



# Reregistration Eligibility Decision (RED)

## Tetrachlorvinphos



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Tetrachlorvinphos. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Jeff Billingslea at (703) 308-8004. Address any questions on required generic data to the Special Review and Reregistration Division representative Bill Wooge at (703) 308-8794.

Sincerely yours,

Lois A. Rossi, Director  
Special Review  
and Reregistration Division

Enclosures

**SUMMARY OF INSTRUCTIONS FOR RESPONDING TO  
THE REREGISTRATION ELIGIBILITY DECISION (RED)**

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"**--**You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal**

**concentration.** You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements.** Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

**By U.S. Mail:**

Document Processing Desk (**RED-SRRD-PRB**)  
Office of Pesticide Programs (7504C)  
EPA, 401 M St. S.W.  
Washington, D.C. 20460-0001

**By express:**

Document Processing Desk (**RED-SRRD-PRB**)  
Office of Pesticide Programs (7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Hwy.  
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

**REREGISTRATION ELIGIBILITY DECISION**

**Tetrachlorvinphos**

**LIST A**

**CASE 0321**

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# **TETRACHLORVINPHOS REREGISTRATION ELIGIBILITY DECISION TEAM**

## **Office of Pesticide Programs:**

### Biological and Economic Analysis Division

Douglas W. Sutherland	Biological Analysis Branch
Ghulam Ali	Economic Analysis Branch
Steve Jarboe	LUIS

### Environmental Fate and Effects Division

Sharlene R. Matten	Science Analysis and Coordination Staff
Allen Vaughn	Ecological Effects Branch
William R. Effland	Environmental Fate and Groundwater Branch

### Health Effects Division

David J. Miller	Reregistration Support Chemistry Branch
Patricia McLaughlin	Toxicology Branch II
Byron Backus	Toxicology Branch II
Kathryn Boyle	Risk Characterization and Analysis Branch
Laura E. Morris	Occupational and Residential Exposure Branch
Jennifer Wintersteen	Science Analysis Branch

### Registration Division

John Hebert	Insecticide-Rodenticide Branch
George LaRocca	Insecticide-Rodenticide Branch
Mark Perry	Registration Support Branch

### Special Review and Reregistration Division

Kathy Davis	Accelerated Reregistration Branch
Bill Wooge	Accelerated Reregistration Branch

## **Office of General Counsel:**

Jon Fleuchaus

## **Office of Enforcement and Compliance:**

Rick Colbert



## GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD <sub>10</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
$\mu\text{g/g}$	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

## GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

## EXECUTIVE SUMMARY

As required under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1988, the U. S. Environmental Protection Agency has considered the reregistration eligibility for the pesticide active ingredient tetrachlorvinphos. This eligibility consideration includes a comprehensive reassessment of the required target data base and use patterns of currently registered products. The Agency compared its risk assessment to current science and regulatory policies. Where appropriate, it has imposed changes to the terms for continued registration in order to reduce risks to human health and the environment.

The Agency has determined that the dermal application to livestock, non-food animal, general outdoor treatment, and pet uses of tetrachlorvinphos, specified in this document, will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. However, the Agency cannot make a determination regarding the reregistration eligibility of the feed-through (oral) livestock use at this time.

The Agency has determined that all uses of tetrachlorvinphos, with the exception of oral feed-through larvicide treatment to livestock intended for food use, will not cause unreasonable risk to humans or the environment and these uses are eligible for reregistration. The Agency has reviewed environmental and toxicological data to reach this decision.

### Use Patterns

Tetrachlorvinphos is an organophosphate insecticide. It is currently applied dermally to livestock to control flies and mites. Tetrachlorvinphos is used as a feed-through (oral) larvicide in cattle, hogs, goats and horses; in cattle ear tags to control flies; in cattle feedlots; in poultry dust boxes to control poultry mites; and in poultry houses. Tetrachlorvinphos also is used in pet sleeping areas and pet flea collars. It is used to control nuisance and public health pests (flies) in and around refuse sites, recreational areas, and for general outdoor treatment.

### Human Health Assessment

Tetrachlorvinphos has been classified as a group C (possible human) carcinogen by the Carcinogenicity Peer Review Committee of the Agency's Office of Pesticide Programs. It determined the cancer potency factor ( $Q_1^*$ ) of  $1.83 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup>. Also, a RfD of 0.04 mg/kg body weight/day was established based on a NOEL of 4.23 mg/kg bwt/day from a chronic rat feeding study. There were liver histological changes and adrenal changes at 43.2 mg/kg/day (LOEL) in male rats. An uncertainty factor of 100 was used in setting the RfD.

Because the livestock uses result in human dietary exposure, a tolerance reassessment using Anticipated Residues (ARs) is included in this document. Confirmatory data describing the residues in tissues resulting from the dermal livestock treatments are required for the continued registration of tetrachlorvinphos. These data have been required from the registrant. For feed-through (oral) larvicide use in livestock, a feed additive tolerance has been established. However, this tolerance is barred by the Delaney clause of the Federal Food, Drug and Cosmetic Act (FFDCA) which

provides that a food/feed additive regulation for a livestock feed additive may not be established for a pesticide which induces cancer in man or animals. This is discussed below and in Section IV of this document. Data would also be required for the feed-through (oral) larvicide uses; however, this requirement has been deferred because the feed additive tolerance currently established has been proposed for revocation under the Delaney clause of the FFDCA. The proposed revocation of the existing FFDCA section 409 tolerance for tetrachlorvinphos was issued September 21, 1995 in the 60 FR 49141.

Some of the occupational and residential exposures to tetrachlorvinphos are of concern because of potential cancer risks. Risks to tetrachlorvinphos handlers wearing full protective clothing range from  $5.7 \times 10^{-8}$  to  $1.3 \times 10^{-5}$ . Baseline Personal Protective Equipment (PPE) for occupational handlers of tetrachlorvinphos end-use products are chemical resistant gloves, long-sleeved shirts and long pants, socks, and shoes. PPE for homeowner uses (flea collars, aerosol cans for pet sleeping areas, and dust shakers for pet treatments) are not established in this RED because they are not warranted due to low exposure and risk. Occupational-use products containing tetrachlorvinphos which are used on recreational areas are required to carry labeling to restrict re-entry until sprays have dried, to limit exposure to the wet formulations.

### Environmental Assessment

In the environment, tetrachlorvinphos is not persistent but its mobility increases as soil texture becomes coarse and the organic matter content decreases. The primary route of dissipation is through biotic degradation. Under alkaline conditions, abiotic processes (e.g., hydrolysis) are somewhat effective. Parent tetrachlorvinphos is not available from the manure of treated animals and is therefore not available to the environment from the feed-through (oral) larvicide uses. Based on current product labeling, it is unlikely that serious detrimental impacts to ground or surface water will occur from the use of tetrachlorvinphos. Confirmatory data for describing the hydrolysis of tetrachlorvinphos have been submitted and are in review. The results of this review are not likely to change the environmental assessment for this pesticide.

Under the use patterns described in this RED document, tetrachlorvinphos poses little acute or chronic risk to wildlife. Exposure to the environment is expected to be minimal, especially exposures to aquatic species because of the use patterns. Although the acute levels of concern are exceeded for fresh water invertebrates and endangered fish and invertebrates, significant risk is unlikely due to low exposure. Chronic exposures and risks are unlikely because of the use patterns.

### Product Reregistration

Before reregistering the tetrachlorvinphos products with eligible uses, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry for each registration and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

## **I. INTRODUCTION**

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of tetrachlorvinphos. The document consists of six sections. Section I is the introduction. Section II describes tetrachlorvinphos, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for tetrachlorvinphos. Section V discusses the reregistration requirements for tetrachlorvinphos. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

## II. CASE OVERVIEW

### A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Tetrachlorvinphos
- **Chemical Name:** (Z)-2-chloro-1(2,4,5-trichlorophenyl) vinyl dimethyl phosphate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 22248-79-9 [(Z) - isomer]  
22350-76-1 [(E) - isomer]  
961-11-5 [mixed isomers]
- **OPP Chemical Code:** 083701
- **Empirical Formula:** C<sub>10</sub>H<sub>9</sub>Cl<sub>4</sub>O<sub>4</sub>P
- **Trade and Other Names:** Rabon<sup>®</sup>, Gardona<sup>®</sup>
- **Basic Manufacturers:** Fermenta Animal Health Company  
Hartz Mountain Corporation

### B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of tetrachlorvinphos is in Appendix A.

#### For Tetrachlorvinphos:

**Type of Pesticide:** Organophosphate insecticide

#### **Use Sites:**

TERRESTRIAL FEED: Cattle feedlots

INDOOR FOOD: Agricultural/Farm Structures/Buildings and Equipment, Cattle Feedlots, Beef/Range/Feeder Cattle, Dairy Cattle (Lactating or Unspecified), Dairy Goats (Lactating or Unspecified), Hog/Pig/Swine (Meat), Livestock, Poultry (Egg/Meat), Poultry (Meat).



INDOOR RESIDENTIAL: Cats (Adults/Kittens), Dogs/Canines (Adults/Puppies), Household/Domestic Dwellings Indoor Premises.

INDOOR NONFOOD: Horses (Show/Race/Special/Ponies), Mink (Fur Animal), Specialized Animals (such as racing and hunting dogs, show dogs and cats)

TERRESTRIAL NON-FOOD: Recreational Areas, Refuse/Solid Waste Sites (Outdoor), Wide Area/General Outdoor Treatment (Public Health Use).

**Pests**: Fleas, ticks, lice, flies (adults and larvae), chiggers, mites, spiders, wasps, cattle grubs

**Formulation Types Registered:**

Technical:	98.7% a.i.
Manufacturing use:	97.3% a.i.
Wettable powder:	50% a.i.
Dust:	1%, 3% a.i.
Granular:	0.18% to 7.76% a.i. one product 97.3% a.i.
Pelleted/Tableted	0.3% to 1.25% a.i. primarily mineral blocks for cattle/livestock.
Impregnated material:	3%, 13.7% a.i. pet collars, cattle ear tags.
Liquid, ready-to-use:	1% to 2% a.i. spray on/wipe on/backrub materials for pets, horses, cattle.
Pressurized liquid:	1% a.i. flea and tick spray for cats.
Emulsifiable concentrate:	23%, 24% a.i.

**Methods and Rates of Application:**

Application methods include: hand application, hand and power sprayers and dusters, free-choice mineral blocks, livestock feed supplements, poultry dust boxes, pressurized aerosol cans, pet collars, and cattle ear tags.

Current application rates are largely indeterminate, with directions to spray thoroughly, to cover animal completely, or to permit free access to backrubs or mineral blocks.

**Use Practice Limitations:** None currently.

### C. Usage Data

This section summarizes the best estimates available for the pesticidal uses of tetrachlorvinphos in the U.S. These estimates are derived from a variety of published and proprietary sources available to the Agency. These data reflect variability in using data from various information sources. Table 1, below, summarizes the amounts of tetrachlorvinphos used by site.

**Table 1 - Estimates of Tetrachlorvinphos Use on Livestock**

Site	Pounds a.i. Per Animal <sup>a</sup>	Active Ingredient Used per Year <sup>b</sup> (Million lbs)	Number of Animals Treated <sup>c</sup> (Million)	Total Number of Animals <sup>d</sup> (Million)	Percentage of Animals Treated <sup>e</sup>
Cattle - Feed Through	0.1725	2.1	12	96	12.7
Cattle - Dermal	--	--	--	--	5 - 20 <sup>f</sup>
Hogs	0.0661	0.24	4	111.3	3.18
Horses	0.1808	0.12	1	2.1	31
Poultry -Dermal	--	--	--	--	--
Other <sup>g</sup>	na	0.44	na	na	na
Total <sup>h</sup>		3.05	12	211.5	na

na not available/applicable

a Pounds tetrachlorvinphos (a.i.) per animal was calculated using application rates to determine the amount of tetrachlorvinphos applied to the animal.

b The total use of tetrachlorvinphos per type of livestock was obtained from an EPA proprietary database that contains information about tetrachlorvinphos distribution in the U.S.

c Number animals treated = lbs active ingredient used/lbs used per animal.

d U.S. Dept. of Commerce, 1992 Census of Agriculture, Volume 1, part 51, October 1994

e Percent livestock treated = number animals treated/total number animals.

f Information was provided by Extension Entomologists from Texas A&M and the University of Wisconsin, and faculty from Oklahoma State University.

g Information about the use of tetrachlorvinphos in livestock premises is not readily available. Similarly, information about treated dogs and cats is not available.

h Texas and Oklahoma are assumed to be the major states of tetrachlorvinphos livestock use.

#### **D. Use Profile**

Data required in the October 1988 Registration Standard for tetrachlorvinphos (Guidance for the Reregistration of Pesticide Products Containing Tetrachlorvinphos) included studies on product chemistry, ecological effects, environmental fate, and residue chemistry. These data were required to support the uses listed in the Registration Standard and registered at that time. Appendix B of this RED document includes all data requirements identified by the Agency for a reregistration eligibility decision for the currently registered uses.

#### **E. Regulatory History**

Tetrachlorvinphos (commonly referred to by the trade names Rabon and Gardona) was initially registered for use in the United States in 1966 by the U.S. Department of Agriculture. The original registrant of technical tetrachlorvinphos was Shell Chemical. The registration was subsequently transferred to E. I. duPont de Nemours.

In September, 1992, duPont transferred ownership of technical tetrachlorvinphos data to Hartz Mountain Corporation and Fermenta Animal Health Company. Hartz and Fermenta each received their own technical grade product registrations in 1992. DuPont voluntarily canceled its registration in December 1993. A third technical tetrachlorvinphos product was registered to VMX Pet Products Corporation in 1993. Hartz is responsible for supplying generic data supporting domestic pet uses and Fermenta is responsible for supplying generic data supporting livestock uses.

Tetrachlorvinphos was registered for use on various food crops, livestock, pet animals, and in or around buildings. However, the crop uses were voluntarily canceled from product registrations in 1987. Currently, the primary uses of tetrachlorvinphos are the control of manure flies in livestock applied as a feed through in the form of feed additives; flies and mites in livestock building premises applied as dusts; and ticks and fleas on domestic pets applied as dusts, sprays, and collars.

In October, 1988, the Agency issued a Registration Standard. In the Standard the Agency summarized its assessment of the supporting scientific data available at that time and identified and required the submission of additional data, as mentioned above, to support continued registration of tetrachlorvinphos products.

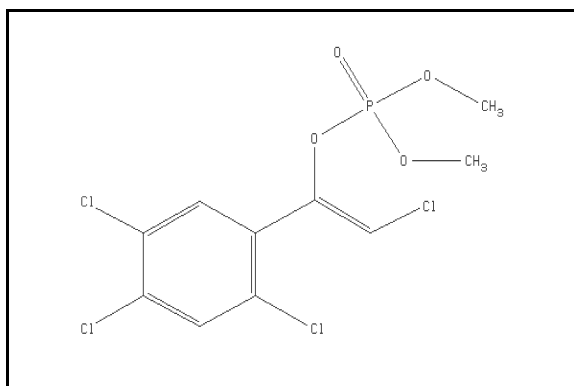
### **III. SCIENCE ASSESSMENT**

#### **A. Physical Chemistry Assessment**

##### **1. Description of Chemical**

Tetrachlorvinphos [(Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl

phosphate] is a non-systemic organophosphate insecticide. Its molecular structure and empirical formula are:



Tetrachlorvinphos (beta isomer)

Empirical Formula:  $C_{10}H_9Cl_4O_4P$

Molecular Weight: 366.0

CAS Registry No.: 22248-79-9

## 2. 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).

## 3. Manufacturing-Use Products

There are five tetrachlorvinphos manufacturing-use products (MPs) currently registered. They are listed below in Table 2.

**Table 2 - 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

## B. Human Health Assessment

### 1. Toxicology Assessment

The toxicological data base for tetrachlorvinphos is adequate and will support reregistration eligibility.

#### a. Acute Toxicity

Acute toxicity values and categories for tetrachlorvinphos are summarized in Table 3.

**Table 3 - Acute Toxicity Data**

TEST	RESULTS	CATEGORY
Oral LD <sub>50</sub> --rat	1480 mg/kg ♂; 465-965 mg/kg ♀	III
Dermal LD <sub>50</sub> --rabbit	> 2 g/kg	III
Inhalation LC <sub>50</sub> --rat	> 3.61 mg/L	IV
Eye irritation--rabbit <sup>1</sup>	moderate	III
Dermal irritation--rabbit <sup>1</sup>	slight	IV
Dermal sensitization--guinea pig <sup>1</sup>	sensitizer	--

<sup>1</sup> Data pertaining to primary eye irritation, dermal irritation, and dermal sensitization are not required to support the reregistration of the TGAI. These data are presented here for informational purposes.

From an acute oral toxicity study with rats, the LD<sub>50</sub> was estimated to be 1480 mg/kg for males and between 465 and 965 mg/kg for females (GDLN 81-1; MRID # 41222504). An acute dermal toxicity study with rabbits estimated the LD<sub>50</sub> to be greater than 2 g/kg (GDLN 81-2; MRID # 41222505). An acute inhalation toxicity study with rats estimated the LC<sub>50</sub> to be greater than 3.61 mg/L (GDLN 81-3; MRID # 138933).

A primary eye irritation study with rabbits resulted in some iritis and redness, clearing by the third day, placing tetrachlorvinphos in Toxicity Category III (GDLN 81-4; MRID # 41222506). In a dermal irritation study, rabbits exhibited slight irritation, placing tetrachlorvinphos in

toxicity category IV, or low toxicity, for this parameter (GDLN 81-5; MRID # 41222507).

Two dermal sensitization studies with Hartley albino guinea pigs indicate that tetrachlorvinphos is a moderate sensitizing agent (GDLN 81-6; MRID # 41377902, 42981001).

Tetrachlorvinphos did not cause delayed neurotoxicity in hens in two studies. In the first study hens were dosed at 300 mg/kg for 5 days or 1.5 g/kg for 1 day. Results were negative. In the second study, tetrachlorvinphos was orally administered to hens in 2 oral doses of 2500 mg/kg, given 21 days apart (cumulative total of 5000 mg/kg). This did not result in delayed neurotoxicity as evidenced by in-life observations and microscopic examinations (GDLN 81-7; MRID #s 115348, 41905901).

In an acute neurotoxicity study, Sprague Dawley rats were orally dosed at 0, 65, 325, or 650 mg/kg. Transient neurotoxic effects were observed in both sexes on day 0 at the two highest doses; these effects were consistent with cholinesterase inhibition. The LOEL was 325 mg/kg and the NOEL was 65 mg/kg. Only minor effects remained by day 7, and all rats were normal by day 14. There was no indication of any permanent behavioral changes or of any adverse neuropathological effects (GDLN 81-8; MRID # 42912501).

#### **b. Subchronic Toxicity**

In a 21-day dermal toxicity study, CrI:CD BR rats were given doses of 0, 10, 100, or 1000 mg/kg/day tetrachlorvinphos which was applied 6 hours/day, 5 days/week for a total of 15 treatments over the 21 day period. The NOEL was determined to be 100 mg/kg/day for females and 1000 mg/kg/day for males. The LOEL was 1000 mg/kg/day for females based on decreased plasma cholinesterase activity. No other systemic effects and no dermal effects were observed (GDLN 82-3; MRID # 41342001).

Tetrachlorvinphos was given to Sprague Dawley rats in the diet at doses of 0, 100, 2000, or 5000 ppm (0, 4.23, 43.2, 88.5 mg/kg/day for males; 0, 5.93, 62.7, 125.3 mg/kg/day for females) for 13 weeks. The Agency concluded the NOEL to be 100 ppm for both sexes. The LOEL was 2000 ppm based on reduced plasma and red blood cell (RBC) cholinesterase activity in both sexes. At the highest dose, these effects were seen along with reduced brain cholinesterase activity in females. Rats treated at the two highest doses had reduced body weights and reduced weight gains, as well as bilateral basophilic tubules of the kidneys in males, increased fat deposition in the adrenal cortex of females, centrilobular

hepatocellular hypertrophy in females and mid-dose males, and higher adjusted adrenal weights in females. In both sexes at the two highest doses there were thyroid follicular cell hypertrophy and higher adjusted liver weights (GDLN 82-1; MRID # 43371201).

**c. Chronic toxicity**

In a one-year oral study, tetrachlorvinphos was given to beagle dogs by capsule at doses of 0, 6.25, 500, or 1000 mg/kg/day. The systemic NOEL was determined to be 6.25 mg/kg/day. The systemic LOEL was 500 mg/kg/day based on decreased RBC counts, hemoglobin, hematocrit, and urine specific gravity. There were also increased mean corpuscular volume, alkaline phosphatase, kidney weights and liver weights. At 1000 mg/kg/day, females showed increased white blood cell (WBC) count and males exhibited increased prostate weight as well as decreased cholesterol. The plasma cholinesterase inhibition NOEL in both sexes was 6.25 mg/kg/day and the LOEL was 500 mg/kg/day (GDLN 83-1; MRID # 42679401).

In a two-year oral toxicity study, beagle dogs were given dietary doses of 0, 5, 25, 125, or 2000 ppm (0, 0.13, 0.63, 3.13, 50 mg/kg/day, respectively). The Agency concluded the NOEL was 3.13 mg/kg/day. The LOEL was 50 mg/kg/day, based on decreased plasma cholinesterase activity and increased relative liver and kidney weights (GDLN 83-1; MRID # 77819).

Tetrachlorvinphos was given to Porton rats at dietary levels of 0, 5, 25, 125, or 2000 ppm (0, 0.25, 1.25, 6.25, and 100 mg/kg/day, respectively) for two years. The NOEL was determined to be 1.25 mg/kg/day. The LOEL was 6.25 mg/kg/day based on increased liver weights in females. At the highest dose, effects included lower body weight, lower food intake, decreased plasma cholinesterase activity in males, decreased RBC counts and plasma cholinesterase activity in females, decreased serum total protein, decreased serum urea, decreased male kidney weights, increased male thyroid weights, and increased female liver weight (GDLN 83-1; MRID # 112525).

A two-year study with Sprague Dawley rats used doses of 0, 100, 1000, or 2000 ppm tetrachlorvinphos (0, 4.23, 43.2, and 88.5 mg/kg/day for males; 0, 5.93, 62.7, and 125.3 mg/kg/day for females) in the feed. The Agency concluded the NOEL for systemic toxicity to be 4.23 mg/kg/day. The LOEL was 43.2 mg/kg/day, based on histological changes in liver and adrenal glands in both sexes, reduced female weight gains, and depression of plasma cholinesterase in females. High dose females also had

elevated cholesterol levels. At termination there were more thyroid C-cell adenomas for male rats in the high dose than in the controls, but this was not statistically significant (GDLN 83-1, 83-2; MRID # 42980901).

**d. Carcinogenicity**

The National Cancer Institute sponsored a carcinogenicity study in Osborne-Mendel rats using tetrachlorvinphos. The doses were 0, 4250, or 8500 ppm given in the diet for 80 weeks which was followed by observation for 31 weeks. Increased incidences of adrenal cortical adenomas and thyroid C-cell adenomas were found in dosed female rats. High incidences of thyroid C-cell hyperplasia in both sexes further indicated an effect on the thyroid (MRID # 117443).

In a carcinogenicity study with B6C3F1 mice, animals were fed diets containing 0, 17.5, 64, 320, 1600, 8000, or 16000 ppm tetrachlorvinphos for two years. For systemic toxicity, the NOEL was 1600 ppm (240 mg/kg/day) and the LOEL was 8000 ppm (1200 mg/kg/day), based on decreased weight gain. In female mice, there were statistically significant increased incidences of hepatocellular carcinoma at 8000 and 16000 ppm, of combined adenomas/carcinomas at the three highest doses, and of adenomas at the highest dose. In male mice, there were statistically significant increases in combined incidences of hepatocellular adenomas and carcinomas at the highest dose, and in adenomas, carcinomas, and combined adenomas/carcinomas of the kidney at the highest dose (GDLN 83-2; MRID # 126039).

The National Cancer Institute reported another carcinogenicity study in B6C3F1 mice. Tetrachlorvinphos was given in the feed at doses of 0, 8000, or 16000 ppm for 80 weeks followed by 12 weeks observation. Increased incidences of hepatocellular carcinomas and granulomatous lesions of the liver were found in the dosed mice (GDLN 83-2; MRID # 117443).

**e. Developmental Toxicity**

A developmental toxicity study was conducted with Sprague Dawley rats. Doses of 0, 75, 150, or 300 mg/kg/day were given to pregnant females by gavage on days 6-15 of gestation. The Agency determined the maternal toxicity NOEL to be 75 mg/kg/day. The LOEL was 150 mg/kg/day based on reduced weight gain at both the 150 and 300 mg/kg/day levels. The NOEL for developmental toxicity was 300 mg/kg/day, the highest dose tested (MRID # 42520101).



Another developmental toxicity study with Sprague Dawley rats tested doses of 0, 75, 150, or 300 mg/kg/day given by gavage on gestation days 6-15. The maternal toxicity NOEL was 75 mg/kg/day. The maternal LOEL was 150 mg/kg/day, based on reductions in weight gain and food consumption. There were also tremors and chromodacryorrhea at this dose. No indications of developmental toxicity were seen at the 300 mg/kg/day dose level (MRID # 40152701). These two studies together fulfill GDLN 83-3.

New Zealand white rabbits were used in a developmental toxicity study. Doses of 0, 150, 375, or 750 mg/kg/day were given by gavage on gestation days 6-19. The maternal toxicity NOEL was 375 mg/kg/day. The maternal LOEL was 750 mg/kg/day based on abortions, red vaginal fluid, and reduced weight gain. The developmental NOEL was 150 mg/kg/day. The developmental LOEL was 375 mg/kg/day, based on reduced numbers of viable fetuses and reduced implantations. Animals treated at the highest dose tested (750 mg/kg/day) also showed an increased incidence of early resorptions (GDLN 83-3; MRID # 127831).

**f. Reproductive Toxicity**

In a two-generation reproductive toxicity study, Sprague Dawley rats were given 0, 100, 500, or 2000 ppm (0, 5, 25, and 100 mg/kg/day, respectively) tetrachlorvinphos in their diets. The NOEL for systemic toxicity was 500 ppm. The LOEL was 2000 ppm, based on reduced weight gains in the F<sub>1</sub> generation, increased adrenal gland weights in F<sub>0</sub> females, and reduced weight gains in F<sub>0</sub> males. The NOEL for reproductive effects was 2000 ppm, the highest dose tested (GDLN 83-4; MRID # 42054301).

A three-generation reproductive toxicity study was conducted in rats with dietary doses of 0, 100, 330, or 1000 ppm (0, 5, 16.5, and 50 mg/kg/day, respectively). The NOEL for the study was 330 ppm. The LOEL was 1000 ppm based on an increase in liver size in the F<sub>3</sub> generation weanlings. However, no effects were noted microscopically in the livers or any of the other organs examined. No effect on fertility (number or size of litters) was noted (GDLN 83-4; MRID # 00077802).

**g. Mutagenicity**

An Ames test in *Salmonella typhimurium* exhibited no mutagenic effect in strains TA98, TA100, TA1535, TA1537, and TA1538, at dose levels of 66.7, 100, 333, 667, 1000, or 3300 ug/plate with activation, or at dose levels of 10, 33.3, 66.7, 100, 333, or 667 ug/plate without activation (MRID # 41222508).

A test for chromosomal aberration was conducted in Chinese hamster ovary cells. The Agency concluded that tetrachlorvinphos was positive for inducing chromosomal aberrations at 59.9, 79.8, and 99.8 ug/mL, but not at 29.9 or 44.9 ug/mL, in the absence of metabolic activation. However, tetrachlorvinphos was negative for inducing chromosomal aberrations at 12.5, 25, 37.6, or 75.1 ug/mL in the presence of rat S9/metabolic activation (MRID # 41312901).

In another study, cultures of rat hepatocytes were dosed with 5, 7.5, 10, 15, 20, 23, 25, 27, 30, 35, or 40 ug/mL of tetrachlorvinphos. Concentrations of 35 and 40 ug/mL were lethal. Only the cultures exposed to doses from 10 to 30 ug/mL were analyzed for evidence of unscheduled DNA synthesis (UDS). The results were negative. (MRID # 42156401). (These studies fulfill GDLNs 84.)

#### **h. Metabolism**

Radiolabelled tetrachlorvinphos was given orally to CD rats as a single low dose (5 mg/kg), as a single high dose (250 mg/kg), and in a series of doses (5 mg/kg). It was almost completely metabolized and most of the label was excreted in urine (46-60%) and feces (38-56%) within 48 hours of dosing. Only minor amounts were found in the tissues. Very little unmetabolized parent compound was recovered. The metabolic processes produced a number of different metabolites which were not all identified. The major metabolite observed in feces was trichlorophenylethanol with females eliminating more of this metabolite (18 - 34% total administered <sup>14</sup>C) than males (13 - 23%) at all three dosing levels. Trichlorophenylethandiol was also found in feces ranging from 4 - 7 % in males and 3 - 6 % in females. A major metabolite in urine, trichloromandelic acid, was excreted in males at 19 - 26% but only 10 - 12% in females. At the high dose, females excreted more (25%) desmethyl tetrachlorvinphos than males (11%). However, there was essentially no difference for the low dose group with males (8%) and females (7%) (GDLN 85-1; MRID # 41988401).

#### **i. Dermal Absorption**

A study was conducted with male CD rats using doses of 0.01, 0.1, 1, or 5 mg/cm<sup>2</sup> radiolabeled tetrachlorvinphos, with some of each dose group sacrificed at 0.5, 1, 2, 4, or 10 hours. Additionally, there was a group of animals, sacrificed at 72 hours, in which the skin was washed at 10 hours. The area of the dermal application was washed to recover unabsorbed tetrachlorvinphos. Then, the skin, urine, feces, and carcass were analyzed for percent of total tetrachlorvinphos applied. For the group

sacrificed at 10 hours, 84% of the total applied (0.1 mg/cm<sup>2</sup>) tetrachlorvinphos was recovered in the wash, and 9.57% remained in the skin, urine, feces, and carcass. This absorption value, 9.57%, is used for assessing human risk following dermal exposure. The percent absorption increased with the duration of exposure and generally decreased with increasing dose. The actual quantity of tetrachlorvinphos absorbed increased with increasing dose (GDLN 85-2; MRID # 42111501).

**j. Reference Dose and Cancer Potency Factor**

The Reference Dose (RfD) Committee of the Agency's Office of Pesticide Programs, Health Effects Division (HED) selected a RfD of 0.04 mg/kg body weight/day, based on the NOEL of 4.23 mg/kg bwt/day in the chronic rat feeding study (MRID # 42980901), discussed above. There were liver histological changes and adrenal changes observed at 43.2 mg/kg/day (LOEL) in male rats. The Committee applied an uncertainty factor of 100 to account for inter-species extrapolation and intra-species variability.

The Cancer Peer Review Committee of HED classified tetrachlorvinphos as a Group C, possible human carcinogen, based on statistically significant increases in combined hepatocellular adenomas/carcinomas (predominantly carcinomas) in the female B6C3F1 mouse, suggestive evidence of thyroid c-cell adenomas and adrenal pheochromocytomas in the rat (MRID # 126039), and mutagenicity concerns. The Agency calculated a cancer potency factor ( $Q_1^*$ ) of  $1.83 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup> using the Weibull 83 time-to-tumor model. A 3/4's scaling factor was used to convert from mouse to human equivalents.

**k. Domestic Animal Safety**

Domestic animal safety tests for pets are generally conducted when cats, dogs, or other domestic animals will be exposed to a given pesticide through direct application for pest control or to support specific label claims for products used on pets. One cat and two dog studies were performed using formulated tetrachlorvinphos products to check for cholinesterase inhibition.

A 1987 dog study was performed using female beagles that wore collars impregnated with 14.5% technical tetrachlorvinphos. The dogs were divided into three groups: control (placebo collar), 1 collar group (recommended usage), and 2 collar group (2x recommended usage). Collars were kept on during pregnancy, parturition, and nursing. Collars identical to the mothers' were placed on the puppies at 4 weeks old. The

greatest mean measured plasma cholinesterase (ChE) inhibition (about 20-30%, which was statistically significant) occurred 12 days after these collars were applied. There was no evidence of any significant plasma ChE inhibition in the mothers or of any red blood cell (RBC) ChE inhibition in either the mothers or puppies. There were no significant dose-related differences in weight gains between the three groups of puppies, particularly when sex ratio differences between the groups were taken into consideration. (This study was undertaken to satisfy labeling requirements; MRID # 40436601)

The second dog study was performed using a formulated dip product (3.1% technical tetrachlorvinphos) applied with a sponge. Each group was composed of 6 dogs ranging in age from 2 to 12 years. Group I was sponged with water (control). Group II was sponged with a mixture of 2 oz. product/1 gallon water (1x label specified use dilution). Group III was sponged with a mixture of 8 oz. product/1 gallon water (4x group). Blood was taken from each animal on days -5, 0 (before treatment), 2, 7, and 14. There was no evidence of any statistically significant reduction in RBC and/or plasma ChE activity in any group. (GDLN 86-1; MRID # 41810102).

The cat study was organized in a manner identical to the second dog study. Groups I, II, and III were the same, with each group composed of 6 cats ranging in age from 3 to 8 years. Blood was taken from each animal on the same days. The results were consistent in that there was no evidence of any statistically significant reduction in RBC and/or plasma ChE activity in any group. (GDLN 86-1; MRID # 41810101)

## **2. Exposure Assessment**

### **a. Dietary Exposure**

#### **Plant Metabolism**

While there are established tolerances for tetrachlorvinphos on certain crops, no currently registered tetrachlorvinphos end-use product is labeled for use on any plant commodity. Therefore, plant metabolism data were not required. The Agency has proposed revocation of the associated tolerances as discussed in Section IV.

#### **Animal Metabolism**

The qualitative nature of the residue in ruminants following oral dosing is adequately understood. In a goat metabolism study

the major metabolites identified were free 1-(2,4,5-trichlorophenyl)ethanol, conjugated 1-(2,4,5-trichlorophenyl)ethanol, and 2,4,5-trichloroacetophenone. 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.

Also, the qualitative nature of the residue in ruminants following dermal application is adequately understood. The major residues identified were the parent tetrachlorvinphos, free 1-(2,4,5-trichlorophenyl)-ethanol, conjugated 1-(2,4,5-trichlorophenyl)ethanol, and 2,4,5-trichloroacetophenone.

Tetrachlorvinphos was 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 was 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 adequately understood. The major residues identified were the parent tetrachlorvinphos, des-O-methyl tetrachlorvinphos, free 1-(2,4,5-trichlorophenyl)-ethanol, and 1-(2,4,5-trichlorophenyl)-ethanediol. The metabolite 2,4,5-trichloroacetophenone was a minor metabolite.

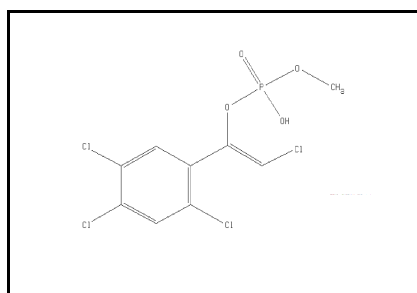
Tetrachlorvinphos was poorly absorbed through the skin of poultry, and most residues adjacent to the application site were either not metabolized or were demethylated to des-O-methyl tetrachlorvinphos. Residues that entered the general circulation were extensively metabolized in tissues distal to the 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.

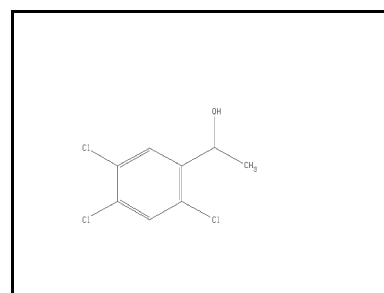
The metabolism of tetrachlorvinphos in ruminants and poultry differs. The metabolites des-O-methyl tetrachlorvinphos and 1-(2,4,5-trichlorophenyl)ethanediol are found only in hens, and the metabolite 1-(2,4,5-trichlorophenyl)ethanol is found only in goats (following both oral and dermal administration). The difference in metabolic profiles between goats and swine, both mammals, would be expected to be less significant than the difference between goats and hens.

From analysis of the above animal metabolism data, the HED Metabolism Committee has determined that 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. See Figure A.

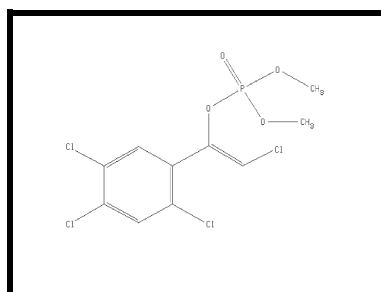
**Figure A. The Chemical Structures of Tetrachlorvinphos and the Metabolites of Concern.**



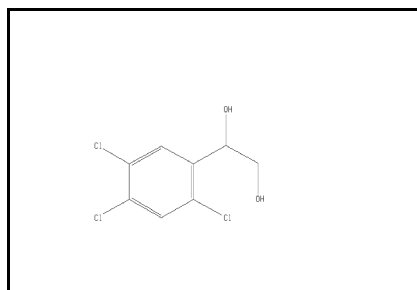
Des-O-methyl tetrachlorvinphos



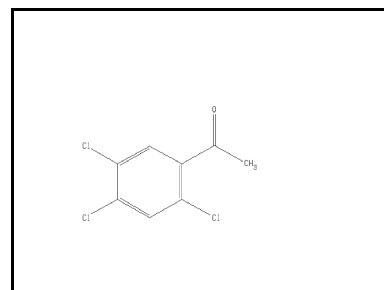
1-(2,4,5- Trichlorophenyl)-ethanol



Tetrachlorvinphos (beta isomer)



1-(2,4,5-Trichlorophenyl)-ethanediol



2,4,5-Trichloroacetophenone

## **Residue Analytical Methods-Plants and Animals**

A gas liquid chromatography (GLC) method for the determination of tetrachlorvinphos *per se* in animal commodities is described in the Pesticide Analytical Method (PAM), Vol. II, as Method I. Methodology to detect and quantitate the above four tetrachlorvinphos metabolites of concern does not exist. Therefore, 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 convert all residues, including the parent, to a common moiety, as long as the parent is 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). The Agency has required these data from the registrants and has required them to be submitted by April 30, 1996. These methods are to be used to recalculate the anticipated residues and the risks as discussed below.

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 must be analyzed by FDA multiresidue protocols A, B, D, and E to ascertain if the methods are capable of accurately quantifying all residues of concern, including the metabolites. The FDA PESTDATA database dated of August 1993 (PAM Vol. I, Appendix II) indicates that tetrachlorvinphos (parent) 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). The Agency has required these data from the registrants and has required them to be submitted by April 30, 1996.

### **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 animal studies. The Agency has required these data from the registrants and has required them to be submitted by April 30, 1996. 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.

### **Magnitude of the Residue in Plants**

#### **Magnitude of the Residue in Processed Food/Feed Confined/Field Rotational Crops**

As stated under Plant Metabolism, no tetrachlorvinphos end-use products are currently registered for use on any plant commodity. Therefore, no field residue data, processing data, or confined/field rotational crop studies were required. The existing tolerances on crops have been proposed for revocation.

### **Magnitude of the Residue in Meat, Milk, Poultry, and Eggs**

Ruminant, swine, and poultry magnitude of the residue studies have been reevaluated for reregistration. The Agency concludes that these studies are inadequate. They failed to reflect dosing rates representing the maximum expected combined exposures and do not contain data for all residues of concern. Therefore, new magnitude of the residue studies reflecting dermal applications to cattle and poultry are required as confirmatory data. The Agency has required these data from the registrants and they are due by April 30, 1996.

Because the Agency cannot make an eligibility determination for livestock oral feed-through use (refer to Section IV of this document for more detail), the Agency has deferred the requirement for new magnitude of the residue studies reflecting oral application to cattle and swine.

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) must be amended to prohibit treatment of horses



destined for slaughter, or registrants must include the horse in their magnitude of residue studies.

### **Anticipated Residues (ARs)**

Due to the inadequate studies for magnitude of the residue in meat/milk/poultry/eggs, 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 have been required and are due by April 30, 1996.

The Agency used anticipated residues (ARs) to estimate human exposures for both chronic and upper bound carcinogenic dietary risk. The estimates (see Table 4) were developed based on data from metabolism studies, which at the present time are the best available residue data. Some of the AR estimates exceed the current tolerance levels. This results from 1) the use of data from the nature of the residue studies (metabolism) instead of the use of data from the magnitude of the residue studies (due to their inadequacies), and 2) use of a revised tolerance expression which includes tetrachlorvinphos and the four metabolites of concern.

The Agency's anticipated residue estimates were further refined using percent uses of livestock treated in the United States. Two methods were used to estimate the percentages. For dermally-treated cattle and poultry, percent estimates were obtained from various sources. These percentages and sources are specified in Table 1. Five to twenty percent of cattle are treated dermally and about eleven percent of poultry are treated. For all other livestock, the percents were calculated using application rates from labels. These ranged from 3.18 percent for hogs, 12.7 percent for orally-treated cattle, and 31 percent for horses. Until the oral (feed-through) tolerance is revoked, it must still be considered in this evaluation. It should be noted that these estimates are derived on the basis of certain assumptions and therefore may have a significant degree of uncertainty. It should be further emphasized that these estimates were made for the purpose of data refinement only, since magnitude of the residue data were not available. Once the required studies have been submitted and evaluated, ARs for tetrachlorvinphos and its metabolites will be recalculated and the risk will be re-examined in light of this new information.

**Table 4 - Anticipated Residues of Tetrachlorvinphos and Metabolites in Animal Commodities**

<b>Commodity</b>	<b>Tetrachlorvinphos Plus Regulated Metabolites From Oral Nature of the Residue Studies<sup>a</sup> (ppm)</b>	<b>Tetrachlorvinphos Plus Regulated Metabolites From Dermal Nature of the Residue Studies<sup>a</sup> (ppm)</b>	<b>Refined Residues Using Percent Livestock Treated Data</b>
Cattle, meat [loin muscle, round muscle]	<i>[&lt;0.01, &lt;0.01]<sup>b</sup></i>	<i>[1.87, 0.01]</i>	0.077
Cattle, fat	0.06	0.10	0.028
Cattle, mbyp	0.50	0.13	0.090
Eggs	n/a	0.28	0.0308
Goats, meat	<0.01	1.87	0.387
Goats, fat	0.06	0.10	0.160
Goats, mbyp	0.50	0.13	0.630
Hogs, meat	<0.01	1.87	0.012
Hogs, fat	0.06	0.10	0.005
Hogs, mbyp	0.50	0.13	0.020
Horses, meat	<0.01	1.87	0.000
Horses, fat	0.06	0.10	0.000
Horses, mbyp	0.50	0.13	0.000
Milk	0.005	0.02	0.005
Poultry, meat [breast muscle, thigh muscle]	na <sup>c</sup>	<i>[0.059, 2.90]</i>	0.192
Poultry, fat	na <sup>c</sup>	6.94	0.763
Poultry, mbyp	na <sup>c</sup>	1.27	0.140
Sheep, meat	<0.01	1.87	0.000
Sheep, fat	0.06	0.10	0.000
Sheep, mbyp	0.50	0.13	0.000

- a These concentrations represent parent plus four metabolites and are to be used for chronic and carcinogenic dietary risk evaluation.
- b Apparent analytical limit of quantification (LOQ) 0.01 ppm; ½ LOQ 0.005 ppm.
- c Not applicable. Not fed to poultry.

Currently, tolerances for tetrachlorvinphos *per se* exist for alfalfa; apples; cherries; corn, grain (sweet and pop); cranberries; peaches; pears; tomatoes; and horse meat, fat and byproducts. The use of tetrachlorvinphos on these fruit and vegetable commodities has been voluntarily canceled. The use of tetrachlorvinphos on horses used for food is prohibited by labeling. Dietary risk was calculated both with and without these tolerances, based on the assumption that until these tolerances are revoked, the use of tetrachlorvinphos could still occur on imported commodities.

**b. Occupational and Residential Exposure**

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are met and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. These criteria for tetrachlorvinphos and its uses are met. Therefore, the Agency conducted a limited exposure/risk assessment for handlers of tetrachlorvinphos using chemical-specific data and other generic data obtained from the Pesticide Handlers Exposure Database (PHED).

**Handler (Mixer/Loader/Applicators) Exposures**

In an occupational setting, tetrachlorvinphos is applied by hand application (e.g., treating cattle with dust formulation), hand and power sprayers and dusters, free-choice mineral blocks, granular feed supplements, dust boxes (for poultry), cattle ear tags, pressurized aerosol cans, and pet collars.

Product label directions permit "free access" (e.g., free-choice mineral blocks), and include specific maximum rates for cattle/swine and other farm animal treatments. Products containing tetrachlorvinphos intended primarily for homeowner use are for controlling fleas on cats, dogs, and in pet sleeping areas. Application rates for these spot treatments, when given, are to "spray thoroughly."

The Agency has determined that there is potential exposure to mixers, loaders, applicators, or other handlers for use patterns associated with tetrachlorvinphos. Specifically, the Agency focused on potential exposures arising from mixing and loading liquids, wettable powders, and granulars, and from applications of aerosols, dusters, pellets, power sprayers, low pressure handwands, and impregnated material (backrubbers).

The Agency required two mixer/loader/applicator (M/L/A) exposure studies per the Registration Standard for Tetrachlorvinphos (October 1988). Studies at one indoor site and one outdoor site were required.

Chemical-specific M/L/A data using the product Rabon® 50 WP were generated by registrants using power sprayers for the interior of poultry houses (MRID # 42622301). The acceptability of this study is pending the Agency's verification of the storage duration of the field samples versus the storage duration of the field recovery samples. This verification is necessary to validate the storage stability of tetrachlorvinphos.

Based on the use patterns and potential exposures described above, EPA identified the major exposure scenarios for tetrachlorvinphos. These exposure scenarios are presented in Table 5. Table 6 summarizes the personal protective clothing, equipment, and other assumptions used for each exposure scenario. Protection factors were applied, when needed, to the exposure data reported in Table 6 to simulate personal protective equipment such as long-sleeved shirt and long pants, and the use or absence of gloves. The Agency relied on the results of the dermal absorption study (MRID # 42111501, summarized previously) conducted on male CD rats, which found a 9.57% dermal absorption rate.

**Table 5 - Exposure Estimates for Tetrachlorvinphos (Mixer/Loader/Applicator)**

Exposure Scenario (Scenario. #)	Dermal Exposure <sup>a</sup> (mg/lb ai)	Inhalation Exposure <sup>b</sup> (mg/lb ai)	Maximum Label Application Rate <sup>c</sup>	Daily Max <sup>d</sup> Treated	Daily Dermal Dose <sup>e</sup> (mg/kg/day)	Daily Inhalation Dose <sup>f</sup> (mg/kg/day)	LADD <sup>g</sup> (mg/kg/day)
Mixer/Loader Exposure							
Liquids (I)	0.3	0.0004	0.027 lb ai/cow	400 cattle	0.0044	.00006	1.1 x 10 <sup>-4</sup>
Granules (II)	0.03	0.0024	0.14 lb ai/cow	400 cattle	0.0023	.0019	1 x 10 <sup>-4</sup>
Wettable Powder (IIIa) [gloves]	0.3	0.024	40 lb ai/poultry house	1 poultry house	0.016	.014	5.3 x 10 <sup>-4</sup>
Wettable Powder (IIIb) [no gloves]	1.2	0.005	40 lb ai/poultry house	1 poultry house	0.067	.0028	1.2 x 10 <sup>-3</sup>
Applicator Exposure Only							
Aerosol Can (IV) <sup>h</sup>	109	3.5	0.00433 lb ai/can	1 can	0.00064	.00022	3.1 x 10 <sup>-5</sup>
Dusters (V) <sup>h</sup>	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Power Sprayers (VII)	0.6 (gloves)	0.006	40 lb ai/poultry house	1 poultry house	0.033	.0034	6.4 x 10 <sup>-4</sup>
Impregnating Material (VIII)	No Data	No Data	1% solution, 1 gallon per 20 linear feet	No Data	No Data	No Data	No Data
Mixer/Loader/Applicator							
Low Pressure Handwand (IX)	103	0.039	1.4 lb ai/A	1 acre	0.20	.00078	7.1 x 10 <sup>-3</sup>
Backpack/Knapsack (X)	2.6	0.03	1.4 lb ai/A	1 acre	0.0048	.0006	1.9 x 10 <sup>-4</sup>

<sup>a</sup> Dermal unit exposures are reported as the best fit mean to simulate workers wearing long pants, long-sleeved shirts, and no gloves. The best fit mean is the composite total dermal exposure based on using the geometric mean for log normal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. The tetrachlorvinphos generated mixer/loader and applicator data are reported as the geometric mean. Protection factors were used to calculate dermal exposure values because insufficient data are available for PPE in these scenarios. Fifty percent of the total dermal exposure is assumed to be attributed to hand exposure. Fifty percent protection factor is applied to the dermal (non-hand) exposure for simulating long pants and long-sleeved shirts. NOTE: Worker wore chemical-resistant gloves in MRID # 42622301.

<sup>b</sup> Inhalation exposure values are reported as geometric means (log normal distribution). No adjustment has been made to simulate workers wearing dust/mist respirators.  
<sup>c</sup> Tetrachlorvinphos labels (56493-29, 56493-34, 56493-13).

<sup>d</sup> Values represent the maximum area which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

<sup>e</sup> The Daily Dermal Dose has been adjusted for dermal absorption based on the data presently available. The Agency assumed ten hours exposure (a typical 8 hour work day plus time before washing any material from the skin). The value used (9.57%) is a combination of tetrachlorvinphos bound to the skin, that could not be washed off and is therefore available for absorption, and absorbed tetrachlorvinphos. (MRID 42111501)

$$\text{Daily Dermal Dose (mg/kg/day)} = \frac{\text{Exposure (mg/lb ai)} \times \text{Max. Appl. Rate (lb ai/cycle)} \times \text{Max. Treated} \times 0.0957 \text{ absorbed}}{70 \text{ kg}}$$

<sup>f</sup> 
$$\text{Inhalation Daily Dose (mg/kg/day)} = \frac{\text{Exposure (mg/lb ai)} \times \text{Max. Appl. Rate (lb ai/cycle)} \times \text{Max. Treated}}{70 \text{ kg}}$$

(Assumed 100 % absorption via the inhalation pathway.)

<sup>g</sup> 
$$\text{LADD (mg/kg/day)} = [\text{Daily Dermal Dose} + \text{Daily Inhalation Dose(mg/kg/day)}] \times (\text{Work Days Per Yr}/365 \text{ Days Per Year}) \times (35 \text{ Yrs}/70 \text{ Yrs})$$

<sup>h</sup> May be homeowner and/or occupational use

#### Exposure Scenarios

- |       |                        |  |
|-------|------------------------|--|
| I.    | Liquids                | - Preparation of livestock, pet, and premise sprays, wipe-ons, and back-rubbers                          |
| II.   | Granular               | - Preparation of pesticide to livestock feeds  |
| III.  | Wettable Powder        | - Preparation of dust for poultry dust boxes   |
| IV.   | Aerosol Can            | - Application of pesticide by aerosols to dogs, cats for controlling fleas, ticks                        |
| V.    | Dusters                | - Application of dusts to livestock - manually and with dust bags, dust boxes for poultry                |
| VI.   | Pellets                | - Application of mineral blocks or the additive to animal feeds  |
| VII.  | Power Sprayers         | - Application of liquid to poultry houses using pressure sprayers  |
| VIII. | Impregnating Materials | - Application of soluble liquid to burlap or rope backrubber   |
| XI.   | Low Pressure Handwand  | - Application of liquid to cattle feed lots and general outdoor areas (picnic areas, recreational areas) |
| X.    | Backpack/Knapsack      | - Application of liquid to cattle feed lots and general outdoor areas (picnic areas, recreational areas) |

**Table 6 - Exposure Scenario Descriptions for Tetrachlorvinphos**

Exposure Scenario (Scenario #)	Data Source	Clothing Scenario <sup>a</sup>	Equipment	Standard Assumptions <sup>b</sup>	Comments <sup>c</sup>
Mixer/Loader Exposure					
Liquids(I)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	Open Mixing	Treat cattle every 10 days for 6 months (18 treatments)	Acceptable grades; Dermal = 14+ replicates; Inhalation = 40 replicates; High confidence in data
Granules (II)	PHED	Total Deposition, No Gloves	Open Mixing	Feed to cattle every 10 days for 6 months (18 treatments)	All grades; Dermal = 3 to 14 replicates; Inhalation = 14 replicates; Low confidence in data
Wettable Powders (IIIa)	MRID # 42622301	Single Layer Coveralls, Gloves	Open Mixing	4 lb ai/100 gal; 1 gal/100 birds; 100,000 birds/facility; treat once every 14 days for 6 months (13 treatments)	Acceptable grades (pending verification of storage stability); Dermal and inhalation = 16 replicates; High confidence in data (based on preliminary findings)
Wettable Powders (IIIb)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	Open Mixing	4 lb ai/100 gal; 1 gal/100 birds; 100,000 birds/facility; treat once every 14 days for 6 months (13 treatments)	All grades; Dermal = 4 to 33 replicates; Inhalation = 35 replicates; Medium to low confidence in data
Applicator Exposure Only					
Aerosol Can (IV)	PHED	Total Deposition, Gloves	Aerosol Can	1 can - 1 animal treated once per week for 6 months (26 treatments)	All C grades; Dermal and Inhalation = 15 replicates; Medium confidence in data
Dusters (V)	No Data	No Data	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data	No Data	No Data
Power Sprayers (VII)	MRID # 42622301	Single Layer Coveralls, Gloves	Wandtype Sprayers, Coarse Spray, Single Nozzle, 100 ft. long hose	4 lb ai/100 gal; 1 gal/100 birds; 100,000 birds/facility; treat once every 14 days for 6 months (13 treatments)	Acceptable grades (pending verification of storage stability); Dermal and inhalation = 16 replicates; High confidence in data (based on preliminary findings)
Impregnating Material (VIII)	No Data	No Data	Burlap or Rope Backrubber	No Data	No Data
Mixer/Loader/Applicator					
Low Pressure Handwand (IX)	PHED	Long Pants, Long-Sleeved Shirt, No Gloves	2 to 3 gallon low pressure single wand	1 acre treated once per week for 6 months (26 treatments)	All grades; Inhalation = 95 replicates; Dermal = 25 to 95 replicates; Medium confidence in data
Backpack/Knapsack (X)	PHED	Long Pants, Long-Sleeved Shirt, Gloves	2 gallon Knapsack	1 acre treated once per week for 6 months (26 treatments)	Acceptable grades (except for hand exposure); Inhalation = 9 replicates; Dermal = 9 replicates; Medium confidence in data

<sup>a</sup> Clothing scenario represents actual monitored exposure data. The dermal exposure values in Table 5 have been adjusted using protection factors to simulate long pants, long-sleeved shirt and gloves/no gloves, as noted.

<sup>b</sup> Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

<sup>c</sup> These grades are based on Quality Assurance/Quality Control data provided as part of the exposure studies. "Acceptable grades" for dermal and inhalation studies are A and B as defined in Subdivision U Guidelines. All grades that do not meet the guidelines are listed separately. A replicate refers to data acquired during one complete work cycle. High confidence in data indicates that there were at least 15 replicates of Grades A and B data. Medium confidence in data indicates that there were at least 15 replicates, but that some of the data did not meet the criteria for Grades A and B data. Low confidence in data indicates that there were less than 15 replicates of data.

## **Post-Application Exposure**

The Agency believes that there is potential exposure to persons entering treated sites after application is complete.

As discussed above, tetrachlorvinphos meets the toxicological criteria (classification as Group C-possible human carcinogen) for consideration of a risk assessment. However, because the uses are primarily to animals and in animal areas, the potential for post-application exposure should be minimal. For example, for indoor premise-residential use (i.e., aerosol can) the label states that application to pets and bedding is a spot treatment. Therefore, post-application exposure data have not been required.

### **3. Risk Assessment**

#### **a. Dietary Risk**

An acute dietary risk assessment was not required since an appropriate toxicological endpoint was not identified.

##### **(1) Chronic Dietary Risk**

EPA performed a chronic dietary risk assessment based on the RfD for tetrachlorvinphos. As discussed previously, the RfD is 0.04 mg/kg body wt/day based on a chronic rat feeding study (MRID 42980901).

For this assessment, the Agency performed four analyses based on different assumptions of residues available in the human diet. Each assessment calculated the chronic dietary risk for the overall U.S. population and 22 population subgroups. In Analysis I (see Table 7), exposure was calculated for all commodities with established tolerances and commodities where tolerances are to be established. Assessment Ia was performed using tolerance level residues. Tolerances for meat and meat by-product commodities do not currently exist for cattle, hogs, goats, sheep, and poultry. These commodities were included in this assessment by extending the existing fat tolerances to meat and meat-by-products (i.e., the established tolerance of 0.75 part per million for poultry fat was used for chicken and turkey). This could result in an overestimation or underestimation of risk, but due to data limitations, it was the only method available to the Agency at this time. A second assessment (Ib) was performed using anticipated



residues for meat, milk, poultry, and eggs (See Table 8). Use of anticipated residues is considered to be a more accurate estimate of dietary exposure and therefore a more realistic scenario. However, for this scenario, anticipated residues were not available for fruit and vegetable commodities; therefore, it was necessary to use tolerance level residues for fruits and vegetables in the anticipated residue calculation. This could result in a possible overestimation of risk.

In Analysis II, only those commodities supported by the registrants for reregistration (orally and dermally treated livestock) were included in the exposure assessments. Alfalfa, apples, cherries, corn (grain, sweet and pop), cranberries, peaches, pears, tomatoes, and horse (meat, fat, and byproducts) have been proposed for revocation, and are not included in this Analysis. Analysis IIa used tolerance values for residues and Analysis IIb used anticipated residue values from Table 4.

In these four analyses the Agency compared the estimated dietary exposures to the reference dose (0.04 mg/kg bwt/day) for a measure of dietary risk. The % RfD is a measure of how much of the RfD has been taken up by the estimated exposure.

**Table 7 - Analysis I: All Commodities with Established and Extended<sup>1</sup> Tolerances**

<b>Assumed Residues</b>	<b>Subgroup</b>	<b>Exposure (mg/kg/day)</b>	<b>%Reference Dose</b>
Using Tolerance Level Residues (Ia)	U.S. Population	0.031951	80
	Non-nursing Infants (< 1 year)	0.153108	380
	Nursing Infants (< 1 year)	0.088606	220
	Children (1 - 6 years)	0.082572	210
	Children (7 - 12 years)	0.049890	120
	All other subgroups were less than 100% of the RfD		
Using Anticipated Residues (Ib)	U.S. Population	0.023441	59
	Non-nursing Infants (< 1 year)	0.117466	290
	Nursing Infants (< 1 year)	0.079950	200
	Children (1 - 6 years)	0.061191	150
	All other subgroups were less than 100% of the RfD		

<sup>1</sup> Tolerances for meat and meat by-product commodities do not currently exist for cattle, hogs, goats, sheep, and poultry. These commodities were included in this assessment by extending the existing fat tolerances to meat and meat-by-products.

**Table 8 - Analysis II: Only Uses Supported for Reregistration**

Assumed Residues	Subgroup	Exposure (mg/kg/day)	%Reference Dose
Using Tolerance Level Residues (IIa)	U.S. Population	0.009036	23
	Non-nursing Infants (< 1 year)	0.036636	92
	All other subgroups were less than 57% of the RfD		
Using Anticipated Residues (IIb)	U.S. Population	0.000525	1
	Non-nursing Infants (< 1 year)	0.000994	2
	Children (1 -6 years)	0.001100	3
	All other subgroups were less than 3% of the RfD		

Overall, chronic dietary risk appears to be minimal when only uses supported for reregistration are included in the calculation (Analyses IIa and IIb).

## (2) Carcinogenic Dietary Risk

The Agency also calculated the upper bound carcinogenic risk from consumption of food commodities, using anticipated residues of tetrachlorvinphos in animal products and tolerance levels in vegetables and fruits, in the following equation:

$$\text{Upper Bound Cancer Risk} = \text{Anticipated Dietary Exposure} \times Q_1^*$$

For the U.S. population, based on a  $Q_1^*$  of  $1.83 \times 10^0$  (mg/kg/day)<sup>-1</sup>, the upper bound cancer risk was calculated to be  $4.3 \times 10^{-5}$ , contributed through all the published tolerances (supported and unsupported uses) for tetrachlorvinphos. This assumes that 100% of the fruit and vegetable commodities consumed by the U.S. population are imported and contain tetrachlorvinphos at tolerance levels.

However, when only commodities of supported food uses (meat, milk, poultry, and eggs) are considered, the dietary cancer risk is  $1 \times 10^{-6}$ .

**b. Occupational and Residential Risk**

A short term or intermediate term occupational or residential risk assessment was not required since an appropriate toxicological endpoint was not identified.

The Agency's cancer risk estimates for occupational and home uses of tetrachlorvinphos are presented in Table 9. The Agency lacks data to evaluate the risks in three worker exposure scenarios: dusters, pellets, and impregnating material. The Agency believes that the uses of low-pressure handwands and power sprayers represent worst-case exposure scenarios (due to the nature of a spraying operation) for the current uses of tetrachlorvinphos. Since risks to workers under these worst-case scenarios do not exceed the Agency's level of concern, it is not likely that exposures resulting from applications of dusts, pellets, or impregnating materials will exceed the Agency's level of concern. The upper bound estimates of carcinogenic risk range from  $1.3 \times 10^{-5}$  (low-pressure handwand/applicator) to  $5.7 \times 10^{-8}$  (aerosol can/applicator).

**Table 9 - Risk Estimates for Occupational/Residential Uses of Tetrachlorvinphos**

Exposure Scenario (Scenario #)	Dermal Exposure <sup>a</sup> (mg/lb ai)	Inhalation Exposure <sup>b</sup> (mg/lb ai)	Maximum Label Application Rate <sup>c</sup>	Daily Max <sup>d</sup> Treated	Daily Dermal Dose <sup>e</sup> (mg/kg/day)	Daily Inhalation Dose <sup>f</sup> (mg/kg/day)	Mixer/Loader/Applicator	
							LADD <sup>g</sup> (mg/kg/day)	RISK <sup>h</sup>
Mixer/Loader Exposure								
Liquids (I)	0.3	0.0004	0.027 lb ai/cow	400 cattle	0.0044	.00006	1.1 x 10 <sup>-4</sup>	2.0 x 10 <sup>-7</sup>
Granules (II)	0.03	0.0024	0.14 lb ai/cow	400 cattle	0.0023	.0019	1 x 10 <sup>-4</sup>	1.8 x 10 <sup>-7</sup>
Wettable Powder (IIIa) [gloves]	0.3	0.024	40 lb ai/poultry house	1 poultry house	0.016	.014	5.3 x 10 <sup>-4</sup>	9.7 x 10 <sup>-7</sup>
Wettable Powder (IIIb) [gloves]	1.2	0.005	40 lb ai/poultry house	1 poultry house	0.067	.0028	1.2 x 10 <sup>-3</sup>	2.2 x 10 <sup>-6</sup>
Applicator Exposure Only								
Aerosol Can (IV) <sup>i</sup>	109	3.5	0.00433 lb ai/can	1 can	0.00064	.00022	3.1 x 10 <sup>-5</sup>	5.7 x 10 <sup>-8</sup>
Dusters (V) <sup>i</sup>	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Pellets (VI)	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Power Sprayers (VII) [gloves]	0.6 (gloves)	0.006	40 lb ai/poultry house	1 poultry house	0.033	.0034	6.4 x 10 <sup>-4</sup>	1.2 x 10 <sup>-6</sup>
Impregnating Material (VIII)	No Data	No Data	1% solution, 1 gallon per 20 linear feet	No Data	No Data	No Data	No Data	No Data
Mixer/Loader/Applicator								
Low Pressure Handwand (IX)	103	0.039	1.4 lb ai/A	1 acre	0.20	.00078	7.1 x 10 <sup>-3</sup>	1.3 x 10 <sup>-5</sup>
Backpack/Knapsack (X)	2.6	0.03	1.4 lb ai/A	1 acre	0.0048	.0006	1.9 x 10 <sup>-4</sup>	3.5 x 10 <sup>-7</sup>

<sup>a</sup> Dermal unit exposures are reported as the best fit mean to simulate workers wearing long pants, long-sleeved shirts, and no gloves. The best fit mean is the composite total dermal exposure based on using the geometric mean for log normal distributed data, arithmetic mean for normal distributed data, and the median for all other distribution types. The tetrachlorvinphos generated mixer/loader and applicator data are reported as the geometric mean. Protection factors were used to calculate dermal exposure values because insufficient data are available for PPE in these scenarios. Fifty percent of the total dermal exposure is assumed to be attributed to hand exposure. Fifty percent protection factor is applied to the dermal (non-hand) exposure for simulating long pants and long-sleeved shirts. NOTE: Worker wore chemical-resistant gloves in MRID # 426220301.

<sup>b</sup> Inhalation exposure values are reported as geometric means (log normal distribution). No adjustment has been made to simulate workers wearing dust/mist respirators.

<sup>c</sup> Tetrachlorvinphos labels (56493-29, 56493-34, 56493-13).

<sup>d</sup> Values represent the maximum area which is assumed to be used in a single day to complete treatments for each exposure scenario of concern.

<sup>e</sup> The Daily Dermal Dose has been adjusted for dermal absorption based on the data presently available. The Agency assumed ten hours exposure (a typical 8 hour work day plus time before washing any material from the skin). The value used (9.57%) is a combination of tetrachlorvinphos bound to the skin, that could not be washed off and is therefore available for absorption, and absorbed tetrachlorvinphos.

(MRID # 42111501)

$$\text{Daily Dermal Dose (mg/kg/day)} = \frac{\text{Exposure (mg/lb ai)} \times \text{Max. Appl. Rate (lb ai/cycle)} \times \text{Max. Treated} \times 0.0957}{70 \text{ kg}}$$

<sup>f</sup> 
$$\text{Inhalation Daily Dose (mg/kg/day)} = \frac{\text{Exposure (mg/lb ai)} \times \text{Max. Appl. Rate (lb ai/cycle)} \times \text{Max. Treated}}{70 \text{ kg}}$$

(Assumed 100% absorption via the inhalation pathway)

<sup>g</sup> 
$$\text{LADD (mg/kg/day)} = [\text{Daily Dermal Dose} + \text{Daily Inhalation Dose (mg/kg/day)}] \times (\text{Work Days Per Yr}/365 \text{ Days Per Year}) * (35 \text{ Yrs}/70 \text{ Yrs})$$

<sup>h</sup> 
$$\text{Risk} = \text{LADD (mg/kg/day)} \times (Q_1^*); \text{ where } Q_1^* = 1.83 \times 10^{-3} \text{ mg/kg/day}^{-1}.$$

<sup>i</sup> May be homeowner and/or occupational use

**c. Domestic Animal Safety**

Tetrachlorvinphos may be applied directly to pets for flea control. Based on the results of studies on cats and dogs, risks to domestic animals from tetrachlorvinphos products are expected to be minimal.

**C. Environmental Assessment**

**1. Ecological Toxicity**

The ecotoxicological data base is adequate to characterize the toxicity of tetrachlorvinphos to nontarget terrestrial and aquatic organisms when used on the registered sites.

**a. Toxicity to Terrestrial Animals**

**(1) Birds, Acute and Subacute**

In order to establish the toxicity of tetrachlorvinphos to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD<sub>50</sub>) study on one species (preferably mallard or bobwhite quail); two subacute dietary studies (LC<sub>50</sub>) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant).

**(a) Avian Acute Toxicity**

The Agency relied on studies (MRID # 160000) using three avian test species. From its review of these data, the Agency concludes that tetrachlorvinphos is practically non-toxic to birds.

**Table 10 - Avian Acute Oral Toxicity Findings**

<b>Species</b>	<b>% Test Material (TGAI)</b>	<b>LD<sub>50</sub></b>	<b>Conclusions</b>
Mallard duck	Tech.	> 2000 mg/kg	practically non-toxic
Ring-necked pheasant	Tech.	> 2000 mg/kg	practically non-toxic
Chukar <sup>1</sup>	Tech.	> 2000 mg/kg	practically non-toxic

<sup>1</sup> Study is supplemental because chukar is not a recommended species for this test.

These results show that tetrachlorvinphos is practically non-toxic to birds. The guideline requirement for the avian acute oral LD<sub>50</sub> study is fulfilled. (MRID # 160000)

**(b) Avian Subacute Dietary Toxicity**

**Table 11 - Avian Subacute Dietary Toxicity Findings**

Species	% Test Material	LC <sub>50</sub>	Conclusions
Bobwhite Quail	96	> 5000 ppm	practically nontoxic
Mallard Duck	96	> 5000 ppm	practically nontoxic

On a subacute dietary basis, tetrachlorvinphos is practically nontoxic to birds. Two studies, one on the mallard duck and one on the bobwhite quail produced LC<sub>50</sub>s > 5000 ppm (MRID # 22923).

**(2) Birds, Chronic**

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive toxicity. These conditions do not apply to the current registered uses of tetrachlorvinphos, therefore, avian reproduction studies are not required at this time.

**(3) Mammals**

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. Data to describe toxicity to wild mammals were not required for tetrachlorvinphos.

**Table 12 - Mammalian Acute Oral Toxicity Findings**

Species	LD <sub>50</sub> (mg/kg)	Conclusion
Rat	1480	slightly toxic

The available mammalian data indicate that tetrachlorvinphos is slightly toxic to small mammals on an acute basis.

As stated in our discussion of the toxicological database above, on a chronic basis, a three-generation reproduction study with rats produced a reproductive NOEL of 330 ppm and an LOEL of 1000 ppm. (MRID # 77802)

**(4) Insects**

A honey bee acute contact LD<sub>50</sub> study is required if the proposed use will result in honey bee exposure. The minimum data required to establish the acute toxicity to honey bees is an acute contact LD<sub>50</sub> study with the technical material. Through the general outdoor treatments, some exposure to honey bees is expected, therefore, these data were required for tetrachlorvinphos.

**Table 13 - Nontarget Insect Acute Contact Toxicity Findings**

Species	% Test Material	LD <sub>50</sub>	Conclusion
<i>Apis mellifera</i>	Technical	1.37 µg/bee	highly toxic

There is sufficient information to characterize tetrachlorvinphos as highly toxic to bees. The guideline requirement is fulfilled (MRID # 36935).

When data from the acute study provide an LD<sub>50</sub> < 11 µg/bee, a foliar residue toxicity study is required.

**Table 14 - Nontarget Insect Foliar Residue Toxicity Findings**

Species	% Test Material	Conclusion
<i>Apis mellifera</i>	2 lb EC	At 1 lb a.i./A, 3 hour old residues caused 4% mortality

Results from this study indicate that tetrachlorvinphos foliar residues remained toxic to honey bees for less than 3 hours. The honey bee foliar residue testing requirement is fulfilled (MRID # 5000837).



**b. Toxicity to Aquatic Animals**

**(1) Freshwater Fish Toxicity**

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

**Table 15 - Freshwater Fish Acute Toxicity Findings**

<b>Species</b>	<b>% Test Material (TGAI)</b>	<b>LC<sub>50</sub></b>	<b>Conclusions</b>
Rainbow trout	75 (formulated product)	0.43 ppm	highly toxic
Bluegill sunfish	94	0.53 ppm	highly toxic
Channel catfish <sup>1</sup>	94	>0.5 ppm	highly toxic

<sup>1</sup> Study is supplemental, because an LC<sub>50</sub> was not determined.

The results of the two 96-hour acute toxicity studies indicate that tetrachlorvinphos is highly toxic to both cold- and warmwater fish. The guideline requirement for acute toxicity testing of the technical ingredient on freshwater fish (warmwater) is fulfilled (MRID # 40098001). However, the requirement for testing the technical pesticide on coldwater fish has not been satisfied. Because of mitigating factors (data are available for other fish species, end use product data are available for rainbow trout, and the likelihood that exposure is minimal), the Agency is not requiring this study.

Formulated product testing on fish has been required because the LC<sub>50</sub> values of the technical pesticide is less than the EEC in the aquatic environment. The results of the 96-hour acute toxicity study with rainbow trout as the test species and with a 75% formulated product indicate that tetrachlorvinphos is highly toxic to freshwater fish (MRID # 40098001).

**(2) Freshwater Invertebrate Toxicity**

The minimum testing required to assess the hazard of a pesticide is a freshwater aquatic invertebrate toxicity test, preferably

using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

**Table 16 - Freshwater Invertebrate Toxicity Findings**

Species	% Test Material (TGAI)	LC <sub>50</sub>	Conclusions
<i>Daphnia magna</i>	99	1.9 ppb	very highly toxic

There is sufficient information to characterize tetrachlorvinphos as very highly toxic to aquatic invertebrates. The guideline requirement is fulfilled (MRID # 41257101).

An aquatic invertebrate life cycle test is required when a product is applied directly to water or is expected to be transported to aquatic sites and 1) exposure of aquatic organisms will be continual or recurrent; or 2) the lowest EC<sub>50</sub> is 1 mg/L or less; or 3) the EEC in water is equal to or greater than 0.01 of any EC<sub>50</sub>; or 4) if the EEC is less than any EC<sub>50</sub> and the product has reproductive effects on, or cumulative effects in aquatic organisms, or has a half-life in water greater than 4 days.

For tetrachlorvinphos, the laboratory EC<sub>50</sub> value is less than 1 mg/L. No acceptable aquatic invertebrate life cycle data are available for tetrachlorvinphos. The requirement was previously reserved pending review of the manure dissipation study. Because no parent compound was found in manure following the feed-through study, data from an aquatic invertebrate life cycle study are not required.

### **(3) Estuarine/Marine Animal Toxicity**

Acute toxicity testing with marine and estuarine organisms is required when an end-use product is intended for direct application to the marine and estuarine environment or is expected to reach this environment in significant concentrations. The uses of tetrachlorvinphos are unlikely to result in exposure to the marine and estuarine environment.

The requirements under this category include a 96-hour LC<sub>50</sub> for an estuarine fish, a 96-hour LC<sub>50</sub> for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

**Table 17 - Estuarine/Marine Acute Toxicity Findings**

<b>Species</b>	<b>% Test Material (TGAI)</b>	<b>LC<sub>50</sub></b>	<b>Conclusions</b>
Eastern oyster embryo larvae	94	> 1000 ppb	moderately toxic
Pink Shrimp	94	280 ppb	very highly toxic
Spot	94	> 1000 ppb	moderately toxic

There is sufficient information to characterize tetrachlorvinphos as highly toxic to marine and estuarine shrimp. No studies were required to fulfill this guideline. However, the submitted studies were reviewed and are considered supplemental. (MRID # 40228401)

**c. Toxicity to Plants**

Terrestrial and aquatic plant testing is not required for tetrachlorvinphos. Non-target plant testing is only required for insecticides if there are reported incidents of adverse effects to non-target plants, which there are not for tetrachlorvinphos.

**2. Environmental Fate**

Environmental fate data requirements are fulfilled except for hydrolysis (161-1). The submitted hydrolysis study is partially acceptable; information on the fate of tetrachlorvinphos is acceptable for acidic (pH 5) and neutral (pH 7) conditions. Clarification has been required from the registrant to characterize the [<sup>14</sup>C] residues in the pH 9 solutions at the 21- and 30-day sampling intervals. The clarification will be used to assess the fate of the primary degradates of tetrachlorvinphos which form during alkaline hydrolysis. The Agency believes the clarification regarding the alkaline (pH 9) hydrolysis study will supply confirmatory data and the attached environmental fate assessment will not change appreciably with the confirmatory data. Sufficient data for a comprehensive qualitative environmental fate assessment of tetrachlorvinphos are available and are summarized below.

**a. Environmental Fate Assessment**

Based on the current information in the environmental fate data base required for reregistration of tetrachlorvinphos, the Agency considers tetrachlorvinphos to be non-persistent and has a mobility that varies from

mobile in coarse-textured, low organic matter soils to relatively immobile in fine-textured soils with 2-3% organic matter. The principal route of dissipation for tetrachlorvinphos is through biotic processes such as microbially-mediated metabolism (aerobic soil metabolism half-life of 4.4 days). Abiotic processes such as hydrolysis are more effective at degrading tetrachlorvinphos under alkaline ( $t_{1/2 @pH 9} = 10$  days) conditions; however, hydrolytic degradation is relatively ineffective at neutral to acid pH conditions ( $t_{1/2 @pH 7} = 30$  days;  $t_{1/2 @pH 5} = 57$  days). Based on the submitted batch equilibrium studies, the mobility of tetrachlorvinphos varies from mobile ( $K_d$ s ranged from 0.6-4.0 mL/g) in coarse-textured soils (e.g., sands, sandy loams with < 1% organic matter) to relatively immobile ( $K_d$ s ranged from 8.2-13.7 mL/g) in fine-textured soils (e.g., loams, silty clays with 2-3% organic matter). Under simulated field conditions, parent tetrachlorvinphos was not detected in manure which had been collected from a beef cow treated with tetrachlorvinphos as a feed additive. Based on the environmental fate assessment for tetrachlorvinphos, the use of tetrachlorvinphos will not, according to current product labeling, create serious detrimental impacts to either ground water or surface water environmental media.

**b. Environmental Chemistry, Fate and Transport**

**Table 18 - Summary of Environmental Chemistry , Fate and Transport Data**

GUIDELINE #	DATA REQUIREMENT	SUMMARY
161-1	Hydrolysis	Hydrolysis is more rapid under alkaline conditions (partially acceptable study). $t_{1/2 @pH 9}$ : 10 days < $t_{1/2 @pH 7}$ : 30 days < $t_{1/2 @pH 5}$ : 57 days
162-1	Aerobic soil metabolism	Nonpersistent; $t_{1/2} = 4.4$ days (Blackoar loam); acceptable study $t_{1/2} < 8$ days (medium loam); supplemental study
163-1	Mobility	Varies from mobile ( $K_d$ s: 0.6-4.0 mL/g) in coarse-textured soils (e.g., sands, sandy loams with < 1% organic matter) to relatively immobile ( $K_d$ s: 8.2-13.7 mL/g) in fine-textured soils (e.g., loams, silty clays with 2-3% organic matter)
164-A-SS	Dissipation of Residue in Livestock Manure	Tetrachlorvinphos administered to a beef cow as a feed additive was not detected in manure which had weathered under simulated field conditions.

**(1) Hydrolysis (161-1)**

Hydrolysis data at pH 5 and 7 indicate that hydrolysis is more rapid under alkaline conditions. Tetrachlorvinphos was

shown to degrade via hydrolysis with the most rapid hydrolytic degradation occurring under alkaline conditions ( $t_{1/2} \approx$  (approximately) 10 days at pH 9;  $t_{1/2} \approx$  30 days at pH 7;  $t_{1/2} \approx$  57 days at pH 5).

The study by Blumhorst (1991) was found partially acceptable for fulfilling the hydrolysis data requirement. The portions of this study conducted at pH 5 and 7 are acceptable. Tetrachlorvinphos degraded with a half-life of 10.3 days in a sterile pH 9, 0.01 M aqueous buffer solution that was incubated in the dark at 25°C; the hydrolytic half-lives were 29.8 and 57.3 days for pH 7 and 5 solutions, respectively, that were incubated under similar conditions. Two major degradates, 1-oxo-1-[2,4,5-trichlorophenyl]-2-hydroxyethane and 1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate (TVDP) (or its cyclic isomer, CTVDP), were identified in the treated buffer solutions. The TVDP/CTVDP isomers were identified only in the pH 9 test solutions with maximum concentrations of  $\approx$ 28% of the applied radioactivity at 21 days which decreased to  $\approx$ 15% of the applied at 30 days. During the study, material balances ranged from 97.6-101.8% of the applied. (MRID # 41929101)

In order for the pH 9 test solution data to contribute towards the fulfillment of the hydrolysis data requirement, the registrant must clarify the discrepancies between the UV and radioactivity detection and must conclusively identify [ $^{14}\text{C}$ ] residues present in the methylene chloride extracts of the 21- and 30-day pH 9 solutions. The clarification will be used to assess the fate of the primary degradates of tetrachlorvinphos which form during alkaline hydrolysis. The Agency believes that clarification regarding the alkaline (pH 9) hydrolysis study will simply supply confirmatory data. The registrant has submitted additional hydrolysis data (MRID # 43663501) to upgrade the existing study, and these data are in review. The overall environmental fate assessment will not change appreciably with the addition of this confirmatory data.

## **(2) Aerobic Soil Metabolism (162-1)**

Tetrachlorvinphos degraded rapidly with a calculated half-life of 4.4 days, in Blackoak loam soil (MO; fine-silty, mixed, mesic Fluvaquentic Haplaquolls) that was incubated in the dark at  $22 \pm 2$  °C and 75% of 0.33 bar moisture capacity. Five degradates were identified. For carbon dioxide, approximately 9% of the applied remained at 302 days post-application. For 2-chloro-1-

(2,4,5-trichlorophenyl)ethanol, a maximum of 14.1% of the applied remained at 7 days post-treatment, decreasing to approximately 0.40% by 60 days post-treatment. For 1-(2,4,5-trichlorophenyl)ethanol, a maximum of 28.3% of the applied remained at 4 days post-treatment, decreasing to approximately 1% of the applied by 302 days post-treatment. For 2,4,5-trichloroacetophenone, a maximum of 50.7% of the applied remained at 60 days post-treatment, decreasing to 19.1% by 302 days post-treatment. For 2,4,5-trichlorobenzoic acid and one or more dichlorobenzoic acid isomers, a maximum of 17.4% of the applied remained at 99 days post-treatment, and decreased to 14.4% of the applied at 302 days post-treatment. In the sterile soil system, tetrachlorvinphos monomethyl ester was the only degradate detected (concentrations remaining ranged from approximately 0.6% of the applied at 3 days post-treatment to a maximum of approximately 4% of the applied at day 31) (MRID #42082401). This study may be upgraded to acceptable by providing information on the aerobic metabolism of phenyl-labeled tetrachlorvinphos in a Blackoar loam soil; however, no further information is required. The information provided in this study and in the study described below provide adequate aerobic soil metabolism data.

A study by Beynon and Wright (1968) provides supplemental data on the aerobic soil metabolism of tetrachlorvinphos in a "medium" loam soil. In this study, vinyl carbon-labeled [<sup>14</sup>C] tetrachlorvinphos (purity unspecified), at 13.4 ppm, degraded with a half-life of < 8 days. Two major degradates, each accounting for ≤28% of the applied in the medium loam soil, were identified as 1-(2,4,5-trichlorophenyl)-2-chloroethan-1-ol (maximum of 28% of the applied at day 16, decreasing to 18% of the applied at 30 days) and 1-(2,4,5-trichlorophenyl)ethan-1-ol (maximum of ≈25% of the applied at day 16 and 30). Additional minor degradates detected were 1-chloroacetyl-2,4,5-trichlorobenzene (<5% at all sampling times), 2,4,5-trichloroacetophenone (maximum of 9% at day 30), and 1-(2,4,5-trichlorophenyl)ethane-diol (<1% at all sampling times). The distribution of the unextractable radioactivity ranged from 23% of the applied at day 8 to a maximum of 33% of the applied at day 30. Data on the clay loam, sandy loam, and peat soil textures were not acceptable because only one sampling period (day 30) was conducted. New data for the three soils (clay loam, sandy loam, peat) are not needed, however, because the other two soils tested (Blackoar loam and "medium" loam) showed tetrachlorvinphos is not persistent (half-lives of 4-8 days). (MRID # 77821)

**(3) Leaching/Adsorption/Desorption (163-1)**

Results of the batch equilibrium tests indicates tetrachlorvinphos is mobile ( $K_d < 1.0$ ) in sandy loam, slightly mobile ( $K_d \leq 5.0$ ) in sand, and relatively immobile ( $K_d > 5.0$ ) in loam and silty clay soils. Reported Freundlich  $K_{ads-des}$  values were 0.60-0.69 for sandy loam (pH = 8.0;  $K_{om} = 1038-1195$ ), 4.04-5.09 for sand (pH = 5.6;  $K_{om} = 871-1097$ ), 8.18-9.04 for loam (pH = 6.1;  $K_{om} = 522-577$ ), and 13.7-13.8 for the silty clay soil (pH = 5.6;  $K_{om} = 1074-1081$ ). Data collected during the batch equilibrium tests suggests that sorption of tetrachlorvinphos probably results from binding to soil organic matter and/or clay.

**Table 19 - Leaching/Adsorption/Desorption Data for Tetrachlorvinphos in 4 Soils**

Soil Texture	Clay (%)	Organic Matter (%)	CEC (meq/100g)	$K_{ads}$ (mL/g)	$K_{des}$ (mL/g)	$K_{ads,om}$ (mL/g)	$K_{des,om}$ (mL/g)
sand	4	0.8	2.0	4.04	5.09	871	1097
sandy loam	7	0.1	8.1	0.60	0.69	1038	1195
loam	14	2.7	10.1	8.18	9.04	522	577
silty clay	40	2.2	21.1	13.7	13.8	1074	1081

This study (Blumhorst, 1990) is acceptable and can be used to fulfill the Mobility by Leaching/Adsorption/Desorption data requirement. However, the  $K_{ds}$  determined in this study may overestimate the mobility of tetrachlorvinphos because of uncertainty regarding the soil/testing solution equilibration time. During preliminary testing, the degradation of tetrachlorvinphos after 24 and 48 hours necessitated establishing a study equilibration time of 4 hours. However, it could not be determined if tetrachlorvinphos had established equilibrium between the soil and water phases at the time of sampling. (MRID # 41681301)

**(4) Dissipation of Residues in Livestock Manure (164-A-SS)**

The standard guideline data requirement Terrestrial Field Dissipation was replaced with the special study Dissipation of Residues in Livestock Manure because tetrachlorvinphos is used primarily as a feed additive for controlling flies associated with livestock, leaving tetrachlorvinphos residues in the feces. The manure dissipation study (Krautter, 1993) was required to assess the

dissipation of tetrachlorvinphos under simulated field conditions. The study measured tetrachlorvinphos and its residues present in manure from a treated beef cow. The manure from treated cows may be applied to agricultural fields prior to planting food crops.

Parent tetrachlorvinphos was not isolated in the compost samples at any sampling interval. Total residues of tetrachlorvinphos [beta isomer, (Z)-2-chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate] did not decline during 6 months of storage from composted manure collected throughout treatment from a cow treated orally at 70.4 mg a.i./100 pounds/day for 14 days. There were several degradates identified in the compost samples. Sixty-nine percent of the radioactivity at day 0 was found in 1-(2,4,5-trichlorophenyl)-ethanol and approximately 40% of the recovered radioactivity at 3 and 6 months sampling times. Seven percent of the radioactivity was recovered as 1-(2,4,5-trichlorophenyl)-2-chloroethanol at day 0, but not detected at 3 and 6 months sampling times. Approximately 10% of the recovered radioactivity was detected as 2,4,5-trichlorobenzoic acid at the 6 month sampling time. Eight additional degradates were isolated from the manure at 0.3 to 5.3 ppm (maximum concentrations of 10% of the recovered radioactivity) but were not identified. The unidentified compounds were not characterized following attempted extraction with strong acid (6N HCl) or strong base (6N NaOH) extractants. Unextracted radioactivity was 9.2% and 23% of the recovered radioactivity at the Day 0 and 6 month sampling times, respectively. (MRID # 42848501)

### **3. Ecological Exposure and Risk Characterization**

#### **a. Exposure and Risk to Nontarget Terrestrial Animals**

Given the use patterns of tetrachlorvinphos, exposure of nontarget terrestrial organisms to tetrachlorvinphos will be minimal. The uses most likely to result in exposure would be the general outdoor and agricultural premise treatments. The maximum application rate for such uses is 1 lb a.i./A.

The Agency's acute toxicity level of concern for an avian or mammalian species is a risk quotient value greater than or equal to 0.5. The risk quotient (RQ) is calculated from the preliminary estimated environmental concentration (EEC) divided by the lowest LC<sub>50</sub> value for birds and mammals. There is a potential for acute risk if the risk quotient is greater than or equal to 0.5.



The maximum concentration of residues of tetrachlorvinphos which may be expected to occur on selected avian or mammalian dietary food items following a single foliar application at two application rates is provided in the table below:

**Table 20 - Residues on Avian and Mammalian Dietary Food Items in PPM**

Use Sites	Application rates (lb a.i./A)	
	0.75	1.0
Range Grasses (short)	180	240
Fruit/Vegetable Leaves	95	125
Forage and Insects	44	58
Seeds	9	12
Fruits	6	7

\* Residue data are from the Kenaga nomograph. Most current reference is Fletcher *et. al.*, 1994.

**(1) Birds**

Avian acute oral or subacute dietary risks are not expected for tetrachlorvinphos. Residues found on dietary food items following a single application of tetrachlorvinphos may be compared to LC<sub>50</sub> values to predict hazard.

Tetrachlorvinphos is practically nontoxic to birds, as indicated by tests conducted on the representative test species, mallard duck, ring-necked pheasant, and chukar. Acute LD<sub>50</sub> and LC<sub>50</sub> values are >2000 mg/kg and >5000 ppm, respectively.

The highest expected environmental concentration is 240 ppm on short range grasses for the maximum application of 1.0 lb of active ingredient per acre (see Table 20).

$$\frac{EEC}{LC_{50}} = \frac{240 \text{ ppm}}{5000 \text{ ppm}} = .05$$

This suggests that tetrachlorvinphos is unlikely to be of risk to birds, from acute oral or subacute dietary exposure.

Because exposure to birds is not expected to be repeated or continuous, chronic effects are not anticipated.

Nonendangered or endangered omnivorous bird species, and bird species that eat only seeds, only insects, or only fruit are also unlikely to be affected (risk quotients less than 0.1).

## (2) Mammals

Acute toxicological data show tetrachlorvinphos to be slightly toxic to mammals on an acute basis (rat  $LD_{50} = 1480$  mg/kg) (MRID # 41222504). In the absence of mammalian  $LC_{50}$  data, hazard assessment will be based on the  $LD_{50}$  value, as follows.

Using the relationship (pesticide residue in the diet (ppm) \* food consumption (kg)/body weight (kg) = mg pesticide/kg/day) (Lehman, 1959), one can determine the amount of daily dietary residue needed to obtain the  $LD_{50}$  of an organism. For example:

- i The food consumption and body weight for a young rat are typically 0.01 kg and 0.1 kg, respectively. Therefore, a young rat consumes food at a rate of 10 % of its body weight on a daily basis.
- ii The  $LD_{50}$  for tetrachlorvinphos to rats is 1480 mg/kg. This represents an  $LC_{50}$  of 148 mg/animal (1480 mg/kg \* 0.1 kg = 148 mg/animal).
- iii To obtain an  $LD_{50}$  of 148 mg/animal a dietary residue of 14,800 ppm is required:

$$\text{ppm} * \text{food consumption (kg)/body weight (kg)} = \text{mg/kg/day}$$

$$\text{ppm} * 0.01 \text{ kg}/0.1 \text{ kg} = 1480 \text{ mg/kg/day}$$

$$\text{ppm} = 14,800$$

The high risk LOC for terrestrial organisms is 0.5. When the acute risk quotient (RQ) ( $RQ = EEC/LC_{50}$ ) reaches, or exceeds, this value (0.5) high risk is presumed. For tetrachlorvinphos, a terrestrial EEC of 7400 ppm is required to obtain 0.5 ( $RQ = 7400 \text{ ppm}/14,800 \text{ ppm} = 0.5$ ).

As can be seen in the residue table above (Table 20), residues at this level will not be found, even following application at the highest rate. Thus, significant acute hazard to mammals is not expected. (Reference: Lehman, A. J. 1959. In: Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics. Association of Food and Drug Officials of the United States. Austin, Texas.)

### **(3) Insects**

Significant risk to non-target insect species is not expected from use of tetrachlorvinphos. For nontarget insects, the honeybee is the representative test species; with an acute contact LD<sub>50</sub> value of 1.37 µg/bee, tetrachlorvinphos is highly toxic to honeybees. However, registered uses of this pesticide are unlikely to result in significant exposure to bees. Hence, an insignificant risk is expected to nontarget insects as a result of exposure to tetrachlorvinphos.

#### **b. Exposure and Risk to Nontarget Aquatic Animals**

Given the use information available for tetrachlorvinphos, exposure of nontarget aquatic organisms to tetrachlorvinphos will be minimal. The uses most likely to result in exposure would be the general outdoor and agricultural premise treatments. Aquatic organisms may be exposed to tetrachlorvinphos via runoff from agricultural premises (e.g., feedlots). The maximum rate for such uses would be 1 lb a.i./A.

Minimal acute risk to aquatic animals is expected. Moreover, chronic risk to aquatic animals is not anticipated because of the relatively low potential for chronic exposure.

The freshwater EEC following application at 1 lb a.i./A would be 30.5 ppb.

For unincorporated ground application

1 lb X 0.05 (5% runoff) X 10 A (from 10 acre drainage basin) = 0.5 lb

\*EEC of 1 lb a.i. direct application to 1 A surface water body 6-feet deep  
= 61 ppm

Therefore, EEC = 61 ppb X 0.5 lb total runoff = 30.5 ppb.

To estimate acute risk to aquatic animals, the Agency compared the risk quotient (EEC of 30.5 ppb/LC<sub>50</sub>) to the level of concern value (greater than or equal to 0.5). The ecotoxicity values used in this risk assessment are: rainbow trout LC<sub>50</sub> = 0.43 ppm and *Daphnia magna* EC<sub>50</sub> = 1.9 ppb. The freshwater fish LOC is exceeded with a risk quotient of 0.07. The aquatic invertebrate LOC is also exceeded with a risk quotient of 16.05, indicating a potential for acute risk to freshwater invertebrates. However, these risks are considered to be minimal because tetrachlorvinphos is used primarily in applications which will not result in exposure to the aquatic environment. The only exposure of concern for tetrachlorvinphos is possible runoff from the manure of treated farm animals. However, the manure dissipation study (see Environmental Fate section) indicates that no tetrachlorvinphos was found in weathered manure following feed-through treatment. Therefore, no acute risk to aquatic organisms is anticipated. Chronic risk to aquatic organisms is not expected because chronic exposure is not expected.

**c. Exposure and Risk to Nontarget Terrestrial, Semi-Aquatic, and Aquatic Plants**

Unless there are known reports of phytotoxicity resulting from the use of a specific insecticide, terrestrial and aquatic plant testing are not required. There are no known incidents of adverse effects to plants resulting from tetrachlorvinphos use that have been reported to the Agency. Therefore, the Agency assumes the potential risk to plants is insignificant.

**d. Endangered Species**

For endangered avian and mammalian species the level of concern is a risk quotient value greater than or equal to 0.1. For endangered aquatic vertebrate and invertebrate species, the LOC is a risk quotient value greater than or equal to 0.05. And for endangered plant species, the LOC is greater than or equal to 1.0.

The Agency believes significant acute and chronic risks to endangered birds and small mammals is not expected. Chronic exposure to birds and small mammals is not expected. For endangered aquatic organisms, acute levels of concern are exceeded for both fish and invertebrate species with risk quotients of 0.07 and 16.05, respectively. However, as noted earlier in the discussion on nonendangered aquatic species, the likelihood of exposure is so low that acute toxicity risk to endangered aquatic organisms is expected to be insignificant. Because chronic exposure is not expected for aquatic organisms, significant chronic toxicity risk to aquatic organisms is not expected.

The Endangered Species Protection Program is expected to become final in 1996. Limitations in the use of tetrachlorvinphos may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

#### **IV. RISK MANAGEMENT AND REREGISTRATION DECISION**

##### **A. Determination of Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing tetrachlorvinphos. The Agency has completed its review of these generic data, and has determined that, based on the information currently available, there are data to support reregistration of all products containing tetrachlorvinphos; however, a reregistration eligibility decision on products registered for livestock feed-through (oral) larvicide uses cannot be made at this time for reasons discussed below. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of tetrachlorvinphos, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of tetrachlorvinphos. The Agency has determined that except for the use as a feed-through larvicide for livestock, tetrachlorvinphos can be used as described in this document without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing tetrachlorvinphos as the sole active ingredient are eligible for reregistration, with the exception of those products labeled for the livestock feed-through use. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, other available information, and the data identified in Appendix B. Although the Agency has found that all uses of tetrachlorvinphos are eligible for reregistration, with the exception of the livestock feed-through use, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of

products containing tetrachlorvinphos, if new information comes to the Agency's attention or if the data requirements for registration or the guidelines for generating such data change.

## **1. Eligibility Decision**

Based on the reviews of the generic data for the active ingredient tetrachlorvinphos, the Agency has sufficient information on the potential health effects of tetrachlorvinphos and on its potential for causing adverse effects in wildlife and the environment. The Agency has determined that tetrachlorvinphos products except those with feed-through larvicide uses, labeled and used as specified in this RED document will not pose unreasonable risks to humans or the environment. However, the Agency cannot make a determination as to the eligibility of the use of tetrachlorvinphos as a livestock feed-through larvicide, for the reason discussed below. Therefore, the Agency considers that products containing tetrachlorvinphos for all uses except the livestock feed-through use are eligible for reregistration.

The feed additive tolerance regulations which cover residues of tetrachlorvinphos in livestock feeds for the feed-through use have been proposed for revocation. The Delaney clause of Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) prohibits the Agency from approving food or feed additive tolerances for a chemical that induces cancer in animals or humans within the meaning of the Delaney clause. The Agency cannot make a determination with regard to the eligibility of the livestock feed-through use because EPA has not made a final determination on the proposed revocation and EPA is currently reevaluating how it will coordinate its actions under the FFDCA and FIFRA. This issue is discussed in greater detail below in the Regulatory Position section of this document.

## **2. Eligible Uses**

The domestic animal and agricultural premise treatments, general outdoor/recreational area uses, uses on horses (provided labels restrict use from horses meant for slaughter), dermal applications to livestock, and pet uses are eligible for reregistration.

The Agency cannot make a determination as to the eligibility of the use of tetrachlorvinphos as a livestock feed-through larvicide, for the reason discussed below.

## **B. Regulatory Position**

The following is the regulatory position and rationale for the reregistration eligibility decision for tetrachlorvinphos. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

### **1. Tolerance Reassessment**

As part of its reregistration eligibility decision, the Agency reassessed the tolerances of tetrachlorvinphos residues in or on food or feed commodities. The purpose of this reassessment was to determine whether the uses of currently registered tetrachlorvinphos products are adequately and appropriately supported by residue tolerances as required under the FFDCA. Where deficiencies are noted, the Agency presents a course of appropriate action to resolve the deficiencies. A summary analysis of the current tolerances is presented in Table 21 after the following discussion.

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 rate of 0.00015 lb per 100 lb body weight per day for beef and dairy cattle and horses, and 0.00011 lb per 100 lb of body weight per day for swine (40 CFR §186.950).

The chemical name of tetrachlorvinphos as specified in 40 CFR §180.252 and §186.950, "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**

Currently, the tolerances specified for the raw agricultural commodities (RACs) 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 also be regulated. The tolerance definition should therefore be revised to include the residues of these four metabolites of tetrachlorvinphos.

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). In October, 1993, the Agency required registrants to submit new studies reflecting oral and dermal exposure of beef cattle,

dairy cattle, and hogs, and dermal exposure of poultry to tetrachlorvinphos. The Agency required the registrants to analyze all residues of concern in cattle, hogs, and poultry using validated analytical methods. These data are due by April, 1996.

Currently, there are not any registered tetrachlorvinphos products for use on plants. All uses on food or feed plant commodities were voluntarily canceled in 1987. The established tolerances for alfalfa; apples; cherries; field corn fodder and forage; fresh corn (kernel plus cob with husks removed (K+CWHR)); corn grain; pop corn fodder and forage; sweet corn (K+CWHR); sweet corn fodder and forage; cranberries; peaches; pears; and tomatoes should therefore be revoked. The Agency published notice of the proposed revocation in the Federal Register. Refer to "Tetrachlorvinphos, Terbutrin, and Etridiazole; removals"; Federal Register, Volume 59, No. 138, July 20, 1994.

#### **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, hogs and horses for control of fecal flies in manure of these animals.

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 have been required. Because of the proposal to revoke feed additive tolerances (described below), the Agency has deferred the requirement for the submission of new residue studies reflecting oral exposure to tetrachlorvinphos. However, residue data for dermal uses remain required because the Agency is concerned about residues from tetrachlorvinphos from dermal uses. All residues of concern should be analyzed in cattle, hogs, and poultry using validated analytical methods.

As noted previously, in 60FR 49141 published September 21, 1995, the Agency has proposed to revoke the feed additive tolerance set at 40 CFR § 186.950 due to the Delaney clause of FFDCA. This clause prohibits the establishment of a regulation for any food/feed additive that is found to induce cancer in man or animals. The Ninth Circuit Court of Appeals ruled in July 1992 that the Agency must interpret this provision strictly. Therefore, since EPA has concluded that tetrachlorvinphos is an animal carcinogen within the meaning of the Delaney clause, EPA has proposed to revoke the animal feed additive tolerance. Further, under



current Agency policy if a needed food/feed additive tolerance cannot be continued, EPA will neither register nor leave in effect a registration under FIFRA for the associated use. EPA is currently reevaluating this policy and a decision is expected by the end of 1995. Once EPA makes a decision on this policy and a final determination on the proposed revocation, a determination on the eligibility of the livestock feed-through use will be made.

**Table 21 - Tolerance Reassessment Summary**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment	
<b>Tolerances listed under 40 CFR §180.252</b>				
Alfalfa	110.0	Revoke	No registered uses exist.	
Apples	10.0	Revoke		
Cattle, fat	1.5	TBD <sup>a</sup>	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, mbyop	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, mbyop	None	TBD		
Hogs, fat	1.5	TBD		
Hog, meat	None	TBD		
Hog, mbyop	None	TBD		

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
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, mbyop	None	Revoke	
Milk, fat (N) <sup>b</sup>	0.5	TBD	See comment above referring to additional data required.
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, mbyop	None	TBD	
Sheep, fat	0.5	Revoke	No registered uses exist.
Sheep, meat	None	Revoke	
Sheep, mbyop	None	Revoke	
Tomatoes	5.0	Revoke	No registered uses exist.
<b>Tolerances listed under 40 CFR §186.950</b>			
Feed items (feed additive regulation)	--	Revoke	Delaney clause Policy - carcinogens in animal feeds

<sup>a</sup> TBD = To Be Determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.

<sup>b</sup> Reflecting negligible residues in whole milk.

### **CODEX Harmonization**

There are no Codex maximum residue limits (MRLs) established or proposed for residues of tetrachlorvinphos. Therefore, there are no issues with respect to compatibility of U.S. tolerances with Codex MRLs.

## **2. Human Health Risks and Eligibility**

All uses of tetrachlorvinphos, with the exception of the oral livestock larvicide use, are eligible for reregistration. Although there are risks posed by the carcinogenic potential of this compound from dietary and occupational/residential exposure, these risks are considered to be within an acceptable range for regulatory purposes.

### **a. Dietary Risk**

Both chronic systemic, and carcinogenic dietary risks were calculated (see Section III.B.3.). These risks appear to be minimal when only uses supported for reregistration are included in the assessment.

For the U.S. population, the upperbound carcinogenic risk was calculated using anticipated residues for meat, milk, poultry, and eggs and refined by percent livestock treated estimates. The carcinogenic risk for all published and supported uses was  $4.3 \times 10^{-5}$ . This assumes that 100% of the fruit and vegetable commodities consumed are imported and contain tetrachlorvinphos at tolerance levels. However, only meat, milk, poultry, and eggs are supported for reregistration. When only these commodities are considered the dietary cancer risk is  $1 \times 10^{-6}$ .

When dietary risk from chronic systemic effects was assessed, the calculated percent RfD for the U.S. population was 59%. When only the anticipated residues from supported uses were included, the percent RfD for the U.S. population is 1%.

The Agency is proceeding to revoke the feed additive tolerances as required by the Delaney clause. When these tolerances are revoked and the uses removed from labeling, the risk will change. It is not possible to estimate the amount that the risk would be reduced or increased since it is possible that some users of tetrachlorvinphos would switch from a feed-through application to a dermal application.

#### **b. Worker Risk**

Table 9, *Risk Estimates for Occupational/Residential uses of Tetrachlorvinphos*, presents the upper bound carcinogenic risk for mixers/loaders/applicators from exposure to tetrachlorvinphos products for ten different use scenarios. The highest calculated risk is for the low pressure handwand scenario which is  $1.3 \times 10^{-5}$ . This is below the Agency's  $10^{-4}$  level of concern for worker exposure.

The Agency lacks data to evaluate the risks in three worker exposure scenarios: dusters, pellets, and impregnating material. The Agency believes that the uses of low-pressure handwands and power sprayers represent worst-case exposure scenarios (due to the nature of a spraying operation) for the current uses of tetrachlorvinphos. Since risks to workers under these worst-case scenarios do not exceed the Agency's level of concern, it is not likely that exposures resulting from applications of dusts, pellets, or impregnating materials will exceed the Agency's level of concern.

To minimize worker exposure and reduce the risk to handlers, baseline PPE are set through this document: long-sleeved shirt, long pants, socks and shoes, and chemical-resistant gloves. The Agency expects that these PPEs will adequately protect workers from exposures to

tetrachlorvinphos. The use of chemical-resistant gloves in the PPE for applicators using low pressure handwands should further reduce the potential carcinogenic risk.

**c. Homeowner Risk**

Although there is the potential for homeowner exposures to tetrachlorvinphos, it is unlikely that homeowners would experience significant exposure resulting from the uses described below.

impregnated flea collars for pets

Homeowners would experience transient and brief exposures from application of these flea collars to pets.

aerosols and dust shakers

Tetrachlorvinphos products formulated as aerosols and dusts are intended for spot applications and do not pose significant exposure to homeowners.

Similarly, reentry exposures to homeowners from these uses, including the pet dusts and collars are expected to be minimal. Reentry restrictions for homeowners are not warranted.

**3. Domestic Animal Safety**

Tetrachlorvinphos may be applied directly to dogs and cats to control fleas. Data submitted to describe cholinesterase inhibition from formulated products suggests there is little risk to pets from these applications.

**4. Labeling Rationale/Risk Mitigation**

**a. Personal Protection Equipment (PPE) Requirements**

**(1) PPE for Handlers (Mixer/Loader/Applicators)  
Occupational Use Products**

The Agency has concerns of potential carcinogenic and chronic risk to workers from exposure to tetrachlorvinphos. Because of this and since there are no engineering control requirements, such as closed systems, currently on product labeling of tetrachlorvinphos products which would mitigate exposures to handlers, the Agency is establishing minimum or "baseline" handler

PPE requirements for all occupational end-use products (not intended for homeowner use) containing this active ingredient.

The minimum (baseline) PPE requirements for handlers of all end-use products primarily intended for occupational use of tetrachlorvinphos are: chemical-resistant gloves and long-sleeved shirt and long pants, socks and shoes for all handlers.

These minimum PPE requirements must then be compared with the PPE that the Agency will designate on the basis of the acute toxicity of each end-use product. The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must then be placed on the label of the end-use product to be reregistered.

**(2) Handler PPE for Homeowner-Use Products**

There are several products containing tetrachlorvinphos that are intended primarily for homeowner use (impregnated pet collar, aerosol can, and dust shaker). At this time the Agency will not establish minimum (baseline) PPE for homeowner-use products based on toxicity of tetrachlorvinphos *per se*, since the Agency believes exposures are likely to be much less than those from occupational uses.

**b. Entry Restrictions**

**(1) Entry Restrictions for Occupational-Use Products**

The Agency is not establishing entry restrictions for uses of occupational-use products on livestock, poultry, or other commercial animals, since entry restrictions for these uses are impractical or probably unnecessary. However, for uses of occupational-use products on recreational sites, the Agency is establishing an entry restriction for liquid application. This restriction requires that sprays have dried before entering treated areas.

**(2) Entry Restrictions for Homeowner-Use Products**

At this time the Agency will not establish entry restrictions for indoor homeowner-use products, since entry restrictions for such uses as formulated for homeowner use (i.e., impregnated collar, aerosol can, and dust shaker) are not necessary due to very low exposure.

**c. Product Specific Labeling Changes**

A label amendment is required to prohibit treatment of horses destined for slaughter. Uses on horses for slaughter and the resulting potential for residues in these tissues have not have not been supported with the submission of data.

Label amendments are required in the use directions to clarify that weights of pesticide to be added to feed refer to weights of active ingredient and not weights of product in order to avoid confusion in dosing.

In addition, because tetrachlorvinphos is classified as a skin sensitizer, the Agency is requiring a warning statement be placed on labels.

**5. Endangered Species Statement**

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement, requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in 1996. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

**V. ACTIONS REQUIRED BY REGISTRANTS**

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

**A. Manufacturing-Use Products**

**1. Additional Generic Data Requirements**

The generic data base supporting the reregistration of tetrachlorvinphos for the above eligible uses has been reviewed and determined to be substantially

complete. However, the Agency has required the submission of additional data as confirmatory information. Analytical methods and data to describe the residues of tetrachlorvinphos and its regulated metabolites for cattle, hogs, and poultry are required. These data have been required and their due dates are listed below.

<u>Guideline No.</u>	<u>Study Name</u>	<u>Due Date</u>
171-4(d)	Residue Analytical Methods	4/30/96
171-4(j)	Magnitude of the Residue in Dermally-Treated Cattle and Poultry	4/30/96

Because of the feed additive tolerance issue with the Delaney clause the requirement for the livestock residue data for the feed-through use oral exposure is deferred.

Data are also required to upgrade the Mixer/Loader/Applicator study, (MRID # 42622301). These data must supply information to verify the storage duration of the field samples versus the field recovery samples.

## **B. End-Use Products**

### **1. Additional Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

### **2. General Labeling Requirements for Products**

#### **a. All Products**

Because tetrachlorvinphos is classified as a skin sensitizer, the Agency requires that the following statement appear on all tetrachlorvinphos

labels in the "Hazards to Humans (and Domestic Animals)" section of the Precautionary Statements:

"This product may cause skin sensitization reactions in certain individuals."

**b. Products Intended Primarily for Occupational Use**

The Agency is requiring the following labeling statements to be located on all end-use products containing tetrachlorvinphos that are intended primarily for occupational use:

(1) Application Restrictions:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

(2) User Safety Requirements:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

(3) User Safety Recommendations:

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."
- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."



**c. Occupational Products Used in Recreational Areas**

The following entry restriction must be added to the labels of all products used occupationally in recreational areas:

For Liquid Application:

"Do not enter or allow others to enter the treated area until sprays have dried."

**d. Products with Feed-Through Uses**

All products labeled for use on horses (currently EPA Reg. No. 56493-35) must have the following restriction:

"This product is not to be used on horses destined for slaughter."

Labels of all products with directions for use as a feed-through for livestock (currently EPA Reg. Nos. 56493-34 and 56493-35) must be clarified so that weights of pesticide to be added to feed refer to weights of active ingredient and not weights of product.

**C. Existing Stocks**

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell tetrachlorvinphos products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.



## **VI. APPENDICES**



SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. /crop /year	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES

BARNYARDS/AUCTION BARNYARDS Use Group: INDOOR FOOD

Enclosed premise treatment., When needed., Knapsack sprayer.	EC	NA	.3233 lb 1K sq.ft	* NS NS	NS NS	NS NS	NS NS	NS NS			CAE
	WP	NA	.3333 lb 1K sq.ft	* NS NS	NS NS	NS NS	NS NS	NS NS			CAE
	WP/D	NA	.3333 lb 1K sq.ft	* NS NS	NS NS	NS NS	NS NS	NS NS			CAC, CAG
	WP/D	NA	.3333 lb 1K sq.ft	* NS NS	NS NS	NS NS	NS NS	NS NS			CAE
Enclosed premise treatment., When needed., Power sprayer.	EC	NA	.3233 lb 1K sq.ft	* NS NS	NS NS	NS NS	NS NS	NS NS			CAE
	WP	NA	.3333 lb 1K sq.ft	* NS NS	NS NS	NS NS	NS NS	NS NS			CAE
	WP/D	NA	.3333 lb 1K sq.ft	* NS NS	NS NS	NS NS	NS NS	NS NS			CAE

BEEF/RANGE/FEEDER CATTLE (MEAT) Use Group: INDOOR FOOD

Animal treatment (back rubber)., When needed., Hand held sprayer.	EC	NA		UC * NS NS	NS NS	NS NS	10 NS	NS NS			CAD
Animal treatment (dust)., When needed., Dust bag.	D	NA		UC * NS NS	NS NS	NS NS	1 NS	NS NS			CAC
	D	NA		UC * NS NS	NS NS	NS NS	NS NS	NS NS			
	D	NA		UC * NS NS	NS NS	NS NS	NS NS	NS NS			CAC
	D	NA		UC * NS NS	NS NS	NS NS	NS NS	NS NS			CAE
Animal treatment (dust)., When needed., Rotary duster.	D	NA	.00375 lb animal	* NS NS	NS NS	NS NS	1 NS	NS NS			CAC
	D	NA	.0075 lb animal	* NS NS	NS NS	NS NS	NS NS	NS NS			
	D	NA	.00375 lb animal	* NS NS	NS NS	NS NS	NS NS	NS NS			CAC
	D	NA	.00375 lb animal	* NS NS	NS NS	NS NS	NS NS	NS NS			CAE
Animal treatment (dust)., When needed., Shaker can.	D	NA	.00375 lb animal	* NS NS	NS NS	NS NS	1 NS	NS NS			CAC
	D	NA	.0075 lb animal	* NS NS	NS NS	NS NS	NS NS	NS NS			
	D	NA	.00375 lb animal	* NS NS	NS NS	NS NS	NS NS	NS NS			CAC

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

BEEF/RANGE/FEEDER CATTLE (MEAT) (con't) Use Group: INDOOR FOOD (con't)

	D	NA	.00375 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (face rubber).. When needed., Hand held sprayer.	EC	NA		UC * NS NS	NS	NS	10	NS			CAD
Animal treatment (spray).. Not on label., Knapsack sprayer.	EC	NA	.03988 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAD
Animal treatment (spray).. Not on label., Power sprayer.	EC	NA	.03988 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAD
Animal treatment (spray).. When needed., Knapsack sprayer.	EC	NA	.03984 lb animal	* NS NS	NS	NS	10	NS			CAD
	WP	NA	.04167 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	
	WP	NA	.04 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAE
	WP/D	NA	.04167 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (spray).. When needed., Power sprayer.	EC	NA	.03984 lb animal	* NS NS	NS	NS	10	NS			CAD
	WP	NA	.04167 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	
	WP	NA	.04 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAE
	WP/D	NA	.04167 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAE
Animal treatment.. When needed., Knapsack sprayer.	EC	NA	.04209 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAE
Animal treatment.. When needed., Power sprayer.	EC	NA	.04209 lb animal	* NS NS	NS	NS	NS	NS	NS	NS	CAE
Back rubber. Use code ATK., When needed., By hand.	RTU	NA		UC * NS NS	NS	NS	NS	NS	NS	NS	CAC
Back rubber. Use code ATK., When needed., Not applicable.	EC	NA	.003988 lb linear ft	* NS NS	NS	NS	NS	NS	NS	NS	CAD
Ear tag. Use code ATO., When needed., Pliers.	IMPR	NA	.009061 lb animal	* NS NS	NS	NS	AN	NS			S09(0)
Enclosed premise treatment.. When needed., Knapsack sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS NS	NS	NS	NS	NS	NS	NS	CAD

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

BEEF/RANGE/FEEDER CATTLE (MEAT) (con't) Use Group: INDOOR FOOD (con't)

Enclosed premise treatment., When needed., Power sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAD
Face rubber. Use code ATR, When needed., Not applicable.	EC	NA	.003988 lb linear ft	* NS	NS	NS	NS	NS	NS	NS	CAD
Feed through., When needed., By hand.	G	NA	.198 lb ton	* NS	NS	NS	NS	NS	NS	NS	CAC
Feed through., When needed., Not on label.	FM?	NA	UC	* NS	NS	NS	NS	1	NS		
	G	NA	NA 1.595E-04 lb 100 lb body wt 1.500E-06 lb lb body wt	* NS *	NS	NS	NS	NS	1	NS	
	G	NA	1.309E-06 lb 100 lb body wt 1.929E-08 lb lb body wt	* NS *	NS	NS	NS	NS	1	NS	C93
	G	NA	UC 1.543E-08 lb lb body wt	* NS *	NS	NS	NS	NS	1	NS	CAA
	G	NA	1.550E-06 lb lb body wt	* NS	NS	NS	NS	NS	1	NS	CAC
	G	NA	3.387E-07 lb lb body wt	* NS	NS	NS	NS	NS	1	NS	CAE
	G	NA	.004631 lb 100 lb body wt 2.120E-08 lb lb body wt	* NS *	NS	NS	NS	NS	7	NS	
	G	NA	3.387E-07 lb lb body wt	* NS	NS	NS	NS	NS	NS	NS	
	G	NA	.198 lb ton	* NS	NS	NS	NS	NS	NS	NS	CAC
	P/T	NA	UC 1.543E-08 lb lb body wt	* NS *	NS	NS	NS	NS	1	NS	

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

BEEF/RANGE/FEEDER CATTLE (MEAT) (con't)		Use Group: INDOOR FOOD (con't)									
	P/T	NA	1.157E-08 lb lb body wt	*	NS	NS	NS	NS	1	NS	C93
	P/T	NA	4.630E-09 lb lb body wt	*	NS	NS	NS	NS	1	NS	CAA
	P/T	NA	1.235E-08 lb lb body wt	*	NS	NS	NS	NS	1	NS	CAC
	P/T	NA	UC	*	NS	NS	NS	NS	NS	NS	
Manure treatment. Use site code 40001., When needed., Knapsack sprayer.	EC	NA	.79764 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	CAD
Manure treatment. Use site code 40001., When needed., Power sprayer.	EC	NA	.79764 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	CAD
CALVES (MEAT)		Use Group: INDOOR FOOD									
Enclosed premise treatment., When needed., Knapsack sprayer.	EC	NA	.3233 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	CAE
Enclosed premise treatment., When needed., Power sprayer.	EC	NA	.3233 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	CAE
DAIRY CATTLE (LACTATING OR UNSPECIFIED)		Use Group: INDOOR FOOD									
Animal treatment (back rubber)., When needed., Hand held sprayer.	EC	NA	UC	*	NS	NS	NS	NS	NS	NS	CAD
Animal treatment (dust)., When needed., Dust bag.	D	NA	UC	*	NS	NS	NS	NS	1	NS	CAC
	D	NA	UC	*	NS	NS	NS	NS	1	NS	CAE
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	CAC
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Hand held duster.	D	NA	.0075 lb animal	*	NS	NS	NS	NS	NS	NS	
Animal treatment (dust)., When needed., Rotary duster.	D	NA	.00375 lb animal	*	NS	NS	NS	NS	1	NS	



SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

DAIRY CATTLE (LACTATING OR UNSPECIFIED) (con't) Use Group: INDOOR FOOD (con't)

	D	NA	.00375 lb animal	* NS	NS	NS	NS	1	NS	CAC
	D	NA	.00375 lb animal	* NS	NS	NS	NS	1	NS	CAE
	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	CAC
	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Shaker can.	D	NA	.00375 lb animal	* NS	NS	NS	NS	1	NS	
	D	NA	.00375 lb animal	* NS	NS	NS	NS	1	NS	CAC
	D	NA	.00375 lb animal	* NS	NS	NS	NS	1	NS	CAE
	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	CAC
	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (face rubber)., When needed., Hand held sprayer.	EC	NA	UC	* NS	NS	NS	NS	NS	NS	CAD
Animal treatment (spray)., Not on label., Knapsack sprayer.	EC	NA	UC .04985 lb animal	* NS	NS	NS	NS	NS	NS	CAD
Animal treatment (spray)., Not on label., Power sprayer.	EC	NA	UC	* NS	NS	NS	NS	NS	NS	CAD
Animal treatment (spray)., When needed., Power sprayer.	EC	NA	UC	* NS	NS	NS	NS	NS	NS	CAD
Back rubber. Use code ATK., When needed., By hand.	RTU	NA	UC	* NS	NS	NS	NS	NS	NS	CAC
Back rubber. Use code ATK., When needed., Not applicable.	EC	NA	.003988 lb linear ft	* NS	NS	NS	NS	NS	NS	CAD
Ear tag. Use code ATO., When needed., Pliers.	IMPR	NA	.009061 lb animal	* NS	NS	NS	NS	AN	NS	S09(0)
Enclosed premise treatment., When needed., Knapsack sprayer.	EC	NA	.3191 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	CAD

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

DAIRY CATTLE (LACTATING OR UNSPECIFIED) (con't) Use Group: INDOOR FOOD (con't)

	EC	NA	.3233 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	CAE
	WP	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	
	WP/D	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	7	NS	CAC, CAG
Enclosed premise treatment., When needed., Power sprayer.	EC	NA	.3191 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	CAD
	EC	NA	.3233 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	CAE
	WP	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	
	WP/D	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	7	NS	CAC, CAG
Face rubber. Use code ATR, When needed., Not applicable.	EC	NA	.003988 lb linear ft	* NS	NS	NS	NS	NS	NS	CAD
Feed through., When needed., By hand.	G	NA	.198 lb ton	* NS	NS	NS	NS	1	NS	CAC
Feed through., When needed., Not on label.	FM?	NA	UC	* NS	NS	NS	NS	1	NS	
	G	NA	NA	* NS	NS	NS	NS	1	NS	
			.004631 lb 100 lb body wt	*						
			1.500E-06 lb lb body wt	*						
	G	NA	1.309E-06 lb 100 lb body wt	* NS	NS	NS	NS	1	NS	C93
			1.198E-07 lb lb body wt	*						
	G	NA	UC	* NS	NS	NS	NS	1	NS	CAA
			1.543E-08 lb lb body wt	*						
	G	NA	3.387E-07 lb lb body wt	* NS	NS	NS	NS	1	NS	CAC
			.198 lb ton	*						
	G	NA	3.387E-07 lb lb body wt	* NS	NS	NS	NS	1	NS	CAE

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

DAIRY CATTLE (LACTATING OR UNSPECIFIED) (con't) Use Group: INDOOR FOOD (con't)

G	NA	2.120E-08 lb lb	body wt	*	NS	NS	NS	NS	7	NS	
G	NA	1.476E-04 lb 100	lb body wt	*	NS	NS	NS	NS	NS	NS	
		.001595 lb animal		*							
		3.387E-07 lb lb	body wt	*							
P/T	NA	1.543E-08 lb lb	UC body wt	*	NS	NS	NS	NS	1	NS	
P/T	NA	1.929E-08 lb lb	body wt	*	NS	NS	NS	NS	1	NS	C93
P/T	NA	4.630E-09 lb lb	body wt	*	NS	NS	NS	NS	1	NS	CAA
P/T	NA	1.235E-08 lb lb	body wt	*	NS	NS	NS	NS	1	NS	CAC
Manure treatment. Use site code 40001., When needed., Knapsack sprayer.	EC	NA	.79764 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	CAD
	WP/D	NA	.8333 lb 1K sq.ft	*	NS	NS	NS	NS	7	NS	CAC, CAG
Manure treatment. Use site code 40001., When needed., Power sprayer.	WP/D	NA	.8333 lb 1K sq.ft	*	NS	NS	NS	NS	7	NS	CAC, CAG

EGG HANDLING ROOMS (COMMERCIAL) Use Group: INDOOR FOOD

Enclosed premise treatment., When needed., Duster.	WP/D	NA	UC	*	NS	NS	NS	NS	NS	NS	CAC, CAG
Enclosed premise treatment., When needed., Knapsack sprayer.	WP/D	NA	.08333 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	CAC, CAG
Enclosed premise treatment., When needed., Power sprayer.	WP/D	NA	.08333 lb 1K sq.ft	*	NS	NS	NS	NS	NS	NS	CAC, CAG

HOG/PIG/SWINE (MEAT) Use Group: INDOOR FOOD

Animal bedding/litter treatment., When needed., Hand held duster.	D	NA	.2 lb 1K sq.ft	*	NS	NS	NS	NS	14	NS	
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SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

HOG/PIG/SWINE (MEAT) (con't)

Use Group: INDOOR FOOD (con't)

	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAE
Animal bedding/litter treatment., When needed., Power duster.	D	NA	.2 lb 1K sq.ft	* NS	NS	NS	NS	1	NS		CAC
	D	NA	.2 lb 1K sq.ft	* NS	NS	NS	NS	14	NS		
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAE
Animal treatment (dust)., When needed., Hand held duster.	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAE
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAE
Animal treatment (dust)., When needed., Power duster.	D	NA	.0075 lb animal	* NS	NS	NS	NS	1	NS		CAC
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAC
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAE
	D	NA	UC	* NS	NS	NS	NS	NS	NS		CAE
Animal treatment (dust)., When needed., Rotary duster.	D	NA	.0075 lb animal	* NS	NS	NS	NS	1	NS		
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAC
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAE
Animal treatment (dust)., When needed., Shaker can.	D	NA	.0075 lb animal	* NS	NS	NS	NS	1	NS		
	D	NA	.0075 lb animal	* NS	NS	NS	NS	14	NS		CAC
	D	NA	.0075 lb animal	* NS	NS	NS	NS	NS	NS		CAE
Animal treatment (spray)., Not on label., EC Knapsack sprayer.	NA	NA	.01992 lb animal	* NS	NS	NS	NS	14	NS		CAD
Animal treatment (spray)., Not on label., EC Power sprayer.	NA	NA	.01992 lb animal	* NS	NS	NS	NS	14	NS		CAD

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

HOG/PIG/SWINE (MEAT) (con't)

Use Group: INDOOR FOOD (con't)

Animal treatment (spray).. When needed., Knapsack sprayer.	WP	NA	.02083 lb animal	* NS	NS	NS	NS	14	NS		
	WP	NA	.02 lb animal	* NS	NS	NS	NS	14	NS		CAE
	WP/D	NA	.02083 lb animal	* NS	NS	NS	NS	NS	NS		CAE
Animal treatment (spray).. When needed., Power sprayer.	WP	NA	.02083 lb animal	* NS	NS	NS	NS	14	NS		
	WP	NA	.02 lb animal	* NS	NS	NS	NS	14	NS		CAE
	WP/D	NA	.02083 lb animal	* NS	NS	NS	NS	NS	NS		CAE
Animal treatment.. When needed., Knapsack sprayer.	EC	NA	.02105 lb animal	* NS	NS	NS	NS	14	NS		CAE
Animal treatment.. When needed., Power sprayer.	EC	NA	.02105 lb animal	* NS	NS	NS	NS	14	NS		CAE
Enclosed premise treatment.. When needed., Knapsack sprayer.	EC	NA	.3233 lb 1K sq.ft	* NS	NS	NS	NS	14	NS		CAE
	EC	NA	.3191 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAD
	WP/D	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAC, CAG
Enclosed premise treatment.. When needed., Power sprayer.	EC	NA	.3233 lb 1K sq.ft	* NS	NS	NS	NS	14	NS		CAE
	EC	NA	.3191 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAD
	WP/D	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAC, CAG
Feed through.. When needed., By hand.	G	NA	.198 lb ton	* NS	NS	NS	NS	1	NS		CAC
Feed through.. When needed., Not on label.	G	NA	UC 4.653E-05 lb animal	* NS *	NS	NS	NS	1	NS		
	G	NA	UC	* NS	NS	NS	NS	1	NS		C93
	G	NA	UC 4.653E-05 lb animal .198 lb ton	* NS *	NS	NS	NS	1	NS		CAC

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

HOG/PIG/SWINE (MEAT) (con't)

Use Group: INDOOR FOOD (con't)

	G	NA		UC	* NS NS	NS	NS	1	NS		CAE
	G	NA		UC	* NS NS	NS	NS	NS	NS		
Litter and bedding treatment. Use code AAL., When needed., Hand held duster.	D	NA	.2 lb 1K sq.ft	*	NS NS	NS	NS	14	NS		CAE
Litter and bedding treatment. Use code AAL., When needed., Power duster.	D	NA	.2 lb 1K sq.ft	*	NS NS	NS	NS	14	NS		
	D	NA	.2 lb 1K sq.ft	*	NS NS	NS	NS	14	NS		CAE
Litter and bedding treatment. Use code AAL., When needed., Rotary duster.	D	NA	.2 lb 1K sq.ft	*	NS NS	NS	NS	14	NS		CAC
	D	NA	.2 lb 1K sq.ft	*	NS NS	NS	NS	14	NS		CAE
Litter and bedding treatment. Use code AAL., When needed., Shaker can.	D	NA	.2 lb 1K sq.ft	*	NS NS	NS	NS	14	NS		CAC
	D	NA	.2 lb 1K sq.ft	*	NS NS	NS	NS	14	NS		CAE
Manure treatment. Use site code 40001., When needed., Knapsack sprayer.	EC	NA	.79764 lb 1K sq.ft	*	NS NS	NS	NS	NS	NS		CAD
Manure treatment. Use site code 40001., When needed., Power sprayer.	EC	NA	.79764 lb 1K sq.ft	*	NS NS	NS	NS	NS	NS		CAD

POULTRY (EGG/MEAT)

Use Group: INDOOR FOOD

Animal equipment treatment., When needed., Paintbrush.	D	NA	2.4 lb 1K ft	*	NS NS	NS	NS	14	NS		CAE
	D	NA	2.4 lb 1K ft 2.4 lb 1K sq.ft	*	NS NS	NS	NS	NS	NS		
	D	NA	.3 lb 1K ft	*	NS NS	NS	NS	NS	NS		CAC
	D	NA	2.4 lb 1K ft	*	NS NS	NS	NS	NS	NS		CAE
	WP	NA	.1 lb 1K ft	*	NS NS	NS	NS	NS	NS		CAE
	WP/D	NA	.1042 lb 1K ft	*	NS NS	NS	NS	NS	NS		CAE
Animal treatment (dust)., When needed., Dust box.	D	NA	.0006 lb bird	*	NS NS	NS	NS	NS	NS		

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

POULTRY (EGG/MEAT) (con't) Use Group: INDOOR FOOD (con't)

	D	NA	.0006 lb bird	* NS	NS	NS	NS	NS	NS	CAC
	D	NA	.0006 lb bird	* NS	NS	NS	NS	NS	NS	CAE
	WP	NA	.15625 lb 100 birds	* NS	NS	NS	NS	NS	NS	CAE
	WP/D	NA	.15625 lb 100 birds	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Rotary duster.	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	1	NS	CAC
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	14	NS	CAC
	D	NA	.009999 lb 100 birds .0001 lb bird	* NS	NS	NS	NS	14	NS	CAE
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	NS	NS	
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Shaker can.	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	1	NS	CAC
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	14	NS	CAC
	D	NA	.009999 lb 100 birds .0001 lb bird	* NS	NS	NS	NS	14	NS	CAE
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	NS	NS	
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (spray)., When needed., Knapsack sprayer.	EC	NA	3.988E-04 lb bird	* NS	NS	NS	NS	14	NS	CAD
	WP	NA	.0004 lb bird	* NS	NS	NS	NS	14	NS	CAE

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

POULTRY (EGG/MEAT) (con't)

Use Group: INDOOR FOOD (con't)

	WP/D	NA	.005 gal bird	* NS	NS	NS	NS	14	NS		CAE
Animal treatment (spray) ., When needed ., Power sprayer.	EC	NA	3.988E-04 lb bird	* NS	NS	NS	NS	14	NS		CAD
	WP	NA	.0004 lb bird	* NS	NS	NS	NS	14	NS		CAE
	WP/D	NA	.005 gal bird	* NS	NS	NS	NS	14	NS		CAE
Brush-on ., When needed ., Brush.	WP	NA	.1042 lb 1K ft	* NS	NS	NS	NS	NS	NS		
Brush-on ., When needed ., Paintbrush.	D	NA	.3 lb 1K ft	* NS	NS	NS	NS	14	NS		CAE
Dust ., When needed ., Rotary duster.	D	NA	.0006 lb bird	* NS	NS	NS	NS	14	NS		CAE
Enclosed premise treatment ., When needed ., Brush.	WP/D	NA	.1042 lb 1K ft	* NS	NS	NS	NS	NS	NS		CAC, CAG
Enclosed premise treatment ., When needed ., High pressure sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAD
Enclosed premise treatment ., When needed ., Knapsack sprayer.	EC	NA	.09971 lb 1K linear ft	* NS	NS	NS	NS	NS	NS		CAD
	EC	NA	.1616 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
	WP	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		
	WP	NA	.8 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
	WP/D	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAC, CAG
Enclosed premise treatment ., When needed ., Power sprayer.	EC	NA	.09971 lb 1K linear ft	* NS	NS	NS	NS	NS	NS		CAD
	EC	NA	.1616 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
	WP	NA	.8333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		
	WP	NA	.8 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
	WP/D	NA	.3333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAC, CAG
Equipment treatment ., When needed ., Paintbrush.	D	NA	2.4 lb 1K linear ft	* NS	NS	NS	NS	1	NS		CAC



SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

POULTRY (EGG/MEAT) (con't)

Use Group: INDOOR FOOD (con't)

	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Equipment treatment., When needed., Rotary duster.	D	NA		* NS	NS	NS	NS	1	NS		CAC
Litter and bedding treatment. Use code AAL., When needed., Duster.	WP	NA	.15625 lb 100 birds	* NS	NS	NS	NS	NS	NS		
Litter and bedding treatment. Use code AAL., When needed., Knapsack sprayer.	WP	NA	.08 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
	WP/D	NA	1.6 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
Litter and bedding treatment. Use code AAL., When needed., Power sprayer.	WP	NA	.08 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
	WP/D	NA	1.6 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
Litter and bedding treatment. Use code AAL., When needed., Rotary duster.	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	1	NS		CAC
	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	14	NS		CAE
	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		
	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAC
	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
Litter and bedding treatment. Use code AAL., When needed., Shaker can.	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	14	NS		CAE
	D	NA	.1 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		
	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
Manure treatment. Use site code 40001., When needed., Knapsack sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAD
	EC	NA	.8081 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAE
	WP/D	NA	.8333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAC, CAG
Manure treatment. Use site code 40001., When needed., Power sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS		CAD

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

POULTRY (EGG/MEAT) (con't)

Use Group: INDOOR FOOD (con't)

EC	NA	.8081 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
WP/D	NA	.8333 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAC, CAG

POULTRY (MEAT)

Use Group: INDOOR FOOD

Animal equipment treatment., When needed., Paintbrush.	D	NA	2.4 lb 1K ft 2.4 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	CAE
	WP/D	NA	.1042 lb 1K ft	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Dust box.	D	NA	.0006 lb bird	* NS	NS	NS	NS	14	NS	CAE
	D	NA	.0006 lb bird	* NS	NS	NS	NS	NS	NS	CAE
	WP/D	NA	.15625 lb 100 birds	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Rotary duster.	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	14	NS	CAE
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	14	NS	CAE
Animal treatment (dust)., When needed., Shaker can.	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	14	NS	CAE
	D	NA	.009999 lb 100 birds	* NS	NS	NS	NS	14	NS	CAE
Animal treatment (spray)., When needed., Knapsack sprayer.	EC	NA	3.988E-04 lb bird	* NS	NS	NS	NS	14	NS	CAD
	WP/D	NA	4.167E-04 lb bird	* NS	NS	NS	NS	NS	NS	CAE
Animal treatment (spray)., When needed., Power sprayer.	EC	NA	3.988E-04 lb bird	* NS	NS	NS	NS	14	NS	CAD
	WP/D	NA	4.167E-04 lb bird	* NS	NS	NS	NS	NS	NS	CAE
Enclosed premise treatment., When needed., High pressure sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	CAD
Enclosed premise treatment., When needed., Knapsack sprayer.	EC	NA	.09971 lb 1K linear ft	* NS	NS	NS	NS	NS	NS	CAD

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

FOOD/FEED USES (con't)

POULTRY (MEAT) (con't) Use Group: INDOOR FOOD (con't)

	EC	NA	.1616 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Enclosed premise treatment., When needed., Power sprayer.	EC	NA	.09971 lb 1K linear ft	* NS	NS	NS	NS	NS	NS	NS	CAD
	EC	NA	.1616 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Equipment treatment., When needed., Paintbrush.	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	14	NS	NS	CAE
Litter and bedding treatment. Use code AAL., When needed., Electric duster.	WP/D	NA	.2344 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Litter and bedding treatment. Use code AAL., When needed., Knapsack sprayer.	WP/D	NA	1.6 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Litter and bedding treatment. Use code AAL., When needed., Mechanical duster.	WP/D	NA	.2344 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Litter and bedding treatment. Use code AAL., When needed., Power sprayer.	WP/D	NA	1.6 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Litter and bedding treatment. Use code AAL., When needed., Rotary duster.	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	14	NS	NS	CAE
	D	NA	.3 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	
	WP/D	NA	.2344 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Litter and bedding treatment. Use code AAL., When needed., Shaker can.	D	NA	.1 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	
Manure treatment. Use site code 40001., When needed., Knapsack sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAD
	EC	NA	.8081 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE
Manure treatment. Use site code 40001., When needed., Power sprayer.	EC	NA	.79764 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAD
	EC	NA	.8081 lb 1K sq.ft	* NS	NS	NS	NS	NS	NS	NS	CAE

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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED

ANIMAL KENNELS/SLEEPING QUARTERS (COMMERCIAL)

Use Group: INDOOR NON-FOOD

Animal treatment (dust)., When needed., Hand held duster.	D	NA		UC	* NS NS	NS NS NS	NS NS NS	NS NS NS			CAE
Animal treatment (spray)., When needed., Knapsack sprayer.	WP/D	NA	.05 lb 1K sq.ft		* NS NS	NS NS NS	NS NS NS	NS NS NS			CAE
Animal treatment (spray)., When needed., Power sprayer.	WP/D	NA	.05 lb 1K sq.ft		* NS NS	NS NS NS	NS NS NS	NS NS NS			CAE
Premise treatment., When needed., Knapsack sprayer.	EC	NA	.3335 lb 1K sq.ft		* NS NS	NS NS NS	NS NS NS	NS NS NS			CAD
Premise treatment., When needed., Power sprayer.	EC	NA	.3335 lb 1K sq.ft		* NS NS	NS NS NS	NS NS NS	NS NS NS			CAD

Use Group: TERRESTRIAL NON-FOOD CROP

Premise treatment., Not on label., Knapsack sprayer.	EC	NA	.996 lb A		* NS NS	NS NS NS	NS NS NS	NS NS NS			CAD
Premise treatment., Not on label., Power sprayer.	EC	NA	.996 lb A		* NS NS	NS NS NS	NS NS NS	NS NS NS			CAD

CATS (ADULTS/KITTENS)

Use Group: INDOOR RESIDENTIAL

Animal bedding/litter treatment., When needed., Aerosol can.	PRL	NA		UC	* NS NS	NS NS NS	NS NS NS	NS NS NS			
Animal bedding/litter treatment., When needed., By hand.	D	NA		UC	* NS NS	NS NS NS	NS NS NS	7 NS NS			CAC
Animal bedding/litter treatment., When needed., Hand held duster.	D	NA		UC	* NS NS	NS NS NS	NS NS NS	7 NS NS			
Animal bedding/litter treatment., When needed., Mist sprayer.	RTU	NA		UC	* NS NS	NS NS NS	NS NS NS	7 NS NS			
Animal treatment (collar)., When needed., By hand.	IMPR	NA		UC	* NS NS	NS NS NS	NS NS NS	120 NS NS			
	IMPR	NA		UC	* NS NS	NS NS NS	NS NS NS	150 NS NS			
	IMPR	NA		UC	* NS NS	NS NS NS	NS NS NS	60 NS NS			

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

CATS (ADULTS/KITTENS) (con't)

Use Group: INDOOR RESIDENTIAL (con't)

Animal treatment (dust)., When needed., By hand.	D	NA	UC	*	NS	NS	NS	NS	7	NS	
	D	NA	UC	*	NS	NS	NS	NS	7	NS	CAC
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Hand held duster.	D	NA	UC	*	NS	NS	NS	NS	7	NS	
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (spray)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS	
	RTU	NA	UC	*	NS	NS	NS	NS	7	NS	
Enclosed premise treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS	
Indoor premise treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS	
Indoor premise treatment., When needed., Mist sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	7	NS	
Sponge-on., When needed., Sponge.	WP	NA	UC	*	NS	NS	NS	NS	NS	NS	
			.04409 lb animal	*							

DOGS/CANINES (ADULTS/PUPPIES)

Use Group: INDOOR RESIDENTIAL

Animal bedding/litter treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS	
	RTU	NA	UC	*	NS	NS	NS	NS	7	NS	
Animal bedding/litter treatment., When needed., By hand.	D	NA	UC	*	NS	NS	NS	NS	7	NS	CAC
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

DOGS/CANINES (ADULTS/PUPPIES) (con't)

Use Group: INDOOR RESIDENTIAL (con't)

Animal bedding/litter treatment., When needed., Hand held duster.	D	NA	UC	*	NS	NS	NS	NS	7	NS	
Animal bedding/litter treatment., When needed., Mist sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	7	NS	
Animal treatment (collar)., When needed., By hand.	IMPR	NA	UC	*	NS	NS	NS	NS	150	NS	
	IMPR	NA	UC	*	NS	NS	NS	NS	60	NS	
Animal treatment (dust)., When needed., By hand.	D	NA	UC	*	NS	NS	NS	NS	7	NS	
	D	NA	UC	*	NS	NS	NS	NS	7	NS	CAC
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Hand held duster.	D	NA	UC	*	NS	NS	NS	NS	7	NS	
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	
	D	NA	UC	*	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (spray)., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS	
Animal treatment (spray)., When needed., Mist sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	7	NS	
Indoor premise treatment., When needed., Aerosol can.	PRL	NA	UC	*	NS	NS	NS	NS	NS	NS	
Indoor premise treatment., When needed., Mist sprayer.	RTU	NA	UC	*	NS	NS	NS	NS	7	NS	
Sponge-on., When needed., Sponge.	WP	NA	UC	*	NS	NS	NS	NS	NS	NS	
				*							

HORSES (SHOW/RACE/SPECIAL/PONIES)

Use Group: INDOOR NON-FOOD

Animal treatment (dust)., When needed., Hand held duster.	D	NA	UC	*	NS	NS	NS	NS	7	NS	
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SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

HORSES (SHOW/RACE/SPECIAL/PONIES) (con't)

Use Group: INDOOR NON-FOOD (con't)

Animal treatment (dust)., When needed., Rotary duster.	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (dust)., When needed., Shaker can.	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	NS	
	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	NS	CAE
Animal treatment (spray)., When needed., Sprayer.	RTU	NA	.001039 lb animal	* NS	NS	NS	NS	AN	NS	NS	
Animal treatment (wound)., When needed., By hand.	RTU	NA		UC * NS	NS	NS	NS	NS	NS	NS	
Animal treatment (wound)., When needed., Cloth.	RTU	NA		UC * NS	NS	NS	NS	NS	NS	NS	
Enclosed premise treatment (spot)., When needed., Shaker can.	D	NA	.00375 lb animal	* NS	NS	NS	NS	NS	NS	NS	
Enclosed premise treatment., When needed., Rotary duster.	D	NA		UC * NS	NS	NS	NS	NS	NS	NS	CAE
Enclosed premise treatment., When needed., Shaker can.	D	NA		UC * NS	NS	NS	NS	NS	NS	NS	CAE
Feed through., When needed., Not on label.	G	NA	1.852E-08 lb lb body wt	* NS	NS	NS	NS	1	NS	NS	
	G	NA	1.543E-08 lb lb body wt	* NS	NS	NS	NS	1	NS	NS	C93
	G	NA	2.395E-06 lb lb body wt	* NS	NS	NS	NS	1	NS	NS	CAE
	G	NA	3.809E-06 lb 100 lb body wt	* NS	NS	NS	NS	NS	NS	NS	
	P/T	NA	7.624E-09 lb lb body wt	UC * NS	NS	NS	NS	1	NS	NS	
	P/T	NA	9.753E-09 lb lb body wt	* NS	NS	NS	NS	1	NS	NS	C93
	P/T	NA		UC * NS	NS	NS	NS	NS	NS	NS	

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

HORSES (SHOW/RACE/SPECIAL/PONIES) (con't) Use Group: INDOOR NON-FOOD (con't)

Rub-on., When needed., By hand.	RTU	NA		UC	*	NS	NS	NS	NS	NS	
Rub-on., When needed., Cloth.	RTU	NA		UC	*	NS	NS	NS	NS	NS	
Wipe-on/wiper treatment., When needed., Cloth.	RTU	NA	.001039 lb animal		*	NS	NS	NS	AN	NS	
Wipe-on/wiper treatment., When needed., Glove.	RTU	NA		UC	*	NS	NS	NS	NS	NS	

HOUSEHOLD/DOMESTIC DWELLINGS Use Group: INDOOR RESIDENTIAL

Spot treatment., When needed., Shaker can.	D	NA		UC	*	NS	NS	NS	NS	NS	
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HOUSEHOLD/DOMESTIC DWELLINGS INDOOR PREMISES Use Group: INDOOR RESIDENTIAL

Indoor premise treatment., When needed., Aerosol can.	PRL	NA		UC	*	NS	NS	NS	NS	NS	
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HOUSEHOLD/DOMESTIC DWELLINGS OUTDOOR PREMISES Use Group: OUTDOOR RESIDENTIAL

Outdoor general surface spray., Not on label., Knapsack sprayer.	EC	NA	49.8 lb A		*	NS	NS	NS	NS	NS	CAD
Outdoor general surface spray., Not on label., Power sprayer.	EC	NA	49.8 lb A		*	NS	NS	NS	NS	NS	CAD

MANURE Use Group: OUTDOOR RESIDENTIAL

Manure treatment. Use site code 40001., When needed., Knapsack sprayer.	EC	NA	.83375 lb 1K sq.ft		*	NS	NS	NS	NS	NS	CAD
	WP	NA	.8333 lb 1K sq.ft		*	NS	NS	NS	NS	7	NS
	WP	NA	.8 lb 1K sq.ft		*	NS	NS	NS	NS	7	NS
Manure treatment. Use site code 40001., When needed., Power sprayer.	WP/D	NA	.8333 lb 1K sq.ft		*	NS	NS	NS	NS	7	NS
	EC	NA	.83375 lb 1K sq.ft		*	NS	NS	NS	NS	NS	CAD
	WP	NA	.8333 lb 1K sq.ft		*	NS	NS	NS	NS	7	NS
	WP	NA	.8 lb 1K sq.ft		*	NS	NS	NS	NS	7	NS



SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

MANURE (con't)

Use Group: OUTDOOR RESIDENTIAL (con't)

WP/D	NA	.8333 lb 1K sq.ft	* NS	NS	NS	NS	7	NS	CAE
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MINK

Use Group: INDOOR NON-FOOD

Feed through., When needed., Not on label.	G	NA	3.422E-07 lb lb body wt	* NS	NS	NS	NS	1	NS
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NONAGRICULTURAL UNCULTIVATED AREAS/SOILS

Use Group: TERRESTRIAL NON-FOOD CROP

Mound treatment., When needed., Shaker can.	D	NA	UC	* NS	NS	NS	NS	NS	NS
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PET LIVING/SLEEPING QUARTERS

Use Group: INDOOR RESIDENTIAL

Animal bedding/litter treatment., When needed., Aerosol can.	PRL	NA	UC	* NS	NS	NS	NS	NS	NS
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Enclosed premise treatment., When needed., By hand.	D	NA	UC	* NS	NS	NS	NS	NS	NS
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Enclosed premise treatment., When needed., Hand held duster.	D	NA	UC	* NS	NS	NS	NS	NS	NS
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Indoor premise treatment., When needed., Aerosol can.	PRL	NA	UC	* NS	NS	NS	NS	NS	NS
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RECREATIONAL AREAS

Use Group: TERRESTRIAL NON-FOOD CROP

Outdoor general surface spray., Not on label., Knapsack sprayer.	EC	NA	.996 lb A	* NS	NS	NS	NS	NS	CAD
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Outdoor general surface spray., Not on label., Power sprayer.	EC	NA	.996 lb A	* NS	NS	NS	NS	NS	CAD
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Outdoor general surface spray., When needed., Knapsack sprayer.	WP	NA	1 lb A	* NS	NS	NS	NS	NS	CAE
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	WP/D	NA	.05 lb 1K sq.ft	* NS	NS	NS	NS	NS	CAE
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Outdoor general surface spray., When needed., Power sprayer.	WP	NA	1 lb A	* NS	NS	NS	NS	NS	CAE
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Outdoor premise treatment., When needed., WP Knapsack sprayer.	WP	NA	1.042 lb A	* NS	NS	NS	NS	NS	
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SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. @ Max. Dose cycle	Max. # Apps	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

RECREATIONAL AREAS (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)

Outdoor premise treatment., When needed., WP Power sprayer. NA 1.042 lb A \* NS NS NS NS NS NS

REFUSE/SOLID WASTE SITES (OUTDOOR) Use Group: TERRESTRIAL NON-FOOD CROP

Disposal treatment., When needed., Knapsack sprayer. WP NA .8 lb 1K sq.ft \* NS NS NS NS 7 NS CAE  
 WP/D NA .8333 lb 1K sq.ft \* NS NS NS NS 7 NS CAC, CAG  
 Disposal treatment., When needed., Power sprayer. WP NA .8 lb 1K sq.ft \* NS NS NS NS 7 NS CAE

LEGEND

HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless noted otherwise) : Minimum dose for a single application to a single site. System calculated. Microbial claims only.  
 Max. Appl. Rate (AI unless noted otherwise) : Maximum dose for a single application to a single site. System calculated.  
 Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).  
 Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3 years" is expressed as "4/3 yr"  
 Max. Dose [(AI unless noted otherwise)/A] : Maximum dose applied to a site over a single crop cycle or year. System calculated.  
 Min. Interv (days) : Minimum Interval between Applications (days)  
 Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE

\* : Non-specific  
 C : Coarse  
 M : Medium  
 F : Fine  
 O : Others

FORMULATION CODES

D : DUST  
 EC : EMULSIFIABLE CONCENTRATE  
 FM? : FORM NOT IDENTIFIED  
 G : GRANULAR  
 IMPR : IMPREGNATED MATERIAL  
 P/T : PELLETTED/TABLETED  
 PRL : PRESSURIZED LIQUID  
 RTU : LIQUID-READY TO USE  
 WP : WETTABLE POWDER  
 WP/D : WETTABLE POWDER/DUST

ABBREVIATIONS

AN : As Needed  
 NA : Not Applicable  
 NS : Not Specified (on label)  
 UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC : Dosage Can Not be Calculated  
No Calc : No Calculation can be made  
W : PPM calculated by weight  
V : PPM Calculated by volume  
U : Unknown whether PPM is given by weight or by volume  
cwt : Hundred Weight  
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES

C93 : Do not apply directly to water.  
CAA : Do not apply to any body of water.  
CAC : Keep out of lakes, streams, and ponds.  
CAD : Do not apply directly to water or wetlands.  
CAE : Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes).  
CAG : Do not apply where runoff is likely to occur.  
S09 : \_\_ day(s) preslaughter interval.  
\* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS, DAYS, ETC.) DESCRIBED IN THE LIMITATION.



## **GUIDE TO APPENDIX B**

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Tetrachlorvinphos covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Tetrachlorvinphos in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.



# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of Tetrachlorvinphos

REQUIREMENT	USE PATTERN	CITATION(S)
<b>PRODUCT CHEMISTRY</b>		
61-1	Chemical Identity	All 41222501, 41222502, 43160601
61-2A	Start. Mat. & Mnfg. Process.	All 41222501, 42013001
61-2B	Formation of Impurities	All 40491301, 41222501, 42013001
62-1	Preliminary Analysis	All 40924701, 41222502, 43160601, 43160602
62-2	Certification of limits	All 41222502
62-3	Analytical Method	All 41222502, 42013002, 42275201, 42679201, 43160601
63-2	Color	All 41222503
63-3	Physical State	All 41222503
63-4	Odor	All 41222503
63-5	Melting Point	All 41222503
63-6	Boiling Point	All Not Applicable
63-7	Density	All 41222503
63-8	Solubility	All 41222503
63-9	Vapor Pressure	All 41222503
63-10	Dissociation Constant	All Not Applicable
63-11	Octanol/Water Partition	All 41222503
63-12	pH	All 41222503
63-13	Stability	All 41222503
63-14	Oxidizing/Reducing Action	All Not Applicable
63-15	Flammability	All Not Applicable
63-16	Explodability	All Not Applicable

## Data Supporting Guideline Requirements for the Reregistration of Tetrachlorvinphos

REQUIREMENT	USE PATTERN	CITATION(S)
63-17	Storage stability	All 41222503, 42013003, 42407801
63-18	Viscosity	All Not Applicable
63-19	Miscibility	All Not Applicable
63-20	Corrosion characteristics	All 41222503, 42013003
<b><u>ECOLOGICAL EFFECTS</u></b>		
71-1A	Acute Avian Oral -Quail/Duck	B, C, K 00160000
71-2A	Avian Dietary - Quail	B, C, K 00022923
71-2B	Avian Dietary - Duck	B, C, K 00022923
72-1A	Fish Toxicity Bluegill	B, C, K 40098001
72-1D	Fish Toxicity Rainbow Trout- TEP	40098001
72-2A	Invertebrate Toxicity	B, C, K 41257101
72-3A	Estuarine/Marine Toxicity - Fish	40228401
72-3B	Estuarine/Marine Toxicity - Mollusk	40228401
72-3C	Estuarine/Marine Toxicity - Shrimp	40228401
141-1	Honey Bee Acute Contact	00036935
141-2	Honey Bee Residue on Foliage	05000837
<b><u>TOXICOLOGY</u></b>		
81-1	Acute Oral Toxicity - Rat	All 41222504
81-2	Acute Dermal Toxicity - Rabbit/Rat	All 41222505
81-3	Acute Inhalation Toxicity - Rat	All 00138933
81-4	Primary Eye Irritation - Rabbit	All 41222506
81-5	Primary Dermal Irritation - Rabbit	All 41222507
81-6	Dermal Sensitization - Guinea Pig	All 41377902, 42981001
81-7	Acute Delayed Neurotoxicity - Hen	00079791, 41905901



## Data Supporting Guideline Requirements for the Reregistration of Tetrachlorvinphos

REQUIREMENT	USE PATTERN	CITATION(S)
81-8	Acute Neurotoxicity - Rat	42912501
82-1	90-Day Feeding - Rodent	B, L 43371201
82-3	90-Day Dermal - Rodent	41342001
83-1A	Chronic Feeding Toxicity - Rodent	B, L 00112525, 42980901
83-1B	Chronic Feeding Toxicity - Non-Rodent	B, L 00077819, 42679401
83-2A	Oncogenicity - Rat	B, L 00117443, 42980901
83-2B	Oncogenicity - Mouse	B, L 00117443, 00126039
83-3A	Developmental Toxicity - Rat	B, L 40152701, 42520101
83-3B	Developmental Toxicity - Rabbit	B, L 00127831
83-4	2-Generation Reproduction - Rat	B, L 00077802, 42054301
84-2A	Gene Mutation (Ames Test)	B, C, K, L, M 41222508
84-2B	Structural Chromosomal Aberration	B, C, K, L, M 41312901
84-4	Other Genotoxic Effects	B, C, K, L, M 42156401
85-1	General Metabolism	B, L 41988401
85-2	Dermal Penetration	42111501
86-1	Domestic Animal Safety	40436601, 41810101, 41810102
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>		
133-3	Dermal Passive Dosimetry Exposure	42622301
133-4	Inhalation Passive Dosimetry Exposure	42622301
<b><u>ENVIRONMENTAL FATE</u></b>		
160-5	Chemical Identity	All 41222501, 41222502, 43160601
161-1	Hydrolysis	All 41929101
162-1	Aerobic Soil Metabolism	B, C, K 00077821, 42082401
163-1	Leaching/Adsorption/Desorption	B, C, K 41681301

## Data Supporting Guideline Requirements for the Reregistration of Tetrachlorvinphos

REQUIREMENT	USE PATTERN	CITATION(S)
164-A-SS      Dissipation of Residues in Excrement		42848501
<b><u>RESIDUE CHEMISTRY</u></b>		
171-4B      Nature of Residue - Livestock	B	00116020, 00117354, 00120147, 00120204, 42828801, 42828802, 42828803
171-4 C & D      Residue Analytical Method - Plants/Animals	B	00038458, 00077812, 00077814, 00077816, 00115939, 00116020, 00116553, 00117329, 00117340, 00117351, 00117354, 00117389, 00118265, 00120147, 00120200, 00120205, 00120206, 00120229, 00130705, 00133913, 05004211
171-4E      Storage Stability	B	00117329, 00117354, 00117361, 00117389, 00133913
171-4J      Magnitude of Residues - Meat/Milk/Poultry/Egg	B	00038458, 00084189, 00115939, 00117298, 00117339, 00117340, 00117354, 00117389, 00118265, 00120200, 00120206, 00120225, 00120227, 05006630

## GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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- 00022923 Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
- 00036935 Atkins, E.L.; Greywood, E.A.; Macdonald, R.L. (1975) Toxicity of Pesticides and Other Agricultural Chemicals to Honey Bees: Laboratory Studies. By University of California, Dept. of Entomology. ? : UC, Cooperative Extension. (Leaflet 2287; published study.)
- 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)
- 00077802 Eisenlord, G.; Loquvam, G.S.; Nemenzo, J.; et al. (1966) Results of Reproduction Study of Rats Fed Diets Containing SD 8447 Insecticide over Three Generations: Report No. 28. (Unpublished study received May 23, 1967 under 8G0665; prepared by Hine Laboratories, Inc., submitted by Shell Chemical Co., Washington, D.C.; CDL:091166-M)
- 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)
- 00077819 Doyle, R.L.; Teske, R.H.; Elsea, J.R. (1968) Two-year Dietary Administration of SD 8447 to Dogs: P-99A. (Unpublished study received Aug 17, 1968 under 9F0739; prepared by Hill Top Research, Inc., submitted by Shell Chemical Co., Washington, D.C.; CDL: 091273-A)
- 00077821 Beynon, K.I.; Wright, A.N. (1968) The Breakdown of the Insecticide Gardona (SD 8447, 2-Chloro-1-(2',4',5'-trichlorophenyl)vinyl Dimethyl Phosphate) on Plants and in Soils: WP-193-68. (Unpublished study received Aug 17, 1968 under 9F0739; submitted by Shell Chemical Co., Washington, D.C.; CDL:091273-F)

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- 00112525 Walker, A.; Hunter, C. (1967) The Oral Toxicity of the Halophenyl Vinyl Phosphate Insecticide Gardona (SD 8447): Two Year Oral Experiment in Rats: Research Report R(T)-9-67. (Unpublished study received Aug 17, 1968 under 9F0739; prepared by Shell Research Ltd., Eng., submitted by Shell Chemical Co., Washington, DC; CDL:091274-O)
- 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: çRabon|. (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: çGardona|. (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 In unpublished submission received Oct 17, 1973 under 201-359; submitted by Shell Chemical Co., Washington, DC; CDL:050006-G)
- 00117329 Shell Chemical Co. (1969) çGardona: 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: çGardona|. (Compilation; unpublished study received Aug 6, 1971 under 2F1187; CDL:093510-C)
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- 00117443 U.S. National Institutes of Health (1978) Bioassay of tetrachlorvinphos for possible carcinogenicity. By National Cancer Institute, Div. of Cancer Cause and Prevention, Carcinogenesis Program, Carcinogen Bioassay and Program Resources Branch. Bethesda, MD: USNIH. (NCI-CG-TR-33; CAS No. 961-11-5; DHEW publication no. (NIH)78-833; published study; CDL:238926-A)
- 00118265 Shell Oil Co. (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)
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- 00120200 Shell Chemical Co. (1968) The Residue Data Developed from Test Plots Including a Description of the Analytical Methods Used: cGardona Insecticide|. (Compilation; unpublished study received Apr 27, 1969 under 9F0804; CDL:091388-B)
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

- Section I - Why You Are Receiving This Notice
- Section II - Data Required By This Notice
- Section III - Compliance With Requirements Of This Notice
- Section IV - Consequences Of Failure To Comply With This Notice
- Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
- Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Compensation Forms

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

### II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

## II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

## II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

## SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

### III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

### III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product

specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

### III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item



number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified time frame (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted

must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

### III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

## SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

### IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
  - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;
  - b. fulfill the commitment to develop and submit the data as required by this Notice; or
  - c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

#### **IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE**

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

#### IV-C EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

#### SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

## SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois Rossi, Division Director  
Special Review and  
Reregistration Division

### Attachments

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form



## TETRACHLORVINPHOS DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Tetrachlorvinphos.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Tetrachlorvinphos. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this Tetrachlorvinphos Product Specific Data Call-In (Attachment (6)). Instructions and guidance accompany each form.

### DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Tetrachlorvinphos are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Tetrachlorvinphos are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Tetrachlorvinphos products.

### INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jeffrey Billingslea at (703) 308-8004.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Jeffrey Billingslea  
Chemical Review Manager Team 81  
Product Reregistration Branch  
Special Review and Reregistration Branch 7508W  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Washington, D.C. 20460

**RE: Tetrachlorvinphos**



**INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM FOR  
PRODUCT SPECIFIC DATA**

- Item 1-4.      Already completed by EPA.
- Item 5.        If you wish to **voluntarily cancel** your product, answer "yes." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).
- Item 6.        Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "yes" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.
- Item 7a.       For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."
- Item 7b.       For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." If you are requesting a **data waiver**, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.
- Items 8-11.    Self-explanatory.
- NOTE:**        You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

DATA CALL-IN RESPONSE Page 1 of 1

**INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND  
REGISTRANT'S RESPONSE FORM FOR PRODUCT SPECIFIC DATA**

- Item 1-3      Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.
- Item 4.        The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.
- Item 5.        The study title associated with the guideline reference number is identified.
- Item 6.        The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.
- Item 7.        The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8.        The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.
- Item 9.        **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.
1.            I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
  2.            I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product

is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section

III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

**NOTE:** You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.





**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE Page 1 of 2**



REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE Page 2 of 2



FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS Page 1 of 2

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS Page 2 of 2

## **EPA'S BATCHING OF TETRACHLORVINPHOS PRODUCTS FOR MEETING REREGISTRATION ACUTE TOXICITY DATA REQUIREMENTS**

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing TETRACHLORVINPHOS as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrant's option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should

know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

One hundred thirty two products were found which contain TETRACHLORVINPHOS as the active ingredient. The products have been placed into twelve batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the products in each batch. Table 2 lists the products which has been placed in the "no batch" category. The following summarizes acute data requirement by batch:

- Registrants with products in **Batch 1** may cite acute data on the technical product.
- Registrants with products in **Batch 2** may cite acute data on the technical product with the exception of the eye irritation study. Since the products in this batch may be more irritating to the eyes, an eye irritation study performed on a product in this batch is needed.
- Registrants with products in **Batch 3** need to cite/submit all acute data on one of the subject products.
- Registrants with products in **Batch 4** may cite acute data on the technical product.
- All products in **Batch 5** are already supported by currently acceptable acute data. The registrant of the products in this batch should reference the existing data to support reregistration.
- Registrants with products in **Batch 6** may cite acute data on the technical product.
- Registrants with products in **Batch 7** may cite acute data on the technical product with the exception of the eye irritation study. Since the products in this batch may be more irritating to the eye, an eye irritation study performed on a product in this batch is needed.
- Registrants with products in **Batch 8** may cite acute data on the technical product with the exception of the eye irritation study. Since the products in this batch may be more irritating to the eye, an eye irritation study performed on a product in this batch is needed.
- Registrants with products in **Batch 9** may cite acute data on the technical product with the exception of the eye irritation study. Since the products in this batch may be more irritating to the eye, an eye irritation study performed on a product in this batch is needed.
- Registrants with products in **Batch 10** may cite acute data on the technical product.
- Registrants with products in **Batch 11** may cite acute data on the technical product with the exception of the eye irritation study. Since the products in this batch may be more irritating to the eye, an eye irritation study performed on a product in this batch is needed.
- Registrants with products in **Batch 12** need to cite/submit all acute data on one of the subject products.

Since acute data generated with the technical material can be cited in most cases, a complete set of new acutes is only needed for products in batch 3, batch 12 and the no batch group. If a registrant does not believe that the results of the technical data apply to a particular end use product or group of products within a batch, product/batch specific data may be submitted.



Table 1

<b>Batch</b>	<b>EPA Reg. No.</b>	<b>Percent Tetrachlorvinphos</b>	<b>Formulation Type</b>
1	2596-131	99.0	Solid
	56493-34	97.3	Solid
	56493-38	97.3	Solid
	56493-88	98.7	Solid
	62725-1	98.8	Solid
2	70-191	50.0	Solid
	28293-76	50.0	Solid
	34704-432	50.0	Solid
	47000-68	50.0	Solid
	56493-13	50.0	Solid
	56493-45	50.0	Solid
3	56493-42	23.0 Dichlorvos 5.3	Spray
	56493-43	23.0 Dichlorvos 5.3	Spray
4	2596-49	13.7	Collar
	2596-50	13.7	Collar
	2596-62	13.7	Collar
	2596-63	13.7	Collar
	2596-83	14.55	Collar
	2596-84	14.55	Collar
	56493-50	13.7	Tag
	56493-89	13.7	Collar
	56493-90	13.7	Collar
5	2596-122	0.96	Spray
	2596-123	0.96	Spray
	2596-125	1.07	Spray
	2596-126	1.07	Spray
6	270-164	2.46	Solid
	1352-62	0.40	Solid
	6482-8	0.15	Solid
	11715-202	0.47	Solid
	11715-203	0.30	Solid
	11715-217	2.96	Solid
	40833-5	0.30	Solid
	65901-1	0.47	Solid

<b>Batch</b>	<b>EPA Reg. No.</b>	<b>Percent Tetrachlorvinphos</b>	<b>Formulation Type</b>
7	70-192	3.0	Solid
	70-224	1.0	Solid
	299-188	3.0	Solid
	572-295	3.0	Solid
	2393-393	3.0	Solid
	2596-78	3.0	Solid
	2596-79	3.0	Solid
	11715-208	3.0	Solid
	19713-340	3.0	Solid
	28293-13	3.0	Solid
	34704-266	3.0	Solid
	34704-276	1.0	Solid
	34704-307	3.0	Solid
	47000-66	3.0	Solid
	47000-67	3.0	Solid
	56493-28	3.0	Solid
	56493-44	3.0	Solid
	58210-3	3.0	Solid
	67517-40	3.0	Solid
8	99-118	0.84	Solid
	534-94	0.40	Solid
	602-267	1.45	Solid
	602-268	1.45	Solid
	602-311	1.23	Solid
	602-359	0.57	Solid
	602-360	0.77	Solid
	1304-64	0.98	Solid
	1304-66	0.98	Solid
	1304-68	0.68	Solid
	1352-26	1.72	Solid
	1352-56	0.50	Solid
	1352-60	0.30	Solid
	1352-61	1.2	Solid
	1352-63	0.61	Solid
	1990-386	1.0	Solid
	1990-387	0.46	Solid
	1990-517	1.0	Solid
	2011-5	1.0	Solid
	2011-6	1.0	Solid

<b>Batch</b>	<b>EPA Reg. No.</b>	<b>Percent Tetrachlorvinphos</b>	<b>Formulation Type</b>
8	2011-7	1.0	Solid
	4089-5	1.24	Solid
	6552-12	1.25	Solid
	6552-13	0.75	Solid
	6552-14	1.25	Solid
	6552-17	0.47	Solid
	7138-12	0.35	Solid
	7455-32	1.0	Solid
	7627-21	0.60	Solid
	7627-22	0.30	Solid
	7627-26	0.63	Solid
	7698-7	1.40	Solid
	7702-5	1.0	Solid
	9078-6	0.93	Solid
	9078-12	0.31	Solid
	9374-8	0.30	Solid
	9374-9	0.80	Solid
	11715-284	0.46	Solid
	12714-3	1.79	Solid
	20552-2	0.30	Solid
	37774-9	4.0	Solid
	38110-4	1.0	Solid
	38110-7	1.0	Solid
	40833-4	0.49	Solid
	40833-6	0.60	Solid
	40833-9	1.0	Solid
	40833-10	1.0	Solid
	40833-11	1.0	Solid
	40833-12	0.30	Solid
	40833-13	1.24	Solid
	41200-2	1.23	Solid
	43757-1	1.0	Solid
44666-1	1.0	Solid	
46911-1	0.70	Solid	
55392-1	0.80	Solid	

<b>Batch</b>	<b>EPA Reg. No.</b>	<b>Percent Tetrachlorvinphos</b>	<b>Formulation Type</b>
9	1352-24	7.76	Solid
	3213-36	7.76	Solid
	4987-5	7.76	Solid
	7455-23	7.76	Solid
	38092-3	7.76	Solid
	39258-11	7.76	Solid
	39409-1	7.76	Solid
	48390-1	7.76	Solid
	56493-35	7.76	Solid
10	99-121	6.60	Solid
	67517-26	7.76	Solid
11	1304-63	7.76	Solid
	2011-10	7.76	Solid
	37774-1	7.76	Solid
	40833-8	7.76	Solid
12	56493-29	24.0	Liquid
	67517-33	24.0	Liquid

The following table lists products that were either considered not to be similar or the Agency lacked sufficient information for decision making and were not placed in any batch. The registrants of these products are responsible for meeting the acute toxicity data requirements separately.

Table 2 (No Batch)

<b>EPA Reg. No.</b>	<b>% Tetrachlorovinphos</b>	<b>Formulation Type</b>
1352-59	0.18	Solid
2596-89	0.99	Spray
2596-119	2.8	Liquid
56493-27	1.0 Dichlorvos 0.23	Liquid
28293-28	2.0 Pyrethrins 0.09 Piperonyl butoxide, tech 0.18 N-octyl bicycloheptene 0.30	Gel
28293-27	1.0 Pyrethrins 0.09 Piperonyl butoxide, tech 0.18 N-octyl bicycloheptene 0.30 Di-n-propyl iso- cinchomerionate 0.50	Spray
56493-19	75.0	Solid

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE Page 1 of 2

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE Page 1 of 2

## Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.











United States Environmental Protection Agency  
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST  
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106  
2070-0057

Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

**Please fill in blanks below.**

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer
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**Certification:**

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	



**United States Environmental Protection Agency  
Washington, DC 20460**



Form Approved  
OMB No. 2070-0107,  
2070-0057  
Approval Expires  
3-31-96

**CERTIFICATION WITH RESPECT TO  
DATA COMPENSATION REQUIREMENTS**

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

**Please fill in blanks below.**

Company Name	Company Number
Product Name	EPA Reg. No.

**I Certify that:**

- For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
- That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)  
  
 The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
- That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
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Name and Title (Please Type or Print)

**GENERAL OFFER TO PAY:** I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date
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Name and Title (Please Type or Print)



The following is a list of available documents for Tetrachlorvinphos that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jeffrey Billingslea at (703)-308-8004.

1. PR Notice 86-5.
2. PR Notice 91-2 (pertains to the Label Ingredient Statement).
3. A full copy of this RED document.
4. A copy of the fact sheet for Tetrachlorvinphos.

The following documents are part of the Administrative Record for Tetrachlorvinphos and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.
2. EPA Acceptance Criteria