Read 7-6-94

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

JUL 6 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

**MEMORANDUM**

Subject: Tetrachlorvinphos (Case 0321, Chemical 083701). Product Chemistry Chapter and Residue Chemistry Chapter for the Reregistration Eligibility Decision Document. DP Barcodes D199644, CBRS No.13243

From: Francis B. Suhre, Section Head
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

Through: Edward Zager, Chief
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

To: Linda Propst, CRM 73
Reregistration Section 3
Reregistration Branch
Special Review and Reregistration Division (7508W)

and

Flora Chow, Section Head
Chemical Coordination Branch
Health Effects Division (7509C)

Attached are the *Product Chemistry Chapter* and the *Residue Chemistry Chapter* for the *Tetrachlorvinphos Reregistration Eligibility Decision Document* (RED). The chapters were prepared by Dynamac Corporation under supervision of CBRS, HED. The assessment has undergone secondary review in the Branch and has been revised to reflect Branch policies.

The current tolerances for the raw agricultural commodities listed in 40 CFR §180.252 are expressed in terms of residues of tetrachlorvinphos *per se*. The Agency has concluded that the tetrachlorvinphos metabolites des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichloro-

phenylethanediol are of toxicological concern and should be regulated. This list of metabolites may be revised or expanded following submission and review of outstanding ruminant oral and poultry dermal magnitude of the residue studies.

Available data are insufficient to reassess established tolerances for residues of tetrachlorvinphos in the fat of cattle, goats, hogs, horses, sheep, and poultry, in eggs, and in milk fat. New magnitude of the residue studies reflecting oral and dermal exposure of beef cattle, dairy cattle, and hogs, and dermal exposure of poultry to tetrachlorvinphos are required. All residues of concern should be analyzed in cattle, hogs, and poultry using validated analytical methods.

All tolerances on plant commodities should be revoked since plant uses were canceled in 1987.

The 40 CFR §186.950 lists no tolerances, but describes the conditions for use of tetrachlorvinphos as an additive in the feed of beef and dairy cattle and horses for control of fecal flies in manure of treated cattle, horses, and swine.

Available data are insufficient to assess the appropriateness of established feed additive regulation for residues of tetrachlorvinphos. New studies reflecting oral exposure of beef and dairy cattle, and hogs to tetrachlorvinphos are required. All residues of concern should be analyzed in cattle and hogs using validated analytical methods. We note that Delaney clause issues may affect this feed additive regulation.

Anticipated residues in livestock commodities for use in carcinogenic or chronic risk assessment are given in Table C of the Residue Chemistry Chapter. Residue estimates are based on the most recent metabolism studies. Percent of livestock treated data were not available. Many of the anticipated residue estimates exceed the current tolerance levels. This results from the use of nature of the residue data instead of magnitude of the residue data, consideration of livestock commodities (meat, mbyp) not currently covered by the tolerance expression, and a revised tolerance expression which include 4 metabolites of tetrachlorvinphos.

Uncertainty associated with this exposure assessment results primarily from the lack of magnitude of the residue data for livestock and lack of data on the percent of livestock treated. Because of these uncertainties, CBRS considers estimated anticipated residues to reflect a conservative (high) exposure assessment. These estimates will be refined upon receipt of additional data.

Please advise if additional information is needed.

Attachments: *Task 2A: Reregistration Eligibility Decision Document: Product Chemistry Considerations, Task 2B: Reregistration Eligibility Decision Document: Residue Chemistry Considerations.*

cc: Tetrachlorvinphos List A File, Circ., Subject File, RF, Dynamac Corp.
RDI:M. Metzger: 6/27/94:E. Zager:6/27/94
H7509C:CBRS:FSuhre:07/01/94.



3

# TETRACHLORVINPHOS

## REREGISTRATION ELIGIBILITY DOCUMENT:

## PRODUCT CHEMISTRY CONSIDERATIONS

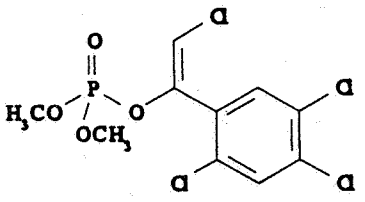
(Shaughnessy No. 083701; Case No. 0321)

CBRS No. 13243; DP Barcode D199644

TASK 2A

## DESCRIPTION OF CHEMICAL

Tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate] is a non-systemic organophosphate insecticide.




| | |
|---|---|
| Empirical Formula: | $C_{10}H_9Cl_4O_4P$ |
| Molecular Weight: | 366.0 |
| CAS Registry No.: | 22248-79-9 |
| Shaughnessy No.: | 083701 |

## IDENTIFICATION OF ACTIVE INGREDIENT

Technical tetrachlorvinphos is a tan to brown crystalline solid with a melting point of 93-98 C and a bulk density of 50-55 lb/cu ft. The solubility of tetrachlorvinphos in water at 24 C is 15 ppm. Tetrachlorvinphos has limited solubility in most aromatic hydrocarbons (i.e., 40 ppm in chloroform and dichloromethane, 20 ppm in acetone, and 8 ppm in xylene at 0 C).

## MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 3/16/94 identified the five tetrachlorvinphos manufacturing-use products (MPs) listed in Table 1. At the time of the Tetrachlorvinphos Guidance Document (10/88), E.I. du Pont de Nemours and Company was the only producer of technical tetrachlorvinphos (99.1% T; EPA Reg. No. 352-460); this

product had been registered to Shell Chemical Company under EPA Reg. No. 201-225 prior to the Guidance Document. The du Pont 99.1% T was voluntarily canceled 12/93. The Fermenta 97.3% and 75% formulation intermediates (FIs; EPA Reg Nos. 56493-38 and 56493-19, respectively) were also registered at the time of the Guidance Document and were formulated at that time from the du Pont technical. The three technicals listed in Table 1 are "me too" registrations which rely on the du Pont database. The products listed in Table 1 are the only MPs subject to a reregistration eligibility decision.

Table 1. Registered tetrachlorvinphos manufacturing-use products.

| Formulation | EPA Reg. No. | Registrant | Date Registered |
|---|---|---|---|
| 98.8% T | 62725-1 | VMX Pet Products Corp. | 11/93 |
| 98.7% T | 2596-131 | Hartz Mountain Corp. | 9/92 |
| 98.7% T | 56493-88 | Fermenta Animal Health Company | 10/92 |
| 97.3% FI | 56493-38 | | 8/86 |
| 75% FI | 56493-19 | | 8/86 |

## REGULATORY BACKGROUND

The Tetrachlorvinphos Guidance Document dated 10/88 required that all new product chemistry data be submitted in support of the reregistration of tetrachlorvinphos.

Tetrachlorvinphos products are also subject to a 6/87 Data Call-In Notice (DCI) for analytical chemistry data on polyhalogenated dibenzo-p-dioxins/dibenzofurans. The Agency determined (CBRS No. 3519, dated 4/8/88, by R. Loranger) that analysis of tetrachlorvinphos for 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD) and 2,3,7,8-tetrachlorodibenzofuran (2,3,7,8-TCDF) at 0.1 ppb and 1.0 ppb, respectively, would be sufficient to fulfill the DCI requirements. Polychlorinated dibenzo-p-dioxins and dibenzofurans are not expected to be of concern in tetrachlorvinphos products based on studies submitted for the du Pont technical in which 2,3,7,8-TCDD and 2,3,7,8-TCDF were not detected at levels above the DCI-specified LOQs.

A 9/92 DCI which requires analytical chemistry data on hexachlorobenzene (HCB) and pentachlorobenzene (PCB) is also in effect for technical tetrachlorvinphos. Data concerning this requirement have not been submitted for the registered tetrachlorvinphos products; however, an acceptable protocol was submitted by du Pont (CBRS Nos. 13016 and 13025, D197423 and D197977, dated 1/11/94, by S. Funk) prior to cancellation of the 99.1% T. All product chemistry requirements were fulfilled for the du Pont 99.1% T prior to its cancellation (12/93), except for those specified in the 9/92 HCB/PCB DCI.



5

The VMX, Hartz, and Fermenta technicals are "me too" registrations, which rely on the du Pont database. VMX, Hartz, and Fermenta must clarify the type of "me too" registrations being requested. If the "me too" product is repackaged from a product manufactured by du Pont, then the du Pont product must be registered. If the "me too" product is manufactured by the registrant, then the product chemistry database required to establish product similarity must be submitted (i.e., all data required under GLNs 61, 62, and 63, except PAI data).

Product chemistry data submitted for the Fermenta 97.3% and 75% FIs in response to the Guidance Document were generated using products formulated from the canceled du Pont technical. Fermenta must identify the current source of the TGAI. If the FIs are formulated from an EPA-registered product, then TGAI data requirements will be the responsibility of the registrant of the technical source.

The current status of the product chemistry data requirements for tetrachlorvinphos manufacturing-use products is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements. In addition, the du Pont product chemistry database for the canceled 99.1% T (EPA Reg. No. 352-460) is presented for informational purposes.

## CONCLUSIONS

All product chemistry data requirements except for those specified under the HCB/PCB DCI dated 9/92 had been satisfied for the canceled du Pont tetrachlorvinphos TGAI. The registrants of the "me too" technical products must clarify the type of "me too" registration being requested before CBRS can determine if the du Pont database is applicable. Additional data are required for the Fermenta FIs. Provided that the registrants submit the product chemistry data required in the attached summary tables for the tetrachlorvinphos technicals, and submit information sufficient to resolve the issue of "me too" registration or submit a complete updated product chemistry data package, CBRS has no objections to the reregistration of tetrachlorvinphos with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

| | |
|---|---|
| CBRS No(s).: | 3519 |
| Subject: | EPA Reg. No. 352-460. Du Pont Response to Dioxin Data Call-In for Gardona (Tetrachlorvinphos, Rabon). |
| From: | R. Loranger |
| To: | G. LaRocca |
| Dated: | 4/8/88 |
| MRID(s): | 40491301 |

| | |
|---|---|
| CBRS No(s).: | 5315 |
| Subject: | Tetrachlorvinphos: Request for Waiver of Certain Physical/Chemical Data Requirements of Section 63 of Product Chemistry Data Requirements. ID No. 352-460. |
| From: | J. Garbus |
| To: | B. Crompton |
| Dated: | 6/13/89 |
| MRID(s): | none |

| | |
|---|---|
| CBRS No(s).: | 7468 |
| Subject: | Response to the Tetrachlorvinphos Reregistration Standard: Product Chemistry Data. |
| From: | R. Perfetti |
| To: | R. Engler and L. Rossi |
| Dated: | 4/3/91 |
| MRID(s): | 40491301, 41117401 through 41117404, 41222501 through 41222503, and 41314002 |

| | |
|---|---|
| CBRS No(s).: | 8037 |
| DP Barcode(s): | D164431 |
| Subject: | Analysis of Technical Tetrachlorvinphos for Polychlorinated Dibenzo-p-Dioxins and Dibenzofurans. ID No. 352-460. |
| From: | S. Funk |
| To: | L. Schnaubelt |
| Dated: | 11/8/91 |
| MRID(s): | 40924701 |

| | |
|---|---|
| CBRS No(s).: | 8622 |
| DP Barcode(s): | D169006 |
| Subject: | Response to the Tetrachlorvinphos Reregistration Standard: Product Chemistry Data. |
| From: | R. Perfetti |
| To: | W. Burnam and L. Rossi |
| Dated: | 1/30/92 |
| MRID(s): | 42013001 through 42013003 |

| | |
|---|---|
| CBRS No(s).: | 9769 |
| DP Barcode(s): | D177244 |
| Subject: | Reregistration of Tetrachlorvinphos. Du Pont Response to Product Chemistry Requirements. |
| From: | W. Smith |
| To: | L. Propst/J. Edwards |
| Dated: | 7/27/92 |
| MRID(s): | 42275201 |

| | |
|---|---|
| CBRS No(s).: | 10347 |
| DP Barcode(s): | D181373 |
| Subject: | Tetrachlorvinphos Reregistration (a List A Chemical): Du Pont Response to Tetrachlorvinphos (Case # 0321; Chemical # 083701) Reregistration Product Chemistry Data Requirements (Regarding Storage Stability Guideline # 63-17). |
| From: | F. Toghrol |
| To: | L. Rossi and L. Propst |
| Dated: | 9/23/92 |
| MRID(s): | 42407801 |

| | |
|---|---|
| CBRS No(s).: | 11529 |
| DP Barcode(s): | D188917 |
| Subject: | Tetrachlorvinphos. Du Pont's 01/27/93 Response [62-3 Linearity Data] to CBRS 01/30/92 Review; #8622. |
| From: | K. Dockter |
| To: | L. Propst/J. Edwards |
| Dated: | 4/15/93 |
| MRID(s): | 42679201 |



8

CBRS No(s).: 13016 and 13025
DP Barcode(s): D197423 and D197977
Subject: Data Call-In for Hexachlorobenzene and Pentachlorobenzene in Technical Tetrachlorvinphos (Rabon®): Protocol for the Analysis of 1,2,4-Trichlorobenzene.
From: S. Funk
To: R. Dumas/D. Utterback
Dated: 1/11/94
MRID(s): none

PRODUCT CHEMISTRY CITATIONS

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

40491301 Sheeran, P. (1987) Rabon Product Chemistry: Du Pont Report #8447/PC-1. Unpublished compilation prepared by E.I. du Pont de Nemours & Co. 68 p.

40924701 Keeler, D. (1988) Determination of 2,3,7,8-Tetrachloro-p-dibenzodioxin and 2,3,7,8-Tetrachlorodibenzofuran in Technical Tetrachlorvinphos: Laboratory Project ID: Y2033.A. Unpublished study prepared by Triangle Laboratories, Inc. 177 p.

41117401 Shoup, R. (1989) Rabon Oral Larvicide Manufacturing Base: Product Identity and Composition. Unpublished study prepared by Fermenta Animal Health Co. 16 p.

41117402 Shoup, R. (1989) Rabon Oral Larvicide Manufacturing Base: Physical and Chemical Characteristics. Unpublished study prepared by Fermenta Animal Health Company. 5 p.

41117403 Shoup, R. (1989) 75% Rabon Insecticide Wettable Powder: Product Identity and Composition. Unpublished study prepared by Fermenta Animal Health Co. 16 p.

41117404 Shoup, R. (1989) 75% Rabon Insecticide Wettable Powder: Physical and Chemical Characteristics. Unpublished study prepared by Fermenta Animal Health Co. 5 p.

41222501 Silveira, E. (1989) Technical Rabon Insecticide: Product Identity and Composition: Project ID Y2033.C. Unpublished study prepared Du Pont de Nemours and Co. 97 p.

41222502 Silveira, E. (1989) Technical Rabon Insecticide: Analysis and Certification of Product Ingredients: Project ID Y2033.D. Unpublished study prepared by Du Pont de Nemours and Co. 40 p.

41222503 Silveira, E. (1989) Technical Rabon Insecticide: Physical and Chemical Characteristics: Project ID Y2033.B. Unpublished study prepared by Du Pont de Nemours

and Co. 65 p.

41314002 Shoup, R. (1989) 75% Rabon Insecticide Wettable Powder: Analysis and Certification of Product Ingredients: Method Number PMS-644/82. Unpublished study prepared by Fermenta Animal Health Co. 37 p.

42013001 Silveira, E. (1991) Technical Rabon Insecticide: Product Identity and Composition: Lab Project Number: Y2033.C. Unpublished study prepared by E. I. du Pont de Nemours and Co. 20 p.

42013002 Silveira, E. (1991) Technical Rabon Insecticide: Analysis and Certification of Product Ingredients: Lab Project Number: Y2033.D. Unpublished study prepared by E.I. du Pont de Nemours and Co. 10 p.

42013003 Silveira, E. (1991) Technical Rabon Insecticide: Physical and Chemical Properties: Lab Project Number: Y2033.B. Unpublished study prepared by E.I. du Pont de Nemours and Co. 11 p.

42275201 Silveira, E. (1992) Technical Rabon Insecticide: Analysis and Certification of Product Ingredients: Lab Project Number: Y2033.D. Unpublished study prepared by E.I. du Pont de Nemours and Co., Inc. 6 p.

42407801 Silveira, E. (1992) Technical Rabon Insecticide: Physical and Chemical Characteristics: [Supplement No. 2]: Lab Project Number: Y2033. B. Unpublished study prepared by E. I. Du Pont de Nemours & Co. 9 p.

42679201 Silveira, E. (1993) Technical Rabon Insecticide Analysis and Certification of Product Ingredients: Supplement No. 3: Lab Project Number: Y2033.D. Unpublished study prepared by E.I. du Pont de Nemours and Co. 9 p.

Case No. 0321
Chemical No. 083701
Case Name: Tetrachlorvinphos

The following product chemistry database for the canceled du Pont 99.1% T (EPA Reg. No. 352-460) is presented for informational purposes.

PRODUCT CHEMISTRY DATA SUMMARY

| Guideline Number | Requirement | Are Data Requirements Fulfilled? [a] | MRID Number [b] |
|---|---|---|---|
| 61-1 | Product Identity and Disclosure of Ingredients | Y | **41222501 41222502** |
| 61-2 | Starting Materials and Manufacturing Process | Y | **41222501** 42013001 |
| 61-3 | Discussion of Formation of Impurities | Y | **40491301 41222501** 42013001 |
| 62-1 | Preliminary Analysis | N [c] | 40924701 [d] **41222502** |
| 62-2 | Certification of Ingredient Limits | Y | **41222502** |
| 62-3 | Analytical Methods to Verify the Certified Limits | Y | **41222502** 42013002 42275201 [e] 42679201 [f] |
| 63-2 | Color | Y | **41222503** |
| 63-3 | Physical State | Y | **41222503** |
| 63-4 | Odor | Y | **41222503** |
| 63-5 | Melting Point | Y | **41222503** |
| 63-6 | Boiling Point | N/A [g] | |
| 63-7 | Density, Bulk Density or Specific Gravity | Y | **41222503** |
| 63-8 | Solubility | Y | **41222503** |
| 63-9 | Vapor Pressure | Y | **41222503** |
| 63-10 | Dissociation Constant | N/A [h] | |
| 63-11 | Octanol/Water Partition Coefficient | Y | **41222503** |
| 63-12 | pH | Y | **41222503** |
| 63-13 | Stability | Y | **41222503** |
| 63-14 | Oxidizing or Reducing Action | N/A [i] | |
| 63-15 | Flammability | N/A [j] | |
| 63-16 | Explodability | N/A [k] | |
| 63-17 | Storage Stability | Y | **41222503** 42013003 42407801 [l] |
| 63-18 | Viscosity | N/A [g] | |
| 63-19 | Miscibility | N/A [g] | |
| 63-20 | Corrosion Characteristics | Y | **41222503** 42013003 |

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

[b] **Bolded** citations were reviewed under CBRS No. 7468, dated 4/3/91, by R. Perfetti; underlined citations were reviewed under CBRS No. 8622, D169006, dated 1/30/92, by R. Perfetti; all remaining references were reviewed as noted.

[c] Data are satisfied for 40 CFR §158.170 (Guideline Reference No. 62-1) concerning preliminary analysis and analysis for dioxins; however, data concerning the HCB/PCB Data Call-In dated 9/92 remain outstanding (CBRS Nos. 13016 and 13025, D197423 and D197977, dated 1/11/94, by S. Funk).

[d] CBRS No. 8037, D164431, dated 11/8/91, by S. Funk; dioxin data.

[e] CBRS No. 9769, D177244, dated 7/27/92, by W. Smith.

[f] CBRS No. 11529, D188917, dated 4/15/93, by K. Dockter.

[g] Data are not required because the TGAI/MP is a solid at room temperature (CBRS No. 5315, dated 6/13/89, by J. Garbus).

[h] Data are not required because the TGAI/PAI is non-ionizable in aqueous solution and has no acid/base properties (CBRS No. 5315, dated 6/13/89, by J. Garbus).

[i] Data are not required because the MP has no significant oxidizing or reducing character (CBRS No. 5315, dated 6/13/89, by J. Garbus).

[j] Data are not required because the MP is not a combustible liquid (CBRS No. 5315, dated 6/13/89, by J. Garbus).

[k] Data are not required because the MP does not contain any potentially explosive ingredients (CBRS No. 5315, dated 6/13/89, by J. Garbus).

[l] CBRS No. 10347, D181373, dated 9/23/92, by F. Toghrol.

Case No. 0321
Chemical No. 083701
Case Name: Tetrachlorvinphos

The following products are "me too" registrations which rely on the du Pont database reflected in the preceding Data Summary Table. The registrants must clarify the type of "me too" registration requested and submit the applicable product chemistry data before CBRS can determine if the du Pont database can be used to support the product chemistry requirements.

Product(s): 98.8% T (EPA Reg. No. 62725-1) VMX Pet Products Corporation
98.7% T (EPA Reg. No. 2596-131) Hartz Mountain Corporation
98.7% T (EPA Reg. No. 56493-88) Fermenta Animal Health Company

PRODUCT CHEMISTRY DATA SUMMARY

| Guideline Number | Requirement | Are Data Requirements Fulfilled? * | MRID Number |
|---|---|---|---|
| 61-1 | Product Identity and Disclosure of Ingredients | N | |
| 61-2 | Starting Materials and Manufacturing Process | N | |
| 61-3 | Discussion of Formation of Impurities | N | |
| 62-1 | Preliminary Analysis | N | |
| 62-2 | Certification of Ingredient Limits | N | |
| 62-3 | Analytical Methods to Verify the Certified Limits | N | |
| 63-2 | Color | N | |
| 63-3 | Physical State | N | |
| 63-4 | Odor | N | |
| 63-5 | Melting Point | N | |
| 63-6 | Boiling Point | N | |
| 63-7 | Density, Bulk Density or Specific Gravity | N | |
| 63-8 | Solubility | N | |
| 63-9 | Vapor Pressure | N | |
| 63-10 | Dissociation Constant | N | |
| 63-11 | Octanol/Water Partition Coefficient | N | |
| 63-12 | pH | N | |
| 63-13 | Stability | N | |
| 63-14 | Oxidizing or Reducing Action | N | |
| 63-15 | Flammability | N | |
| 63-16 | Explodability | N | |
| 63-17 | Storage Stability | N | |
| 63-18 | Viscosity | N | |
| 63-19 | Miscibility | N | |
| 63-20 | Corrosion Characteristics | N | |

* Y = Yes; N = No; N/A = Not Applicable. VMX, Hartz, and Fermenta must clarify the type of "me too" registrations being requested. If the "me too" product is repackaged from a

product manufactured by du Pont, then the du Pont product must be registered. If the "me too" product is manufactured by the registrant, then the product chemistry database required to establish product similarity must be submitted (i.e., all data required under GLNs 61, 62, and 63, except PAI data).

Case No. 0321
Chemical No. 083701

Case Name: Tetrachlorvinphos
Registrant: Fermenta Animal Health Company
Product(s): 97.3% FI (EPA Reg. No. 56493-38)

PRODUCT CHEMISTRY DATA SUMMARY

| Guideline Number | Requirement | Are Data Requirements Fulfilled? [a] | MRID Number [b] |
|---|---|---|---|
| 61-1 | Product Identity and Disclosure of Ingredients | N [c] | 41117401 |
| 61-2 | Starting Materials and Manufacturing Process | N [d] | 41117401 |
| 61-3 | Discussion of Formation of Impurities | N [d,e] | 41117401 |
| 62-1 | Preliminary Analysis | N [d] | |
| 62-2 | Certification of Ingredient Limits | N [f] | 41117401 |
| 62-3 | Analytical Methods to Verify the Certified Limits | N | |
| 63-2 | Color | N [d] | 41117402 |
| 63-3 | Physical State | N [d] | 41117402 |
| 63-4 | Odor | N [d] | 41117402 |
| 63-5 | Melting Point | N [d] | |
| 63-6 | Boiling Point | N [d] | |
| 63-7 | Density, Bulk Density or Specific Gravity | N [d] | 41117402 |
| 63-8 | Solubility | N [d] | |
| 63-9 | Vapor Pressure | N [d] | |
| 63-10 | Dissociation Constant | N [d] | |
| 63-11 | Octanol/Water Partition Coefficient | N [d] | |
| 63-12 | pH | N [d,g] | 41117402 |
| 63-13 | Stability | N [d] | |
| 63-14 | Oxidizing or Reducing Action | N/A [h] | 41117402 |
| 63-15 | Flammability | N/A [i] | |
| 63-16 | Explodability | N/A [j] | 41117402 |
| 63-17 | Storage Stability | N | |
| 63-18 | Viscosity | N/A [i] | |
| 63-19 | Miscibility | N/A [i] | |
| 63-20 | Corrosion Characteristics | Y | 41117402 |

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

[b] All references were reviewed under CBRS No. 7468, dated 4/3/91, by R. Perfetti.

[c] The technical source product used to formulate the FI has been canceled. The registrant must identify the current source of the tetrachlorvinphos TGAI. In addition, the available data do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product identity because the nominal concentration of the active ingredient must be based on the percentage of the active ingredient in the source product.

[d] The technical source product used to formulate the FI has been canceled. The registrant must identify the current source of tetrachlorvinphos TGAI. If the FI is manufactured from an EPA-registered product, then the registrant of the technical source product is responsible for the TGAI data.

[e] The available data do not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities because the registrant must submit a discussion regarding possible post-production reactions between the active ingredient and other constituents of the product or packaging components.

[f] A revised CSF reflecting the new source of the TGAI is required on EPA Form 8570-4 (Rev. 12/90).

[g] Data on pH are required if the test substance is dispersible in water regardless of whether or not the product is to be used dispersed in water.

[h] Data are not required because the MP does not contain an oxidizing or reducing agent.

[i] Data are not required because the MP is a solid at room temperature.

[j] Data are not required because the MP is not explosive and does not contain an explosive agent.

Case No. 0321
Chemical No. 083701

Case Name: Tetrachlorvinphos
Registrant: Fermenta Animal Health Company
Product(s): 75% FI (EPA Reg. No. 56493-19)

PRODUCT CHEMISTRY DATA SUMMARY

| Guideline Number | Requirement | Are Data Requirements Fulfilled? [a] | MRID Number [b] |
|---|---|---|---|
| 61-1 | Product Identity and Disclosure of Ingredients | N [c] | 41117403 |
| 61-2 | Starting Materials and Manufacturing Process | N [d] | 41117403 |
| 61-3 | Discussion of Formation of Impurities | N [d,e] | 41117403 |
| 62-1 | Preliminary Analysis | N [d] | |
| 62-2 | Certification of Ingredient Limits | N [f] | 41314002 |
| 62-3 | Analytical Methods to Verify the Certified Limits | Y | 41314002 |
| 63-2 | Color | N [d] | 41117404 |
| 63-3 | Physical State | N [d] | 41117404 |
| 63-4 | Odor | N [d] | 41117404 |
| 63-5 | Melting Point | N [d] | |
| 63-6 | Boiling Point | N [d] | |
| 63-7 | Density, Bulk Density or Specific Gravity | N [d] | 41117404 |
| 63-8 | Solubility | N [d] | |
| 63-9 | Vapor Pressure | N [d] | |
| 63-10 | Dissociation Constant | N [d] | |
| 63-11 | Octanol/Water Partition Coefficient | N [d] | |
| 63-12 | pH | N [d] | 41117404 |
| 63-13 | Stability | N [d] | |
| 63-14 | Oxidizing or Reducing Action | N/A [g] | 41117404 |
| 63-15 | Flammability | N/A [h] | |
| 63-16 | Explodability | N/A [i] | 41117404 |
| 63-17 | Storage Stability | N | |
| 63-18 | Viscosity | N/A [h] | |
| 63-19 | Miscibility | N/A [h] | |
| 63-20 | Corrosion Characteristics | Y | 41117404 |

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

[b] All references were reviewed under CBRS No. 7468, dated 4/3/91, by R. Perfetti.

[c] The technical source product used to formulate the FI has been canceled. The registrant must identify the current source of the tetrachlorvinphos TGAI. In addition, the available data do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product identity because the nominal concentration of the active ingredient must be based on the percentage of the active ingredient in the source product.

[d] The technical source product used to formulate the FI has been canceled. The registrant must identify the current source of tetrachlorvinphos TGAI. If the FI is manufactured from an EPA-registered product, then the registrant of the technical source product is responsible for the TGAI data.

[e] The available data do not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities because the registrant must submit discussion regarding the possible carryover of impurities from the inert ingredients, and post-production reactions between the active ingredient and other constituents of the product or packaging components.

[f] A revised CSF reflecting the new source of the TGAI is required on EPA Form 8570-4 (Rev. 12/90).

[g] Data are not required because the MP does not contain an oxidizing or reducing agent.

[h] Data are not required because the MP is a solid at room temperature.

[i] Data are not required because the MP is not explosive and does not contain an explosive agent.



(8

# TETRACHLORVINPHOS

## REREGISTRATION ELIGIBILITY DOCUMENT

## RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy Nos. 083701; Case 0321

(CBRS No. 13243; DP Barcode D199644)

TASK 2B

TABLE OF CONTENTS page

# TETRACHLORVINPHOS

## REREGISTRATION ELIGIBILITY DOCUMENT

## RESIDUE CHEMISTRY CONSIDERATIONS

(Shaughnessy No. 083701; Case 0321)

(DP Barcode D199644; CBRS No. 13243)

TASK 2B

## INTRODUCTION

Tetrachlorvinphos ((Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate) is an insecticide federally registered for use as an oral larvicide for livestock and for direct treatment of beef cattle, dairy cattle (including lactating animals), horses, poultry, swine, and livestock premises.

The formulations registered for use on animals include the granular (G), wettable powder (WP), impregnated material (Impr), dust (D), ready-to-use solution (RTU) and emulsifiable concentrate (EC). These formulations may be applied directly as a spray, backrubber solution, dust-bag, and dust. Tetrachlorvinphos may also be used as a feed additive or supplement to control fecal flies (oral larvicide) and as impregnated material for ear tags. The formulations registered for animal premise treatments include the wettable powder, dust, and emulsifiable concentrate, which may be applied as paint and/or residual spray. *[Source: REFS search conducted 4/7/94].*

## REGULATORY BACKGROUND

The Tetrachlorvinphos Reregistration Standard Guidance Document was issued 10/88 and was based on the Tetrachlorvinphos Reregistration Standard Science Chapter dated 9/4/87. The information contained in this document outlines the Residue Chemistry Science Assessments with respect to the reregistration of tetrachlorvinphos. Animal metabolism studies have been submitted since issuance of these documents and have been evaluated by CBRS.

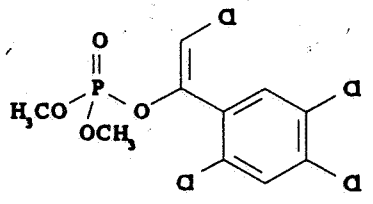
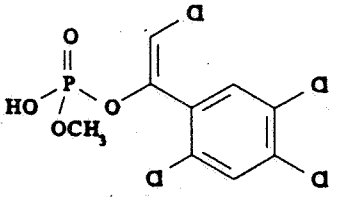
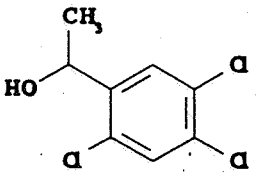
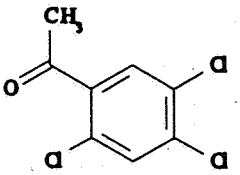
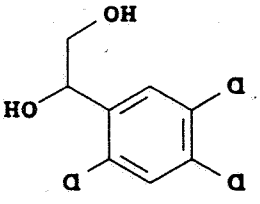
Tolerances for residues of tetrachlorvinphos in/on commodities of plants and animals are currently expressed in terms of 2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate *[Source: 40 CFR §180.252]*. These tolerances range from 0.1 ppm for eggs to 110 ppm for corn forage and fodder. The Science Chapter recommended that all tolerances for plant commodities be revoked since no plant uses of tetrachlorvinphos are registered. The HED Metabolism Committee has concluded that, pending submission of data to upgrade



20

metabolism studies, the residues of concern in animal commodities are tetrachlorvinphos, des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)ethanol, 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)ethanediol. The chemical structures of tetrachlorvinphos and the metabolites of concern are presented in Figure A. A feed additive regulation has been established for tetrachlorvinphos for use as an additive in the feed of beef cattle, dairy cattle, horses, and swine at the rates of 0.00015 lb per 100 lb body weight per day for cattle and horses, and 0.00011 lb per 100 lb of body weight per day for swine *[Source: 40 CFR §186.950]*. An adequate enforcement method is available for the determination of residues of tetrachlorvinphos *per se* in animal commodities; however, no methods are currently available for the determination of residues of tetrachlorvinphos metabolites of concern in animal commodities.

Figure A. The chemical structures of tetrachlorvinphos and the metabolites of concern.

| Structure<br>**Metabolite:** Chemical name | Structure<br>**Metabolite:** Chemical name |
|---|---|
|  <br>**tetrachlorvinphos:** (Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate |  <br>**des-O-methyl tetrachlorvinphos:** (Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl methyl phosphoric acid |
|  <br>**1-(2,4,5-trichlorophenyl)ethanol** |  <br>**2,4,5-trichloroacetophenone** |
|  <br>**1-(2,4,5-trichlorophenyl)ethanediol** | |



21

The information contained in this document summarizes the status of the residue chemistry data requirements, in accordance with Subdivision O's Pesticide Assessment Guidelines, with respect to the reregistration of tetrachlorvinphos.

## SUMMARY OF SCIENCE FINDINGS

### GLN 171-3: Directions for use

A REFS search conducted 4/7/94 identified 9 tetrachlorvinphos end-use products (EPs) with food/feed uses registered to Fermenta Animal Health Company. These EPs are listed in the table below.

| EPA Reg. No. | Acceptance Date | Formulation Class | Product Name |
|---|---|---|---|
| 56493-13 | 10/29/90 | 50% WP | Rabon 50 WP Insecticide |
| 56493-27 | 9/18/75 | 1% RTU | Ravap Backrubber Solution |
| 56493-28 | 2/13/90 | 3% D | Rabon 3 Insecticide Dust |
| 56493-29 | 1/31/91 | 2 lb/gal EC | Rabon E.C. Livestock, Poultry, and Premise Insecticide |
| 56493-34 | 11/13/89 | 97.3% G | Rabon 97.3 Oral Larvicide |
| 56493-35 | 5/29/90 | 7.76% G | Rabon 7.76 Oral Larvicide |
| 56493-42 | 8/25/92 | 23% EC | Ravap E.C. Livestock, Poultry and Premise Insecticide Spray |
| 56493-43 | 9/14/88 | 23% EC | Kennel and Yard Spray Concentrate |
| 56493-50 | 7/3/90 | 13.7% Impr | Rabon Insecticide Cattle Ear Tag |

A label amendment is required for the 7.76% G formulation (EPA Reg. No. 56493-35) to prohibit treatment of horses destined for slaughter. In addition, label amendments are required in the use directions for the 7.76% G and 97.3% G (EPA Reg. No. 56943-34) formulations to clarify that weights of pesticide to be added to feed refer to weights of active ingredient and not weights of product. A comprehensive summary of the registered food/feed use patterns of tetrachlorvinphos, based on these product labels, is presented in Table A. A tabular summary of the residue chemistry science assessments for reregistration of tetrachlorvinphos is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of tetrachlorvinphos food/feed uses are based on the use patterns registered by the basic producer, Fermenta Animal Health Company. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

GLN 171-4 (a): Plant Metabolism

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no plant metabolism data are required.

GLN 171-4 (b): Animal Metabolism

The qualitative nature of the residue in **ruminants** following **oral dosing** is not adequately understood. Additional data pertaining to storage stability are required to upgrade the previously submitted goat metabolism study. In the goat metabolism study, lactating goats were dosed with uniformly ring-labeled [$^{14}$C-phenyl]tetrachlorvinphos at 40 ppm (1x) in the diet for three days. Radioactive residues in the excreta accounted for 72% of the administered dose. The total radioactive residues in milk reached a maximum (0.026 ppm tetrachlorvinphos equivalents) 36 hours after the first dose. The animals were sacrificed 12 hours after administration of the last dose. Total radioactive residues (TRR; expressed as tetrachlorvinphos equivalents) were 0.087 ppm in fat, 0.783 ppm in kidney, 0.847 ppm in liver, 0.026 ppm in milk, and 0.011 ppm in muscle.

The major metabolites identified were free 1-(2,4,5-trichlorophenyl)ethanol which accounted for 64.1% of TRR in fat, conjugated 1-(2,4,5-trichlorophenyl)ethanol which accounted for 13.6% of TRR in liver and 63.4% of TRR in kidney, and 2,4,5-trichloroacetophenone which accounted for 43.6% of TRR in liver. The proposed metabolic pathway in ruminants following oral administration involves conversion of tetrachlorvinphos to trichlorophenylethanol, which is conjugated to glucuronide or further metabolized to trichloroacetophenone.

The qualitative nature of the residue in **ruminants** following **dermal application** is adequately understood. In the ruminant metabolism study, uniformly ring-labeled [$^{14}$C-phenyl]tetrachlorvinphos was applied twice on the same day to the skin of the back of a goat at 48 mg/kg body weight/day (0.5x/application). The animal was sacrificed 22 hours after the last application. Total radioactive residues (expressed as tetrachlorvinphos equivalents) were 0.108 ppm in fat, 0.283 ppm in kidney, 0.041 ppm in liver, 0.022 ppm in milk, 2.084 ppm in loin muscle, and 0.019 ppm in round muscle.

The major metabolites identified were the parent tetrachlorvinphos which accounted for 89.2% of TRR in loin muscle and 87.8% of TRR in milk, free 1-(2,4,5-trichlorophenyl)-ethanol which accounted for 48.9% of TRR in round muscle and 64.8% of TRR in fat, conjugated 1-(2,4,5-trichlorophenyl)ethanol which accounted for 28.3% of TRR in kidney, and 2,4,5-trichloroacetophenone which accounted for 29.0% of TRR in fat.

Tetrachlorvinphos is poorly absorbed through the skin, and most residues adjacent to the application site were not metabolized. Residues that entered the general circulation were extensively metabolized in tissues distal to the application site. In the proposed metabolic

pathway in ruminants following dermal application, tetrachlorvinphos is metabolized to either 1-(2,4,5-trichlorophenyl)ethanol, which is conjugated to glucuronic acid, or to 2,4,5-trichloroacetophenone, which is converted to 2,4,5-trichlorobenzoic acid.

The qualitative nature of the residue in **poultry** following **dermal application** is not adequately understood. Additional data to identify one unknown metabolite are required to upgrade a previously submitted poultry metabolism study. In the poultry metabolism study, uniformly ring-labeled [$^{14}$C-phenyl]tetrachlorvinphos was applied twice on the same day to the skin on the abdomen of a hen at 107 mg/kg mean body weight/day (0.5x/application). The animals were sacrificed 22 hours after the last application. Total radioactive residues (expressed as tetrachlorvinphos equivalents) were 0.358 ppm in whole eggs (shelled), 13.5 ppm in fat, 1.62 ppm in liver, 0.630 ppm in breast muscle, and 3.12 ppm in thigh muscle.

The major metabolites identified were the parent tetrachlorvinphos which accounted for 74.5% of TRR in thigh muscle and 44.9% of TRR in fat, des-O-methyl tetrachlorvinphos which accounted for 19.8% of TRR in breast muscle, free 1-(2,4,5-trichlorophenyl)-ethanol which accounted for 10.0% of TRR in liver, and 1-(2,4,5-trichlorophenyl)-ethanediol which accounted for 68.3% of TRR in liver and 36.3% of TRR in eggs. The metabolite 2,4,5-trichloroacetophenone was a minor metabolite and accounted for $<10\%$ of TRR in all tissues. An unknown metabolite, M7, which accounted for 24.2% of TRR, was detected in eggs.

Tetrachlorvinphos is poorly absorbed through the skin, and most residues adjacent to the application site were either not metabolized or were demethylated to des-O-methyl tetrachlorvinphos. Residues that entered the general circulation were extensively metabolized in tissues distal to the application site. The proposed metabolic pathway in poultry following dermal application is similar to that of ruminants except that 1-(2,4,5-trichlorophenyl)ethanol is not conjugated, but may be metabolized to the mandelic acid and benzoic acid derivatives via trichlorophenylethanediol and 2,4,5-trichloroacetophenone.

The metabolism of tetrachlorvinphos in ruminants and poultry differs. The metabolites des-O-methyl tetrachlorvinphos and 1-(2,4,5-trichlorophenyl)ethanediol are found only in hens, and the metabolite 1-(2,4,5-trichlorophenyl)ethanol is found only in goats (following both oral and dermal administration). The unknown metabolite M7 was only found, at significant levels, in hen eggs. The difference in metabolic profiles between goats and swine, both mammals, would be expected to be less significant than the difference between goat and hens. Therefore, the requirements for swine metabolism studies have been waived, provided that a magnitude of the residue study with swine is conducted including analysis of all residues of concern.

The HED Metabolism Committee has determined that, pending the submission of data to upgrade the metabolism studies, the residues of concern are tetrachlorvinphos, des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)ethanediol.

GLN 171-4 (c) and (d): Residue Analytical Methods-Plants and Animals

Currently, PAM Vol. II lists a GLC method (designated as Method I) with phosphorus-sensitive thermionic detection and a detection limit of 0.03 ppm as available for determination of tetrachlorvinphos *per se* in animal commodities.

In consideration of the Agency's decision to regulate four metabolites of tetrachlorvinphos in addition to the parent, new or revised methods must be developed for tolerance enforcement and data collection purposes. The enforcement method may determine residues of the parent and four metabolites individually, or may involve conversion of all residues, including parent, to a common moiety, as long as the levels of parent are also determined individually. The purpose of the requirement for individual determination of residues of tetrachlorvinphos is to allow separate risk assessments for cholinesterase inhibition (involving parent only) and carcinogenicity (involving parent and four metabolites). In addition, if CBRS determines that metabolite M7 in eggs is of toxicological concern and should be regulated, then a new or revised analytical method will also need to be developed for this metabolite.

The enforcement method(s) should be radiovalidated using samples from the animal metabolism studies and should be validated by an independent laboratory (according to PR Notice 88-5).

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, methods for analysis of tetrachlorvinphos residues in plants are not required.

No data pertaining to the behavior of tetrachlorvinphos using FDA's multiresidue protocols have been submitted. Samples from the animal metabolism studies should be analyzed by FDA multiresidue protocols A, B, D, and E to ascertain that the methods are capable of accurately quantifying all of the residues of concern. The FDA PESTDATA database dated 8/93 (PAM Vol. I, Appendix II) indicates that tetrachlorvinphos is completely recovered (>80%) using FDA multiresidue method protocol D (Section 232.4) but is not recovered using protocol E (Sections 211.1/231.1 and 212.1/232.1, fatty and nonfatty matrices).

GLN 171-4 (e): Storage Stability

All data requirements pertaining to storage stability have been evaluated and deemed adequate, except that additional storage stability data are required for tetrachlorvinphos and its four metabolites of concern in animal tissues and milk to support the required magnitude of the residue in animals studies. In addition, if CBRS determines that metabolite M7 in eggs is of toxicological concern and should be regulated, then additional storage stability data will also be required for this metabolite. Storage stability studies have been conducted using fortified samples of milk and animal tissues. Residues of the tetrachlorvinphos *per se* are stable for 25 days at 0 C in milk, for 31 days at 0 C in milk fat, for 3 days at room

temperature in muscle, for 4 days at room temperature in kidney, for 5 days at room temperature in liver, and for 11 days at room temperature in fat.

GLN 171-4 (k): Magnitude of the Residue in Plants

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no field residue data are required.

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no processing data are required.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Ruminant, swine, and poultry magnitude of the residue studies that were summarized in the Residue Chemistry Chapter have recently been reevaluated and found to be inadequate because none of the studies reflected dosing rates representing the maximum expected combined exposures and contained data for all residues of concern. Therefore, new magnitude of the residue studies with cattle, poultry, and swine are required. Since the precise metabolism in swine is not understood, and because a magnitude of the residue study is conducted over a longer term, all residues of concern must be analyzed. If CBRS determines that metabolite M7 in eggs is of toxicological concern and should be regulated, then data reflecting residues of this metabolite in eggs will be required.

No residue data are required for horses provided that all applicable labels prohibit treatment of horses destined for slaughter. The label for the 7.76% G oral larvacide formulation (EPA. Reg. No. 56493-35) should be amended to prohibit treatment of horses destined for slaughter.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no confined or field rotational crop studies are required.

Table A. Food/Feed Use Patterns Subject to Reregistration for Tetrachlorvinphos (Case 0321).

| Site<br>Application type | Form | Max. Single Application Rate | Min. Retreatment Interval (Days) | Use Limitations |
|---|---|---|---|---|
| **Beef Cattle** | | | | |
| Coarse spray | 50% WP | 0.5% finished spray (1 gal/animal; 0.04 lb ai/animal) | -- | |
| Backrubber | 1% RTU | 1% finished spray | -- | Mix with suitable oil. |
| Self-treating dust-bag or hand dusting | 3% D | 0.12 oz ai/animal | -- | |
| Spray | 2 lb/gal EC | 0.5% finished spray (1 gal/animal; 0.04 lb ai/animal) | 10 | |
| Spray | 23% EC | 0.5% finished spray (1 gal/animal; 0.04 lb ai/animal) | 10 | Use on calves under six months of age and on Brahman and Brahman-cross cattle is prohibited. Application in combination with other organophosphate pesticides is prohibited. |
| Backrubber/facerubber | 2 lb/gal EC<br>23% EC | 1% finished spray | -- | Mix with a suitable oil. |
| Ear tag treatment | 13.7% Impr | Two ear tags/animal | -- | Tags may be replaced as needed. |
| Feed additive | 7.76% G<br>97.3% G | 70 mg ai/cwt of animal/day<br>or<br>26.4 mg ai/lb of feed | -- | |
| Feed supplement | 7.76% G<br>97.3% G | 792-1188 mg ai/animal/day | -- | |
| **Dairy cattle** | | | | |
| Self-treating dust-bag or hand dusting | 3% D | 0.12 oz ai/animal | -- | Treatment may be repeated as needed. |
| Backrubber/facerubber | 2 lb/gal EC<br>1% RTU | 1% solution | -- | Mix with a suitable oil. |

*(continued)*

Table A *(continued)*.

| Site<br>Application type | Form | Max. Single Application Rate | Min. Retreatment Interval (Days) | Use Limitations |
|---|---|---|---|---|
| **Dairy cattle (continued)** | | | | |
| Ear tag treatment | 13.7% Impr | Two ear tags/animal | -- | Tags may be replaced as needed. |
| Feed additive | 7.76% G<br>97.3% G | 70 mg ai/cwt of animal/day<br>or<br>26.4 mg ai/lb of feed | -- | |
| Feed supplement | 7.76% G<br>97.3% G | 792-1188 mg ai/animal/day | -- | |
| **Lactating dairy cattle** | | | | |
| Spray | 2 lb/gal EC | 0.12% finished spray (0.5 gal/animal; 0.01 lb ai/animal) | -- | Treatment may be repeated as needed. |
| Spray | 23% EC | 0.12% finished spray (0.5 gal/animal; 0.01 lb ai/animal) | -- | Treatment may be repeated as needed. Use on calves under six months of age is prohibited. |
| Feed additive | 7.76% G | 70 mg ai/cwt of animal/day<br>or<br>26.4 mg ai/lb of feed | -- | |
| Feed additive | 97.3% G | 70 mg ai/cwt of animal/day<br>or<br>66 mg ai/lb of feed | -- | |
| Feed supplement | 7.76% G | 792-1188 mg ai/animal/day | -- | |
| **Hogs** | | | | |
| Spray | 50% WP | 0.5% finished spray (0.5 gal/animal; 0.02 lb ai/animal) | 14 | |
| Hand dust | 3% D | 0.12 oz ai/animal | 14 | |
| Spray | 2 lb/gal EC | 0.5% finished spray (0.5 gal/animal; 0.02 lb ai/animal) | 14 | |

*(continued)*

Table A *(continued)*.

| Site<br>Application type | Form | Max. Single Application Rate | Min. Retreatment Interval (Days) | Use Limitations |
|---|---|---|---|---|
| **Hogs (continued)** | | | | |
| Feed additive | 7.76% G | 22.7 mg ai/lb of feed | -- | For use on weaners to market-weight animals. |
| | | 45.4 mg ai/lb of feed | -- | For use on sows, boars, and breeding gilts |
| **Horses** | | | | |
| Feed additive | 7.76% G | 70 mg ai/cwt of animal/day | -- | |
| **Poultry** | | | | |
| Spray | 50% WP | 0.5% finished spray (1 gal/100 birds; 0.04 lb ai/100 birds) | 14 | |
| Duster | 3% D | 0.03 lb ai/300 birds | 14 | |
| Dust box | 3% D | 0.06 lb ai/100 birds | -- | |
| Dust box | 50% WP | 0.08 lb ai/50 birds | -- | |
| High pressure spray | 2 lb/gal EC<br>23% EC | 0.5% finished spray (1 gal/100 birds; 0.04 lb ai/bird) | 14 | Use high pressure sprayer at ≥100-125 psi. |
| **Livestock premises** | | | | |
| Dry whitewashed wood or concrete block surfaces | 50% WP | 2% finished spray (1 gal/500 sq. ft.; 0.16 lb ai/500 sq. ft.) | -- | |
| Masonite or galvanized sheet metal surfaces | 50% WP | 1% finished spray (0.5 gal/500 sq. ft.; 0.04 lb ai/500 sq. ft.) | -- | |
| Bedding of swine | 3% D | 0.03 lb ai/150 sq. ft. | -- | |
| Walls, ceilings, etc. | 2 lb/gal EC<br>23% EC | 2% finished spray (1 gal/500 sq. ft.; 0.16 lb ai/500 sq. ft.) | -- | |

*(continued)*

Table A *(continued)*.

| Site<br>Application type | Form | Max. Single Application Rate | Min. Retreatment Interval (Days) | Use Limitations |
|---|---|---|---|---|
| **Poultry premises** | | | | |
| Litter | 2 lb/gal EC<br>23% EC | 0.5% finished spray (2 gal/1000 sq. ft.) | -- | |
| | 50% WP | 0.5% finished spray (2 gal/100 sq. ft.)<br>or<br>0.08 lb ai/100 sq. ft. | -- | |
| | 50% WP | 0.375 oz ai/100 sq. ft. | -- | |
| Paint | 2 lb/gal EC<br>50% WP<br>23% EC | 1% finished spray (1 pt/100 ft.) | -- | |
| Building | 2 lb/gal EC<br>50% WP<br>23% EC | 2% finished spray (1 gal/500 sq. ft.; 0.16 lb ai/500 sq. ft.) | -- | |
| Building; residual surface spray | 2 lb/gal EC<br>50% WP<br>23% EC | 1% finished spray (1 gal/100 sq. ft.; 0.08 lb ai/100 sq. ft.) | | |
| Litter or paint | 3% D | 0.03 lb ai/100 sq. ft. | -- | |

Table B. Residue Chemistry Science Assessments for the Reregistration of Tetrachlorvinphos.

| GLN: Data Requirements | Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References[1] |
|---|---|---|---|
| 171-3: Directions for Use | N/A = Not Applicable | Reserved [2] | See Table A. |
| 171-4 (a): Plant Metabolism | N/A | No [3] | |
| 171-4 (b): Animal Metabolism | N/A | Yes [4] | 00116020, 00117354, 00120147, 00120204, 42828801,[5]42828802,[5] 42828803 [5] |
| 171-4 (c/d): Residue Analytical Methods | N/A | Yes [6] | 00038458, 00077812, 00077814, 00077816, 00115939, 00116020, 00116553, 00117329, 00117340, 00117351, 00117354, 00117389, 00118265, 00120147, 00120200, 00120205, 00120206, 00120229, 00130705, 00133913, 05004211 |
| 171-4 (e): Storage Stability | N/A | Yes [7] | 00117329, 00117354, 00117361, 00117389, 00133913 |
| 171-4 (k): Magnitude of the Residue in Plants | | No [8] | |
| 171-4 (l): Magnitude of the Residue in Processed Food/Feed | | No [9] | |
| 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs | | | |
| - Fat of cattle and hogs | 1.5 [§180.252] | Yes [10] | 00038458, 00117298, 00117339, 00117354, 00117389, 00118265, 00120200, 00120206 |
| - Fat of goats, horses, and sheep | 0.5 [§180.252] | Yes [10,11] | 00115939 |



*(continued; footnotes follow)*

Table B *(continued)*.

| GLN: Data Requirements | Tolerances, ppm [40 CFR] | Must Additional Data Be Submitted? | References[1] |
|---|---|---|---|
| - Fat of poultry | 0.75 [§180.252] | Yes [10] | 00084189, 00117340, 00120225, 00120227 |
| - Milk | 0.5 for milk fat (reflecting negligible residues in whole milk) [§180.252] | Yes [10] | 00117298, 00117354, 00117389, 00118265, 00120206, 05006630 |
| - Eggs | 0.1 [§180.252] | Yes [10,12] | 00084189, 00117340, 00120225, 00120227 |
| 165-1: Rotational Crops (Confined) | | No [13] | |
| 165-2: Rotational Crops (Field) | | No [13] | |

1. All references were reviewed in the Tetrachlorvinphos Reregistration Standard Science Chapter dated 9/4/87 unless otherwise noted.

2. A label amendment is required for the 7.76% G formulation (EPA Reg. No. 56493-35) to prohibit treatment of horses destined for slaughter. In addition, label amendments are required in the use directions for the 7.76% G and 97.3% G (EPA Reg. No. 56943-34) formulations to clarify that weights of pesticide to be added to feed refer to weights of active ingredient and not weights of product.

3. No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no plant metabolism data are required.

4. Additional data are required to upgrade previously submitted metabolism studies following oral dosing of goats and dermal treatment of poultry. The requirements for swine metabolism studies have been waived, provided that a magnitude of the residue study is conducted with swine, including analysis of all residues of concern (CBRS No. 12240, DP Barcode D193268, 10/5/93, J. Abbotts).

5. CBRS No. 12240, DP Barcode D193268, 10/5/93, J. Abbotts.

6. In consideration of the Agency's decision to regulate four metabolites of tetrachlorvinphos in addition to the parent, new or revised methods must be developed for tolerance enforcement and data collection purposes. The enforcement method may determine residues of the parent and four metabolites individually, or may involve conversion of all residues, including parent, to a common moiety, as long as the levels of parent are also determined individually. The purpose of the requirement for individual determination of residues of tetrachlorvinphos is to allow separate risk assessments for cholinesterase inhibition (involving parent only) and carcinogenicity (involving parent and four metabolites). In addition, if CBRS determines that metabolite M7 in eggs is of toxicological concern and should be regulated, then a new or revised analytical method will also need to be developed for this metabolite. The enforcement method(s) should be radiovalidated using samples from the animal metabolism studies and should be validated by an independent laboratory (according to PR Notice 88-5). No data pertaining to the behavior of tetrachlorvinphos using FDA's multiresidue protocols have been submitted. Samples from the animal metabolism studies should be analyzed by FDA multiresidue protocols A, B, D, and E

Table B *(continued)*.

to ascertain that the methods are capable of accurately quantifying all of the residues of concern. (CBRS No. 12240, DP Barcode D193268, 10/5/93, J. Abbotts).

No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, methods for analysis of tetrachlorvinphos residues in plants are not required.

7. Additional storage stability data are required for tetrachlorvinphos and its four metabolites of concern in animal tissues and milk to support the required magnitude of the residue in animals studies. In addition, if CBRS determines that metabolite M7 in eggs is of toxicological concern and should be regulated, then additional storage stability data will also be required for this metabolite (CBRS No. 12240, DP Barcode D193268, 10/5/93, J. Abbotts).

8. No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no field residue data are required.

9. No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no processing data are required.

10. Ruminant, swine, and poultry magnitude of the residue studies that were summarized in the Residue Chemistry Chapter have recently been reevaluated and found to be inadequate because none of the studies reflected dosing rates representing the maximum expected combined exposures and contained data for all residues of concern. Therefore, new magnitude of the residue studies with cattle, poultry, and swine are required. Since the precise metabolism in swine is not understood, and because a magnitude of the residue study is conducted over a longer term, all residues of concern must be analyzed (CBRS No. 12240, DP Barcode D193268, 10/5/93, J. Abbotts).

11. No residue data are required for horses provided that all applicable labels prohibit treatment of horses destined for slaughter (CBRS No. 12240, DP Barcode D193268, 10/5/93, J. Abbotts).

12. If CBRS determines that metabolite M7 in eggs is of toxicological concern and should be regulated, then data reflecting residues of this metabolite in eggs will be required (CBRS No. 12240, DP Barcode, D193268, 10/5/93, J. Abbotts).

13. No tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Provided existing tolerances on crops are revoked, no studies pertaining to rotational crops are required.

TOLERANCE REASSESSMENT SUMMARY

The chemical name of tetrachlorvinphos in 40 CFR §180.252 and §186.950 is not the full chemical name. The name "2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate" should be replaced with "(Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate".

Tolerances Listed Under 40 CFR §180.252

The current tolerances for the raw agricultural commodities listed in 40 CFR §180.252 are expressed in terms of residues of tetrachlorvinphos *per se*. The Agency has concluded that, pending submission of additional data to upgrade the metabolism studies, the tetrachlorvinphos metabolites des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichloro-phenylethanediol are of toxicological concern and should be regulated. When the Agency has determined all the residues of concern that need to be regulated, the tolerance definition should be amended to depict the combined residues of tetrachlorvinphos and its metabolites which are to be regulated.

The available data are insufficient to assess the established tolerances for residues of tetrachlorvinphos in the fat of cattle, goats, hogs, horses, sheep, and poultry, in eggs, and in milk fat (including negligible residues in whole milk). New studies reflecting oral and dermal exposure of beef cattle, dairy cattle, and hogs, and dermal exposure of poultry to tetrachlorvinphos are required. All residues of concern should be analyzed in cattle, hogs, and poultry using validated analytical methods.

The Science Chapter recommended that all tolerances on plant commodities be revoked since no plant uses were registered for tetrachlorvinphos. All plant uses were canceled in 1987. The established tolerances for alfalfa; apples; cherries; field corn fodder and forage; fresh corn (K+CWHR); corn grain; pop corn fodder and forage; sweet corn (K+CWHR); sweet corn fodder and forage; cranberries; peaches; pears; and tomatoes should be revoked since there are no registered uses of tetrachlorvinphos on any plant commodities.

Tolerances Listed Under 40 CFR §186.950

The 40 CFR §186.950 lists no tolerances, but describes the prescribed conditions for use of tetrachlorvinphos as an additive in the feed of beef and dairy cattle and horses for control of fecal flies in manure of treated cattle, horses, and swine.

The available data are insufficient to assess the established feed additive regulation for residues of tetrachlorvinphos. New studies reflecting oral and dermal exposure of beef, cattle, dairy cattle, and hogs, and dermal exposure of poultry to tetrachlorvinphos are required. All residues of concern should be analyzed in cattle, hogs, and poultry using validated analytical methods. We note that Delaney clause issues may affect this feed additive regulation.

Table D. Tolerance Reassessment Summary

| Commodity | Current Tolerance (ppm) | Tolerance Reassessment (ppm) | ±ufosinate-ammonium Comment |
|---|---|---|---|
| **Tolerances listed under 40 CFR §180.252** | | | |
| Alfalfa | 110.0 | Revoke | No registered uses exist. |
| Apples | 10.0 | Revoke | |
| Cattle, fat | 1.5 | TBD [a] | Additional data are required. New magnitude of the residue studies with cattle are required because submitted studies do not reflect dosing rates representing the maximum expected combined exposures and do not contain data for all residues of concern. |
| Cattle, meat | None | TBD | |
| Cattle, mbyp | None | TBD | |
| Cherries | 10.0 | Revoke | No registered uses exist. |
| Corn, field, fodder | 110.0 | Revoke | |
| Corn, field, forage | 110.0 | Revoke | |
| Corn, fresh (K+CWHR) | 10.0 | Revoke | |
| Corn, grain | 10.0 | Revoke | |
| Corn, pop, fodder | 110.0 | Revoke | |
| Corn, pop, forage | 110.0 | Revoke | |
| Corn, sweet, (K+CWHR) | 10.0 | Revoke | |
| Corn, sweet, fodder | 110.0 | Revoke | |
| Corn, sweet, forage | 110.0 | Revoke | |
| Cranberries | 10.0 | Revoke | |
| Eggs | 0.1 | TBD | Additional data are required. New magnitude of the residue studies with cattle, poultry and hogs are required because submitted studies do not reflect dosing rates representing the maximum expected combined exposures and do not contain data for all residues of concern. |
| Goats, fat | 0.5 | TBD | |
| Goat, meat | None | TBD | |
| Goat, mbyp | None | TBD | |
| Hogs, fat | 1.5 | TBD | |
| Hog, meat | None | TBD | |
| Hog, mbyp | None | TBD | |
| Horses, fat | 0.5 | Revoke | No additional data required for horses provided all applicable labels prohibit treatment of horses destined for slaughter. |
| Horses, meat | None | Revoke | |
| Horses, mbyp | None | Revoke | |
| Milk, fat (N) [b] | 0.5 | TBD | |
| Peaches | 0.1 | Revoke | No registered uses exist. |
| Pears | 10.0 | Revoke | |

| | | | |
|---|---|---|---|
| Poultry, fat | 0.75 | TBD | Additional data are required. New magnitude of the residue studies with poultry are required because submitted studies do not contain data for all residues of concern. |
| Poultry, meat | None | TBD | |
| Poultry, mbyp | None | TBD | |
| Sheep, fat | 0.5 | TBD | |
| Sheep, meat | None | TBD | |
| Sheep, mbyp | None | TBD | |
| Tomatoes | 5.0 | Revoke | No registered uses exist. |
| **Tolerances listed under 40 CFR §186.950** | | | |
| Feed items (feed additive regulation) [c] | -- | TBD | |

[a] TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.

[b] Reflecting negligible residues in whole milk.

[c] Delaney clause issues may affect the continuation of this tolerance.

DIETARY EXPOSURE ASSESSMENT

The HED Metabolism Committee has determined that, pending the submission of data to upgrade the metabolism studies, the residues of concern are tetrachlorvinphos, des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)ethanediol. The enforcement analytical method must individually determine residues of the parent compound to allow determination of residues to be used for risk assessment separately for cholinesterase inhibition (parent only) and carcinogenicity (parent plus four metabolites).

Available residue data are insufficient to assess the established tolerances for residues of tetrachlorvinphos in the fat of cattle, goats, hogs, horses, sheep, and poultry, in eggs, and in milk fat (including negligible residues in whole milk). New magnitude of the residue studies reflecting oral and dermal exposure of beef cattle, dairy cattle, and hogs, and dermal exposure of poultry to tetrachlorvinphos are required. All residues of concern should be analyzed in cattle, hogs, and poultry using validated analytical methods.

Anticipated residues in livestock commodities for use in carcinogenic or chronic risk assessment are given in Table C. Estimates are derived from measured residues of tetrachlorvinphos, des-O-methyl tetrachlorvinphos, 1-(2,4,5-trichlorophenyl)ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)ethanediol from oral and dermal metabolism studies. Percent of livestock treated data were not available. Nature of the residue studies in livestock indicated that 23 to 94% of the radiolabeled residue could be attributed to residues of concern, depending on the specific commodity and route of exposure. The anticipated residues given in the last colunm (total tetrachlorvinphos/metabolites residues) should be used by DRES for risk assessment.

For the oral metabolism study, daily doses (3 days) approximating the labeled feed additive dose of 1.54 mg/kg body wt/day were fed. For the dermal goat metaboilism study, goats received two separate dermal applications on the same day, after morning and evening milkings. The application site was prepared by clipping hair off a retangular area (ca. 8.5 x 11 in.) of the goat's back. The dose to the goat was 48 mg/kg body wt/day. For the dermal poultry metabolism study birds received two separate dermal applications on the same day, in the morning and evening. The application site was prepared by clipping the down off a 4 sq. in. area of the abdomen. The dose to the birds was 107 mg/kg mean body wt/day. Clipping hair or down at the application site prior to treatment of test animals exaggerates dermal exposure to tetrachlorvinphos. Commerical use is likely to result in less dermal exposure and absorption of tetrachlorvinphos residues.

Anticipated residues estimates provided below are based on the best available residue data. Many of the anticipated residue estimates exceed the current tolerance levels. This results from the use of nature of the residue data instead of magnitude of the residue data, consideration of livestock commodities (meat, mbyp) not currently covered by the tolerance expression, and a revised tolerance expression which include 4 metabolites of tetrachlorvinphos.

Uncertainties associated with this exposure assessment result primarily from the lack of magnitude of the residue data for livestock and lack of data on the percent of livestock treated. Because of these uncertainties, CBRS considers these anticipated residues to reflect a conservative (high) exposure assessment. Anticipated residue estimates will be refined upon receipt of additional data.

Table C: Anticipated Residues of tetrachlorvinphos and Metabolites in Animal Commodities

| Commodity | Reassessed Tolerance (ppm) | Tetrachlorvinphos Plus Regulated Metabolites From Oral Nature of the Residue Studies[2] [parent only] (ppm) | Tetrachlorvinphos Plus Regulated Metabolites From Dermal Nature of the Residue Studies[2] [parent only] (ppm) | Total tetrachlorvinphos residues from dermal and oral dose [parent only] (ppm) |
|---|---|---|---|---|
| Cattle, meat loin muscle | TBD[1] | <0.01 [0.005][3] | 1.87 [0.01] | 1.88 [0.015] |
| Cattle, meat round muscle | | <0.01 [0.005] | 0.01 [0.01] | 0.02 [0.015] |
| Cattle, fat | TBD | 0.06 [0.005] | 0.10 [0.005] | 0.16 [0.01] |
| Cattle, mbyp | TBD | 0.50 [0.005] | 0.13 [0.005] | 0.63 [0.01] |
| Eggs | TBD | n/a | 0.28 [0.03] | 0.28 [0.03] |
| Goats, meat | TBD | <0.01 [0.005] | 1.87 [0.01] | 1.88 [0.015] |
| Goats, fat | TBD | 0.06 [0.005] | 0.10 [0.01] | 0.16 [0.015] |
| Goats, mbyp | TBD | 0.50 [0.005] | 0.13 [0.005] | 0.63 [0.01] |
| Hogs, meat | TBD | <0.01 [0.005] | 1.87 [0.01] | 1.88 [0.01] |
| Hogs, fat | TBD | 0.06 [0.005] | 0.10 [0.005] | 0.16 [0.01] |
| Hogs, mbyp | TBD | 0.50 [0.005] | 0.13 [0.005] | 0.63 [0.01] |
| Horses, meat | TBD | <0.01 [0.005] | 1.87 [0.01] | 1.88 [0.015] |
| Horses, fat | TBD | 0.06 [0.005] | 0.10 [0.01] | 0.16 [0.015] |
| Horses, mbyp | TBD | 0.50 [0.005] | 0.13 [0.005] | 0.63 [0.01] |
| Milk | TBD | 0.005 [0.005] | 0.02 [0.02] | 0.02 [0.025] |

| | | | | |
|---|---|---|---|---|
| Poultry, meat | TBD | na[4] | 2.90 [0.37] | 2.90 [0.37] |
| Poultry, fat | TBD | na | 6.94 [6.06] | 6.94 [6.06] |
| Poultry, mbyp | TBD | na | 1.27 [0.005] | 1.27 [0.005] |
| Sheep, meat | TBD | <0.01 [0.005] | 1.87 [0.01] | 1.88 [0.015] |
| Sheep, fat | TBD | 0.06 [0.005] | 0.10 [0.01] | 0.16 [0.015] |
| Sheep, mbyp | TBD | 0.50 [0.005] | 0.13 [0.005] | 0.63 [0.01] |

[1] To be determined. Inadequate data to evaluate.
[2] CBRS 12240, JAbbotts 10/5/93. Cholinesterase inhibition (parent only); Carcinogenicity (parent plus four metabolites).
[3] Apparent analytical limit of quantification (LOQ) 0.01 ppm; 1/2 LOQ 0.005 ppm.
[4] Not applicable. Not fed to poultry.

## CODEX HARMONIZATION

There are no Codex MRLs established or proposed for residues of tetrachlorvinphos. Therefore, there are no questions with respect to compatibility of U.S. tolerances with Codex MRLs.

## AGENCY MEMORANDA CITED IN THIS DOCUMENT

| | |
|---|---|
| CBRS No.: | None |
| Subject: | Addendum to Residue Chemistry Chapter for Tetrachlorvinphos (Gardona) Registration Standard: Tolerance Assessment System Tolerance Reassessment and Oncogenic Risk Assessment. |
| From: | C. Frick, HED |
| To: | A. Rispin, HED, and G. LaRocca, RD |
| Dated: | 11/20/87 |
| MRID(s): | None |

| | |
|---|---|
| CBRS No.: | None |
| Subject: | Addendum to the Residue Chemistry Chapter of the Tetrachlorvinphos Registration Standard -- FDA Domestic and Import Surveillance and Total Diet Study Data |
| From: | D. Edwards, CBRS, HED |
| To: | A. Rispin, HED, and G. LaRocca, RD |
| Dated: | 12/08/87 |
| MRID(s): | None |

| | |
|---|---|
| CBRS No.: | 5925 |
| Subject: | Tetrachlorvinphos. Nomenclature and Isomer Identification. |
| From: | M. Flood, CBTS, HED |
| To: | J. Edwards, SRRD |
| Dated: | 12/01/89 |
| MRID(s): | None. |

| | |
|---|---|
| CBRS No.: | None |
| Subject: | Results of the HED Metabolism Committee Meeting Held on 9/8/93: Tetrachlorvinphos Metabolism in Animals. |
| From: | J. Abbotts, CBRS, HED |
| To: | HED Metabolism Committee |
| Dated: | 09/14/93 |
| MRID(s): | None |

| | |
|---|---|
| CBRS No.: | 12240 |
| DP Barcode: | D193268 |
| Subject: | Tetrachlorvinphos, Reregistration. Nature of the Residue In Ruminant, Oral Administration In Poultry, Dermal Application, and Ruminant, Dermal Application. |
| From: | J. Abbotts, CBRS, HED |
| To: | J. Edwards, SRRD |
| Dated: | 10/05/93 |
| MRID(s): | 42828801 through 42828803 |

| | |
|---|---|
| CB Nos.: | 12437, 12644, and 12645 |
| DP Barcode: | D194553, D194554, and D194555 |
| Subject: | Terbutryn, Terrazole, Tetrachlorvinphos. Tolerance Revocation; Assessment of the Need for FDA Monitoring Data, Action Levels. |
| From: | M. Metzger, CBRS, HED |
| To: | S. Hobgood, RD |
| Dated: | 10/13/93 |
| MRID(s): | None |

| | |
|---|---|
| CBRS No.: | 12567 |
| DP Barcode: | D195232 |
| Subject: | Tetrachlorvinphos, Reregistration. Animal Metabolism and Analytical Method. |
| From: | J. Abbotts, CBRS, HED |
| To: | J. Edwards, SRRD |
| Dated: | 10/15/93 |
| MRID(s): | None. |

MASTER RECORD IDENTIFICATION NUMBERS

00038458 Schultz, D.R.; Rawn, D.T.; DeKay, D.E. (1973) Residues of SD 8447 in Biopsy Fat Samples from Pigs Fed 400 and 800 PPM Stirofos in the Ration: TIR-26-005-73. (Unpublished study received Jun 27, 1980 under 0H5269; prepared by Shell Development Co., submitted by Diamond Shamrock Agricultural Chemicals, Cleveland, Ohio; CDL:242780-G)

00077812 Shell Development Company (1966) Residue Determination of SD 8447 and Its Low-melting Isomer SD 13462 in Agricultural Crops: GLC Electron Capture Method. Analytical method MMS-71/66 dated Jan 21, 1966. (Unpublished study received May 23, 1967 under 8G0665; CDL:091166-AE)

00077814 Shell Development Company (1966) Residue Determination of SD 8447 and Its Low-melting Isomer SD 13462 in Agricultural Crops: GLC Phosphorus Detector Method. Analytical method MMS-80/66 dated Dec 1966. (Unpublished study received May 23, 1967 under 8G0665; CDL:091166-AG)

00077816 Shell Development Company (1967) Residue Determination of Acid Hydrolyzable Conjugate Metabolites from SD 8447 Treated Crops: GLC Electron-capture method. Analytical method MMS-85/67 dated Apr 1967. (Unpublished study received May 23, 1967 under 8G0665; CDL:091166-AI)

00084189 Ivey, M.C.; DeVaney, J.A.; Ivie, G.W. (1981) Residues of Stirofos (Rabon®) in Eggs of Laying Hens Treated for Northern Fowl Mite Control by Dipping. (U.S. Dept. of Agriculture, Science and Education Administration, Agricultural Research, Veterinary Toxicology and Entomology Research Laboratory; unpublished study; CDL:245949-A)

00115939 Shell Chemical Co. (1972) Residue Data in Reply to EPA's July 10, 1972 Letter of Special Review for Ciovap EC Insecticide. (Compilation; unpublished study received Sep 20, 1972 under 201-244; CDL:000948-A)

00116020 Shell Chemical Co. (1970) Residue Data Developed from the Use of Dairy Cattle: [Rabon]. (Compilation; unpublished study received Jan 19, 1970 under 1F1090; CDL:090850-B)

00116553 Shell Chemical Co. (1971) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: [Gardona]. (Compilation; unpublished study received Oct 12, 1972 under 2F1281; CDL:091818-B)

00117298 Miller, R.; Gordon, C. (19??) Effect of feeding Rabon to dairy cows over extended periods. Journal of Economic Entomology 66(1): 135-138. (Also unpublished submission received Oct 17, 1973 under 201-359; submitted by Shell Chemical Co., Washington, DC; CDL:050006-G)

00117329 Shell Chemical Co. (1969) [Gardona: Residues in Milk and Other Subjects]. (Compilation; unpublished study received on unknown date under 9F0805; CDL:093114-C)

00117339 Shell Chemical Co. (1969) Residue Data Developed from the Use of Rabon on Livestock. (Compilation; unpublished study received Dec 13, 1970 under 1F1121; CDL:093431-C)

00117340 Shell Chemical Co. (1969) Residue Data for Rabon Metabolites in Chicken Tissues and Eggs from California. (Compilation; unpublished study received Dec 1, 1969 under 9F0835; CDL:093538-A)

00117351 Shell Chemical Co. (1971) Analytical Methods for the Determination of the Pesticide Chemical: [Gardona]. (Compilation; unpublished study received Aug 6, 1971 under 2F1187; CDL:093510-C)

00117354 Shell Chemical Co. (1973) Residue Data: [SD-8447]. (Compilation; unpublished study received Oct 17, 1973 under 201-359; CDL:101173-A)

00117361 Shell Chemical Co. (1975) Rabon Oral Larvicide Self-fed Supplement: Label Application. (Compilation; unpublished study received Jul 22, 1975 under 201-392; CDL:220992-A)

00117389 Shell Chemical Co. (1978) [Rabon: Residues in Tissue, Milk, and Fat of Cattle]. (Compilation; unpublished study received Mar 30, 1979 under 201-407; CDL:237924-A)

00118265 Tennessee (1975) Residue Data in Support of the Use of Rabon Insecticide Cattle Ear Tags. (Compilation; unpublished study received Apr 12, 1979 under TN 79/1; CDL:238024-B)

00120147 Shell Chemical Co. (1967) [Determination of Gardona Residues in Various Products]. (Compilation; unpublished study received Jun 12, 1968 under 9F0739; CDL:091275-A)

00120200 Shell Chemical Co. (1968) The Residue Data Developed from Test Plots Including a Description of the Analytical Methods Used: [Gardona Insecticide]. (Compilation; unpublished study received Apr 27, 1969 under 9F0804; CDL:091388-B)

00120204 Shell Chemical Co. (1969) [Determination of Residues of SD 8447 and Rabon in Goats and Poultry]. (Compilation; unpublished study received Apr 27, 1969 under 9F0804; CDL:091387-A)

00120205 Shell Chemical Co. (1968) The Results of Tests on the Amount of Residues Remaining, Including a Description of the Analytical Methods Used: [Rabon]. (Compilation; unpublished study received Apr 26, 1969 under 9F0805; CDL:091389-A)

00120206 Shell Chemical Co. (1969) The Results of Tests on the Amount of Residues Remaining Including a Description of the Analytical Methods Used: [Rabon]. (Compilation; unpublished study received Apr 26, 1969 under 9F0805; CDL:091390-A)

00120225 Yadava, C. (1969) An Investigation of the Toxicology and Residues of Rabon in Poultry. Doctoral dissertation, Univ. of Massachusetts. (Unpublished study received Oct 4, 1969 under 9F0835; submitted by Shell Chemical Co., Washington, DC; CDL:091439-C)

00120227 Shell Chemical Co. (1969) The Results of the Amount of Residues Remaining, Including a Description of the Analytical Method: [Rabon]. (Compilation; unpublished study received Oct 4, 1969 under 9F0835; CDL:091439-G)

00120229 Shell Chemical Co. (1969) Rabon Insecticide on Poultry. (Unpublished study received Oct 5, 1969 under 9F0835; CDL:091440-B)

00130705 Ralston Purina Co. (1969) Residue Data Developed from the Use of Dairy Cattle. (Compilation; unpublished study received Jun 17, 1983 under 602-301; CDL:251028-A)

00133913 Shell Chemical Co. (1973) Summary - Residues: [Toxicity of SD 8447 in Cattle and Other Mammals]. (Compilation; unpublished study received Dec 20, 1974 under 4H5047; CDL:223244-B)

05004211 Bowman, M.C.; Beroza, M. (1967) Temperature-programmed gas chromatography of 20 phosphorus-containing insecticides on 4 different columns and its application to the analysis of milk and corn silage. Journal of the Association of Official Analytical Chemists 50(6):1228-1236.

05006630 Oehler, D.D.; Eschle, J.L.; Miller, J.A.; Claborn, H.V.; Ivey, M.C. (1969) Residues in milk resulting from ultra-low-volume sprays of malathion, methoxychlor, coumaphos, ronnel, or Gardona for control of the horn fly. Journal of Economic Entomology 62(6):1481-1483.

42828801 Krautter, G. (1993) The Metabolism of (carbon 14) Tetrachlorvinphos in the Lactating Goat Following Oral Administration for 3 Consecutive Days: Lab Project Number: 542: 1508. Unpublished study prepared by PTRL East, Inc. 131 p.

42828802 Krautter, G. (1993) The Metabolism of (carbon 14) Tetrachlorvinphos in Laying Hens Following Dermal Application: Lab Project Number: 540: 1532. Unpublished study prepared by PTRL East, Inc. 166 p.

42828803 Krautter, G. (1993) The Metabolism of (carbon 14) Tetrachlorvinphos in the Lactating Goat Following Dermal Application: Lab Project Number: 541: 1531. Unpublished study prepared by PTRL East, Inc. 127 p.