling Point	TGAI	N/A[6]		
63-7. Density, Bulk Density, or Specific Gravity	TGAI	No		Yes[4]
63-8. Solubility	TGAI or PAI	Yes		No
63-9. Vapor Pressure	TGAI or PAI	No		Yes[4]
63-10. Dissociation Constant	TGAI or PAI	No		Yes[4]

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-11. Octanol/Water Partition Coefficient	PAI	Yes		No
63-12. pH	TGAI	Yes		No
63-13. Stability	TGAI	Yes		No
Other Requirements				
64-1. Submittal of Samples	TGAI or PAI			Reserved[7]

[1]Data requirements pertain to the Atochem North America, Inc. 96% T (EPA Reg. No. 5204-86). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Atochem Manufacturing-Use Products."

[2]Test Substance: TGAI = technical grade of the active ingredient; PAI = pure active ingredient; MP = manufacturing use product.

[3]These references were submitted in respose to the TPTH Guidance Document (September, 1984). Underlining indicates documents that have been reviewed for this update.

[4]Atochem North America, Inc. has not responded for the 96% T (EPA Reg. No. 5204-86). All data pertaining to this topic are required for this product.

[5]As required in 40 CFR 158.190 and more fully described in the pesticide Assessment Guidelines, Subdivision D, Guidelines References Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics. There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing-use products.

[6]N/A = Not Applicable

[7]If samples are needed, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE ATOCHEM TPTH MANUFACTURING-USE PRODUCTS.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Identity and Disclosure of Ingredients	MP	No		Yes[4]
61-2. Beginning Materials and Production Process	MP	No		Yes[5]
61-3. Formation of Impurities	MP	No		Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	No		Yes[5]
62-2. Certification of Ingredient Limits	MP	No		Yes[5]
62-3. Analytical Methods to Verify Certified Limits	MP	No		Yes[5]
Physical and Chemical Characteristics[6]				
63-2. Color	MP	Yes		No
63-3. Physical State	MP	Yes		No
63-4. Odor	MP	Yes		No
63-7. Density, Bulk Density, or Specific Gravity	MP	No		Yes[5]
63-12. pH	MP	Yes		No
63-14. Oxidizing or Reducing Action	MP	No		Yes[5]
63-15. Flammability	MP	N/A		N/A
63-16. Explodability	MP	No		Yes[5]

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-17. Storage Stability	MP	No		Yes[5]
63-18. Viscosity	MP	N/A		No
63-19. Miscibility	MP	N/A		No
63-20. Corrosion Characteristics	MP	No		Yes[5]
Other Requirements				
64-1. Submittal of Samples	MP			Reserved[7]

[1]Data requirements pertain to the Atochem North America, Inc. 96% T (EPA Reg. No. 5204-86). Additional data can be found in the preceding Table A, "Generic Data Requirements for the Atochem Technical or Pure Grade of the Active Ingredient."

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the TPTH Guidance Document (September, 1984). Underlining indicates documents that have been reviewed for this update.

[4]Atochem must submit updated information pertaining to product composition to satisfy current criteria.

[5]Atochem North America, Inc. has not responded for the 96% T (EPA Reg. No. 5482-86). All data pertaining to this topic are required for this product.

[6]As required in 40 CFR 158.190 and more fully described in the pesticide Assessment Guidelines, Subdivision D, Guidelines References Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity,. miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use products which contain only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the TPTH Technical Grade of the Active Ingredient."

[7]If samples are needed, the Agency will request them.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE HOECHST CELANESE TPTH TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Yes	00147329	No
61-3. Formation of Impurities	TGAI	Yes	00147329	No
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	Yes	00147329 00161669 40802501	No[4]
Physical and Chemical Characteristics[5]				
63-2. Color	TGAI	Yes		No
63-3. Physical State	TGAI	Yes		No
63-4. Odor	TGAI	Yes		No
63-5. Melting Point	TGAI	Yes		No
63-6. Boiling Point	TGAI	N/A[6]		No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Yes	00147329	No
63-8. Solubility	TGAI or PAI	Yes		No
63-9. Vapor Pressure	TGAI or PAI	Yes	00147329	No
63-10. Dissociation Constant	TGAI or PAI	Yes	00147329	No

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-11. Octanol/Water Partition Coefficient	PAI	Yes		No
63-12. pH	TGAI	Yes		No
63-13. Stability	TGAI	Yes		No
Other Requirements				
64-1. Submittal of Samples	TGAI or PAI			Reserved[7]

[1]Data requirements pertain to the Hoechst Celanese Corp. 96% T (EPA Reg. No. 8340-17). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Hoechst Celanese Corp. Manufacturing-Use Products."

[2]Test Substance: TGAI = technical grade of the active ingredient; PAI = pure active ingredient; MP = manufacturing use product.

[3]These references were submitted in response to the TPTH Guidance Document (September, 1984). Underlining indicates documents that have been reviewed for this topic.

[4]The registrant has responded to the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) for the 96% T (EPA Reg. No. 8340-17). No additional data are required.

[5]As required in 40 CFR 158.190 and more fully described in the pesticide Assessment Guidelines, Subdivision D, Guidelines References Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics. There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing-use products.

[6]N/A = Not Applicable

[7]If samples are required, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE HOECHST CELANESE TPTH MANUFACTURING-USE PRODUCTS.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Identity and Disclosure of Ingredients	MP	Partially		Yes[4]
61-2. Beginning Materials and Production Process	MP	Yes	00147329	No
61-3. Formation of Impurities	MP	Yes	00147329	No
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	Yes	00147329 00161669 40802501	No[5]
62-2. Certification of Ingredient Limits	MP	Partially	00147329 00161669	Yes[6]
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	00147329 00142876 00161669 40802501	Yes[7]
Physical and Chemical Characteristics[8]				
63-2. Color	MP	Yes		No
63-3. Physical State	MP	Yes		No
63-4. Odor	MP	Yes		No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	00147329	No
63-12. pH	MP	Yes		No
63-14. Oxidizing or Reducing Action	MP	No		Yes[9]
63-15. Flammability	MP	N/A[10]		No

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-16. Explodability	MP	No		Yes[11]
63-17. Storage Stability	MP	No		Yes[12]
63-18. Viscosity	MP	N/A	N/A	No
63-19. Miscibility	MP	N/A	N/A	No
63-20. Corrosion Characteristics	MP	No		Yes[13]
Other Requirements				
64-1. Submittal of Samples	MP			Reserved[14]

[1]Data requirements pertain to the Hoechst Celanese Corp. 96% T (EPA Reg. No.8340-17). Additional data requirements are listed in the preceding Table A "Generic Data Requirements for the Hoechst Celanese TPTH Technical Grade of the Active Ingredient."

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the TPTH Guidance Document (September, 1984). Underlining indicates documents that have been reviewed for this topic.

[4]Hoechst Celanese must submit updated information pertaining to product composition to satisfy current criteria.

[5]The registrant has responded to the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) for the 96% T (EPA Reg. No. 8340-17). No additional data are required.

[6]The registrant has responded to the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) for the 96% T (EPA Reg. No. 8340-17); however, the limits for the active ingredient were not given to one decimal place and one of the impurities was not sufficiently defined. Additional data are required for this product.

[7]The registrant has responded to the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) for the 96% T (EPA Reg. No. 8340-17); however, despite Hoechst's justification of the analyses that are used, it is possible to perform more specific analyses for the impurities. Additional data are required.

TABLE B. (Continued)

[8]As required in 40 CFR 158.190 and more fully described in the pesticide Assessment Guidelines, Subdivision D, Guidelines References Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use products which contain only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the TPTH Technical Grade of the Active Ingredient."

[9]Hoechst has not responded to the requirements of 40 CFR §158.190 (Guideline Reference No. 63-14) for the 96% T (EPA Reg. No. 8340-17). All data pertaining to this topic are required for this product.

[10]N/A = Not Applicable

[11]Hoechst has not responded to the requirements of 40 CFR §158.190 (Guideline Reference No. 63-16) for the 96% T (EPA Reg. No. 8340-17). All data pertaining to this topic are required for this product.

[12]Hoechst has not responded for the 96% T (EPA Reg. No. 8340-17); in order to satisfy current requirements data pertaining to storage stability (Guideline Reference No. 63-17) are required.

[13]Hoechst has not responded for the 96% T (EPA Reg. No. 8340-17); in order to satisfy current requirements data pertaining to corrosion characteristics (Guideline Reference No. 63-20) are required.

[14]If samples are required, the Agency will request them.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE GRIFFIN CORP. TPTH TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-2. Beginning Materials and Production Process	TGAI	Partially	00142930 00142951 00150573	Yes[4]
61-3. Formation of Impurities	TGAI	Partially	00142930 00142951	Yes[5]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	00142930 00142951 00150573	Yes[6]
Physical and Chemical Characteristics[7]				
63-2. Color	TGAI	Partially		Yes[1]
63-3. Physical State	TGAI	Partially		Yes[1]
63-4. Odor	TGAI	Partially		Yes[1]
63-5. Melting Point	TGAI	Partially		Yes[1]
63-6. Boiling Point	TGAI	N/A[8]		No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Partially	00142930 00142951 00150573	Yes[9]
63-8. Solubility	TGAI	Partially		Yes[1]
63-9. Vapor Pressure	TGAI or PAI	Partially	00142930 00142951 00150573	Yes[10]

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-10. Dissociation Constant	TGAI or PAI	Partially	00142951 00150573	Yes[11]
63-11. Octanol/Water Partition Coefficient	PAI	Partially		Yes[1]
63-12. pH	TGAI	Partially		Yes[1]
63-13. Stability	TGAI	Partially		Yes[1]
Other Requirements				
64-1. Submittal of Samples	TGAI or PAI			Reserved[12]

[1]Data requirements pertain to the Griffin Corp. 96% Ts (EPA Reg. Nos. 1812-279 and 1812-337). The Griffin 96% T (EPA Reg. No. 1812-337) was transferred from Wesley Industries. Data reviewed in this Update document are conditional; upon notification from Griffin that the manufacturing process has not changed since the transfer, the data submitted by Wesley Industries may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). If the manufacturing process has changed, all product chemistry data will be required for the 96% T (EPA Reg. No. 1812-337). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for Griffin Corp. Manufacturing-Use Products."

[2]Test Substance: TGAI = technical grade of the active ingredient; PAI = pure active ingredient; MP = manufacturing use product.

[3]These references were submitted in response to the TPTH Guidance Document (September, 1984). Underlining indicates documents that have been reviewed for this topic.

[4]Griffin Corp. has adequately responded to the requirements of 40 CFR §158.160-165 (Guideline Reference No. 61-2) for the 96% T (EPA Reg. No. 1812-279). If the data submitted by Wesley Industries are applicable (see footnote 1) to the Griffin 96% T (EPA Reg. No. 1812-337), Griffin Corp. needs to submit technical data for the starting materials and the names and addresses of the manufacturers of the starting materials. Additional data are required.

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TABLE A. (Continued)

[5]Griffin Corp. has adequately responded to the requirements of 40 CFR 158.167 for their 96% T (EPA Reg. No. 1812-279). If the data submitted by Wesley Industries are applicable (see footnote 1) to the Griffin 96% T (EPA Reg. No. 1812-337), then the data requiements for the 96% T (EPA Reg. No. 1812-337) will be satisfied.

[6]Griffin Corp. has adequately responded to the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) for the 96% T 96% T (EPA Reg. No. 1812-279). If the data submitted by Wesley Industries are applicable (see footnote 1) to the Griffin 96% T (EPA Reg. No. 1812-337), Griffin Corp. needs to submit additional data regarding the analyses of all of the impurities. Additional data are required.

[7]As required in 40 CFR 158.190 and more fully described in the pesticide Assessment Guidelines, Subdivision D, Guidelines References Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics. There are additional data requirements listed in Table B pertaining to physicochemical characteristics of those technical products which are also manufacturing-use products.

[8]N/A = Not Applicable

[9]Griffin Corp. has responded to the requirements of 40 CFR §158.190 (Guideline Reference No. 63-7) for the 96% T (EPA Reg. No. 1812-279); however, units and temperature were not given. Additional data are required. Upon notification from Griffin that the manufacturing process has not changed since the transfer of ownership from Wesley, these data may be applied to the reregistation of the Griffin 96% T (EPA Reg. No. 1812-337).

[10]Griffin Corp. has responded to the requirements of 40 CFR §158.190 (Guideline Reference No. 63-9) for the 96% T (EPA Reg. No. 1812-279); however, the vapor pressure should be expressed in quantitative terms. Additional data are required. Upon notification from Griffin that the manufacturing process has not changed since the transfer of ownership from Wesley, these data may be applied to the reregistation of the Griffin 96% T (EPA Reg. No. 1812-337).

[11]Data on dissociation constant submitted in response to the Guidance Document for the 96% T (EPA Reg. No. 1812-337) do not satisfy requirements for this topic. Additional verification regarding the reported value for dissociation constant in water is required for the 96% T (EPA Reg. No. 1812-337). Upon notification from Griffin that the manufacturing process has not changed since the transfer of ownership from Wesley, these data may be applied to the reregistation of the Griffin 96% T (EPA Reg. No. 1812-337). No data have been submitted for the 96% T (EPA Reg. No. 1812-279); these data remain outstanding.

[12]If samples are required, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE GRIFFIN CORP. TPTH MANUFACTURING-USE PRODUCTS.[1]

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
40 CFR §158.155-190 Product Chemistry				
Product Composition				
61-1. Product Identity and Disclosure of Ingredients	MP	Partially		Yes[4]
61-2. Beginning Materials and Production Process	MP	Partially	00142930 00142951 00150573	Yes[5]
61-3. Formation of Impurities	MP	Partially	00142930 00142951	Yes[6]
Analysis and Certification of Product Ingredients				
62-1. Preliminary Analysis of Product Samples	MP	Partially	00142930 00142951 00150573	Yes[7]
62-2. Certification of Ingredient Limits	MP	Partially	00142930 00142951 00150573	Yes[8]
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	00142930 00142951 00150573	Yes[9]
Physical and Chemical Characteristics[10]				
63-2. Color	MP	Partially		Yes[1]
63-3. Physical State	MP	Partially		Yes[1]
63-4. Odor	MP	Partially		Yes[1]
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	00142930 00142951 00150573	Yes[11,1]

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-12. pH	MP	Partially		Yes[1]
63-14. Oxidizing or Reducing Action	MP	Partially	00142930	Yes[12,1]
63-15. Flammability	MP	N/A[13]		No
63-16. Explodability	MP	No		Yes[14]
63-17. Storage Stability	MP	No		Yes[14]
63-18. Viscosity	MP	N/A		No
63-19. Miscibility	MP	N/A		No
63-20. Corrosion Characteristics	MP	No		Yes[14]
Other Requirements				
64-1. Submittal of Samples	MP			Reserved[15]

[1]Data requirements pertain to the Griffin Corp. 96% Ts (EPA Reg. Nos. 1812-279 and 1812-337). The Griffin 96% T (EPA Reg. No. 1812-337) was transferred from Wesley Industries. Data reviewed in this Update document are conditional; upon notification from Griffin that the manufacturing process has not changed since the transfer, the data submitted by Wesley Industries may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). If the manufacturing process has changed, all product chemistry data will be required for the 96% T (EPA Reg. No. 1812-337). Additional data requirements can be found in the preceding Table A "Product Specific Data Requirements for the Griffin Corp. Technical Grade of the Active Ingredient and the Pure Grade of the Active Ingredient."

[2]Test Substance: MP = manufacturing use product.

[3]These references were submitted in response to the TPTH Guidance Document (September, 1984). Underlining indicates documents that have been reviewed for this topic.

[4]Griffin must submit updated information pertaining to product composition to satisfy current criteria.

TABLE B. (Continued)

[5]Griffin has submitted data which satisfy the requirements of 40 CFR §158.160-165 (Guideline Reference No. 61-2) for the 96% T (EPA Reg. No. 1812-279). Data submitted by Wesley are insufficient. The names and addresses of the producers or suppliers of each starting material, purity, and other data regarding the starting materials were not provided. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

[6]Griffin has submitted data which fulfill the requirements of 40 CFR 158.167 (Guideline Reference No. 61-3) for the 96% T (EPA Reg. No. 1812-279). Upon notification from Griffin that the manufacturing process has not changed since the transfer, the data submitted by Wesley Industries may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337).

[7]Griffin has submitted adequate data to fulfill the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) for the 96% T (EPA Reg. No. 1812-279). Data submitted by Wesley are insufficient. Analyses were not performed for some of the impurities. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

[8]Griffin has satisfied the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) for the 96% T (EPA Reg. No. 1812-279). Data submitted by Wesley are insufficient. The data included only a partial list of the impurities. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

[9]The registrant has responded to the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) has responded for the 96% T (EPA Reg. No. 1812-279); however, validation data were not given, and the methods were unclear. Also, the data submitted by Wesley are insufficient. Validation data were not given, and it was not clear that the method was specific for TPTH and one impurity. Upon notification from Griffin that the manufacturing processes have not changed since the transfer of ownership from Wesley to Griffin, the existing and newly requested data may be applied to the reregistration of the Griffin 96% T (EPA Reg. No. 1812-337). Additional data are required.

[10]As required in 40 CFR 158.190 and more fully described in the pesticide Assessment Guidelines, Subdivision D, Guidelines References Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of manufacturing-use products which contain only the technical grade of the active ingredient are listed in Table A, "Generic Data Requirements for the

TABLE B. (Continued)

TPTH Technical Grade of the Active Ingredient."

[11]The registrant has responded to the requirements of 40 CFR §158.190 (Guideline Reference No. 63-7) for the 96% T (EPA Reg. No. 1812-279); however, the units of measurement and temperature were not given. Additional data are required.

[12]Griffin submitted data for their 96% T (EPA Reg. No. 1812-279), saying that there were not oxidizing or reducing actions defined narrowly: this statement is not clear. Additional data are required.

[13]N/A = Not Applicable

[14]The registrant has not responded to the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-16, 63-17, and 63-20) for either of the 96% Ts (EPA Reg. Nos. 1812-279 and 1812-337). Data pertaining to this topic are required for these products.

[15]If samples are required, the Agency will request them.

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ATTACHMENT 2

TRIPHENYL HYDROXIDE (TPTH)

(Chemical Code 083601)

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

(Final Report)

CONFIDENTIAL APPENDIX

Appendix: 3 Page(s)

Confidential Appendix to the Scientific Review of the Registration Standard Update Report for the pesticide TPTH by the Chemistry Branch II/Reregistration Section [Confidential FIFRA Trade Secret/CBI].

TPTH

Page _____ is not included in this copy.

Pages 33 through 35 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

X FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

TRIPHENYLTIN HYDROXIDE (TPTH)
(Chemical Code 083601)

TASK 3

Reregistration Standard Update

Residue Chemistry

August 16, 1991

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

Acurex Corporation
Environmental Systems Division
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P.O. Box 13109
Research Triangle Park, NC 27709

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TRIPHENYLTIN HYDROXIDE (TPTH)

(Chemical Code No. 083601)

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 3

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TRIPHENYLTIN HYDROXIDE

(Chemical Code No. 083601)

REREGISTRATION STANDARD UPDATE

RESIDUE CHEMISTRY

Task - 3

INTRODUCTION

Triphenyltin hydroxide (TPTH) is a fungicide classified by EPA as a Restricted Use Pesticide registered for use on pecans, peanuts, potatoes, sugar beets, carrots, and tobacco (SPO5 Site Listing printout dated 3/21/91). TPTH formulations used on food/feed crops include the 1.875 and 4 lb/gal flowable concentrate (FlC), the 19.7 and 47.5% wettable powder (WP), and the 4.72% multiple active ingredient (MAI) soluble concentrate (SC/S). The 4 lb/gal FlC (EPA Reg. No. 1812-244) is registered for a special local need on sugar beets in Texas (SLN TX890009).

Tolerances have been established for residues of TPTH per se, in or on raw agricultural commodities as follows: 0.05 ppm in or on pecans, peanuts, and potatoes, 0.4 ppm in or on peanut hulls, 0.1 ppm in or on carrots and sugar beet roots, and 0.05 ppm in the kidney and liver of cattle, goats, hogs, horses, and sheep (40 CFR §180.236).

TPTH was the subject of a Residue Chemistry Chapter dated April, 1984, and a Guidance Document dated September, 1984. The TPTH Guidance Document required data on residue analytical methods, storage stability, and magnitude of the residue on potatoes, sugar beets, carrots, pecans, peanuts, tobacco, and on meat, milk, poultry, and eggs.

The 1984 Residue Chemistry Chapter recommended that tolerances for TPTH in or on potatoes, sugar beets, carrots, pecans, peanuts and in meat, milk, poultry and eggs be revised to include the intermediary degradation products diphenyltin and monophenyltin hydroxides and oxides. The Guidance Document dated September, 1984, reiterated that the tolerances should be revised and further stated that based on a review and evaluation of all available data and other relevant information on TPTH, the Agency had initiated a Special Review of TPTH. It was also stated that the Agency would not reregister any current products or register any new uses of TPTH until the special review was completed and the Agency had received a commitment to fulfill all data gaps.

In response to the 1984 Guidance Document, the TPTH registrants submitted protocols for field trials and storage stability studies which were reviewed by R. Loranger (CBRS Nos. 799 and 1040, 6/21/85). In addition, the registrants submitted residue analytical methods and supporting validation data for the analysis of sugar beets (1985; MRID 00156382) reviewed by S. Hummel (CBRS No. 127, 2/26/86) and similar methods for sugar beets,

soybeans, peanuts, peanut hulls, pecans, carrots, and potatoes that were reviewed by S. Hummel (CBRS No. 813, 7/9/86). The registrants also submitted analytical methods along with residue data (1986; MRIDs 00160465, 00160466, 00160467, 00160468, 00160469) that were reviewed by S. Hummel (CBRS No. 1096, 9/4/86) and similar submissions (1986; MRIDs 00165010 and 00165025) reviewed by F. Suhre (CBRS No. 1702, 5/1/87). Additional residue data were submitted (1985; MRIDs 40149301, 40149302, 40149304, 1986; 40149303, 40149305) and reviewed by F. Suhre (CBRS No. 2264, 9/2/87) and R. Perfetti (CBRS No. 5985, 1/10/90, 1989; MRID 41267101).

In addition, data have been submitted pertaining to analytical methods and magnitude of the residue in or on potatoes (1990; MRID 41785202 and 1991; MRID 41785204), and sugar beets (1990; MRID 41556601, 41785201, and 1991; 41785203). These data (CBRS No. 7770) are reviewed in this update for their adequacy in fulfilling outstanding data requirements.

SUMMARY

The following additional data are required:

- The registrants must amend all pertinent product labels to specify a PHI and a maximum seasonal application equivalent to that reflected in the data used to support the tolerances for sugar beets and potatoes.

- As required by the Agency, the registrants must submit data depicting TPTH residues of concern in or on sugar beet tops and propose a suitable tolerance. All pertinent product labels must be amended to delete grazing/feeding restrictions for sugar beet tops.

- Additional data are required on the magnitude of the residue in sugar beets, peanuts and potatoes.

- Additional data on analytical methods are required.

- Additional data on storage stability are required.

QUALITATIVE NATURE OF THE RESIDUE IN PLANTS

Conclusions:

The 1984 TPTH Guidance Document concluded that the nature of the residue in plants is adequately understood based on studies conducted on potatoes, soybeans and rice. Data reviewed in the Residue Chemistry Chapter indicated that TPTH is not significantly absorbed and translocated in plants. The degradation of TPTH that does occur in plants involves

cleavage of the carbon-tin bond to produce diphenyltin hydroxide (or oxide) and monophenyltin hydroxide (or oxide) as intermediary products. Inorganic tin, benzene, phenol, and thiophenol and its conjugates are the final products of degradation of TPTH. The molecular structures of TPTH and its metabolites are presented in Table 1. The Residue Chemistry Chapter referred to a TOX Branch memorandum (J. Doherty, TOX Branch memo PP#3F2823/FAB#3H5384 dated October 28, 1983) in which it was concluded that the tolerance expression for TPTH should include the parent compound, and the di- and monophenyltin metabolites.

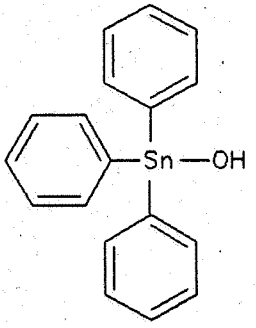
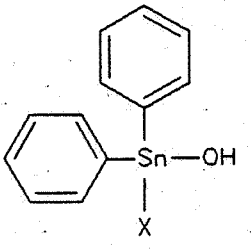
References (used):

N/A.

Discussion of the data:

N/A.

Table 1. Molecular structures of TPTH and its metabolites (X = oxides or hydroxides).

Chemical Name	Chemical Structure
Triphenyltin hydroxide (TPTH)	
Diphenyltin hydroxide (DPTH)	

(continued)

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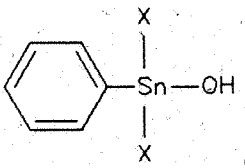
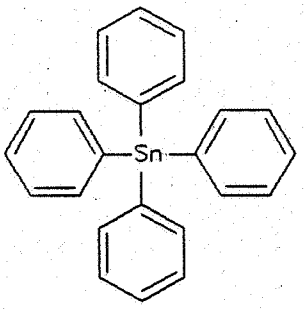
Table 1. (continued)

Chemical Name	Chemical Structure
Monophenyltin hydroxide (MPTH)	
Tetraphenyltin (TTPH)	

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QUALITATIVE NATURE OF THE RESIDUE IN ANIMALS

Conclusions:

The 1984 TPTH Guidance Document concluded that the nature of the residue in animals is similar to that in plants and is adequately understood, based on studies conducted on laying hens, swine, dairy cows, goats, sheep and rats. The residue consists of intact TPTH, TPTH as transient conjugate(s) with natural components of tissues, and as diphenyltin, possibly as transient conjugates, and monophenyltin compounds (hydroxides, oxides, acetates or chlorides). The terminal products of degradation are inorganic tin compounds, phenol and products related to phenol. The residues of concern in meat, milk, poultry, and eggs are the parent compound per se, and its di- and monophenyltin hydroxides (or oxides). The molecular structures of TPTH and its metabolites are presented in Table 1.

References (used):

N/A.

Discussion of the data:

N/A.

RESIDUE ANALYTICAL METHODS

Conclusions:

The qualitative nature of the residue in plants and animals is adequately understood. The residues of concern are TPTH and its di- and monophenyltin hydroxide/oxide degradates (DPTH and MPTH). The Guidance Document recommended that the tolerance definition be revised to include the parent and the di- and monophenyltin metabolites, and required the development of tolerance enforcement methodology capable of quantifying TPTH and the two degradates either collectively or separately. The Guidance Document also required the development of methodology, which includes a base hydrolysis step to release conjugated residues, for determination of TPTH and the two degradates either collectively or separately in meat, milk, poultry, and eggs.

PAM Vol. II Methods I-IV are colorimetric methods that determine TPTH per se. While these methods are adequate to enforce the existing tolerances for residues of TPTH per se, none of these methods would be adequate to enforce the recommended revised tolerances.

Numerous submissions (tabulated below) containing descriptions of methods for the determination of individual organotin species in plant commodities have been submitted in response to the Guidance Document. These submissions represent several iterations of

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Agency review and the subsequent registrant response to deficiencies in the methodology. The Agency (CBRS No. 2213 dated 9/1/87 by F.B. Suhre) concluded that the deficiencies cited for methods TA-46, -47, -48, and -49 were resolved and recommended that the registrant submit non-confidential copies of the these methods to the Agency for validation trials.

MRID	Method No.	Reviewer	CBRS No.	Date	Commodity
00156382	TA-43	S. Hummel	127	2/26/86	sugar beets
00160465	TA-47	S. Hummel	1096	9/4/86	carrots
00160466	TA-47				potatoes
00160467	TA-48				peanut hulls
00160468	TA-47				sugar beets
00169469	TA-46				soybeans
00165010	TA-49	F.B. Suhre	1702	5/1/87	peanuts
00165025	TA-49				pecans

Recent submissions discussed in this Update, contain residue data from crop field trials that were collected using methods designed to screen for residues of total extractable organotin (ΣOT), also picking up some inorganic tin, followed by separation and quantification of organotin species as needed. These methods are not designated by method numbers as were those submitted by Griffin. Moreover, they differ substantially from the numbered methods cited above.

Residue data on potatoes (1990; MRID 41556602) and sugar beets (1990; MRID 41556601) were collected using a method that employs extraction and chelation steps prior to GFAA analysis of ΣOT. Individual phenyltin species are analyzed by GLC/FPD. Brief descriptions of these methods and a summary of the submitted validation data are presented below.

The available data indicate that the GFAA/GLC methodology would be inadequate to enforce tolerances for combined phenyltin residues, and may be inadequate for data collection. For the GLC analysis of phenyltin species, the registrant reports statistically derived detection limits for potatoes and sugar beets (RACs only), but does not provide the experimental data used to derive these values, nor do they explain their rationale for estimating limits of detection in this manner. Furthermore, the tendency of untreated samples, particularly those of processed commodities, to acquire tin residues from the environment may need to be taken into account in assigning limits of detection for some commodities. It should be noted also that the method should be able to adequately recover each residue of concern at fortifications as low as or lower than the stated limit of detection; this is not the case for MPTH, which is not adequately recovered from sugar beets fortified at 0.02 ppm.

The method does not consistently produce adequate recoveries from some commodities, including samples fortified at the tolerance (e.g., time zero potato and sugar beet samples fortified at 0.1 ppm in storage stability studies). The registrant needs to demonstrate that adequate recoveries can be relied upon using these methods.

The registrant reports information regarding the degradation of TPTH to DPTH and MPTH, but does not provide the data upon which these conclusions were based or provide a description of the experimental conditions surrounding the gathering of these data. Conflicting information concerning the stability of TTPTH was given and this needs to be clarified. In addition, more information is needed regarding the rate of degradation of phenyltins to inorganic tin. The contribution that inorganic tin makes to the total organotin measurements needs to be investigated also.

The recovery from fortified samples analyzed concurrently with residue and storage stability study samples needs to be reported. The registrant reports a single average concurrent recovery value of 85.5% for both potatoes and sugar beets in the residue reports.

The method uses an internal standard, tripropyltin chloride, added to the sample prior to derivatization of residues for GLC analysis. The Agency considers the use of an internal standard in enforcement methodology suitable only if added just prior to injection. The method could be modified so that the internal standard is derivatized separately from the phenyltin residues and added to the sample immediately before injection.

The use of triphenyltin chloride compounds as standards for ΣOT analysis needs further justification. All data need to be reported as TPTH equivalents.

In summary, the registrant has not provided sufficient data to demonstrate that the GFAA/GLC method used to screen for ΣOT and subsequently analyze individual phenyltin species is adequate for data collection or tolerance enforcement. Additional data are required and the method must undergo modification if it is to be suitable for enforcement. The following additional data are required:

- The registrant must provide additional data to allow judgement as to the adequacy of their GFAA/GLC methodology used to collect data on potatoes, sugar beets, and processed commodities. Raw data are needed from the analyses used to derive the theoretical method limits of detection reported for DPTH and MPTH, and the registrant must explain their rationale for determining the method limits of detection in this manner. The registrant must also provide data to demonstrate that each phenyltin species can be adequately recovered from each regulated commodity fortified at the stated limit of detection and tolerance level. The registrant must provide data to back up their claim that analysis of organotin compounds is independent of the counterions present, in order to support their use of triphenyltin chloride compounds as standards. The data from the registrant's determination of phenyltin degradation rates must be submitted, and data to quantify the rate of breakdown to inorganic tin should be

included. The registrant must clarify the discrepancy concerning the stability of TTPTH during the extraction procedure. The contribution of inorganic tin to the total organotin analysis needs to be quantified in order to more accurately determine total phenyltin and to resolve the discrepancies between ΣOT from GFAA analysis and the sum of phenyltins from GLC analysis. We note that some of these data requirements may necessitate modifications to the method. If the registrant wishes to submit this GFAA/GLC methodology for enforcement use, in addition to the data specified above, the method must be modified so that the tripropyl tin internal standard is derivatized separately from the TPTH residues and is added to the sample just prior to injection into the GLC. Complete descriptions and appropriate validation data must be submitted for modified methods. All data must be reported as TPTH equivalents.

The Guidance Document required methodology suitable for analyzing TPTH, DPTH, and MPTH in animal tissues, milk, and eggs, and specified that the method should include a base hydrolysis step to release residues from conjugates. In response, the registrant submitted a HPLC/GFAA method for phenyltins designated TA-50 (MRID 40149402), that is essentially the same as those submitted for plant commodities. The registrant stated that the base hydrolysis step was neither required nor beneficial. The Agency review of this method (F. Suhre, CBRS No. 2213, 9/1/87) noted that no validation data were submitted with the method and the registrant did not provide any data to support the claim that base hydrolysis was unnecessary. Nothing further has been submitted regarding methodology for TPTH residues in or on animal products. The following data requirement remains outstanding:

- The registrant must submit methodology for enforcement of tolerances for residues of TPTH, DPTH, and MPTH in meat, milk, poultry, and eggs. The method(s) should include a base hydrolysis step to release conjugated residues. Alternatively, the registrant must provide data indicating that base hydrolysis is unnecessary for adequate recovery of the total toxic residue. A complete description of the method(s) and appropriate validation data must be submitted.

- Proposed tolerance enforcement methodology must undergo successful confirmatory trials conducted by an independent laboratory. Results of at least one set of samples per commodity (a total of six samples, including two control samples, two control samples fortified at the tolerance level, and two control samples fortified ar 2-5 times the tolerance level) must be submitted. No more than three sets of samples per commodity may be tested to achieve successful recovery rates of 70-120% with negligible interference compared to the established tolerances. For additional details of data requirements, refer to PR Notice 88-5, Tolerance Enforcement Methods-Independent Laboratory Confirmation by Petitioner.

- Representative samples from plant and animal metabolism studies must be analyzed using proposed enforcement methodology in order to ascertain that these methods are capable of recovering all residues of concern. If analysis of samples from previously

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accepted metabolism studies is impractical, the registrant must provide data from other sources to demonstrate adequate recovery of the total toxic residue.

The Pestrak Data Base (PAM, Vol. I Appendix, dated 11/6/90) indicates that recovery of triphenyltin hydroxide residues is not likely through the FDA Multiresidue Methods. However, the Pestrak did indicate that method research is being conducted on phenyltins.

References (used):

MRIDs: 00156382. 00160465. 00160466. 00160467. 00160468. 00160469. 00165010. 00165025. 40149301. 40149302. 40149303. 40149304. 40149305. 40149401. 40149402. 41556601. 41556602. 41785201. 41785202. 41785203. 41785204.

Discussion of the data:

Data submitted by Atochem, N.A. for potatoes and sugar beets (1990; MRIDs 41556601 and 41556602) were collected using a method for the screening of total extractable organotin (ΣOT) by GFAA and subsequent analysis of individual phenyltin species as needed. The registrant stated that because the ΣOT method does not totally exclude soluble inorganic tin, those samples in which the total organic tin exceeded 0.01 ppm were further analyzed by GC/FPD to quantify phenyltin residues.

Samples are homogenized with tartaric acid, sodium bromide, and acetic acid, sodium sulfate is added to remove water, and the residues are extracted into THF containing 0.05% tropolone. A portion of the extract is analyzed by GFAA at 286.3 nm. Phenyltin chloride compounds were used for the preparation of the MPTH, DPTH, and TPTH fortification standards for the ΣOT method. The registrant contended that the organotin compound counterions (chloride, bromide, hydroxide, etc.) can exchange in an aqueous medium, resulting in the formation of a complex mixture of equilibrium products, the composition of which is a function of the counterions present in solution and the respective thermodynamic equilibrium constants; therefore, analysis of these organotin compounds is independent of the counterion present. The registrant did not, however, provide experimental data to support this claim.

The remaining portion of the THF/tropolone extract is redissolved in toluene, fortified with tripropyltin chloride as an internal standard, derivatized with n-butylmagnesium chloride, and cleaned up through a Florisil/silica gel column. The residues are eluted with dichlormethane:hexane 50:50, and the samples are reserved for further analysis. Samples containing detectable total organotin residues are analyzed for individual species by GC/FPD using a 5% methyl/95% phenylsilicone capillary column. The calibration standards for the GLC/FPD analysis are derivatized from MPTH, DPTH, TPTH and tripropyltin chloride. The derivatized standards are subjected to Florisil column cleanup. Losses may be incurred during this step, and no experimental data were provided to ensure adequate recovery.

This method was also used to collect residue data in potato and sugar beet processing studies (1991; MRIDs 41785201, 41785202, 41785203, 41785204). These submissions included validation data from processed commodities of potatoes and sugar beets using the ΣOT method and the GC/FPD to quantify phenyltin residues. These submissions also included a copy of the method validation study on potatoes and sugar beets submitted with the method in MRID 41556601. Recovery data are presented in Table 3. Additional validation data were provided for processed commodities, but actual fortification levels were not reported; therefore, these data are not included in Table 3.

Table 3. Recoveries of phenyltin compounds from commodities as measured by GFAA (ΣOT) and GC/FPD[a].

Commodity	MRID	Fortification compound	Fortification level (ppm)	Percent recovery (std deviation) ΣOT method	Percent recovery (std deviation) GC/FPD method
potatoes	41556601 41556602 41785201 41785202 41785203 41785204	TPTH	0.005 0.01 0.1	114 (15) 148 (26) 112 (11)	83 (19) 103 (8) 111 (11)
		DPTH	0.005 0.01 0.1	105 (11) 100 (19) 110 (22)	61 (14) 130 (9) 106 (15)
		MPTH	0.005 0.01 0.1	154 (20) 105 (9) 108 (18)	21 (1) 64 (22) 68 (18)
		TTPTH	0.1	43 (10)	125 (6)
potatoes	41785204	ΣOT[b]	1.0	NP[c]	45
potato w/peel			1.0	NP	100
potato peeled			1.0	NP	116
boiled peeled			1.0	NP	37
boiled w/peel			1.0	NP	100
granules			1.0	NP	84
wet peel			1.0	NP	24

Commodity	MRID	Fortification compound	Fortification level (ppm)	Percent recovery (std deviation) ΣOT method	Percent recovery (std deviation) GC/FPD method
dried peel			1.0	NP	24
baked w/peel			1.0	NP	67
dried peel	41785202	ΣOT[d]	0.5	112	85
wet peel			0.5	121	125
granules			0.5	72	98
chips			0.5	70	matrix interference
sugar beets	41556601 41556602 41785201 41785202 41785203 41785204	TPTH	0.005 0.02 0.1	187 (58) 79 (2) 76 (4)	101 (21) 116 (49) 84 (8)
		DPTH	0.005 0.02 0.1	143 (34) 83 (18) 86 (1)	94 (30) 88 (16) 80 (6)
		MPTH	0.005 0.02 0.1	102 (11) 102 (37) 87 (1)	44 (7) 53 (7) 69 (12)
		TTPTH	0.1	36 (4)	113 (21)
sugar beet	41785203	ΣOT	1.0	NP	87
dehy. pulp			1.0	NP	50
molasses			1.0	NP	93
refined sugar			1.0	NP	107
sugar	41785201	ΣOT[d]	0.5	98	89
dehyd pulp			0.5	181	81
molasses			0.4	139	87

[a]Recoveries from samples fortified with TPTH were determined based on the sum of TPTH, DPTH, and MPTH found in the sample. Likewise the sum of MPTH and DPTH were used to represent the recovery of DPTH. MPTH recoveries were based on MPTH only. [b] Reported as the sum of MPTH, DPTH, and TPTH. [c]Data not provided. [d]Average of two determinations; fortification levels calculated by reviewer.

(continued)

The instrument detection limit for GFAA ΣOT analysis, defined as the amount of tin that produces a signal 3x that of mean background detector noise, of 0.0045 ppm of tin (Sn) was reported. The registrant reported a statistically derived method detection limit for GFAA ΣOT analysis of 0.0088 ppm of Sn in potatoes and 0.011 ppm in sugar beets. The method detection limits were based on a *t* value for seven measurements (99% confidence limit) and the standard deviation of the mean for seven measurements. No further information on exactly what samples were analyzed, how the measurements were done, or data from these measurements were reported. Furthermore, the report provided no explanation of the rationale for calculating method limits of detection in this manner. Apparent residues in or on untreated sugar beet and potato matrices ranged from less than the method limit of detection to 0.04 ppm (refer to the individual crop sections for details of apparent residues in or on controls). Adequate recovery of phenyltins have been obtained at fortification levels as low as 0.005 ppm. Additional data are required in order to determine the limits of detection for potato and sugar beet matrices using the method.

The instrument detection limit for GLC phenyltin species analysis was 0.002 ppm. Statistically derived detection limits (calculated as described above and expressed as Sn) were 0.0146 ppm MPTH and 0.012 ppm DPTH in potatoes and 0.013 ppm MPTH and 0.0123 ppm DPTH for sugar beets. These determinations were done for the RACs only. Method detection limits were determined for MPTH and DPTH only, due to the apparent breakdown of TPTH and TTPTH when added to the fleshy root matrices. Adequate recovery was shown at the 0.010 ppm level for DPTH- and TPTH-fortified samples; however, consistently low recoveries (average of 44-69% with standard deviation as high as 22%) were reported for MPTH at all fortification levels (0.005-0.1 ppm).

The registrant also discussed the stability of each of the analytes during the analysis procedure. The report indicated that the phenyltin compounds are not stable in the presence of plant matrices and that in potato matrix TPTH rapidly degrades to DPTH (80-100%) and MPTH (0-10%). DPTH was also found to degrade to MPTH (ca. 10%) and MPTH may degrade slightly to inorganic tin. TTPTH is stable in potato matrix. In the presence of sugar beet matrix TPTH rapidly degrades to DPTH (80-100%) and MPTH (0-20%). DPTH was also found to degrade to MPTH (20-30%). The rate at which MPTH degraded to inorganic tin was reported to be uncertain. It should be noted that the data indicate that the recovery of TTPTH by the ΣOT method is affected by plant matrices; therefore recoveries are unacceptably low. However, the same samples analyzed by the GC/FPD method indicate adequate recoveries. The registrant included in one submission (MRID 41785201) a report indicating that TTPTH is stable in sugar beets during the extraction procedure. In the same submission, the registrant stated that TTPTH is not stable and that recovery of TTPTH residues are determined by measuring DPTH and MPTH. This discrepancy must be resolved. No actual data from phenyltin degradation studies were provided. Additional data are required to assess the breakdown patterns of the phenyltin species.

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Data to quantify the degradation of MPTH to inorganic tin are needed in order to determine accurate MPTH recoveries. If TTPTH is found to be stable, then results should be reported as TTPTH. If degradation is found, then results should be reported as the sum of the degradation products.

The GFAA/GLC method used to screen for ΣOT residues and for subsequent determination of phenyltins may not be adequate for data collection or tolerance enforcement. The available data are insufficient to determine accurate limits of detection for all regulated commodities. The data fail to show consistently adequate recoveries of all phenyltins. The registrant's claims regarding the degradation patterns of phenyltin residues and the suitability of using phenyltin chlorides for standards need to be supported by quantitative data. The contribution of inorganic tin to the total organic tin measurement should be quantified. For enforcement purposes, the method would have to be modified so that the internal standard is derivatized separately and not added to the residue sample until just prior to injection into the GLC. Additional data are required.

STORAGE STABILITY

Conclusions:

The 1984 Guidance Document stated that no storage stability data were available and indicated that although some previously submitted residue samples were said to have been stored at -2 °C, no information was furnished concerning the duration of storage and stability of the residues when stored for periods longer than 2 months. The Guidance Document also indicated that data on storage stability for di- and monophenyltin hydroxide (or oxides) in potatoes, sugar beets, carrots, pecans and meat, milk, poultry, and eggs were required. Data on storage stability for tetraphenyltin, in addition to data on TPTH and its di- and monophenyltin metabolites, were required from processed commodities from potatoes, sugar beets, and peanuts.

In response to the requirements in the 1984 Guidance Document, the registrants submitted protocols for storage stability studies that were reviewed by the Agency (R. Loranger, CBRS Nos. 799 and 1040, 6/21/85). The Agency concluded that storage stability studies on pecans and one of the root crops would be sufficient. In addition, it was noted that storage stability studies on the raw agricultural commodities (RACs) should include fortification of the RAC homogenate separately with TPTH, DPTH and MPTH.

The Agency also informed the registrant (Memorandum of Meeting dated 9/25/87 by F.B. Suhre) that sugar beet tops were no longer considered to be under the control of the grower and that residue data and supporting storage stability data were required for sugar beet tops.

The registrants have submitted data pertaining to residues in or on sugar beets (1990; MRIDs 41556601 and 41785201) and potatoes (1990; MRIDs 41556602 and 41785202, 41785203 and 41785204). The four submissions consisted of summary tables depicting the recovery data for total phenyltins and total organotin in sugar beet roots and potatoes stored at -29 °C for 7 weeks. The data on sugar beets show low recoveries of phenyltins in the time zero samples then adequate recoveries from the 1- to 5-week samples, declining after 5 weeks. Similarly, recoveries were low from 0- to 1-week potato samples, but adequate thereafter to 7-weeks. The registrant needs to explain the low phenyltin recoveries from the time-zero analyses. Furthermore, it should be noted that samples from the residue studies that these data are intended to support were stored for intervals up to 58 days for potatoes and 95 days for some of the potato processed commodities and 61 days for sugar beets. The actual fortification levels were not provided. The submissions cannot be evaluated until the registrant provides all relevant information to the conduct of the storage stability studies on sugar beets and potatoes. We note that residue samples discussed in this update were stored for up to approximately 14 weeks. No data were submitted pertaining to storage stability of residues in or on sugar beet tops and processed sugar beet and potato commodities.

The following data are required:

- Storage stability data are required in support of all required residue studies, reflecting the actual storage conditions and intervals for samples used to generate the residue data. All information relevant to fortification of samples must be provided. All samples must be fortified with TPTH and its di- and monophenyltin metabolites. If the registrant wishes to use the data from the studies submitted in MRIDs 41556601, 41556602, 41785201 and 41785202, to fulfill storage stability data requirements, an adequate explanation for the low zero day recoveries must be provided. Storage stability data must be collected using adequate analytical methodology. Data on the storage stability of TPTH, its di- and monophenyltin metabolites and of tetraphenlytin in sugar beet and potato processed commodities are required.

- Data on the storage stability of TPTH residues of concern in or on sugar beet tops are required.

- Data are required depicting the storage stability of TPTH and its di- and monophenyltin metabolites in meat, milk, poultry, and eggs.

References (used):

MRIDs: 41556601. 41556602. 41785201. 41785202.

Discussion of the data:

Atochem, N.A., on behalf of the TPTH registrants submitted data pertaining to the storage stability of TPTH residues (MPTH,DPTH,TPTH,TTPH) in or on sugar beet roots (1990;

MRIDs 41556601 and 41785201) and potatoes (1990; MRIDS 41556602 and 41785202). The four submissions consisted of summary tables (presented in Tables 4 and 5) depicting the recovery data for total phenyltins and total organotin in sugar beet roots and potatoes stored at -29 °C for 7 weeks. The data on sugar beets show low recoveries of phenyltins in the time zero samples then adequate recoveries from the 1- to 5-week samples, declining after 5 weeks. Similarly, recoveries were low from 0- to 1-week potato samples, but adequate thereafter to 7-weeks. The registrant needs to explain the low phenyltin recoveries from the time-zero analyses. It was stated that stability of ΣOT in frozen sugar beets and potatoes was demonstrated concurrently with the field sample analyses by spiking TPTH into the homogenized raw commodities and storing the samples for various intervals. The fortification levels were reported as μg added to an unknown weight of sample; the concentration (in ppm) could not be determined. Data on samples stored for 9 and 14 weeks, respectively, are needed to support the residue data on sugar beets and potatoes. Note: The acceptability of this method for data collection cannot be determined until the deficiencies listed in the Residue Analytical Methods section of this Update have been resolved. The registrant must provide all relevant information to the conduct of the storage stability studies on sugar beets and potatoes. The submissions cannot be evaluated until this information is provided. Finally, storage stability data are needed to support the data being requested on sugar beet tops.

Table 4. Stability of phenyltin in fortified sugar beets stored at -29 °C for seven weeks.

		Recovered					
Interval	REP	MPTH	DPTH	TPTH	ΣPT[a]	Percent Phenyltin Recovery	Percent Organotin Recovery
		----------μg----------					
Time 0	1	0.153	0.329	0.017	0.499	42	96
Time 0	2	0.190	0.123	ND	0.313	27	116
1 Week	1	0.258	0.530	0.143	0.931	79	68
1 Week	2	0.143	0.750	0.116	1.009	86	75
3 Weeks	1	0.061	0.236	1.151	0.448	38	97
3 Weeks	2	0.193	0.745	1.227	2.165	184	122
5 Weeks	1	0.946	0.717	0.046	1.709	145	100
5 Weeks	2	0.515	0.969	ND	1.484	126	117
7 Weeks	1	ND	0.047	0.385	0.432	37	65
7 Weeks	2	ND	0.081	0.455	0.536	46	57

[a]Registrant stated that TTPTH was not detected in any sample.

Table 5. Stability of ΣOT and phenyltin residues in potatoes fortified with 1.47 μg TPTH stored at -29 °C for seven weeks.

Interval	REP	Recovered MPTH	DPTH	TPTH	ΣPT[a]	Percent Phenyltin Recovery	Percent Organotin Recovery
		----------μg----------					
Time 0	1	0.165	0.197	0.065	0.427	36	100
Time 0	2	0.128	0.630	ND[b]	0.758	64	89
1 Week	1	0.052	0.353	0.140	0.545	46	78
1 Week	2	0.097	0.595	0.018	0.710	60	78
3 Weeks	1	0.119	1.004	0.289	1.412	120	121
3 Weeks	2	0.070	0.732	ND	0.802	68	126
5 Weeks	1	0.091	1.121	ND	1.212	103	153
5 Weeks	2	0.114	1.451	ND	1.565	133	208
7 Weeks	1	ND	0.476	0.499	0.975	83	108

[a]Registrant stated that TTPTH was not detected in any sample.

[b]ND = No detectable limit (not specified).

MAGNITUDE OF THE RESIDUE IN PLANTS

It should be noted that the conclusions stated in this section regarding the adequacy of established tolerances may change on receipt of the analytical method validation and storage stability data. The Agency has concluded that all established tolerances for residues of TPTH must be revised to include TPTH, DPTH, and MPTH and that the revised tolerances should be expressed in terms of TPTH equivalents. However, appropriate levels for revised tolerances and food/feed additive tolerances cannot be determined at this time. Deficiencies in the analytical methodology used to generate these residue data need to be resolved before the adequacy of these data can be determined. Furthermore, additional storage stability data are required. Following receipt of the data requested on analytical methodology and storage stability, either additional studies will be required or appropriate levels for revised tolerances determined based on the available data. The registrant should note that all residue data used to support revised tolerances must be expressed in terms of TPTH equivalents.

The 1984 TPTH Guidance Document required data on residues of di-and monophenyltin hydroxides (or oxides) in or on pecans, peanuts, potatoes, sugar beets, carrots, green (freshly harvested) tobacco, and meat, milk, poultry, and eggs. In addition, the Guidance Document required data on residues of di-and monophenyltin hydroxides (or oxides) and tetraphenyltin in processed commodities from potatoes, sugar beets and peanuts.

In response to the 1984 Guidance Document, the registrants submitted protocols for trials to determine residues in pecans, carrots, sugar beets, peanuts, and potatoes. The protocols were reviewed by the Agency (CBRS Nos. 799 dated 6/21/85 and 1040 dated 6/21/85 by R. Loranger). Among other recommendations forwarded to the registrants, CBRS stated that since residues of TPTH in peanuts, potatoes, and sugar beets were primarily on the surface, the processing studies could be conducted by spiking untreated crops in the laboratory. Also, the Agency (Memorandum of Meeting dated 8/30/88 by F. Suhre) has confirmed that for future crop field trials and storage stability studies, samples may be initially assayed for total tin and total organotin, and only those samples containing organotin residues at or above 0.01 ppm (the speciation methods' reported limit of detection) need be assayed for tetra-, tri, di-, and monophenyltin.

The use patterns for sugar beets, pecans, carrots, and potatoes discussed in the Residue Chemistry update are based on the following Griffin Corporation labels: 4 lb/gal FlC (EPA Reg. No. 1812-244), 1.875 lb/gal FlC (EPA Reg. No. 1812-277), 19.7% WP (EPA Reg. No. 1812-275), 47.5% WP (EPA Reg. No. 1812-276) and the 4.72% SC/S-MAI (EPA Reg. No. 1812-269). 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., any unamended basic producer labels, SLNs, and products covered under the generic data exemption) be amended such that they are consistent with the amended basic producer labels.

Root and Tuber Vegetables Group

Carrots

Tolerance:

A tolerance of 0.1 ppm has been established for the residues of TPTH per se in or on carrots (40 CFR §180.236).

Use directions and limitations:

The 1.875 lb/gal FlC, 4 lb/gal FlC, and the 19.7% WP formulations are registered for six foliar applications per season to carrots at 0.125-0.25 ai/A/application, with a maximum of 1.5 lb ai/A/season, in spray volumes of 5-100 gal/A using ground equipment; the 47.5% WP formulation is registered for foliar application to carrots at 0.12-0.24 lb ai/A/application, with no maximum seasonal rate registered, in 10-100 gal/A using ground equipment or 3-20 gal/A using aerial equipment. The established PHI is 14 days. Surfactants, spreaders or stickers are not to be added. The 47.5% WP may be applied by chemigation. All labels specify a grazing/feed restriction. These use directions were obtained from the product labels from the following Griffin Corporation formulations: the 1.875 lb/gal FlC (EPA Reg. No. 1812-277), 4 lb/gal FlC (EPA Reg. No. 1812-244), and the 19.7 and 47.5% WP (EPA Reg. Nos. 1812-275 and 1812-276, respectively).

Conclusions:

The 1984 TPTH Guidance Document required residue data for TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on carrots.

In response, the registrants submitted (1986; MRIDs 00160465, 40149401, 40149305) residue data along with analytical methods for carrots that were reviewed by S. Hummel (CBRS No. 1096, 9/4/86) and F.B. Suhre (CBRS No. 2213, 9/1/87 and CBRS No. 2264, 9/2/87). Residue data from four field trials on carrots conducted in CA, TX, MI and an unspecified location (one each) reflecting up to eight applications of 4 lb/gal FlC at 0.24 lb ai/A/application and PHI of 14 days were provided. The data indicated that total TPTH residues (TPTH, DPTH and MPTH, expressed as TPTH equivalents) in or on carrots would not exceed 0.05 ppm as a result of application using ground equipment. It was stated that additional data were required from OR/WA. In addition, it was recommended that the established tolerance for residues in or on carrots should be revised from 0.1 ppm for TPTH per se to 0.05 ppm for total TPTH residues (expressed as TPTH), based on the analytical method's (Method TA-47) limit of detection (0.01 ppm) for each of the three TPTH residues of concern. A final recommendation regarding tolerance revisions will be made after review of the additional required residue data. The following additional data are required:

- Additional data are required from tests conducted in WA or OR. A representative FlC or WP formulation must be applied at the maximum label rate and the number of applications must reflect the maximum permitted on the label. Samples must be harvested at a posttreatment interval that corresponds to the PHI on the label.

References (used):

MRIDs: 00160465. 40149401. 40149305.

Discussion of the data:

N/A.

Potatoes

Tolerance:

A tolerance of 0.05 ppm has been established for the residues of TPTH per se in or on potatoes (40 CFR §180.236).

Use directions and limitations:

The 1.875 lb/gal FlC, 4 lb/gal FlC, and the 19.7% WP formulations are registered for three foliar applications per season to potatoes at 0.125-0.25 lb ai/A/application, in spray volumes

of ≥15 gal/A using ground equipment or 3-10 gal/A using aerial equipment; the 0.5 lb/gal SC/S (MAI) and the 47.5% WP formulations are registered for foliar applications to potatoes at 0.15-0.30 lb ai/A/application, with no maximum seasonal rate specified, in ≥10 gal/A using ground equipment or 3-20 gal/A using aerial equipment. Surfactants, spreaders or stickers are not to be added. A PHI of 7 days has been established. The 47.5% WP, the 0.5 lb/gal SC/S and one 4 lb/gal FlC (EPA Reg. No. 1812-244) can be applied by chemigation. These use directions were obtained from the product labels from the following Griffin Corporation formulations: the 1.875 lb/gal (EPA Reg. No. 1812-277), 4 lb/gal FlC (EPA Reg. No. 1812-244), the 19.7 and 47.5% WP (EPA Reg. Nos. 1812-275 and 1812-276, respectively) and the 0.5 lb/gal SC/S (EPA Reg. No. 1812-269).

Conclusions:

The 1984 TPTH Guidance Document required residue data for TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on potatoes and of tetraphenyltin as well in processed potato commodities.

In response, the registrants submitted (1986; MRID 00160466, 40149401, and 40149304) residue data along with analytical methods for potatoes that were reviewed by S. Hummel (CBRS No. 1096, 9/4/86) and F.B. Suhre (CBRS No. 2213, 9/1/87 and CBRS No. 2264, 9/2/87). Four field trials on potatoes conducted in ME, ND, WA, and ID reflecting 3-11 applications with the 4 lb/gal FlC at 0.29 and 0.59 lb ai/A/application were provided. The data indicated that total TPTH residues (TPTH, plus its di- and monophenyltin metabolites expressed as TPTH equivalents) in or on potatoes would not exceed 0.05 ppm in or on samples harvested 11 days following application using ground equipment. The Agency concluded that additional residue data reflecting a 7-day PHI, and data from aerial and sprinkler irrigation applications were required. The Agency also reiterated the requirement for potato processing studies.

Subsequently, Atochem N. A., on behalf of Griffin, submitted data (1990; MRID 41556602) depicting residues in or on raw potato tubers from seven tests conducted in ID, ME, MN, and ND (1 each), and in WA (3), reflecting four to six foliar applications of the 4 lb/gal FlC formulation using ground, aerial, and sprinkler irrigation equipment. Total organotin residues were ≤0.035 ppm in or on 21 treated samples harvested 21 days following the last of 4-6 foliar applications (at 1x maximum use rates). Residues of TPTH, di-, and monophenyltin were each 0.01 ppm. The following is required:

- The registrants must amend all pertinent product labels to specify a PHI and a maximum seasonal application equivalent to that reflected in the data used to support the tolerance. The available data indicate a 21-day PHI and a maximum seasonal application rate of 0.75 lb ai/A would be appropriate. If the registrants elect to propose a different PHI and maximum rate, appropriate supporting residue data must be submitted.

- o A mean recovery value of 85.5% was reported for fortified samples analyzed concurrently with treated samples. We note that this same recovery value was reported in the sugar beet study. The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed.

Atochem, N.A., on behalf of the TPTH registrants, submitted data (1990; MRID 41785202) from a single study pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH and TTPTH) in or on processed commodities from field treated potatoes. The nontreated and treated potato samples contained non-detectable (<0.01 ppm Sn) levels of ΣOT. The nontreated processed commodities, dry peel and wet peel, also contained non-detectable (<0.01 ppm Sn) levels of ΣOT. The nontreated samples of granules and chips both contained 0.018 ppm Sn. Of the treated processed samples three granule samples contained 0.011-0.038 ppm Sn, three chip samples contained 0.009-0.016 ppm Sn, three dry peel samples contained 0.011-0.033 ppm Sn and one wet peel sample contained 0.024 ppm Sn. Of the eight samples that were analyzed for the individual phenyltin species, all bore residues less than the reported limit of detection, 0.0146 ppm Sn for MPTH, and 0.0121 ppm Sn for DPTH. None of the chip samples were analyzed further. Additional information is required to evaluate the residue data provided in this submission.

Atochem, N.A., on behalf of the TPTH registrants, submitted data (1991; MRID 41785204) from a single study pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH and TTPTH) in or on processed commodities from fortified potatoes. Residues of both ΣOT and speciated phenyltins (MPTH, DPTH, TPTH, and TTPTH) concentrated in the wet and dried peel samples. ΣOT residues in or on six treated RAC subsamples averaged 2.53 ppm. The ΣOT residues in or on three treated wet peel and three treated dry peel subsamples averaged 6.42 ppm and 57.78 ppm respectively. Concentrations of average ΣOT residues were 2.5x and 23x for wet and dry peel. The total phenyltin residues in or on the treated RAC subsamples averaged 0.886 ppm. In or on the treated wet peel and dried peel subsamples, the total phenyltins averaged 2.352 ppm and 7.171 ppm, respectively. The average concentration of total phenyltins residues was 3x for wet peel and 8x for dried peel. The difference between the ΣOT and total phenyltins residues found particularly in wet and dry peel was not adequately explained. Given the numerous deficiencies already cited for the reporting and validation of the GFAA/GLC methodology, judgement as to the adequacy of these processing studies is reserved until the additional data requested for these methods has been reviewed.

The Agency has concluded that all established tolerances for residues of TPTH must be revised to include TPTH, DPTH, and MPTH and that the revised tolerances should be expressed in terms of TPTH equivalents. However, appropriate levels for revised tolerances and food/feed additive tolerances cannot be determined at this time. Deficiencies in the analytical methodology used to generate these residue data need to be resolved before the adequacy of these data can be determined. Furthermore, additional storage stability data are required. Following receipt of the data requested on analytical methodology and storage stability, either additional studies will be required or appropriate levels for revised tolerances

determined based on the available data. The registrant should note that all residue data used to support revised tolerances must be expressed in terms of TPTH equivalents.

References (used):

MRIDs: 00160466. 40149401. 40149304. 41556602. 41785202. 41785204.

Discussion of the data:

Potatoes: Atochem N.A., on behalf of the TPTH registrants, submitted data (1990; MRID 41556602) depicting residues in or on raw potato tubers from seven tests conducted in ID, ME, MN, and ND (1 each), and in WA (3), reflecting four to six foliar applications of the 4 lb/gal FlC formulation using ground, aerial, and sprinkler irrigation equipment. The rates of individual applications ranged from 0.094-0.225 lb ai/A delivered in spray volumes of 20-38 gal/A (ground, three tests), 5-8 gal/A (aerial, two tests), and 7,875-12,219 gal/A (chemigation, one test); the total amount of TPTH applied for each test was 0.69-0.83 lb ai/A, with the average rate of 0.755 lb ai/A reflecting (approximately 1x the maximum seasonal rate). Samples were brushed with a dry brush at harvest to remove excess dirt, and were frozen within one hour of collection. Samples were shipped on dry ice or in a freezer truck to the analytical laboratory within four days of harvest, and were stored frozen at approximately -20 °C for 14-58 days prior to analysis.

All samples were initially screened for total organotin residues (ΣOT) using graphite furnace AA. Samples containing levels of ΣOT exceeding 0.01 ppm were further analyzed for the individual phenyltin species (MPTH, DPTH, and TPTH) using GC/FPD. Of 18 treated samples from ground or aerial tests, two bore residues exceeding 0.01 ppm (0.011 and 0.012 ppm) and were further analyzed by GC/FPD. The analysis of one sample was reportedly hindered by "matrix interference." All three treated samples from the irrigation test bore residues exceeding 0.01 ppm (0.013, 0.015, and 0.035 ppm) and were further analyzed by GC/FPD. Residues of total organotin were nondetectable or below the validated method limit of detection in or on seven untreated controls. Of the five samples analyzed by GC/FPD, no residues of individual species were detected at levels above the validated method limits of detection (0.01 ppm for each phenyltin species). A mean recovery value of 85.5% was reported for fortified samples analyzed concurrently with treated samples. We note that this same recovery value was reported in the sugar beet study. The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed.

Geographic representation is adequate. The test states of ID (28%), ME (6%), MN (4%), ND (4%), and WA (17%), and the neighboring states of OR (6%) and WI (6%), collectively accounted for approximately 75% of U.S. potato production in 1989 (Agricultural Statistics, 1990, pp. 159-160).

The registrants should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed. Additionally, the registrants must amend all pertinent product labels to specify a PHI and a maximum seasonal application equivalent to that reflected in the data used to support the tolerance.

Processed commodities:

Atochem N.A., on behalf of the TPTH registrants, submitted data (1990; MRID 41785202) from a single study conducted in WA pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH, and TTPTH) in or on granules, chips, dried peel, and wet peel processed from potatoes harvested 21 days after the last of 4 applications of the 4 lb/gal FlC formulation for a total of approximately 3.75 lb ai/A (5x the maximum registered rate). There was a discrepancy in the reported application rates: the report summary introduction stated that a total of 3.83 lb ai/A in four applications at 0.788-1.347 lb ai/A application was made in 25.2-26.1 gal/A, whereas the table supplied by the cooperator notes that a total of 3.51 lb ai/A in four applications at 0.625-1.325 lb ai/A/application made in 24.72-25.6 gal/A. This discrepancy should be clarified. Three treated RAC samples and one untreated RAC control were shipped at ambient temperature by truck to the processor within 24 hours of harvest. The samples were then stored at 3-9 °C until being processed following normal commercial procedures. Following processing, samples were frozen at approximately -20 °C before being shipped on dry ice to the analytical laboratory where they were stored again at -20 °C until extraction. All of the samples were processed within 19-21 days of harvest. All processed commodities, except for granules, were extracted within 92-95 days after processing. For granules, potatoes were first processed into mash within 21 days following harvest. The mash was stored for 42-46 days until being processed into granules. The granules were then stored 48-51 days prior to extraction. All of the RAC samples were pre-processed, i.e., washed, destoned, and had the green rot and culls removed, prior to processing and analysis.

All samples were analyzed for ΣOT as a screening procedure using graphite furnace AA; the results are presented in Table 6. The pre-processed RAC samples contained non-detectable levels of ΣOT. The granule, chips, dry peel and wet peel samples that contained ΣOT greater than 0.01 ppm were subjected to speciation of the organic tin fraction using GC/FPD; the results are also presented in Table 6. "Matrix interference" reportedly prevented speciation by GLC of the control and two treated potato chip samples that contained 0.009-0.018 ppm of total organotin. Of a total of 12 treated samples of dry peel, granules, and chips that were analyzed for the individual phenyltin species (MPTH, DPTH, and TPTH, TTPT), all bore residues less than the reported limit of detection for MPTH (0.0146 ppm) and for DPTH (0.0121 ppm). A mean recovery for all concurrent matrix spikes of 85.5% was reported. A table titled "data for quality control samples analyzed concurrently with field-treated potatoes for ΣOT and phenyltin species" which presented matrix spike recoveries of 39-234% was included in this submission.

Table 6. Total organotin and phenyltin residue (ppm) in potato processed commodities after crop treatment at 5x.

Commodity	No. of Samples	Residues (ppm)[a] ΣOT[b]	MPTH[c]	DPTH[c]	TPTH[c]	TTPTH[c]
RAC						
Untreated	1	ND[d]	n/a[e]	n/a	n/a	n/a
Treated	3	ND-J	n/a	n/a	n/a	n/a
Granules						
Untreated	1	0.018	ND	ND	ND	ND
Treated	3	0.011-0.038	ND	ND	ND	ND
Chips						
Untreated	1	0.018	S	S	S	S
Treated	3	0.009-0.016	n/a-S	n/a-S	n/a-S	n/a-S
Dry Peel						
Untreated	1	ND	n/a	n/a	n/a	n/a
Treated	3	0.011-0.033	ND	ND	ND	ND
Wet Peel						
Untreated	1	ND	n/a	n/a	n/a	n/a
Treated	3	ND-0.024	n/a-ND	n/a-ND	n/a-ND	n/a-ND

[a]Residue levels expressed as Sn.

[b]GFAA Instrument Detection Limit (IDL) - 0.0045 ppm Sn;
Method Detection Limit (MDL) - 0.0088 ppm Sn.

[c]GLC/FPD Instrument Detection Limit (IDL) - 0.0021 ppm Sn;
Method Detection Limit of MPTH (MDL) - 0.0146 ppm Sn;
Method Detection Limit of DPTH (MDL) - 0.0121 ppm Sn;

[d]ND = <0.002 ppm, the registrant's stated instrument limit of detection.

[e]Not analyzed; below speciation threshold of 0.010 ppm Sn.

It is unclear whether the data present individual concurrent matrix fortification/recovery data or not. The variability in the recoveries was not explained and details concerning the raw data were not provided. This additional information is required to evaluate the residue data provided in this submission.

Atochem, N.A., on behalf of the TPTH registrants, also submitted data (1991; MRID 41785204) from a single study pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH, TTPTH) in or on fortified potato commodities prepared by domestic and commercial

processes. Whole, unpeeled potatoes were dipped into a suspension of the 4 lb/gal FlC formulation that was calculated to leave TPTH residues of 1 ppm in or on the composited RAC, and were then allowed to air dry. To prepare typical domestic products, subsamples from the composited potato RAC were hand washed under running water using a soft-bristled brush, and were cooked in a laboratory "kitchen." Subsamples of the RAC were taken to prepare raw (with and without peel), boiled (with and without peel), fried, and baked (with peel) potatoes. To prepare commercial products, subsamples of the potato RAC were machine washed and destoned as part of initial pre-processing procedures. Subsamples from the composited RAC were used to prepare granules, chips, wet peel, and dried peel. The samples of fried potatoes and chips were reportedly extracted for analysis, but the results were not presented. This omission was not explained, however, it was probably due to the method problems reported for analysis of chips processed from field-treated potatoes (MRID 41785202), attributed to the high oil content of the matrix. RAC samples were stored for 17 days at $\leq$-20 °C between treatment and extraction for analysis. Domestic products were prepared from the RAC on the day of treatment, and were stored at $\leq$-20 °C for 26-34 days between preparation and extraction. Processed products were prepared from the RAC stored at approximately 8 °C for 1-4 days before processing, and were stored at approximately -20 °C for 13-23 days before extraction.

All samples were analyzed for ΣOT (Table 7) and the samples that contained ΣOT greater than 0.01 ppm were subjected to speciation of the organic tin fraction (Table 8). Residues of both ΣOT and speciated phenyltins (MPTH, DPTH, TPTH, and TTPTH) concentrated in the wet and dried peel samples. ΣOT residues in or on 6 treated RAC subsamples averaged 2.53 ppm. The ΣOT residues in or on 3 treated wet peel and 3 treated dry peel subsamples averaged 6.42 ppm and 57.78 ppm, respectively. Average concentrations of ΣOT residues were 2.5x for wet peel and 23x for dried peel. The total phenyltins residues in or on the treated RAC subsamples averaged 0.886 ppm. In or on the treated wet peel and dried peel subsamples, the total phenyltins averaged 2.352 ppm and 7.171 ppm, respectively. The average concentration of total phenyltins residues were 3x for wet peel and 8x for dried peel. The difference between the ΣOT and total phenyltins residues found particularly in wet and dry peel was not adequately explained. Individual concurrent matrix fortification/recovery data were presented (Table 9). Fortification levels in ppm were not reported.

Table 7. Total organotin residues found in potatoes fortified with 1 ppm TPTH and then prepared by domestic and commercial processes.

Commodity	No. of subsamples	Total Organotin (ppm)	
		Untreated	Treated
RAC	6		1.63-3.73
	3	ND[a]	
Home products:			
Raw, w/peel	3	ND	0.093-0.130
Raw, peeled	3	ND	ND
Boiled, w/peel	3	ND	0.067-0.154
Boiled, peeled	3	ND	ND-0.006
Baked, w/peel	3	ND	0.045-0.125
Processed products:			
Granules	3	0.008-0.020	0.008-0.019
Dried peel	3	ND-0.079	53.17-60.24
Wet peel	3	ND	4.53-10.17

[a]Defined by registrant as not detected.

Table 8. Total phenyltin residues found in potatoes treated with 1 ppm TPTH and then prepared by domestic and commercial processes.

TREATED:

Commodity	No. of samples	MPTH (ppm)[a]	DPTH (ppm)	TPTH (ppm)	TTPTH (ppm)	Total phenyltin ppm
RAC	6	0.031-0.145	0.332-0.894	0.007-0.346	0.018-0.046	0.664-1.07
w/peel	3	ND[b]-0.007	ND-0.065	ND-0.003	ND	<0.013-0.065
peeled	3	ND	ND	ND	ND	<0.013
boiled w/peel	3	0.030-0.050	0.052-0.113	ND-0.031	ND-0.007	0.086-0.195
boiled peeled	3	ND	ND	ND	ND	<0.013
baked w/peel	3	0.010-0.078	0.009-0.087	0.007-0.051	ND-0.007	<0.013-0.223
granules	3	ND	ND	ND	ND	<0.013
dried peel	3	0.970-3.555	1.453-2.776	1.493-3.161	0.037-0.193	4.109-9.551
wet peel	3	0.117-1.371	0.989-1.684	0.020-0.290	0.059-0.117	1.185-3.392

CONTROLS:

Commodity	No. of samples	MPTH (ppm)	DPTH (ppm)	TPTH (ppm)	TTPTH (ppm)	Total phenyltin ppm
Potatoes	3	ND	ND	ND	ND	<0.013
w/peel	3	ND	ND	ND-0.009	ND	<0.013
peeled	3	ND	ND	ND-0.015	ND	<0.013-0.015
boiled w/peel	3	ND	ND	ND	ND	<0.013
boiled peeled	3	ND	ND	ND	ND	<0.013
baked w/peel	3	ND-0.004	ND	ND	ND	<0.013
granules	3	ND	ND	ND	ND	<0.013
dried peel	3	ND	ND	ND-0.013	ND	<0.013-0.013
wet peel	3	ND-0.004	ND-0.003	ND	ND	<0.013

[a] Calculated as Sn. [b] Not detected above 2.1 ppb.

(continued)

Table 9. Phenyltin recovery in concurrent matrix spikes in domestic and commercial commodities prepared from potatoes treated with 1 ppm total organotins.

	Nanograms Added				Nanograms Found				
Commodity	MPTH	DPTH	TPTH	TTPTH	MPTH	DPTH	TPTH	TTPTH	Total Recovery
RAC	7410	7230	7350	7290	0	364	1241	11545	45
Raw w/peel	7410	7230	7350	7290	6203	14185	1600	7329	100
Raw peeled	7410	7230	7350	7290	10884	8710	6251	8163	116
Boiled peeled	7410	7230	7350	7290	0	301	90	10509	37
Boiled w/peel	7410	7230	7350	7290	6406	13099	2703	7013	100
Granules	7410	7230	7350	7290	16547	504	7426	0	84
Wet peel	7410	7230	7350	7290	0	1187	2535	3290	24
Dried peel	7410	7230	7350	7290	122	1308	2151	3570	24
Baked w/peel	7410	7230	7350	7290	8602	6676	320	3942	67

Sugar beet roots

Tolerances:

A tolerance of 0.1 ppm has been established for the residues of triphenyltin hydroxide (TPTH) per se in or on sugar beets (40 CFR §180.236).

Use directions and limitations:

The 1.875 and 4 lb/gal FlC, and the 19.7% WP formulations are registered for three foliar applications per season to sugar beets at 0.119-0.263 lb ai/A/application, in spray volumes of $\geq$15 gal/A using ground equipment or 5-10 gal/A using aerial equipment; the 0.5 lb/gal SC/S (MAI) and the 47.5% WP formulations are registered for foliar application to sugar beets at 0.119-0.30 lb ai/A/application, with no maximum seasonal rate registered, in $\geq$10 gal/A using ground equipment or 3-10 gal/A using aerial equipment. Surfactants, spreaders or stickers are not to be added. A PHI of 21 days is in effect. The 47.5% WP and the 0.5 lb/gal MAI can be applied by chemigation. All labels specify a grazing/feeding restriction. Four applications of the 4 lb/gal FLC (EPA Reg. No. 1812-244) is permitted in Texas (EPA SLN No. TX8900009). [Note: The Agency concluded that residues resulting from the Texas special local need use of the 4 lb/gal FlC would not exceed the established tolerance.] These use directions were obtained from the product labels from the following Griffin Corporation formulations: the 1.875 lb/gal (EPA Reg. No. 1812-277) and 4 lb/gal FlC (EPA Reg. No. 1812-244), the 19.7 and 47.5% WP (EPA Reg. Nos. 1812-275 and 1812-276) and the 0.5 lb/gal SC (EPA Reg. No. 1812-269).

Conclusions:

The 1984 TPTH Guidance Document required residue data for TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on sugar beets and of tetraphenyltin as well in processed sugar beet commodities.

In response, the registrants (1985/85; MRIDs 00160468, 40149302, and 40149401) submitted residue data along with analytical methods for sugar beets that were reviewed by S. Hummel (CBRS No. 1096, 9/4/86) and F.B. Suhre (CBRS No. 2213, 9/1/87 and CBRS No. 2264, 9/2/87). A total of four field trials were conducted in MN(2) and ND(2) reflecting four or five applications of the 4 lb/gal FlC at 0.29 and 0.58 lb ai/A, and posttreatment intervals of 14-18 days. Method TA-47, which has been adequately validated for data collection, was used for residue determination. The data indicated that total TPTH residues (TPTH, plus its di- and monophenyltin metabolites expressed as TPTH equivalents) in or on sugar beet roots would not exceed the established tolerance following application at the maximum rate using ground equipment, provided an 18-day PHI was imposed. The Agency reviews concluded that for adequate geographic representation, data from CA, MN/ND, ID, WA, NE, WY, and MI were required.

Atochem N.A., on behalf of the TPTH registrants, subsequently submitted data pertaining to the residues of TPTH in or on sugar beets (1990; MRID 41556601). The data from seven tests conducted in CO, MI, MN, ND, and NE(1 each) and ID(2) indicated that total organotin residues were 0.013-0.016 ppm in or on five root samples harvested 21 days following the last of three foliar applications totalling 0.75 lb ai/A (ca. 1x the seasonal application rate) using ground and aerial equipment. The samples were determined to contain TPTH, DPTH, and MPTH each at <0.01 ppm. However, insufficient recovery data were provided. Furthermore, no test was done in CA as requested by the Agency. The following are required:

- Data depicting residues of TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on sugar beets harvested 21 days following the last of three foliar applications with a representative WP or FlC formulation at 0.25 lb ai/A/application. Samples must be analyzed using an acceptable, validated analytical method. Tests must be conducted in CA as previously requested by the Agency.

- The registrant must amend all pertinent product labels to specify a PHI and a maximum seasonal application equivalent to that reflected in the data used to support the tolerance. The available data indicate that a PHI of 21 days and a maximum seasonal application rate of 0.75 lb ai/A would be appropriate.

- A mean recovery value of 85.5% was reported for fortified samples analyzed concurrently with treated samples reported in MRID 41556601. The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed.

The Guidance Document also required data on sugar beet processed commodities. In the case of TPTH, the Agency determined that fortified samples could be used for processing (R. Loranger, CBRS No. 799, 6/21/85).

In response to the Guidance Document requirement for sugar beet processing data, Atochem, N.A., on behalf of the TPTH registrants submitted data (1990; MRID 41785201) from a single study pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH, and TTPTH) in or on commodities processed from field treated sugar beets. ΣOT residues did not concentrate in any commodity. Whether or not concentration of any of the phenyltins concentrated could not be conclusively determined from the data provided. The possibility of concentration in dehydrated pulp could not be ruled out.

Atochem, N.A., also submitted data (1990; MRID 41785203) from a single study pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH, TTPTH) in or on processed commodities from fortified sugar beets. Residues of ΣOT did not concentrate during processing. However, average total phenyltin residues concentrated 22x in dehydrated pulp and approximately 3x in molasses. Differences between the ΣOT and total phenyltins residues found in or on the treated RAC, and the apparent concentration seen in one analysis

but not the other were not adequately explained. The data on phenyltins indicate that residues concentrate in dehydrated pulp and molasses. The data are insufficient to conclusively determine whether or not residues concentrate during processing of sugar beets. However, only about 10% of the residue expected to occur on fortified sugar beets was detected as phenyltins. Given the numerous deficiencies already cited for the reporting and validation of the GFAA/GLC methodology, judgement as to the adequacy of these processing studies is reserved until the additional data requested for these methods has been reviewed.

The following additional data are required:

- Additional data are needed from the studies submitted in MRIDs 41785201 and 41785203. Chromatograms and/or raw data are needed to estimate total phenyltin residues and determine whether or not residues concentrate. Recovery data, including fortification levels in ppm should be provided also.

The Agency has concluded that all established tolerances for residues of TPTH must be revised to include TPTH, DPTH, and MPTH and that the revised tolerances should be expressed in terms of TPTH equivalents. However, appropriate levels for revised tolerances and food/feed additive tolerances cannot be determined at this time. Deficiencies in the analytical methodology used to generate these residue data need to be resolved before the adequacy of these data can be determined. Furthermore, additional storage stability data are required. Following receipt of the data requested on analytical methodology and storage stability, either additional studies will be required or appropriate levels for revised tolerances determined based on the available data. The registrant should note that all residue data used to support revised tolerances must be expressed in terms of TPTH equivalents.

References (used):

MRIDs: 00160468. 40149302. 40149401. 41556601. 41785201. 41785203.

Discussion of the data:

Sugar beet roots. Atochem N.A., on behalf of the TPTH registrants, submitted data (1990; MRID 41556601) from seven tests conducted in CO, MI, MN, ND, and NE (1 each), and ID (2), pertaining to the residues of TPTH in or on the roots of 21 treated sugar beet samples harvested 21 days after the last of three foliar applications of 4 lb/gal FlC formulations at 0.25 lb ai/A/application (1x the maximum seasonal rate) using ground (five tests, 20-26 gpa) and aerial (two tests, 5 and 8 gpa) equipment. Samples were trimmed to remove tops and brushed with a dry brush to remove excess dirt, then frozen within one hour of collection. Samples were shipped on dry ice to the analyzing laboratory within 24 hours of harvest, and were stored frozen at approximately -20 °C for 23-61 days prior to analysis.

The submission contained two tables of summary residue data on ΣOT in which all reported values, with the exception of one sample, were identical. The sample in question was

reported in one table to contain nondetectable (<0.0117 ppm) residues whereas in the other table it was assigned 0.017 ppm. All samples were initially screened for ΣOT using graphite furnace AA. Samples containing levels of ΣOT exceeding 0.01 ppm were further analyzed for individual phenlytin species (MPTH, DPTH, and TPTH) using GLC/FPD. Of 21 TPTH-treated sugar beet samples analyzed for ΣOT (excluding the sample in question), four samples bore residues of 0.013-0.016 ppm and were further analyzed by GLC/FPD. Residues of total organotin were nondetectable in or on seven untreated controls. Of the samples analyzed by GC/FPD (including the sample in question), no residues of individual species were detected at levels above the validated method limits of detection (0.01 ppm for each phenlytin species). A mean recovery of 85.5% was reported for fortified samples analyzed concurrently with treated samples; these concurrent validation data are not acceptable. Note: The acceptability of this method for data collection cannot be determined until the deficiencies listed in the Residue Analytical Methods section of this Update have been resolved.

In summary, these data do not satisfy the requirements for reregistration. The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed. Also, geographic representation is not adequate. No test was conducted in CA as previously requested by the Agency. Additional data are needed from CA.

Processed commodities:

Atochem, N.A., on behalf of the TPTH registrants, submitted data (1990; MRID 41785201) pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH, and TTPTH) in or on processed sugar beet commodities (dehydrated pulp, molasses, and refined sugar) harvested 21 days after the last of 3 applications of the 4 lb/gal FlC formulation at 1.25 lb ai/A in 25-26.3 gal/A (a total of 3.75 lb ai/A, or 5x the maximum registered rate). One treated RAC sample and one untreated RAC control were shipped at ambient temperatures by overnight express to the processing laboratory within 24 hours of harvest. The samples were then stored at approximately -5 °C for 31-35 days until being processed using procedures that simulated normal commercial practices. Following processing, samples were stored frozen at approximately -20 °C, shipped on dry ice to the analytical laboratory, and again stored at approximately -20 °C until extraction; the total intervals between processing and extraction for analysis were 61 days for molasses and refined sugar samples, and 65 days for dehydrated pulp and RAC samples. All of the RAC samples were pre-processed, i.e., washed, destoned, and had the green rot and culls removed, prior to commercial processing by Spreckels Sugar Co. and analysis.

Treated and untreated control samples were analyzed for ΣOT as a screening procedure using graphite furnace AA; the results are presented in Table 10. Of the treated samples, only molasses contained residues of ΣOT below 0.01 ppm Sn. The remaining samples were analyzed by GLC/FPD for individual phenyltin species. The sum of the phenyltin residues

in the treated sugar beets, molasses, and refined sugar could not be determined because (i) detectable residues below the stated method detection limit (MDL) could not be quantified with the data provided and (ii) the validity of the stated limit of detection has not been adequately demonstrated. Based on the presented data, residues did not appear to concentrate in any processed commodity.

Concurrent sugar beet matrix spike recoveries of phenyltin were reported as 88% and 121%. The registrant also reports a mean recovery of 85.5% for fortified samples analyzed concurrently with treated samples. We note that this same recovery value was reported in the sugar beet study (nonprocessed). The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed. These data are required for all processed commodities.

Table 10. Total organotin (ΣOT) and phenyltins (ppm) in treated and control sugar beet processed commodities.

	Residues (ppm)					
	Controls	Treated Samples	Treated Samples			
Commodity	ΣOT	ΣOT	MPTH	DPTH	TPTH	TTPTH
RAC	<0.0088[d]	0.031	<0.0136[a]	0.027	BDL[b]	<0.0021[c]
Dehy. Pulp	<0.0045[e]	0.032	0.013	<0.0021	0.009	<0.0021
Molasses	<0.0088	<0.0088	--	--	--	--
Refined Sugar	0.041	0.012	<0.0136	<0.0021	<0.0021	<0.0021

[a] GLC/FPD method limit of detection. [b] Undefined by registrant. [c] GLC/FPD instrument detection limit. [d] GFAA method detection limit. [e] GFAA instrument detection limit.

Atochem, N.A., on behalf of the TPTH registrants, also submitted data (1991; MRID 41785203) from a single study pertaining to the combined residues of TPTH (TPTH, MPTH, DPTH, and TTPTH) in or on commodities processed from fortified sugar beets. Whole sugar beets were dipped into a suspension of the 4 lb/gal FlC formulation that was calculated to leave TPTH residues of 1 ppm in or on the RAC, and were then allowed to air dry. Samples were prepared of dehydrated pulp, molasses, and refined sugar, using processing procedures that simulated normal commercial practices. Five treated, and two untreated, RAC samples were stored for 9 days at approximately -20 °C between treatment and extraction for analysis. Conflicting data were reported for two additional samples, one treated and one untreated; the introductory summary table reports storage times of 9 days, while another table prepared by the analytical laboratory reports storage intervals of 125 days for the two samples. Because the patterns of residues found in those samples differed from the patterns found in the other treated and untreated RAC samples, those results are presented separately in the discussion of residues below. Processed products were prepared from the RAC stored at approximately 4 °C for 2 days. Dehydrated pulp samples were

stored at -20 °C for 7 days before extraction, and molasses and refined sugar samples were stored at -20 °C for 12 days before extraction.

All samples were analyzed for ΣOT and the samples that contained ΣOT greater than 0.01 ppm were subjected to analysis by GLC for individual phenyltin species (Table 11). Residues of ΣOT did not concentrate during processing. However, average total phenyltin residues concentrated 22x in dehydrated pulp and approximately 3x in molasses. [The total phenyltin residues in were calculated for this review using 0.002 ppm, the stated instrument limit of detection, for residues reported as nondetectable.] The differences between the ΣOT and total phenyltins residues found in or on the treated RAC, and the apparent concentration seen in one analysis but not the other were not adequately explained. The registrant suggested that the low residues from GLC phenyltin analysis were due to problems with the method, which had been validated only up to 0.1 ppm, and actual residues in the RAC samples being analyzed were up to over 50x this level. The registrant thus chose to disregard the data from phenyltin analysis. It should be noted that residues were clearly higher in the pulp and molasses samples and we contend that problems with method recovery would occur with the processed commodities as well as with the RAC. The registrant needs to provide data to support their claim of residue reduction and to justify disregarding the data on phenyltins.

Table 11. Total organotin (ΣOT) and phenyltins (expressed as ppm Sn equivalents) in sugar beets and processed commodities.

		---------ΣOT (ppm)---------		----------ppm Sn equivalents----------				
Commodity	No. of samples	Untreated	Treated	MPTH	DPTH	TPTH	TTPTH	ΣPT
RAC	2/5[a]	0.004-0.028	3.573-7.928	ND[b]	ND-0.036	ND-0.401	ND-0.087	0.008-0.526
dehydrated pulp	3	0.013-0.025	4.411-5.635	0.007-0.573	0.172-2.270	1.358-2.462	0.205-0.808	2.381-5.009
molasses	3	0.029-0.040	0.656-0.813	0.113-0.402	0.065-0.434	ND-0.017	ND	0.184-0691
refined sugar	3	0.017-0.028	0.047-0.061	ND-0.027	ND	ND	ND	--

[a] Two control and five treated samples. [b] ND = <0.002 ppm, the registrant's stated instrument limit of detection.

Not shown in Table 11 were the two samples mentioned above for which conflicting storage intervals were reported. The treated RAC sample bore ΣOT residues of 3.127 ppm, and 0.286 ppm of MPTH, 0.624 ppm of DPTH, 0.756 ppm of TPTH, and 0.030 ppm of TTPTH. The untreated RAC sample bore ΣOT residues of 0.618 ppm, and MPTH, DPTH, TPTH, and TTPTH residues of 0.024, 0.270, 0.148, and 0.004 ppm, respectively. It was reported within the introductory summary that this control was believed to have been contaminated during shipment. We note that although the ΣOT residues in this treated

sample were lower than those in the other five treated samples, the phenyltin residues were higher in this anomalous sample.

Recoveries from fortified samples with a mixture of the phenyltins at 1 ppm and analyzed concurrently with the residue samples for ΣOT were 87% from sugar beets, 50% from dehydrated pulp, 93% from molasses, and 107% from refined sugar. No recovery data for phenyltin analysis by GLC was reported. Apparent ΣOT residues are shown in Table 5. No explanation was provided for the high apparent residues in these control samples, all but one of which were higher than the stated method detection limit of 0.011 ppm for the sugar beet matrix. Apparent phenyltin residues in or on control samples were reported as below the instrument limit of detection (0.002 ppm) for each species in all samples except one sample of molasses containing 0.005 ppm of MPTH.

The data are insufficient to conclusively determine whether or not residues concentrate during processing of sugar beets. The data on phenyltins indicate that residues concentrate in dehydrated pulp and molasses. However, only about 10% of the residue expected to occur on fortified sugar beets was detected as phenyltins. Given the numerous deficiencies already cited for the reporting and validation of the GFAA/GLC methodology, judgement as to the adequacy of these processing studies is reserved until the additional data requested for these methods has been reviewed.

Leaves of Root and Tuber Vegetables Group

Sugar beet tops

No tolerance currently exists for residues of TPTH in or on sugar beet tops.

Use directions and limitations:

Refer to the section "Sugar beets".

Conclusions:

The 1984 TPTH Guidance Document addressed the need for additional data and a tolerance proposal for residues TPTH residues of concern in or on sugar beet tops, or a label restriction against the use of sugar beet tops as a livestock feed. The Agency has since determined and informed the registrant (F.B. Suhre, CBRS Memorandum of Meeting dated 9/25/87) that a feeding restriction for sugar beet tops is impractical. Data are required depicting TPTH residues of concern in or on sugar beet tops treated in a manner consistent with the registrant's intentions regarding amending the label. The registrants must then propose a suitable tolerance.

- o The Agency has determined that a feeding restriction for sugar beets is impractical. The registrants must submit data depicting TPTH residues of concern in or on sugar beet tops and propose a suitable tolerance. Tests must reflect the maximum application rate and number of applications permitted on the labels. Tests must be conducted in CA(18%), ID(16%), MI(10%), MN(22%) or ND(11%) states which collectively accounted for approximately 80% of U.S. sugar beet production in 1989 (Agricultural Statistics, 1990, p. 74). All pertinent product labels must be amended to delete grazing/feeding restrictions for sugar beet tops.

References (used):

N/A.

Discussion of the data:

N/A.

Tree Nuts Group

Pecans

Tolerance:

A tolerance of 0.05 ppm has been established for the residues of TPTH per se in or on pecans (40 CFR §180.236).

Use directions and limitations:

The 1.875 lb/gal FlC, both 4 lb/gal FlC, and the 19.7% WP formulations are registered for ten applications per season to pecans at 0.25-0.39 lb ai/A/application. Treatments using ground equipment require sufficient water to provide for full coverage and at least 20 gal/A using aerial equipment; the 47.5% WP formulation is registered for application to pecans at 0.36-0.72 lb ai/A/application, with no maximum seasonal rate registered, in 10-100 gal/A using ground equipment or 3-20 gal/A using aerial equipment. Diluted spray is to be directed to all parts of the tree and is not to be applied after shucks have started to open. Surfactants, spreaders or stickers are not to be added. The 47.5% WP can be applied by chemigation and specifies a grazing/feeding restriction. These use directions were obtained from the product labels from the following Griffin Corporation formulations: the 1.875 lb/gal FlC (EPA Reg. No. 1812-277) and both 4 lb/gal FLC (EPA Reg. No. 1812-244), the 19.7 and 47.5% WP (EPA Reg. Nos. 1812-275 and 1812-276, respectively).

Conclusions:

The 1984 TPTH Guidance Document required residue data for TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on pecans.

In response to these data requirements, the registrants submitted residue data for pecans (1986; MRIDs 00165025 and 40149303) that were reviewed by F.B. Suhre (CBRS No. 1702, 5/1/87 and CBRS No. 2264, 9/2/87).

It was concluded that residues of TPTH and its di- and monophenyltin metabolites were each nondetectable (0.05 ppm) in or on pecans harvested 50-78 days following seven ground applications of the 4 lb/gal FlC formulation at 0.28-3.8 lb ai/A. The submitted data indicated that the combined residues of TPTH and its metabolites might exceed the tolerance of 0.05 ppm. The Agency concluded that the established tolerance for residues of TPTH in or on pecans should be changed to reflect a total TPTH residue (expressed as TPTH) of 0.2 ppm. The GLC/GFAA Method TA-49 was used for residue analysis. Subsequently, the registrants submitted one volume of residue data on pecans (1988; 41267101) reviewed by R. Perfetti (CBRS No. 5985, 1/10/90). Four field trials on pecans conducted in GA reflecting 11 applications of the 4 lb/gal FlC formulation a rate of 0.375 lb ai/A/application were provided. Total tin residues were <0.005 (nondetectable)-0.005 ppm in or on seven samples of nutmeat; one additional sample collected 48 days following the last of the aerial applications bore total tin residues of 0.008 ppm. The acceptable HPLC/GFAA Method TA-52 was used for residue analysis. The data indicated that total TPTH residues (TPTH, plus its di- and monophenyltin metabolites expressed as TPTH equivalents) in or on pecans would not exceed 0.05 ppm as a result of ground and aerial applications. It was concluded that the tolerance definition for pecans may be modified to include the TPTH metabolites di- and monphenyltin without requiring an increase in the tolerance level.

References (used):

MRID(s): 00165025. 40149303. 41267101.

Discussion of the data:

N/A.

Peanuts

Tolerance(s):

Tolerances of 0.05 and 0.4 ppm have been established for the residues of TPTH per se in or on peanuts and peanut hulls, respectively (40 CFR §180.236).

Use directions and limitations:

The 47.5% WP formulation is registered for application to peanuts at 0.15-0.24 lb ai/A/application, with no maximum seasonal rate registered, with an interval of 10-14 days, in 10-100 gal/A using ground equipment or 3-20 gal/A using aerial equipment and a PHI of 14 days. Surfactants, spreaders or stickers are not to be added. The formulation can be applied by chemigation and specifies a grazing/feeding restriction for hogs, dairy and meat animals. These use directions were obtained from the product labels from the following Griffin Corporation formulation: the 47.5% WP (EPA Reg. No. 1812-276).

Conclusions:

The 1984 TPTH Guidance Document required residue data for TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on peanuts and processed commodities of peanuts.

In response to these data requirements, the registrants submitted protocols which were reviewed by R. Loranger (CBRS No. 799, 6/21/85). Loranger stated that peanut hulls must be analyzed since they are not subject to feeding restrictions. Residue data along with analytical methods (1986; MRID 00165010) for peanuts were submitted and were reviewed by F.B. Suhre (CBRS No. 1702, 5/1/87). Five field trials on peanuts conducted in GA(2), AL(1), VA(1), and an unspecified location (1) reflecting two applications at 0.24 and 0.6 lb ai/A of a 4 lb/gal FlC with PHIs of 14 to 22 days were provided. The data indicated that residues above the tolerance (0.05 ppm) could occur. Additional information was required.

Residue data along with analytical methods (1986; MRIDs 00160467, 40149401, and 40149301) for peanut hulls were submitted and reviewed by S. Hummel (CBRS No. 1096, 9/4/86) and F.B. Suhre (CBRS No. 2213, 9/1/87 and CBRS No. 2264, 9/2/87). The data from the peanut field trials indicated a total TPTH residue of 0.2 ppm in or on peanut meat and hulls as a result of eight ground applications of a 4 lb/gal FlC at 0.24 lb ai/A and a PHI of 14-22 days. It was concluded that the established tolerance for TPTH residues in or on peanut hulls (0.4 ppm) would not be exceeded, but that the established tolerance in or on peanut meat (0.05 ppm) could be exceeded as a result of the proposed use. The Agency concluded that the residue data were not geographically representative of the peanut growing regions of the U.S. and that additional data were required from TX. Based on the submitted residue data, a PHI of 22 days was recommended by the Agency. Additionally, it was recommended that the established tolerance for residues of TPTH in or on peanuts at 0.05 ppm should be changed to reflect a total TPTH residue (expressed as TPTH) of 0.2 ppm. This conclusion was based on the analytical method's (TA-48) 0.05 ppm limit of detection for each of the three TPTH residues of concern and will be reevaluated after review of the balance of the required residue data.

- o Peanut field trials from TX are required. In addition, peanut hulls must be analyzed since they are not under the control of the grower. The label must state a maximum

number of applications of TPTH per season. Alternatively, residue data reflecting the maximum theoretical number of applications may be submitted.

- o No data from a processing study with peanuts have been submitted. Data are required depicting the potential for residue concentration in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

References (used):

MRID(s): 00160467. 00165010. 40149401. 40149301.

Discussion of the data:

N/A.

MAGNITUDE OF THE RESIDUE IN MEAT, MILK, POULTRY, AND EGGS

Tolerance:

Tolerances of 0.05 ppm have been established for the residues of TPTH per se in the kidney and liver of cattle, goats, hogs, horses, and sheep (40 CFR §180.236).

Conclusions:

The 1984 TPTH Guidance Document reserved judgement on the residue in meat, milk, poultry, and eggs until all requested data regarding storage stability, magnitude of the residue and analytical methods have been received. Additional data are still needed on all of these topics. Following receipt of these requested data, the need for animal feeding studies and adequacy of existing tolerance levels will be assessed.

References (used):

N/A.

Discussion of the data:

N/A.

TOLERANCE REASSESSMENT SUMMARY

The Agency has concluded that all established tolerances for residues of TPTH must be revised to include TPTH, DPTH, and MPTH and that the revised tolerances should be expressed in terms of TPTH equivalents. However, appropriate levels for revised tolerances and food/feed additive tolerances cannot be determined at this time. Deficiencies in the analytical methodology used to generate available residue data need to be resolved before the adequacy of these data can be determined. Furthermore, additional storage stability data are required. Following receipt of the data requested on analytical methodology and storage stability, either additional studies will be required or appropriate levels for revised tolerances determined based on the available data.

A tolerance must be proposed and the appropriate supporting residue data must be submitted for sugar beet tops.

CODEX HARMONIZATION

U.S. tolerances have been established for residues of TPTH per se in or on a variety of raw agricultural commodities (40 CFR §180.236). Codex MRLs (CXL, JMPR 86) have been established for residues of TPTH (fentin), excluding inorganic tin and di- and mono-phenyltin inclusive of all commodities for which U.S. tolerances exist. These are tabulated below.

Commodity	Current U.S. Tolerance (ppm)	Codex MRL (mg/kg)
Carrot	0.1	0.2
Peanut	0.05	0.05
Pecan	0.05	0.05
Potato	0.05	0.1
Sugar beet	0.1	0.2

Presently, CFR and Codex definitions of the residue are equivalent. However, the 1985 TPTH Guidance Document recommended that the CFR definition be revised to include the intermediary degradation products diphenyltin and monophenyltin hydroxides and oxides. The potential for harmonization between U.S. tolerances and Codex MRLs cannot assessed until the needed residue analytical method and crop field trial data are received and evaluated.

MASTER RECORD IDENTIFICATION NUMBERS

MRID documents containing data that have been previously reviewed by the Agency are designated in **bold print** in the following bibliographic listing of Residue Chemistry Citations (used). A summary of the subject memoranda and their associated MRID documents is presented below.

AGENCY MEMORANDA

CBRS No.	799
Subject:	ID #18120. Protocols for TPTH residue field trials and storage stability studies.
From:	R. Loranger
To:	H. Jacoby
Dated:	June 21, 1985
MRIDs:	none

CBRS No.	813
Subject:	Triphenyl Tin Hydroxide, Response to Registration Standard: M&T Residue Analytical Method EPA Reg. No. 8340-17, EPA File Symbol 5204-AO. [Accession No. 260289].
From:	S.V. Hummel
To:	H. Jacoby
Dated:	July 9, 1986
MRIDs:	none

CBRS No.	1040
Subject:	EPA Reg. No. 47916-37. Protocols for TPTH residue field trials and storage stability studies.
From:	R. Loranger
To:	H. Jacoby
Dated:	June 21, 1985
MRIDs:	none

CBRS No.	1096
Subject:	056227 - Triphenyl Tin Hydroxide, Response to Registration Standard: M&T Residue Analytical Method + Residue Data EPA File Symbol 5204-0. [Accession Nos. 263218, 263219, 263220, 263221, 263222].
From:	S.V. Hummel
To:	H. Jacoby
Dated:	September 4, 1986
MRIDs:	00160465. 00160466. 00160467. 00160468. 00160469.

CBRS No. 127
Subject: Triphenyl Tin Hydroxide, Response to Registration Standard: M&T Residue Analytical Method EPA File Symbol 5204-AO. [Accession No. 261251].
From: S.V. Hummel
To: J. Lee
Dated: February 26, 1986
MRIDs: 00156382.

CBRS No. 1702
Subject: Triphenyl Tin Hydroxide; Response to Registration Standard; M&T Residue Analytical Method (TA-49); Residue data for Pecans and Peanuts
From: F.B. Suhre
To: L. Rossi
Dated: May 1, 1987
MRIDs: 00165010. 00165025.

CBRS No. 2213
Subject: Triphenyl Tin Hydroxide (TPTH): Amendment to 056227; Submitted in response to RCB memo of September 4, 1986 (S. Hummel).
From: F.B. Suhre
To: L. Rossi
Dated: September 1, 1987
MRIDs: 40149401. 40149402.

CBRS No. 2264
Subject: Triphenyl Tin Hydroxide (TPTH): Response to Registration Standard; Review of Field Studies for Peanuts, Sugar beets, Pecans, Potatoes and Carrots.
From: F.B. Suhre
To: L. Rossi
Dated: September 2, 1987
MRIDs: 40149301. 40149302. 40149303. 40149304. 40149305.

CBRS No. 3036
Subject: Triphenyl Tim Hydroxide (TPTH): Clarification of previously cited deficiencies; RD Record No. 208184.
From: F.B. Suhre
To: L. Rossi
Dated: January 15, 1988
MRIDs: none

CBRS No. 5985
Subject: M&T Chemicals Inc. Response to the TPTH Reregistration Standard: Residue Chemistry Data.
From: R.B. Perfetti
To: R. Engler
Dated: January 10, 1990
MRIDs: 41267101.

CBRS No. none
Subject: TPTH: Meeting with Registrants.
From: F.B. Suhre
To: RCB Files
Dated: August 30, 1988
MRIDs: none

CBRS No. none
Subject: TPTH: Meeting with Registrants.
From: F.B. Suhre
To: RCB Files
Dated: September 25, 1987
MRIDs: none

CBRS No. none
Subject: TPTH: Meeting with Registrants.
From: F.B. Suhre
To: RCB Files
Dated: September 25, 1987
MRIDs: none

CBRS No. none
Subject: Comments on "Triphenyltin Hydroxide Special Review of Certain Pesticide Products". (PD-1)
From: M.L. Loftus
To: B. Shackleford
Dated: November 8, 1984
MRIDs: none

Residue Chemistry Citations (used)

00156382 **M&T Chemicals, Inc. (1985) Separation and Determination of Phenyltin species (OaSnX2-a) in Residues by Liquid Chromatography/Atomic Absorption spectroscopy: Method No. TA-43. Unpublished study 29 p.**

00160465 Marino, A. (1986) Validation of a Method for the Separation and Determination of Phenyltin Species ([Theta]aSnX4-a) in Carrots by Liquid Chromatography/Atomic Absorption Spectroscopy plus Crop Residue Analyses. Unpublished study prepared by Triphenyltin Hydroxide Task Force. 130 p.

00160466 Marino, A. (1986) Validation of a Method for the Separation and Determination of Phenyltin Species ([Theta]aSnX4-a) in Potatoes by Liquid Chromatography/Atomic Absorption Spectroscopy plus Crop Residue Analysis. Unpublished study prepared by Triphenyltin Hydroxide Task Force. 156 p.

00160467 Marino, A. (1986) Validation of a Method for the separation and determination of Phenyltin Species ([Theta]aSnX4-a) in Peanut Hulls by Liquid Chromatography/Atomic Absorption Spectroscopy plus Crop Residue Analysis. Unpublished study prepared by Triphenyltin Hydroxide Task Force. 134 p.

00160468 Marino, A. (1986) Validation of a Method for the separation and determination of Phenyltin Species ([Theta]aSnX4-a) in Sugar beets by Liquid Chromatography/Atomic Absorption Spectroscopy plus Crop Residue Analysis. Unpublished study prepared by Triphenyltin Hydroxide Task Force. 137 p.

00160469 Marino, A. (1986) Validation of a Method for the Separation and Determination of Phenyltin Species ([Theta]aSnX4-a) in Soybeans by Liquid Chromatography/Atomic Absorption Spectroscopy plus Crop Residue Analyses. Unpublished study prepared by Triphenyltin Hydroxide Task Force.

00165010 Marino, A. (1986) Validation of a Method for the Separation and Determination of Phenyltin Species (OaSnX4-a) in Peanuts by Liquid Chromatography/Atomic Absorption Spectroscopy plus Crop Residue Analyses. Unpublished study prepared by M&T Chemicals Inc. 140 p.

00165025 Marino, A. (1986) Validation of a Method for the Separation and Determination of Phenyltin Species (OaSnX4-a) in Pecans by Liquid Chromatography/Atomic Absorption Spectroscopy plus Crop Residue Analysis. Unpublished study prepared by M&T Chemicals Inc. 146 p.

40149301 Frazee, G. (1985) Triphenyltin Hydroxide: Protocols and Field History for Residue Field Trials on Peanuts. Unpublished compilation prepared by Griffin Corp. 13 p.

40149302 Frazee, G. (1985) Triphenyltin Hydroxide: Protocols and Field History for Residue Field Trials on Sugar beets. Unpublished compilation prepared by Griffin Corp. 13 p.

40149303 Frazee, G. (1986) Triphenyltin Hydroxide: Protocols and Field History for Residue Field Trials on Pecans. Unpublished compilation prepared by Griffin Corp. 13 p.

40149304 Frazee, G. (1985) Triphenyltin Hydroxide: Protocols and Field History for Residue Field Trials on Potatoes. Unpublished compilation prepared by Griffin Corp. 13 p.

40149305 Frazee, G. (1986) Triphenyltin Hydroxide: Protocols and Field History for Residue Field Trials on Carrots. Unpublished compilation prepared by Griffin Corp. 11 p.

40149401 Sheldon, A. (1986) Triphenyltin Hydroxide--Responses to Questions in the EPA Letter dated September 24, 1986 (Jacoby to Sheldon). Unpublished study prepared by M&T Chemicals Inc. 15 p.

40149402 Simmons, I. (1986) (Triphenyltin Hydroxide)--Separation and Determination of Phenyltin Species...in Beef, Milk, Eggs and Poultry by Liquid Chromatography/Atomic Absorption Spectroscopy: Lab Project ID: TA-50. Unpublished study prepared by M&T Chemicals Inc. 25 p.

41267101 Orius Associates Inc. (1989) Magnitude of the Residue in or on Pecans Treated by Ground and Aerial Equipment in Georgia. 160 p.

41556601 Sibuay, J; Guy, S. (1990) LV1169-01 (Triphenyltin Hydroxide): Raw Agricultural Commodity: Field Residue Study on Sugar beet in North Dakota, Minnesota, Idaho, Nebraska, Colorado and Michigan. Lab Project No. N-0535-01: N-0535-0102: 1714-89-01-08B-01. Unpublished study by Battelle Laboratories, Inc. 585 p.

41556602 Sibuay, J; Guy, S. (1990) LV1169-01 (Triphenyltin Hydroxide): Raw Agricultural Commodity: Field Residue Study on Potato in Maine, North Dakota, Washington, Idaho and Minnesota. Lab Project No.: N-0535-01: N-0535-02: 1714-89-169-01-08D-0. Unpublished study by Batelle Laboratories, Inc. 605 p.

41785201 Silvoy, J. (1990) LX1169-01 (TPTH): Processed Commodity Field Residue Study on Sugar beets in Idaho: Final Report: Lab Project No: N-0535-0101: N-0535-0103: 1714-89-169-01-08B-05. Unpublished study prepared by Battelle. 234 p.

41785202 Silvoy, J. (1990) LX1169-01 (TPTH): Processed Commodity Field Residue Study on Potatoes in Washington: Final Report: Lab Project No: N-0535-0101: N-0535-0103: 1714-89-169-01-08D-14. Unpublished study prepared by Battelle. 332 p.

41785203 Silvoy, J. (1991) LX127-01 (Super-Tin 4L): Reduction of TPTH in or on Sugar beet Processed Commodities Treated with 100X the Current Minimum Detection Limit: Final Report: Lab Project No: SD900051: 90-27-01-08B-02. Unpublished study prepared by Battelle. 228 p.

41785204 Silvoy, J. (1991) LX127-01 (Super-Tin 4L): Reduction of TPTH in or on Potato Processed Commodities Treated with 100X the Current Minimum Detection Limit: Final Report: Lab Project No: SD900050: 90-27-01-08B-01. Unpublished study prepared by Battelle. 302 p.

TABLE A. GENERIC DATA REQUIREMENTS FOR TPTH RESIDUE CHEMISTRY.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
40 CFR §158.240 Residue Chemistry				
171-2. Chemical Identity[4]				
171-3. Directions for Use	EP	Partially	N/A	Yes[5]
171-4. Nature of the Residue (Metabolism)				
Plants	PAIRA	Yes	N/A	No
Livestock	PAIRA & Plant Metabolites	Yes	N/A	No
171-4. Residue Analytical Methods[6]				
Plants	TGAI & Metabolites	Partially	00128877 00142876 00153228 00156382 00160465 00160466 00160467 00160468 00160469 00165010 00165025 40149301 41556601 41556602 41785201 41785202 41785203 41785204	Yes[7,8,9]
Livestock	TGAI & Metabolites	Partially	00128877 00142876	Yes[9,10]

(Continued, Footnotes Follow)

TABLE A. (Continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
171-4. Storage Stability	PAI	Partially	41556601 41556602 41785201 41785202 41785203	Yes[11,12,13]
171-4. Magnitude of the Residue in Crop Field Trials[14]				
Root and Tuber Vegetables Group				
- Carrots	TEP	Partially	00160465 40149305 40149401	Yes[15]
- Potatoes	TEP	Partially	00160466 40149304 40149401 41556602	Yes[16]
(Processed Commodities)	TEP	Partially	41785202 41785204	Yes[17]
- Sugar Beets	TEP	Partially	00160468 40149302 40149401 41556601	Yes[18]
(Processed Commodities)	TEP	Partially	41785201 41785203	Yes[19]
Leaves of Root and Tuber Vegetables				
- Sugar beet tops	TEP	No	N/A	Yes[20]
Tree Nuts Group				
- Pecans	TEP	~~Partially~~ YES	00165025 40149303 41267101	~~Yes~~ NO[21]
- Peanuts	TEP	Partially	00160467 00165010 40149301 40149401	Yes[22]

(Continued, Footnotes Follow)

TABLE A. (Continued)

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?
(Processed Commodities)	TEP	No	N/A	Yes[23]
171-4. Magnitude of the Residue in Milk/Meat/Poultry/Eggs[24]	TGAI or Plant Metabolites	Partially	N/A	Reserved[25]

[1]Various registrants have submitted data in response to the 1984 Guidance Document; all topics have been responded to except peanut processed commodities. The data gaps included in this update address specific deficiencies in the submitted data.

[2]Test substance: TGAI = technical grade of the active ingredient; PAI = pure active ingredient; PAIRA = pure active ingredient, radiolabeled; TEP = typical end-use product; EP = end-use product.

[3]These references were submitted in response to the TPTH Guidance Document dated September, 1984. Underlining indicates documents that have been reviewed for this update.

[4]The same chemical identity data are required under 40 CFR 158.150-190, with emphasis on impurities that could constitute residue problems. Refer to product chemistry data requirements tables.

[5]The use patterns for sugar beets, pecans, carrots, and potatoes discussed in the Residue Chemistry update are based on the following Griffin Corporation labels: 40% FlC (EPA Reg. Nos. 1812-336 and 1812-244), 19.7% FlC (EPA Reg. Nos. 1812-277), 19.7% WP (EPA Reg. No. 1812-275), 47.5% WP (EPA Reg. No. 1812-276) and the 4.72% SC/S (MAI) (EPA Reg. No. 1812-269). 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., any unamended basic producer labels, SLNs, and products covered under the generic data exemption) be amended such that they are consistent with the amended basic producer labels

(Continued, Footnotes Follow)

TABLE A. (Continued)

[6]The Agency has concluded that all established tolerances for residues of TPTH must be revised to include TPTH, DPTH, and MPTH and that the revised tolerances should be expressed in terms of TPTH equivalents. However, appropriate levels for revised tolerances and food/feed additive tolerances cannot be determined at this time. Deficiencies in the analytical methodology used to generate these residue data need to be resolved before the adequacy of these data can be determined. Furthermore, additional storage stability data are required. Following receipt of the data requested on analytical methodology and storage stability, either additional studies will be required or appropriate levels for revised tolerances determined based on the available data. The registrant should note that all residue data used to support revised tolerances must be expressed in terms of TPTH equivalents.

[7]The registrants responded by submitting GFAA/GLC methods and validation data. However, the registrant must provide additional data to allow judgement as to the adequacy of their GFAA/GLC methodology used to collect data on potatoes, sugar beets, and processed commodities. Raw data are needed from the analyses used to derive the theoretical method limits of detection reported for DPTH and MPTH, and the registrant must explain their rationale for determining the method limits of detection in this manner. The registrant must also provide data to demonstrate that each phenyltin species can be adequately recovered from each regulated commodity fortified at the stated limit of detection and tolerance level. The registrant must provide data to back up their claim that analysis of organotin compounds is independent of the counterions present, in order to support their use of triphenyltin chloride compounds as standards. The data from the registrant's determination of phenyltin degradation rates must be submitted, and data to quantify the rate of breakdown to inorganic tin should be included. The registrant must clarify the discrepancy concerning the stability of TTPTH during the extraction procedure. The contribution of inorganic tin to the total organotin analysis needs to be quantified in order to more accurately determine total phenyltin and to resolve the discrepancies between ΣOT from GFAA analysis and the sum of phenyltins from GLC analysis. We note that some of these data requirements may necessitate modifications to the method. If the registrant wishes to submit this GFAA/GLC methodology for enforcement use, in addition to the data specified above, the method must be modified so that the tripropyl tin internal standard is derivatized separately from the TPTH residues and is added to the sample just prior to injection into the GLC. Complete descriptions and appropriate validation data must be submitted for modified methods. All data must be reported as TPTH equivalents.

[8]Proposed tolerance enforcement methodology must undergo successful confirmatory trials conducted by an independent laboratory. Results of at least one set of samples per commodity (a total of six samples, including two control samples, two control samples fortified at the tolerance level, and two control samples fortified at 2-5 times the tolerance level) must be submitted. No more than three sets of samples per commodity may be tested to achieve successful recovery rates of 70-120% with negligible interference

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compared to the established tolerances. For additional details of data requirements, refer to PR Notice 88-5, Tolerance Enforcement Methods-Independent Laboratory Confirmation by Petitioner.

[9]Representative samples from plant and animal metabolism studies must be analyzed using proposed enforcement methodology 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 adequate recovery of the total toxic residue.

[10]The Guidance Document stated that the registrant must submit methodology for enforcement of tolerances for residues of TPTH, DPTH, and MPTH in meat, milk, poultry, and eggs. The method(s) should include a base hydrolysis step to release conjugated residues. Alternatively, the registrant must provide data indicating that base hydrolysis is unnecessary for adequate recovery of the total toxic residue. A complete description of the method(s) and appropriate validation data must be submitted.

[11]The registrants submitted data concerning storage stability of TPTH and its residues in sugar beets and potatoes, however, these data are not sufficient. Storage stability data are required in support of all required residue studies, reflecting the actual storage conditions and intervals for samples used to generate the residue data. All information relevant to fortification of samples must be provided. All samples must be fortified with TPTH and its di- and monophenyltin metabolites. If the registrant wishes to use the data from the studies submitted in MRIDs 4156601, 41556602, 41785201 and 41785202, to fulfill storage stability data requirements, an adequate explanation for the low zero day recoveries must be provided. Storage stability data must be collected using adequate analytical methodology. Data on the storage stability of TPTH, its di- and monophenyltin metabolites and of tetraphenlytin in sugar beet and potato processed commodities are required.

[12]The Agency has determined that a feeding restriction for sugar beets is impractical. Data on the storage stability of TPTH residues of concern in or on sugar beet tops are required.

[13]Data are still required depicting the storage stability of TPTH and its di- and monophenyltin metabolites in meat, milk, poultry, and eggs as required by the Guidance Document.

[14]The Agency has concluded that all established tolerances for residues of TPTH must be revised to include TPTH, DPTH, and MPTH and that the revised tolerances should be expressed in terms of TPTH equivalents. However, appropriate levels for revised tolerances and food/feed additive tolerances cannot be determined at this time. Deficiencies in the analytical methodology used to generate these residue data need to be resolved before the adequacy of these data can be determined. Furthermore, additional storage

TABLE A. (Continued)

stability data are required. Following receipt of the data requested on analytical methodology and storage stability, either additional studies will be required or appropriate levels for revised tolerances determined based on the available data. The registrant should note that all residue data used to support revised tolerances must be expressed in terms of TPTH equivalents.

[15]The registrants submitted data depicting TPTH residues in or on carrots that was reviewed by the Agency. Additional data are required from tests conducted in WA or OR. A representative FlC or WP formulation must be applied at the maximum label rate and the number of applications must reflect the maximum permitted on the label. Samples must be harvested at a posttreatment interval that corresponds to the PHI on the label.

[16]The registrants submitted data depicting TPTH residues in or on potatoes, however, the registrant reported a mean recovery value of 85.5% for fortified samples analyzed concurrently with treated samples. We note that this same recovery value was reported in the sugar beet study. The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed. The registrants must amend all pertinent product labels to specify a PHI and a maximum seasonal application equivalent to that reflected in the data used to support the tolerance. The available data indicate a 21-day PHI and a maximum seasonal application rate of 0.75 lb ai/A would be appropriate. If the registrants elect to propose a different PHI and maximum rate, appropriate supporting residue data must be submitted.

[17]The registrants submitted data on processing of field treated and fortified samples of potatoes and sugar beets. The data indicate that concentration occurs up to 23x in dried peel. However, appropriate levels for revised tolerances and food/feed additive tolerances cannot be determined at this time. Deficiencies in the analytical methodology used to generate these residue data need to be resolved before the adequacy of these data can be determined.

[18]The registrants submitted data depicting TPTH residues in or on sugar beets; however, additional data are required. Data depicting residues of TPTH and its metabolites, di- and monophenyltin hydroxide (or oxides) in or on sugar beets harvested 21 days following the last of three foliar applications with a representative WP or FlC formulation at 0.25 lb ai/A/application. Samples must be analyzed using an acceptable, validated analytical method. Tests must be conducted in CA as previously requested by the Agency. The registrant must amend all pertinent product labels to specify a PHI and a maximum seasonal application equivalent to that reflected in the data used to support the tolerance. The available data indicate that a PHI of 21 days and a maximum seasonal application rate of 0.75 lb ai/A would be appropriate. A mean recovery value of 85.5% was reported for fortified samples analyzed concurrently with treated samples reported in MRID 41556601. The registrant should provide data from individual fortified samples, including the fortification level, recovery, and matrix analyzed.

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[19]Additional data are needed from the studies submitted in MRIDs 41785201 and 41785203. Chromatograms and/or raw data are needed to estimate total phenyltin residues and determine whether or not residues concentrate. Recovery data, including fortification levels in ppm should be provided also.

[20]The Agency has determined that a feeding restriction for sugar beets is impractical. The registrants must submit data depicting TPTH residues of concern in or on sugar beet tops and propose a suitable tolerance. Tests must reflect the maximum application rate and number of applications permitted on the labels. Tests must be conducted in CA(18%), ID(16%), MI(10%), MN(22%) or ND(11%) states which collectively accounted for approximately 80% of U.S. sugar beet production in 1989 (Agricultural Statistics, 1990, p. 74). All pertinent product labels must be amended to delete grazing/feeding restrictions for sugar beet tops.

[21]Adequate data have been submitted in response to the Guidance Document. The tolerance definition for pecans may be modified to include the TPTH metabolites di- and monophenyltin without requiring an increase in the tolerance level.

[22]The registrants submitted protocols which were reviewed by the Agency. CBRS has required data from tests conducted in TX. In addition, peanut hulls must be analyzed since they are not under the control of the grower. The label must state a maximum number of applications of TPTH per season. Alternatively, residue data reflecting the maximum theoretical number of applications may be submitted.

[23]No data from a processing study with peanuts have been submitted. Data are required depicting the potential for residue concentration in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any commodity, an appropriate food/feed additive tolerance must be proposed.

[24]Note to SRRD: The tolerance expression in 40 CFR §180.326 should be expressed as combined residues of triphenyltin hydroxide, diphenyltin hydroxide (oxide), and monophenyltin hydroxide (oxide), expressed as TPTH equivalents.

[25]No data are required at this time. After review of the requested animal metabolism data and when appropriate tolerance levels for residues in or on feed items are determined, the requirements for feeding studies to set tolerance levels in animal products will be specified.