



# **Reregistration Eligibility Decision (RED)**

## **Trichlorfon**



# 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 0104 which includes the active ingredient trichlorfon. 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 is due 90 days from the date of receipt of this letter. The second set of required responses is due 8 months from the date of receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in a tolerance is necessary, that tolerance too will be reassessed in the future pursuant to the requirements of FQPA.

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 Barbara Briscoe at (703) 308-8177. Address any questions on required generic data to the Special Review and Reregistration Division representative Dana Lateulere at (703) 208-8044.

Sincerely yours,

Lois 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**

**TRICHLORFON**

**LIST A**

**CASE 0104**



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## **TRICHLORFON REREGISTRATION ELIGIBILITY DECISION TEAM**

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## 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
FAO/WHO	Food and Agriculture Organization/World Health Organization
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.
µg/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

## GLOSSARY OF TERMS AND ABBREVIATIONS

NOEC	No effect concentration
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
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
$Q^*_1$	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
RUP	Restricted Use Pesticide
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.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

## **EXECUTIVE SUMMARY**

### **Background**

This Reregistration Eligibility Decision Document (RED) addresses the reregistration eligibility of the pesticide trichlorfon. Trichlorfon, an organophosphate insecticide, has been registered since 1955 for use on a variety of food and feed crops, recreational areas, lawns and turf, domestic dwellings and livestock. Trichlorfon is currently manufactured by Bayer Corporation (formerly Miles Inc., formerly Mobay Inc.), the sole producer and primary registrant. A Data Call-In issued in the 1984 Trichlorfon Registration Standard as well as a follow-up 1991 Data Call-In required submission of data to support the reregistration of trichlorfon. This document reflects a reassessment of trichlorfon following review of these data.

### **Reregistration Eligibility**

The Agency has determined that products containing trichlorfon are eligible for reregistration if labeling and other changes in this document are implemented. Eligible uses are limited to indoor and outdoor nonfood and nonfeed sites. The use on sod farms and the bait formulation use on residential lawns have been voluntarily canceled by the effected registrants. Also, the use of the bait in indoor domestic areas is prohibited unless prepackaged in child resistant bait stations. All food, feed and field crop registrations have been voluntarily canceled by the registrant; the process of amending all affected labels was complete on November 21, 1995. The Agency is proposing to revoke all tolerances for trichlorfon except cattle meat, cattle fat and cattle meat by-products. The registrant is not supporting the domestic use of the cattle treatment but will support the tolerances needed for the continuing importation of trichlorfon treated cattle products. In order to reassess the tolerances additional residue data are required within 24 months. Residue and metabolism data are required to reassess the tolerances, specifically, dermal metabolism in cattle (171-4b), magnitude of the residue for meat (171-4j), residue analytical method (171-4d), and storage stability (171-4e).

The Agency is requiring the following confirmatory studies for trichlorfon: based on the turf and lawn uses, an estuarine or marine mollusk acute toxicity study (72-3b), life cycle - aquatic invertebrate (72-4d), terrestrial field dissipation (164-1); evaluation of worker exposure from hydraulic low pressure handwand application (231 and 232) and worker reentry exposure from turf and greenhouse use (132-1, 133-3 and 133-4), droplet size spectrum (201-1) and drift field evaluation (202-1) are needed to support the turf and lawn uses due to the methods of application. These data are confirmatory and are not expected to change the regulatory decision on trichlorfon.

## **Health Effects**

The Agency has classified trichlorfon as a Group E chemical, no evidence of carcinogenicity for humans.

Chronic and acute dietary analyses were conducted using all of the published tolerances and assuming 100% of the crops (or cattle, domestic and import) were treated. The Agency generally accepts that acute dietary margins of exposure (MOE's) for cholinesterase inhibition determined to be greater than 10 indicate there is little likelihood of acute dietary risk. The acute dietary MOE's for trichlorfon were greater than 10. The chronic dietary analysis determined that the Reference Dose (RfD) was exceeded using the currently published crop tolerances. However, none of the feed or field crop uses are being supported and revocation of those tolerances is being proposed. Although the dermal cattle treatment is being voluntarily canceled, the cattle tolerances are being supported for import purposes. Chronic dietary analyses were conducted based on the current cattle tolerances and the minimal data available. The theoretical maximum residue contribution (TMRC) for the U.S. population represented 8% of the RfD, indicating that the pour-on use does not present a chronic dietary risk concern. Residue data are required to reassess the cattle tolerances.

## **Occupational and Residential Exposure**

When assessing the risk for occupational and residential exposure, the Agency generally accepts an MOE of greater than 100 as indicating there is little likelihood for an exposure related concern. The MOE's for mixer/loaders are acceptable except for the soluble powder formulation when supporting large (500 acre per day) applications (i.e., sod farms). Even with maximum personal protective equipment (PPE) the MOE's were <20, indicating a risk concern. Also, the MOE of 83 indicates concern for homeowner exposures to the granular formulation when using a chest mounted rotary spreader or other hand-operated-type spreader equipment. MOE's for aerial applications are also low, indicating potential risk. Mitigation for aerial application was determined to be impractical. Also, there are no engineering controls which appear to be feasible to mitigate the mixer/loader exposure to the soluble powder formulations (i.e., water soluble packaging). Therefore, in an effort to mitigate the exposure, the registrant has agreed to cancel all sod farm uses and prohibit aerial application. In order to address the homeowner risk concern, labels will prohibit the use of chest mounted rotary type spreaders for application of the granular formulation. Also, potential risk to children and pets from exposure to the bait formulations will be minimized by prohibiting these from indoor domestic settings unless housed in child resistant bait stations and prohibiting the domestic lawn use.

Product-specific data to assess post-application exposure and risk has been called-in as confirmatory data. Although the Agency has determined that immediate post-application exposures to turf grown for sod and ornamentals grown for sale are a risk concern, these risks have been minimized to an acceptable level based on the registrants omission of all sod farm



uses, mandatory post-treatment watering-in for all other turf uses, and a restricted entry interval which prohibits certain reentry until the treated turf area has dried following the watering-in. Restricted entry intervals have also been established for ornamental uses. Post-application risk concerns for applications to sites other than turfgrass and ornamentals are minimal and the anticipated frequency, duration, and degree of exposure following such applications do not warrant risk mitigation measures.

### **Environmental Fate**

Potential for contamination of groundwater by trichlorfon and trichlorfon degradates cannot be adequately assessed because acceptable field dissipation data are not available. Potential to leach is suggested by findings of high mobility in soil. Risk of contamination of surface and ground water may be moderated by rapid degradation of trichlorfon in soil and water. It appears that hydrolysis and aerobic metabolism are the main routes of dissipation in both soil and water. The major degradate in both soil and water is dichlorvos (DDVP) with desmethyl DDVP also reported as a degradate in soil. DDVP is itself a registered pesticide active ingredient.

The available data, from field studies that were not completely acceptable, suggest that trichlorfon and DDVP may have little potential to contaminate ground water because they degrade rapidly in soil. Acceptable field studies are required to confirm this suggestion.

### **Ecological Effects**

Based on the exposure from the turf uses, acute risk levels of concern are exceeded for freshwater, marine and estuarine fish and invertebrates and birds. Chronic risk levels of concern are exceeded for freshwater invertebrates and birds. The registrant has agreed to require buffer strips from aquatic habitats, mandatory watering-in for turf sites to reduce surface run-off, and the prohibition of aerial application which can result in spray drift. Also, residential lawn use of the bait formulations will be prohibited. These measures will greatly reduce the exposure of aquatic habitats to trichlorfon as well as reduce the residues available for dietary consumption by birds. The acreage of trichlorfon usage has also been greatly reduced by the cancellation of all field crops and sod farm use. The Agency has determined that although levels of concern are exceeded for non-target organisms, the exposure has been adequately mitigated.

Before reregistering the products containing trichlorfon, 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 product, acute toxicity studies for similar formulations, and product performance data for public health uses (cockroaches and houseflies). 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 trichlorfon. The document consists of six sections. Section I is the introduction. Section II describes trichlorfon, 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 trichlorfon. Section V discusses the reregistration requirements for trichlorfon. 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:** Trichlorfon
- **Chemical Name:** Dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate
- **Chemical Family:** Organophosphate
- **CAS Registry Number:** 52-68-6
- **OPP Chemical Code:** 057901
- **Empirical Formula:** C<sub>4</sub>H<sub>8</sub>O<sub>4</sub>Cl<sub>3</sub>P
- **Trade and Other Names:** Dylox, Dipterex, Proxol, and Neguvon
- **Basic Manufacturer:** Bayer Corporation

### B. Use Profile

The following use profile is based on the uses, sites and application methods that were registered when this RED document was initiated. Some uses have been voluntarily canceled or amended as a result of the science assessments; [major changes that have occurred are noted in brackets]. A detailed table of the uses of trichlorfon, eligible and ineligible, is in Appendix A.

**Type of Pesticide:** Insecticide

**Mode of Action:** Acetylcholinesterase inhibitor

#### **Use Sites:**

Terrestrial food/feed/field crops: Brussels sprouts, barley, beets, blueberry, beans (dry and snap), corn, field corn, popcorn, sweet corn, cotton, cow peas, lima beans, tomatoes, cabbage, carrot (including tops), cauliflower, collards, cowpeas, southern peas, black-eyed peas, crowder peas, pumpkins, collards, lettuce and alfalfa, cotton, peanuts, pepper, pumpkin, tobacco, soybeans and treatment to manure. [Voluntary cancellation of all food/feed uses was finalized November 21, 1995.]

Terrestrial non-food crops: Agricultural uncultivated areas, commercial animal kennels and sleeping quarters, recreational area and ornamental lawns, recreational areas, golf course turf, sod farms, outdoor commercial/institutional/industrial premises and equipment, nonagricultural uncultivated areas and soils, ornamental and/or shade trees, ornamental herbaceous plants and ornamental non-flowering plants, ornamental woody shrubs and vines, paths and patios, outdoor refuse/solid waste sites. [Sod farm uses have been voluntarily canceled.]

Indoor non-food/non-feed: Greenhouses, agricultural/farm premises, cattle feedlots, dairy farm milk storage rooms/houses/sheds, dairy farm milking stalls/parlors, non-food contact areas of food processing plant premises, nonfood areas of eating establishments, food/grocery/marketing/ storage/distribution facility premise, household/domestic dwellings, indoor food handling areas, non-food contact meat processing plant premises, non-food contact areas of poultry processing plant equipment, indoor commercial storage/warehouses premises. [All of these sites have required, and will continue to require, label restrictions prohibiting contamination of food/feed or food/feed handling equipment and restricting use to areas inaccessible to animals.]

Indoor food: Dermal treatment to non-lactating dairy and beef cattle, livestock. [Voluntary cancellation has been requested for all dermal treatment uses.]

Indoor residential: Bathroom premises/hard surfaces, indoor premises household/domestic, refuse/solid waste containers (garbage cans).

Outdoor residential: Household/domestic dwellings outdoor premises (i.e., paths and patios).

**Usage Information:**

Turf management: 500,000 to 1,000,000 pounds of active ingredient per year.

Usage information on other sites is not available.

**Pests:**

Products are labeled for outdoor turf, ornamental and perimeter treatments to control a wide variety of lepidopteran larvae (caterpillars), white grubs, mole crickets, sod webworms, leaf miners, stink bugs, ants and other nuisance pests; indoor control of flies, ants, and roaches; mound treatment for Harvester ants; pour-on livestock use to control cattle grubs and cattle lice.

**Formulation Types Registered:**

Technical Active Ingredient:

98.0% trichlorfon

97.0% trichlorfon

Formulation Intermediate Active Ingredient

80.0% trichlorfon

Soluble Powder Active Ingredient

80.0% trichlorfon

Granular Active Ingredient

6.2% trichlorfon

5.0% trichlorfon

Ready-to-Use Solution (voluntary cancellation request has been submitted)

8.0% trichlorfon

Granular Bait Active Ingredient

1.0% trichlorfon

5.0% trichlorfon

**Methods of Application:**

Turf, ornamentals and nurseries: mechanical and hand-held sprayers, spreaders (for granular formulations), aerial equipment, irrigation systems.

Indoor and outdoor treatments: soluble powders in water through hand-held sprayers; dry baits can be “sprinkled” out of a cup or spoon or put onto cardboard or plastic or applied as a mound treatment for ants; bait mixed with water and “sprinkled” out of a cup or watering can.

Pour on: from a cup or dipper onto livestock.

**Rates of Application:**

Rates up to 8.0 lb a.i./acre are registered for turf.

**Types of Treatment:**

Surface spray, granular and bait treatment to lawns and recreational areas; general surface treatment sprays in and around buildings, foliar sprays, mound treatment for ants, bait treatment to cracks, crevices and wall voids.

**Timing:**

Product labels do not give specific timing of application of trichlorfon. The most likely scenario is when pests have reached intolerable or damaging populations. For turf and lawns, most labels indicate application can be made monthly beginning May or June.

### **C. Data Requirements**

Data required in the June 30, 1984 Registration Standard for Trichlorfon include studies on product chemistry, toxicology, ecological effects, environmental fate, and residue chemistry. In addition, a Data Call-In was issued in September 1991 for trichlorfon requiring additional product chemistry, ecological effects, toxicology, residue chemistry and occupational and residential exposure data. Appendix B includes all data requirements identified by the Agency needed to support reregistration for currently registered uses.

### **D. Regulatory History**

Trichlorfon was registered in the United States by the USDA in 1955 for use as an insecticide on a variety of vegetable, fruit and field crops as well as livestock, ornamental and forestry plantings, agricultural premises and domestic dwellings, and for the control of parasites on fish in designated aquatic environments. A Registration Standard for trichlorfon was issued in June 1984 which included a Data Call-In requiring data to support the trichlorfon use patterns. Additional data were required in 1991 to complete the data base for trichlorfon. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and the subsequent 1991 Data Call-In.

Bayer Corporation, the manufacturer of the trichlorfon technical, requested voluntary cancellation of all food, feed and field crop uses; all other registrants were required to remove these uses from their product labels. The process of amendment was complete on November 21, 1995. Bayer Corp. has several products labeled for dermal pour-on treatment to cattle and livestock; they have voluntarily requested cancellation of these products. Bayer has indicated that they will support a "tolerance with no U.S. registration" for import purposes by providing the necessary data to reassess the tolerances within two years.

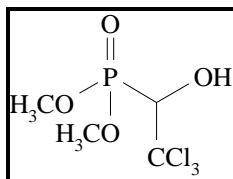
Trichlorfon was originally referred and entered in the Rebuttable Presumption Against Registration (RPAR, now referred to as Special Review) process because scientific studies suggested that trichlorfon might be oncogenic, teratogenic, fetotoxic, and mutagenic (FR Vol. 43, No. 77, 4/20/78). In 1984, the Agency evaluated the available data on trichlorfon and concluded that the existing evidence did not support the issuance of an RPAR for trichlorfon because the existing database was inadequate for valid risk assessment.

### III. SCIENCE ASSESSMENT

#### A. Physical Chemistry Assessment

##### 1. Description of Chemical

Trichlorfon [dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate] is an organophosphorus insecticide, which acts as an acetylcholinesterase inhibitor.



Empirical Formula:	C <sub>4</sub> H <sub>8</sub> O <sub>4</sub> Cl <sub>3</sub> P
Molecular Weight:	257.6
CAS Registry No.:	52-68-6

##### 2. Identification of Active Ingredient

Technical trichlorfon is a white crystalline solid with a melting point of 75-84 C. Trichlorfon is soluble in water, dichloromethane, 2-propanol, and toluene, and nearly insoluble in n-hexane.

##### 3. Manufacturing-use Products

Trichlorfon manufacturing-use products (MPs) are registered to Bayer Corporation (formerly Miles Inc., formerly Mobay Corp.): two 98% technical products (EPA Reg. Nos. 3125-9 and 11556-30), a 97% technical (EPA Reg. No. 3125-404), and an 80% formulation intermediate (EPA Reg. No. 3125-371). The 97% technical (EPA Reg. No. 3125-404) was transferred from Kaw Valley Inc. (EPA Reg. No. 44215-129) on 11/20/90. These products are the only MPs subject to this reregistration eligibility decision.

#### B. Human Health Assessment

##### 1. Toxicology Assessment

###### a. Acute Toxicity

The toxicological data base for trichlorfon is adequate and will support reregistration eligibility. Eye effects, skin effects, and skin sensitization data are not data requirements for



the reregistration of the technical grade of trichlorfon. These data are presented for information purposes only.

**Table 1: Acute Toxicity Values**

Gdln #	Test	MRID #	Result (mg/kg)	Category
81-1	Oral LD <sub>50</sub>	00256446	136 - 173 mg/kg	II
81-2	Dermal LD <sub>50</sub>	00090786	> 2 g/kg	III
81-3	Inhalation LC <sub>50</sub>	00256446	533 mg/m <sup>3</sup> - 4 hours	IV
81-4	Eye effects	41571302	Moderately irritating	III
81-5	Skin effects	40306901	Moderate contact allergen	IV
81-6	Skin Sensitization	00257599	Moderate contact allergen	-

In addition, a single dose human clinical trial conducted in 1990 was reported in a monograph from the Joint Food and Agricultural Organization of the United Nations/World Health Organization (FAO/WHO) for the evaluation of the use of trichlorfon in the treatment of Alzheimer's disease. A single oral dose of 0, 2.5, 5.0, 7.5 or 15 mg/kg/day was administered to humans. The NOEL was 2.5 mg/kg/day and the LOEL was 5.0 mg/kg/day based upon the inhibition of plasma and red blood cell cholinesterase and clinical signs of vomiting, nausea and diarrhea.

**b. Subchronic Toxicity**

In a 21-day toxicity study, trichlorfon was administered dermally to rabbits for 15 days (5 days a week for 3 weeks) at doses of 0, 100, 300 or 1000 mg/kg/day. The systemic NOEL was greater than the highest dose tested. The NOEL for cholinesterase inhibition was 100 mg/kg/day the LOEL for cholinesterase inhibition was 300 mg/kg/day based on depression in red blood cell activity (GLN 82-2, MRID 40306901).

**c. Combined Chronic/Carcinogenicity**

Trichlorfon was administered in the diets of Fischer 344 rats at doses of 0, 100, 300 or 1750 ppm (equivalent to 0, 4.4, 13.3 and 75 mg/kg/day for males; 0, 5.8, 17.4 and 93.7 mg/kg/day for females, respectively) for 24 months. The study was designed to test both the carcinogenic potential and the chronic toxicity of the test material. During the study, several adjustments in the dose were made at the highest dose tested, resulting in an average dose of 1514 ppm for males (75 mg/kg/day). After 27 weeks at 1000 ppm, the dose was increased to 1250 ppm for weeks 28 to 32; increased to 1500 ppm from weeks 33 to 40; and, increased for a third time to 1750 ppm for weeks 41 to 106. The chronic toxicity NOEL was 4.4 mg/kg/day

and the LOEL was 13.3 mg/kg/day based on the observed decreases in red cell (17%) and brain (18%) cholinesterase activity and a statistically significant increase in the incidence of renal calcification in males.

In the highest dose tested, gross findings included granular kidneys and foci in the lungs of females; and, thickened enlarged duodenum and thickened and granular non-glandular stomachs in males. The gross findings were correlated with microscopic findings of cranial hyperplasia of the small intestines, non-glandular gastritis in the stomach, inflammation of the lung and chronic nephropathy, and renal calcification. Decreases in body weight gain were also reported at week 13 of the study for animals in the highest dose tested (10% in males, 18% in females). In high dose animals of both sexes anemia was reported, characterized by statistically significant decreases in the hematocrit, hemoglobin, red blood cell counts, and mean corpuscle volume. Hypercholesterolemia was also present in the high dose males and females and in the mid-dose males. Under the conditions of the study, the test material was associated with an increase in the incidence of benign pheochromocytomas in high dose males which was slightly outside of the historical control range for these tumors. Since this tumor type is very common in this strain of rats and since it was not present in the same strain at a higher dose level (see the next study below), this tumor type was not considered to be compound related by the Office of Pesticide Programs (OPP) Carcinogenicity Peer Review Committee. A statistically significant increase in the incidence of mononuclear cell leukemia was reported for low and high dose males; however, the incidence of this tumor was within the animal supplier's historical control range for this tumor type.

Based on the compound-related effects on clinical chemistry parameters, gross and microscopic pathology and clinical findings of paleness and hunched backs in high dose males and rough hair coats in high dose females, the OPP Carcinogenicity Peer Review Committee determined that trichlorfon was tested at an adequate dose (GLN 83-1(a) and 83-2(a), MRID 41056201).

In an additional 2-year study conducted in Fischer 344 rats at dietary dose levels of 0 or 2500 ppm (equivalent to 0 and 129 mg/kg/day in males, 0 and 159 mg/kg/day in females, respectively), trichlorfon was associated with an increase in the incidence of alveolar/bronchiolar adenomas in males, renal tubular adenomas in males and alveolar/bronchiolar carcinomas in females. While none of these tumors were reported at statistically significant levels, the incidences were well outside of the historical control range for all three tumor types. There was no compound related increase in the incidence of either benign pheochromocytomas or in the incidence of mononuclear cell leukemia.

In this same study, administration of the test material was associated with a decrease in body weight and body weight gain (10.5% males and 18.5 % females), increased incidences of urine stain, rough coats and pale eyes, decreases in erythrocyte parameters (hematocrit, hemoglobin, RBC count and MCV), hypercholesterolemia and increases in hepatic enzymes

(SAP, AST, ALT and GGT). Decreases in plasma (63% males, 52% females) and erythrocyte (38% males, 30% females) cholinesterase activity were reported in both sexes of animals when treated groups were compared to controls. Brain cholinesterase activity was 58 and 54% lower than controls for males and females, respectively. Compound related non-neoplastic lesions included duodenal hyperplasia, gastritis, pulmonary hyperplasia and inflammation, nasolacrimal inflammation, hepatocellular hyperplasia and vacuolation, chronic nephropathy and an increased incidence of dermal lesions were all reported at 2500 ppm. It was concluded by the OPP Carcinogenicity Peer Review Committee that this study was conducted at a level which exceeded the MTD (GLN 83-1(a) and 83-2(a), MRID 41973001, 42510301).

In a twenty-four month chronic/carcinogenicity study in CD-1 mice, trichlorfon was administered at dietary dose levels of 0, 300, 900 or 2700 ppm (equivalent to 0, 45, 135 and 405 mg/kg/day, respectively). Clinical signs of toxicity were observed at all dose levels and included vaginal discharges, urine staining and ear lesions. Depressed plasma (57% males, 74% females at HDT), brain (66% males, 71% females) and erythrocyte (35% males, 38% females) cholinesterase levels were reported in all treated animals. A NOEL for systemic toxicity was not demonstrated in this study. There was a significant trend for increased mortality in female mice. In the low dose females, there was a statistically significant increase in the incidence of alveolar/bronchiolar adenomas and combined alveolar/bronchiolar adenomas and carcinomas. In the mid-dose group, there was a statistically significant increase in the incidence of alveolar/bronchiolar carcinomas and combined alveolar/bronchiolar adenomas and carcinomas. However, this increased incidence of lung tumors was not sustained at the higher dose level and resulted in a flat dose-response curve. Therefore, the OPP Carcinogenicity Peer Review Committee (CPRC) determined the increased incidence of lung tumors in the low and mid-level dose female mice was not compound related. In males, there was an increase in the incidence of hepatocellular adenomas at all dosed groups; however, the increase was not at a statistically significant level. Based on the clinical signs of toxicity and the effects on cholinesterase activity, it was determined by the OPP CPRC that trichlorfon was tested at adequate dose levels (GLN 83-2(b), MRID 40782401, 40844301).

A ten year chronic toxicity/carcinogenicity study was conducted in Rhesus monkeys. Trichlorfon was administered via Tang orange drink at doses of 0, 0.2, 1.0 or 5.0 mg/kg/day for six days a week during the ten year testing period. At the levels tested, the compound did not induce any increases in tumor incidence over controls nor were there any pre-neoplastic lesions reported that could be associated with the administration of trichlorfon. The LOEL was 0.2 mg/kg/day based on findings of decreased plasma (39% females, no decrease in males), red cell (30% males, no change in females) and brain (22% males, no change in females) cholinesterase activity levels. At the highest dose tested (5.0 mg/kg/day), there was a decrease in body weight for both sexes (6 to 33%) and anemia as characterized by decreases in erythrocyte, hemoglobin and hematocrit values. At this same dose level, transitory signs of cholinesterase inhibition were observed in females during the first month of the study. These

consisted of pupillary constriction, muscle fasciculation and diarrhea (GLN 83-1 and 83-2, MRID 40776001).

Trichlorfon was tested in male and female beagles at dietary doses of 0, 50, 250, 500 or 1,000 ppm (equivalent to 0, 1.25, 6.25, 12.5 and 25 mg/kg/day, respectively) for one year. There were no reported effects on mortality or on body weights nor were there any reports of clinical signs that could be associated with trichlorfon administration. Gross findings included mild to moderate enlargement of the spleen at the highest dose tested. Microscopic analysis showed marked congestion of the spleen and lymphoid atrophy of this organ in high dose animals of both sexes. Microscopic findings in the liver of high dose animals consisted of foci of inflammatory cells. The NOEL in this study was 250 ppm and the LOEL was 500 ppm based on decreases in serum and red cell cholinesterase activity. This study was classified as supplementary. The data requirement for a chronic non-rodent study was satisfied by the ten year monkey study (GLN 83-1, MRID 00080593).

#### **d. Developmental Toxicity**

In a developmental toxicity study in rabbits, trichlorfon was administered by gavage to pregnant does on gestation days 6 through 18. The doses were 0, 10, 35 or 110 mg/kg/day. Animals were sacrificed on day 28 of gestation and litters were delivered by Cesarean section. The NOEL and LOEL for maternal toxicity were 10 and 35 mg/kg/day, respectively. Maternal toxicity was based on decreases in brain (38%) and red blood cell (20%) cholinesterase activity and on abortion. The NOEL and LOEL for developmental toxicity were 35 and 110 mg/kg/day, respectively. Developmental toxicity was based on an increase in the number of does with resorptions, decreased fetal body weights in males and delayed ossification, primarily in the first sternebrae (GLN 83-3(b), MRID 41565201).

In a developmental toxicity study in pregnant Sprague Dawley rats, trichlorfon was administered in the diet at dose levels of 0, 500, 1125 or 2500 ppm (equivalent to 0, 45, 102 and 227 mg/kg/day, respectively) from days 6 through 15 of gestation. The NOEL for developmental and maternal toxicity was less than 45 mg/kg/day based on the observed decreases in cholinesterase activity (levels not provided) at this dose level in mothers and reduced ossification of skulls, vertebrae and sternebrae in fetuses (GLN 83-3(a), MRID 40255601).

#### **e. Reproductive Toxicity**

In a two-generation reproduction study conducted in Sprague Dawley rats, trichlorfon was administered at doses of 0, 150, 500 or 1750 ppm (equivalent to 0, 15, 50 and 175 mg/kg/day, respectively). Parental toxicity was observed at the lowest dose tested and was based on decreases in plasma in F<sub>0</sub> animals (24% lower than controls) and brain cholinesterase activity in both generations (12% for F<sub>0</sub> and 14% for F<sub>1</sub> when compared to controls). In the F<sub>0</sub> generation, females had chronic pneumonia and in the F<sub>1</sub> generation,

pulmonary and renal lesions were present in high dose animals of both sexes. The pulmonary lesions consisted of chronic pneumonia characterized by thickened alveolar septa, macrophage accumulation, cholesterol clefts, pneumocyte hyperplasia and neutrophilic infiltration. Renal lesions consisted of mineralization and hydronephrosis. The reproductive NOEL was 500 ppm (50 mg/kg/day) and was considered to be a reproductive/systemic NOEL based on the fact that reproductive effects appeared to be secondary to the systemic toxicity of the compound. The reproductive LOEL was 1750 ppm (175 mg/kg/day) based on the presence of dilated renal pelvises in pups in F<sub>1</sub> generation and decreased weight of F<sub>1</sub> pups on days 7 and 21 (GLN 83-4, MRID 422283-01).

#### **f. Mutagenicity**

In gene mutation assay with *Salmonella typhimurium*, trichlorfon was found to be weakly mutagenic at toxic concentrations with or without activation (MRID 249535). In a gene mutation assay conducted with *S. cerevisiae*, trichlorfon was not mutagenic at levels up to 10,000 µg/ml, in either the presence or absence of activation (MRID 256446). In another gene mutation assay, with *Salmonella* and *E. coli*, trichlorfon was tested at doses from 1 µg to 10,000 µg/plate. Trichlorfon induced reversions in *Salmonella* at doses greater than 5 mg and in *E. coli* at doses greater than 1.0 mg (GLN 84 Series, MRID 00028625).

In an in vitro cytogenetic study in mammalian cells, trichlorfon, at doses ranging from 1 to 145 µg/ml, induced significant increases in mutation frequencies both with and without activation (MRID 00256446).

In an unscheduled DNA synthesis study, trichlorfon was inactive in inducing unscheduled DNA synthesis in rat hepatocytes up to levels of severe cytotoxicity (doses not specified) (MRID 00028625, HED doc. 003267).

Trichlorfon (doses not stated) was positive for DNA damage and repair in *S. typhimurium*, but was negative in relative toxicity assays with *E. coli* and *B. subtilis* strains (MRID 00028625, HED doc. 003267).

In a DNA damage and repair study conducted with *S. cerevisiae*, trichlorfon was positive for mitotic recombination in the presence and absence of S-9 activation at concentrations from 10 to 50 mg/ml (MRID 00028625).

At cytotoxic levels of 1,000 µg/ml, trichlorfon was associated with a marginal but significant increase in sister chromatid exchange in Chinese hamster ovary cells (HED doc. 003267).

Trichlorfon was demonstrated to be clastogenic in human lymphocytes in the absence of S9 activation at doses of 3, 10 or 30 µg/ml (HED Doc. 008481).

In a recombinant DNA study conducted at doses of 3, 30 or 300 mg, trichlorfon did not inhibit the growth of Bacillus subtilis (MRID 00256446).

#### **g. Metabolism**

A metabolism study was conducted in rats using four treatment regimes (single dose of 0.2 mg/kg in water by gavage; single dose of 20 mg/kg in water by gavage; ten gavage doses of 0.2 mg/kg in water followed by the radio-labeled compound in water at a dose of 0.2 mg/kg; and single intravenous dose of 0.2 mg/kg into the tail vein). The data collected from the four regimes demonstrated that 80-90% of the test material was excreted within 24 hours. The major route of excretion was via the urine, followed by feces and expired air. One to 2% of the dose was found in the tissues after 96 hours. In this study, the metabolites were not adequately characterized. This study was classified as supplementary, but information was reported which could be used for regulatory purposes (GLN 85-1, MRID 40438101).

In a 1992, International Programme on Chemical Safety (IPCS) Environmental Health Criteria publication on trichlorfon, it is stated that trichlorfon rearranges to form dichlorvos via dehydrochlorination. The main metabolites of trichlorfon found in mammals were dimethyl trichlorfon, dimethyl dichlorvos, dimethyl hydrogen phosphate, methyl hydrogen phosphate and phosphoric acid. The main degradation routes of trichlorfon are demethylation, P-C bond cleavage and ester hydrolysis.

#### **h. Neurotoxicity**

Acute and subchronic neurotoxicity studies in mammalian species (GLN 81-8 and 82-5) have been required and are currently underway; these studies are considered confirmatory for the purposes of reregistration.

In a 90-day neurotoxicity study conducted in hens, trichlorfon was administered at dose levels of 0, 3, 9 or 18 mg/kg/day. In this study, there were no overt indications of a response characteristic of delayed neurotoxicity; however, histologically, a slight effect on nervous tissue, characterized as axonal degeneration was present in hens receiving 18 mg/kg/day. Based on this finding, the NOEL for neurotoxicity was 9 mg/kg/day (GLN 82-5, MRID 40351201 and 40879301).

#### **i. Reference Dose**

A Reference Dose (RfD) of 0.002 mg/kg/day was established based on the results of a ten year chronic feeding study in monkeys in which a NOEL was not determined and a LOEL of 0.2 mg/kg/day was established. The OPP RfD Peer Review Committee (PRC) considered the inhibition of plasma red blood cells and brain cholinesterase in the monkeys at 0.20 mg/kg/day to be a marginal response. The Committee concluded that the LOEL could be used for risk assessment purposes if an uncertainty factor of 100 was considered when

establishing the RfD. One-hundred was chosen as the uncertainty factor based on the lack of a NOEL, the inter-species extrapolation and intra-species variability. The OPP RfD Peer Review Committee recommended review of trichlorfon by the OPP Carcinogenicity Peer Review Committee.

The FAO/WHO recommended a chronic dietary RfD as a range between 0 and 0.01 mg/kg/day; however, the OPP PRC has deemed the OPP RfD of 0.002 mg/kg/day to be appropriate and will be retained for chronic dietary analysis.

#### **j. Toxicological Endpoints for Risk Assessment**

The OPP Less Than Lifetime Committee determined that an occupational or residential short term and intermediate term exposure assessment would be required based on the results of a 21-day dermal toxicity study in rabbits in which the systemic NOEL was 100 mg/kg/day.

Based on the existing food use, i.e. the dermal pour-on to cattle, an acute dietary toxicity endpoint was established for trichlorfon at 2.5 mg/kg bw/day from a single dose clinical trial in humans conducted in 1990 (reported in a FAO/WHO monograph). Clinical signs, such as vomiting, nausea, and diarrhea were reported as well as plasma and RBC cholinesterase inhibition at 5 mg/kg/day, the LOEL. The NOEL for the study was 2.5 mg/kg/day.

On April 6 and August 31, 1994 the OPP Carcinogenicity Peer Review Committee (CPRC) determined that based on the evidence presented, trichlorfon should be classified as a Group E chemical - no evidence of carcinogenicity for humans. This decision was based on the results of two animal studies in different species (mouse and rat). In the rat, although there were statistically significant increases in tumors (lung and kidney) these occurred only at a dose which the CPRC considered to be excessive. Although tumors of the lung were also seen in female mice, at doses considered to be adequate, the CPRC did not consider these to be compound-related since the increases seen at the low and mid-doses resulted in a flat dose-response curve and were not sustained at the high dose. The increase in pheochromocytomas seen in male rats in the multi-dose study was not confirmed in the single higher dose study.

Trichlorfon, Dichlorvos (DDVP) and Naled are structurally related organophosphate insecticides. DDVP has been classified as a Group C chemical, possible human carcinogen, by the CPRC and the Scientific Advisory Panel. Naled has been classified as a Group E chemical, no evidence of carcinogenicity for humans. The structural relationship of these chemicals was taken into consideration by the CPRC when classifying trichlorfon.

## **k. Other Toxicological Considerations**

Studies have been conducted to determine the toxicity of trichlorfon to various species of livestock such as sheep and cattle. Trichlorfon caused red cell cholinesterase depression (level not specified) in cattle and sheep. This cholinesterase depression was associated with clinical signs, also unspecified (HED Doc 003267).

Antidotal studies have also been conducted to determine the effectiveness of 2-PAM and atropine in cases of trichlorfon poisoning. An intraperitoneal injection of 2-PAM at doses of 50 mg/kg protected against death in rats receiving trichlorfon at doses of 480 or 600 mg/kg. Atropine sulfate at doses of 100 mg/kg counteracted doses that were three times the LD<sub>50</sub> in mice (MRID 00081337, 00090786, 00081186; HED Doc. 003267).

## **2. Exposure Assessment**

### **a. Dietary**

Bayer Corporation, the producer of trichlorfon, has voluntarily canceled the food, feed and field crop uses of trichlorfon. A voluntary request for label amendments deleting these uses was published in the Federal Register (FR Vol. 57, No. 214, 11/4/92) and final comment period ended November 21, 1995. Bayer Corporation has also requested voluntary cancellation of the dermal pour-on use registrations, supporting only the tolerance for imported cattle meat, cattle fat and cattle meat by-products.

The only expected dietary exposure to trichlorfon residues will be in the form of imported cattle meat and by-products. The current tolerance for these commodities is set at 0.1 ppm. Residue and metabolism data are required to reassess the tolerances, specifically, dermal metabolism in cattle (171-4), magnitude of the residue for meat (171-4), residue analytical method (171-4), and storage stability (171-4). Treatment of some of the non-food use sites could possibly result in residues on food and feed items (i.e. food handling establishments and livestock premises). The Agency has imposed, and will continue to impose label restrictions designed to preclude the occurrence of such residues.

Limited residue data were available to perform risk assessments for the current tolerances for cattle meat, fat and meat-by-products (1967, PP7F0612). These data indicate that beef cattle sprayed consecutively for 34 days with 0.04 oz. active ingredient per animal (avg. animal weight of 850 lbs) had a maximum residue level in fat, edible organs or steak of 0.02 ppm of trichlorfon, a level five times lower than the current established tolerances of 0.1 ppm for these commodities. Although the data were classified as valid, they do not represent the current application rate. The current maximum label rate is approximately 0.06 oz active ingredient per 200 lb animal, which is almost 7 times higher than the single daily application rate used in the study.



Although the application rate used in the study is lower than the expected actual use, the study provides an estimate of possible residues. The residues found after 34 consecutive days of application were five times lower than the current tolerance. Based on this, and the fact that in actuality treatment would not occur daily and there is a 21 day pre-slaughter interval, the Agency concludes that tolerances of 0.1 ppm are appropriate for risk assessment purposes for the time being, until data are generated to reassess the tolerances.

Tolerances for residues of trichlorfon in/on food and feed items are currently expressed in terms of trichlorfon [dimethyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate] *per se* [40 CFR §180.198]. These tolerances range from 0.01 ppm (milk) to 240 ppm (range grass and hay). A feed additive tolerance of 2.5 ppm has been established for this same residue in dried citrus pulp [40 CFR §186.2325].

### **b. Occupational and Residential**

Trichlorfon is currently registered for many terrestrial non-food indoor and outdoor uses. Trichlorfon may be applied using a cup (as a pour-on to livestock or to “sprinkle” or pour bait formulations), high-pressure hand-held sprayer, groundboom sprayer, hydraulic low-pressure sprayer, irrigation system, watering can (to pour dissolved bait), aircraft or granular spreader (chest mounted or push-type). (See Use Profile, page 2). Application methods used for terrestrial food scenarios have not been included because the recent voluntary cancellation of these uses has been finalized. Also not included in the occupational and residential exposure analysis is the sod farm use scenario, application by aircraft or chest mounted granular spreaders. These were determined in preliminary analysis to have unacceptable MOE's. As a result of the preliminary analysis, the registrant agreed to voluntarily cancel the sod farm use and prohibit aerial and chest mounted type spreader applications through appropriate label restrictions. (Note: currently there are no trichlorfon products that include label instructions for aerial application, nor specific aerial prohibition).

**Occupational-use Products and Home-use Products:** At this time, there are products containing trichlorfon that are intended primarily for occupational use as well as some intended primarily for homeowner use.

**Summary of Toxicity Concerns Impacting Occupational and Residential Exposure:** Guideline studies for acute toxicity indicate that trichlorfon is classified as category II for acute oral toxicity, category III for acute dermal toxicity, category IV for acute inhalation toxicity, category III for eye irritation potential and category IV for skin irritation potential. It is classified as a moderate contact allergen. The NOEL of 100 mg/kg/day (based on cholinesterase inhibition) from the 21-day dermal rabbit study (MRID 40306901) has been identified as a toxicological endpoint appropriate for short-term and intermediate term occupational and residential exposure assessment.

**Summary of Potential Occupational and Residential Exposure:** An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators) during use or to persons entering treated sites after application is complete. EPA has determined that there is potential exposure to mixers, loaders, applicators, and other handlers during the usual use-patterns associated with trichlorfon. EPA specifically is concerned with potential exposures arising from: mixing and loading soluble powder formulations, application with a high-pressure hand-held sprayer, application with groundboom sprayer, and from mixing/loading/applying (one person) by cup, granular spreader, or watering (“sprinkler”) can.

Based on the use-patterns and potential exposures, several exposure scenarios were analyzed for trichlorfon: (1) mixing/loading the soluble powder formulation to support typical (40-acre per day) applications, including average golf courses or supporting several (8-acre per day) commercial turfgrass applicators, (2) mixing/loading the soluble powder formulation to support typical (1,000 gallons per day) applications to ornamentals, including greenhouse and nursery sites (3) applying (1,000 gallons per day) with a high-pressure handwand sprayer, (4) applying with a hydraulic low-pressure handwand sprayer (commercial turfgrass sprayer), (5) applying (40 acres per day) with a groundboom sprayer, (6) mixing/loading/applying dry bait using a cup, (7) mixing/loading/applying the bait as a liquid using a watering-can type method, (8) mixing/loading/applying with a chest mounted rotary-type (“belly-grinder”) granular spreader by a commercial applicator (8 acres per day) or by homeowner (1 acre per day), and (9) mixing/loading/applying with a push-type granular spreader by a commercial applicator (8 acres per day) or by homeowner (1 acre per day). The exposure scenarios are presented in Table 2 along with the corresponding exposure assessment.

Daily exposure is calculated using the following formulas:

- Daily Dermal Exposure (mg/day)  
$$= \text{Unit Exposure (mg/lb ai)} \times \text{Appl. Rate (lb ai/area)} \times \text{Area (or Volume) Treated (A/day)}$$
- Daily Inhalation Exposure (mg/day)  
$$= \text{Unit Exposure (mg/lb ai)} \times \text{Appl. Rate (lb ai/area)} \times \text{Area (or Volume) Treated (A/day)}$$

These calculations of daily exposure to trichlorfon by handlers are used to assess the risk to those handlers and are summarized in Table 2.

**Table 2. Occupational and Homeowner Exposures to Trichlorfon**

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure (mg/lb ai) <sup>a</sup>	Baseline Inhalation Unit Exposure (ug/lb ai) <sup>b</sup>	Crop and Application Rate (lb ai/acre)	Daily Acres Treated	Daily Dermal Exposure (mg/day) <sup>c</sup>	Daily Inhalation Exposure (mg/day) <sup>d</sup>	Daily Total Exposure (mg/day) <sup>e</sup>
Mixer/Loader Exposure							
Soluble Powder - Golf Course (1)	3.8	43.4	8.2	40	1,246	4.2	1,260
Soluble Powder - Ornamentals (2)			15 lb ai/1,000 gallons	1,000 gallons	57.0	0.65	57.7
Applicator Exposure							
High Pressure Handwand (3)	1.8	78.6	15 lb ai/1,000 gallons	1,000 gallons	27.0	1.18	28.2
Hydraulic Low Pressure Handwand (4)	No data	No data	No data	No data	No data	No data	No data
Groundboom - Golf Course (5)	0.02	0.7	8.2	40	6.6	0.23	6.8
Mixer/Loader/Applicator Exposure							
Cup (6)	No data	No data	No data	No data	No data	No data	No data
Watering Can (7)	No data	No data	No data	No data	No data	No data	No data
Belly Grinder/Chest Mounted Rotary Spreader (8)	(H) 10.4	61.8	8.1	(H) 1 (O) 8	(H) 84.2 (O) 674.0	(H) 0.50 (O) 4.0	(H) 84.7 (O) 678.0
Push-type Granular Spreader (9)	(H) 2.9	6.3	8.1	(H) 1 (O) 8	(H) 23.5 (O) 187.9	(H) 0.05 (O) 0.41	(H) 23.6 (O) 188.3

Note: Originally sod farms were listed as a registered use; however, the registrant has voluntarily proposed to discontinue this use based on preliminary exposure/risk assessment that indicated unacceptable risks.

- a Baseline dermal unit exposure (mg/lb ai) is for single layer clothing and no gloves.
- b Baseline inhalation unit exposure (ug/lb ai) is for no respirator.
- c Daily Dermal Exposure (mg/day) = Dermal Unit Exposure (mg/lb ai) \* Max. Appl. Rate (lb ai/acre) \* Max. Treated (acres).
- d Daily Inhalation Exposure (mg/day) = Inhalation Unit Exposure (mg/lb ai) \* (1mg/1000ug) conversion \* Max. treated
- e Daily Total Exposure (mg/day) = Daily Dermal Exposure + Daily Inhalation Exposure.

**Post-application Exposure:** EPA has determined that there is potential exposure to persons entering treated areas after application is complete. EPA is particularly concerned with potential post-application exposure arising from re-entry into treated greenhouses and treated outdoor ornamental (nursery) and turfgrass sites. Post-application exposures to treated non-sod-farm turf (turf in residential, golf-course, recreational areas, etc.) should be somewhat minimized by a requirement for watering-in all turf applications, thus moving trichlorfon into the soil. This mitigation would not greatly reduce the exposure for sod-farm workers who must have contact with the soil subsurface. The Agency is concerned with the potential exposure to children and pets from the residential uses of the bait formulations; upon recommendation of the Agency the registrants have agreed to voluntarily cancel the residential lawn use and prohibit the use of the bait from indoor use unless housed in prepackaged child resistant bait stations. Post-application concerns from sites other than turfgrass and ornamentals are expected to be minimal due to the limited frequency, duration, and degree of exposure following such applications.

EPA has no active-ingredient-specific data upon which to assess the post-application exposures to trichlorfon.

### **3. Risk Assessment**

#### **a. Dietary**

**Toxicological Endpoints:** The chronic dietary exposure analysis used a Reference Dose (RfD) of 0.002 mg/kg/day calculated from the LOEL of 0.2 mg/kg/day from a chronic feeding study in Rhesus monkeys. The effect observed, decreased brain cholinesterase activity, was marginal and considered to be a threshold effect. Therefore, an uncertainty factor of 100 was applied to account for interspecies extrapolation and intraspecies variability. Trichlorfon has been classified as Group E, no evidence of carcinogenicity in humans, by the OPP Carcinogenicity Peer Review Committee.

An acute dietary risk assessment was conducted using the NOEL of 2.5 mg/kg body weight/day from a single dose clinical trial in humans. At the LOEL (5 mg/kg body weight/day), plasma and RBC cholinesterase inhibition were observed, and clinical signs of nausea, vomiting and diarrhea were reported.

**Residue Data:** Although the Agency anticipates revocation of all existing crop food/feed tolerances for trichlorfon, these tolerances have not yet been revoked. Therefore, chronic and acute dietary risk assessments represent all published uses for trichlorfon. Reassessment of the cattle meat, cattle fat and cattle meat by-products will be performed when the required residue data are submitted within 24 months.

**Chronic Dietary Risk Assessment:** The Agency performed a dietary risk assessment on the published tolerances for trichlorfon. The chronic dietary analysis used tolerance level residues to calculate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. The dietary analysis was conducted at tolerance levels and assumed 100% crop (or cattle) treated. No refinements to the trichlorfon residue data were incorporated in the dietary analysis, including anticipated residues or percent crop treated data.

The TMRC for the U.S. population from the published uses of trichlorfon is  $1.79 \times 10^{-3}$  mg/kg body weight/day which represents 89.35% of the RfD. The TMRC's from published tolerances for the two most highly exposed subgroups, children (1-6 years old) and non-nursing infants (<1 year old) are  $4.20 \times 10^{-3}$  and  $4.71 \times 10^{-3}$  mg/kg body weight/day, respectively. These exposure estimates represent 209.77% and 235.34% of the RfD, respectively. Four other subgroups (Hispanics, non-Hispanics others, nursing infants, and children (7-12 years old) also have exposure estimates exceeding the RfD. Generally, exposure estimates in excess of the RfD indicate a potential risk concern.

The TMRC for meat, fat and meat by-products from cattle treated by the pour-on method (the only use supported for imported meat) with trichlorfon was calculated using the current cattle tolerances. The TMRC for the U.S. population is  $1.58 \times 10^{-4}$  mg/kg body weight/day, representing 7.91% of the RfD. The TMRCs for the two highest exposed subgroups, children (1-6 years old) and non-nursing infants (< 1 year old), are  $2.87 \times 10^{-4}$  and  $1.46 \times 10^{-4}$  mg/kg body weight/day, representing 14.33% and 7.32% of the RfD, respectively. These estimates indicate that the pour-on use does not present a risk concern based on the current published tolerances because the exposure estimates do not exceed the RfD; however residue data are extremely limited for beef products. As noted previously, the only tolerance that will remain for trichlorfon is for the import of cattle products. Since the above dietary risk assessment included domestic usage of trichlorfon, the residue contribution of imported beef *only* would result in a lower percent utilization of the RfD. The Agency is requiring that the necessary residue data needed to reassess the tolerances be submitted within 24 months. For details regarding this issue please see Part IV, C.1. Tolerance Reassessment.

**Acute Dietary Risk Assessment:** The detailed acute dietary exposure analysis evaluates individual consumption as reported by respondents in the USDA 1977-78 Nationwide Food Consumption Survey (NFCS) and estimates the distribution of single day exposures through the diet for the U.S. population and certain subgroups. The analysis assumes uniform distribution of trichlorfon in the commodity supply. Since the toxicological effect to which the high end exposure is compared is cholinesterase inhibition, all standard population subgroups are evaluated. The analysis includes the U.S. population - 48 states and four subgroups: infants (< 1 year old), children (1-6 years old), females (13+ years) and males (13+ years).

The margin of exposure (MOE) is a measure of how closely the high end exposure comes to the NOEL (the highest dose at which no effects were observed in the laboratory test), and is calculated as the ratio of the NOEL to the exposure (NOEL/exposure = MOE). For cholinesterase inhibition from a human study, the Agency generally accepts an MOE of above 10 as not presenting a risk of concern.

In the analysis, tolerance level residues were used to calculate the exposure of the highest exposed individual for the U.S. population and four population subgroups and compared to the NOEL of 2.5 mg/kg body weight/day from a single dose clinical trial in humans. The MOEs calculated for the U.S. population and four population subgroups are summarized below.

**Table 3: Acute Dietary Margins of Exposure based on Published Tolerances (excluding Cattle Pour-on Use)**

DRES Subgroup	MOE* (NOEL/High End Exposure)
U.S. population - 48 states	67
Infants (< 1 year old)	50
Children (1-6 years old)	50
Females (13+ years)	100
Males (13+ years)	100

\* An MOE of less than 10 indicates a potential risk concern.

The high-end MOEs for the published uses for trichlorfon are greater than 10, indicating that there is little likelihood of an appreciable acute dietary risk due to the currently registered uses of trichlorfon.

An acute dietary analysis was also conducted to estimate the potential risk presented by the pour-on cattle use only. As for the chronic dietary analysis, the current tolerance level for beef products of 0.1 ppm was used as the residue level for this analysis. The MOEs calculated for the U.S. population and four population subgroups are as follows:

**Table 4: The Acute Dietary Margins of Exposure based on Tolerances established for the Cattle Pour-on Use Only**

DRES Subgroup	MOE* (NOEL/High End Exposure)
U.S. population - 48 states	2000
Infants (< 1 year old)	2000 <sup>a</sup>
Children (1-6 years old)	2000 <sup>b</sup>

<b>DRES Subgroup</b>	<b>MOE* (NOEL/High End Exposure)</b>
Females (13+ years)	5000 <sup>b</sup>
Males (13+ years)	2500

\*An MOE of less than 10 indicates a potential risk concern.

<sup>a</sup> 97th percentile estimate

<sup>b</sup> 98th percentile estimate

The estimated high-end MOEs for the pour-on use for trichlorfon are greater than 10, suggesting that there is little likelihood of an appreciable acute dietary risk from the pour-on use of trichlorfon based on the established tolerance.

Tolerances will be reassessed when the additional residue data are available. This reassessment will be used to determine appropriate levels for tolerances with no U.S. registration. If these data are not submitted within two years for tolerance reassessment, the tolerances will be proposed for revocation.

### **b. Occupational and Residential Risk**

There is a potential for mixer/loader/applicator exposure via the inhalation and dermal routes. The Margins of Exposure (MOE) for workers involved in handling these chemicals is determined by the following equations:

- Daily Dermal Dose (mg/kg/day)  
= Daily Dermal Exposure (mg/day) ÷ Handler Body Weight (70 kg)
- Daily Inhalation Dose (mg/kg/day)  
= Daily Inhalation Exposure (mg/day) ÷ Handler Body Weight (70 kg)
- Dermal MOE  
= NOEL (100 mg/kg/day) ÷ Daily Dermal Dose (mg/kg/day)
- Inhalation MOE  
= NOEL (mg/kg/day) ÷ Daily Inhalation Dose (mg/kg/day)

The daily exposure values are provided in Table 2 of the occupational exposure/risk assessment. The MOEs for handlers for the various scenarios involved with mixing/loading/applying trichlorfon are provided in Table 5. For occupational and residential exposure, the Agency generally accepts an MOE of above 100 as not presenting a risk of concern.

The MOEs for handlers wearing baseline personal protective equipment (i.e., long-sleeve shirts, long pants, shoes, and socks) using trichlorfon are reasonable with the exception of:

- Mixers and loaders handling the soluble powder formulation to support typical area (40 acre) applications to turfgrass (i.e. golf courses);
- Commercial mixers/loaders/applicators handling granular formulations for application with a push-type spreader; and
- Mixer/loader/applicators handling the granular formulation for application with chest mounted rotary spreaders (“belly grinders”).

As with any risk calculations, there are uncertainties associated with the assumptions.

The addition of personal protective equipment (PPE) or engineering controls could adequately reduce the risk to an acceptable level for several of the handler scenarios:

- The risk to mixers and loaders handling the soluble powder formulation to support typical area (40 acres per day) applications to turfgrass could be adequately mitigated with the addition of chemical-resistant gloves;
- The risk to commercial mixers/loaders/applicators handling the granular formulation for application to turfgrass using push-type spreaders could be adequately mitigated with a double layer of bodywear protection and chemical-resistant gloves.

Additional PPE or other mitigating efforts could not be utilized to bring unacceptable MOE's of less than 100 up to an acceptable level for the following scenarios: 1) mixing/loading and applying using chest-mounted rotary spreader (“belly-grinder”) equipment for both the occupational and homeowner uses, even with maximum PPE of double layers of body protection, chemical resistant gloves and a dust/mist filtering respirator; and 2) mixing/loading/applying for aerial application; and 3) mixers and loaders handling soluble powder formulations to support large area applications (up to 500 acres per day; i.e. sod-farms). Engineering controls consisting of water-soluble packaging are infeasible for trichlorfon and, therefore, cannot be used to adequately reduce the risk to mixers and loaders handling large quantities of the soluble powder formulation. The risk associated with aerial applications could not be any reduced by practical means. Because of this unmitigatable risk, the registrant has agreed to prohibit these uses and therefore they are not included in the exposure or risk Tables.

Table 5 summarizes the dose and MOE values for the trichlorfon.



**Table 5: Occupational and Homeowner Risk from Trichlorfon**

Exposure Scenario (Number)	Baseline Total Dose (mg/kg/day) <sup>a</sup>	Baseline Dermal MOE <sup>b</sup>	Risk Mitigation Measures			
			Additional PPE <sup>c</sup>			
			Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Total Dose (mg/kg/day) <sup>d</sup>	Total MOE <sup>e</sup>
<b>Mixer/Loader Risk</b>						
Soluble Powder - Turfgrass (1)	18.0	5.6	0.16 (gloves)	43.4	0.95	105
Soluble Powder - Ornamentals (2)	0.82	122	N/A	N/A	N/A	N/A
<b>Applicator Risk</b>						
High Pressure Handwand (3)	0.40	250	N/A	N/A	N/A	N/A
Hydraulic Low Pressure Handwand (4)	No data	No data	No data	No data	No data	No data
Groundboom - Golf Course (5)	0.10	1,000	N/A	N/A	N/A	N/A
<b>Mixer/Loader/Applicator Risk</b>						
Cup (6)	No data	No data	No data	No data	No data	No data
Watering Can (7)	No data	No data	No data	No data	No data	No data
Belly Grinder/Chest Mounted Rotary Spreader (8)	(H) 1.21 (O) 9.69	(H) 83 (O) 10	(H) None (O) 4.2	(H) None (O) 12.4	(H) None (O) 3.9	(H) None (O) 26
Push-Type Spreader (9)	(H) 0.34 (O) 2.69	(H) 294 (O) 37	(H) N/A (O) 0.73	(H) N/A (O) 6.3	(H) N/A (O) 0.68	(H) N/A (O) 147

N/A = Not applicable since baseline MOE was over 100, indicating additional mitigation is not necessary.

None = No additional PPE possible.

a Baseline total dose = (daily dermal exposure + daily inhalation exposure)/70 kg.

b Baseline MOE = NOEL (100 mg/kg/day)/Baseline total dose.

c Additional PPE: Scenarios 1a and 4 = single layer clothing and chemical resistant gloves.

Scenarios 8 and 9 = coveralls over single layer clothing and chemical resistant gloves, plus a dust mist respirator (5-fold protection factor) applied to scenario 8.

d Additional PPE Daily Total Dose = Additional PPE Dermal Unit Exposure + Additional PPE Inhalation Unit Exposure \* Application Rate \* Acres Treated per day/70 kg

e Additional PPE MOE = NOEL/Additional PPE Daily Total Dose

## **Risk From Post-application Exposures**

Post-application concerns for applications to sites other than turfgrass and ornamentals appear to be minimal and the anticipated frequency, duration, and degree of exposure following such applications do not warrant risk mitigation measures.

The Agency concludes that risks from post-application exposures to treated turf could be a concern (i.e. golf courses, ornamental lawns); however, post-application risks should be adequately mitigated by a requirement for watering-in all turf applications and by restricting entry until the treated turf had dried following the watering-in. The risk associated with the sod-farm uses have been determined to be unacceptable and the use has been voluntary canceled.

The potential risk to children and pets from exposure to the bait formulations is of concern. Upon recommendation of the Agency, the registrants have agreed to voluntarily cancel the residential lawn use of the baits and restrict indoor domestic use to products prepackaged in child resistant bait stations.

The risk to workers from post-application exposures to treated ornamentals not being grown for research or commercial use (ornamentals in parks, ornamental gardens, interior plantscapes, etc.) should be adequately minimized by restricting entry until the treated surface has dried, since the degree of exposure of the workers to residues remaining on such ornamentals should be relatively infrequent and generally of short duration.

Post-application exposures to ornamentals (greenhouse and nursery) grown for sale are a risk concern for entry immediately following applications. The Agency has determined that post-application exposures do not appear to pose an unreasonable risk to persons entering treated areas, as long as entry is not permitted until 24 hours after application. Therefore, for all uses within the scope of the worker protection standard (ornamentals grown in greenhouses and nursery), EPA is requiring:

- A restricted-entry interval (REI) of 24 hours, and
- Personal protective equipment for workers who enter the treated area before the REI has expired.

## **Exposure Studies for Handlers (Mixers/Loaders/Applicators)**

Requirements for mixer/loader/applicator (i.e., handler) exposure studies are addressed in Subdivision U of the Pesticide Assessment Guidelines. Mixer/loader/applicator exposure studies were not required in the Guidance for the Reregistration of Pesticide Products Containing Trichlorfon issued in June 1984. Review of the exposure data submitted to support reregistration indicates that these data still are not warranted for **most** scenarios. As noted in Table I and II, there are several scenarios for which there are no exposure data

available, including application by hydraulic low-pressure handwand equipment, by cup, and by watering can. Confirmatory exposure data are required for the hydraulic low-pressure handwand equipment. [These data have been designated as confirmatory because the MOE's for similar uses (i.e. high pressure handwand) are above 100].

For the two other scenarios (application by cup and watering can) for which there are no data, it is anticipated that the amount of product handled using these techniques would be less than that in a 'paintbrush' scenario. A paintbrush scenario was utilized as a surrogate worst case scenario for the cup and watering can scenarios. With the addition of chemical resistant gloves, the MOE was 286, indicating there is no risk concern. Therefore, data are still not required for application using a cup or a watering can.

Two studies are required to provide data on applicators during ground applications using hydraulic low-pressure handwand (turf) equipment. They are:

- A dermal exposure study (Guideline 231), and
- An inhalation exposure study (Guideline 232)

These studies should be conducted concurrently; i.e., dermal and inhalation samples should be collected from the same worker and at the same site during each trial.

### **Exposure Studies for Post-Application**

The current data are limited and additional data are needed to confirm that these uses do not pose unreasonable risks to reentry workers. The greenhouse/nursery ornamental uses and residential turfgrass uses are considered worst-case scenarios for post-application exposures to trichlorfon. Data are not being required for the other post-application exposure scenarios because it is anticipated that the exposure levels from these uses are lower than those in the greenhouse/nursery ornamental and turfgrass scenarios.

Postapplication/reentry exposure data are needed to determine definitive REIs for the occupational turfgrass and greenhouse/nursery use sites. The interim REIs established in this document will be adjusted accordingly upon submission of the additional data. In addition, data are needed to determine the post-application exposure following applications to turfgrass at residential sites. Post-application/reentry studies are required as confirmatory data to support the reregistration of trichlorfon, these are to be performed on the following sites:

- Greenhouse-grown ornamental plants, and
- Residential sites (turfgrass)

Requirements for postapplication/reentry exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include:

Guidelines:	132-1(a)	Foliar Residue Dissipation
	*133-3	Postapplication Dermal Passive Dosimetry Exposure
	*133-4	Postapplication Inhalation Passive Dosimetry Exposure

\*Guidelines 133-3 and 133-4 may be reserved at this time pending completion of the databases on agricultural and residential postapplication/reentry exposure currently being developed by the Agricultural Reentry Task Force and Outdoor Residential Exposure Task Force, **provided** the registrant is a member of both Task Forces.

## C. Environmental Assessment

### 1. Ecological Effects

#### a. Ecological Effects Data

##### (1) Toxicity to Terrestrial Animals

In order to assess the toxicity of trichlorfon to birds, the minimum data required on the technical material are: an avian single-dose oral (LD<sub>50</sub>) study on one species, preferably mallard or bobwhite quail; a subacute dietary (LC<sub>50</sub>) study using one waterfowl species, preferably the mallard duck; a subacute dietary (LC<sub>50</sub>) study using one upland game species, preferably bobwhite quail or ring-necked pheasant.

##### (a) Avian Acute Toxicity

Based on acute toxicity data, technical grade trichlorfon is highly toxic to moderately toxic to birds. The available data are adequate to assess the acute toxicity to birds (MRID 00073683, 00091969, 00160000).

**Table 6.**

Toxicity of Trichlorfon to Birds: Acute Toxicity			
Species	% Active Ingredient	LD <sub>50</sub> (mg/kg)	Fulfills Guidelines?
Starling	TGAI	47	No <sup>1</sup>
Red-winged blackbird	TGAI	40	No <sup>1</sup>
Bobwhite quail	42.4% (TEP)	99	Yes <sup>2</sup>
Mallard duck	98	36.8	Yes
Bobwhite quail	98	22.4	Yes
California quail	98	59.3	No <sup>1</sup>

<b>Toxicity of Trichlorfon to Birds: Acute Toxicity</b>			
<b>Species</b>	<b>%Active Ingredient</b>	<b>LD<sub>50</sub> (mg/kg)</b>	<b>Fulfills Guidelines?</b>
Ring-necked pheasant	98	95.9	No <sup>1</sup>
Rock dove	98	123	No <sup>1</sup>

1 The Agency restricts the species that can be used to fulfill guideline requirements. Toxicity data on other species may be considered scientifically valid and used in the ecological risk assessment.

2 Fulfills guideline requirement for testing with an End Use Product.

### (b) Avian Subacute Dietary Toxicity

Based on studies performed with the technical grade, trichlorfon is classified as moderately toxic to practically non-toxic to birds. The available data were determined to be adequate to assess the toxicity of trichlorfon (MRID 00034769).

**Table 7.**

<b>Toxicity of Trichlorfon to Birds: Subacute Dietary Toxicity</b>			
<b>Species</b>	<b>%Active Ingredient</b>	<b>LC<sub>50</sub> (ppm)</b>	<b>Fulfills Guidelines?</b>
Bobwhite Quail	TGAI	720	Yes
Japanese Quail	TGAI	1901	No <sup>1</sup>
Ring-necked pheasant	TGAI	3401	Yes
Mallard Duck	TGAI	>5000	Yes

1 The Agency restricts the species that can be used to fulfill guideline requirements. Toxicity data on other species may be considered scientifically valid and used in the ecological risk assessment.

### (c) Avian Chronic Toxicity

Avian reproduction studies were required for trichlorfon based on the permissibility of multiple applications, which may result in chronic exposure. Two avian reproduction studies show that there will be effects on reproduction at levels of trichlorfon as low as 30 mg/L (MRID 43019601, 43119501).

**Table 8.**

<b>Toxicity of Trichlorfon to Birds: Measurements from Reproduction Studies</b>			
<b>Species</b>	<b>%Active Ingredient</b>	<b>Toxicity (ppm)</b>	<b>Fulfills Guidelines?</b>
Bobwhite Quail	99.8	NOEC= 9 LOEC= 30	Yes
Mallard Duck	99.8	NOEC= 27	Yes

**(d) Toxicity to Mammals**

A rat acute oral study resulted in an LD<sub>50</sub> value of 400 mg/kg. A 3-generation rat reproduction study had reproductive and maternal NOELs of 300 mg/L and an LOEL of 1000 mg/L (MRID 00128682).

**(e) Toxicity to Honeybees**

An acceptable study with the honey bee resulted in an estimated LD<sub>50</sub> of 59.8 µg/bee. This indicates that trichlorfon technical has low toxicity to honey bees (MRID 00036935).

**(2) Aquatic Animal Data****(a) Toxicity to Freshwater Fish**

Acute toxicity measurements with the technical material trichlorfon (displayed below) range from highly toxic to practically non-toxic to freshwater fish, while measurements with formulated product indicate similar results with toxicity ranging from high to slight (MRID 05015393, 40094602, 40098001, 00091881, 00065497, 00091766, 00091942, 00091951).

**Table 9.**

<b>Trichlorfon Toxicity to Fish: (I) Acute Measurements with TGAI</b>			
<b>Species</b>	<b>%Active Ingredient</b>	<b>LC50 (mg/L)</b>	<b>Fulfills Guidelines?</b>
Bluegill Sunfish	98	0.23	Yes
	99	3.8	Yes
Largemouth Bass	98	3.4	Yes
Fathead Minnow	98	7.9	Yes
	99	51	Yes
	99	110	Yes

<b>Trichlorfon Toxicity to Fish: (I) Acute Measurements with TGAI</b>			
<b>Species</b>	<b>%Active Ingredient</b>	<b>LC50 (mg/L)</b>	<b>Fulfills Guidelines?</b>
Striped Bass	80	2	No
Rainbow Trout	98	0.43	Yes
Cutthroat Trout	98	0.38	Yes
Brook Trout	98	0.24	Yes
Lake Trout	98	0.55	Yes
Channel Catfish	98	0.88	Yes
Black Bullhead	98	0.52	Yes
Goldfish	99	100	No <sup>1</sup>
Guppy	99	7.2	No <sup>1</sup>

<sup>1</sup> The Agency restricts the species that can be used to fulfill guideline requirements. Toxicity data on other species may be considered scientifically valid and used in the ecological risk assessment.

**Table 10.**

<b>Trichlorfon Toxicity to Fish: (ii) Acute Measurements with Formulated Product</b>			
<b>Species</b>	<b>%Active Ingredient</b>	<b>LC<sub>50</sub> (mg/L)</b>	<b>Fulfills Guidelines?</b>
Bluegill Sunfish	40EC	5.2	No
	8	100	No
	18.6	10	Yes
Cutthroat Trout	80WP	3.25	No
Rainbow Trout	12.2	<37.1	No
	80WP	0.78	No
	18.6	9.5	Yes

A fish chronic toxicity measurement (i.e., early life stage test) was required because trichlorfon has high potential to be transported to aquatic habitats via runoff, has an LC50 below 1.0 mg/L, and has an EEC greater than 1% of the LC50. A study performed with a 99.6% active ingredient material on rainbow trout, resulted in a MATC between 110 and 160 µg/L. This result was based on the impairment of growth and survival of juvenile rainbow trout at concentrations greater than 110 µg/L (MRID 42571701).

**(b) Toxicity to Freshwater Invertebrates**

Several species of aquatic invertebrates were tested for acute toxicity to technical trichlorfon. The results indicated that trichlorfon is very highly toxic to all tested species except crayfish. Trichlorfon was found to be moderately toxic to crayfish.

Based on this high toxicity and the resultant estimated environmental concentration (EEC) which was greater than the EC50, acute toxicity with the formulated product testing was required. The studies submitted were not entirely acceptable based on Agency guidelines. Nevertheless, these studies gave ample data to determine that the formulated product is more toxic than the technical in those species tested; therefore, no further studies are required (MRID 00065497, 40094602, 40228401, 40098001).

Based on the same criteria as noted for chronic fish testing, chronic toxicity to aquatic invertebrates was required for trichlorfon. The acceptable study performed with Daphnia magna resulted in a MATC between 5.6 and 8.6 ng/L. This result indicates that technical trichlorfon will cause adverse chronic effects to aquatic invertebrates at concentrations greater than 5.6 ng/L (MRID 40452601).

**Table 11.**

<b>Trichlorfon Toxicity to Freshwater Invertebrates</b>			
<b>Species</b>	<b>% Active Ingredient</b>	<b>EC<sub>50</sub> (µg/L)</b>	<b>Fulfills Guidelines?</b>
<b>(I) Acute Toxicity with TGAI</b>			
Water flea ( <i>S. serr.</i> )	98	0.70	Yes
Water flea ( <i>D. pulex</i> )	98	0.18	Yes
Scud ( <i>G. lacrustis</i> )	98	40	No
Scud ( <i>G. pseudolimneus</i> )	98	32	No
Crayfish	98	7800	No
Stonefly ( <i>P. badia</i> )	98	11	No
	98	5.3	No
Stonefly ( <i>P. calif.</i> )	98	35	No
Stonefly ( <i>C. sabulosa</i> )	98	22	No
Stonefly ( <i>Isogenus sp.</i> )	98	24	No
Stonefly ( <i>A. pacifica</i> )	98	16.5	No



<b>Trichlorfon Toxicity to Freshwater Invertebrates</b>			
<b>Species</b>	<b>% Active Ingredient</b>	<b>EC<sub>50</sub> (µg/L)</b>	<b>Fulfills Guidelines?</b>
(ii) Acute Toxicity with Formulated Product			
Scud ( <i>G. pseudo.</i> )	80	17.0	No
Stonefly ( <i>Isogenus sp.</i> )	80WP	12.0	No

**(c) Acute Toxicity to Estuarine and Marine Animals**

Acute toxicity testing on estuarine and marine organisms was required for trichlorfon based upon the turf use which may cause exposure to those habitats. The acceptable studies were performed with fish and shrimp (72-3a,c) but an acceptable test for mollusks (72-3b) has not been submitted. The measurements displayed below indicate that trichlorfon is very highly toxic to moderately toxic to estuarine and marine animals (MRID 40098001, 40228401).

**Table 12.**

<b>Acute Toxicity to Marine and Estuarine Animals</b>			
<b>Species</b>	<b>% Active Ingredient</b>	<b>LC<sub>50</sub> (µg/L)</b>	<b>Fulfills Guidelines?</b>
Pink shrimp	98	0.36	Yes
Eastern oyster	98	>1.0	No
Spot	98	>1000	No
Atlantic salmon	98	300	Yes

Chronic testing with estuarine and marine organisms is also required because trichlorfon is expected to be transported to marine and estuarine habitats on a repeated basis and has acute LC<sub>50</sub> values below 1 mg/L. No studies have yet been submitted. An assessment of chronic risk for marine and estuarine animals is based on MATC values for freshwater fish and invertebrates.

**(3) Terrestrial, Semi-Aquatic and Aquatic Plant Data**

Nontarget plant testing is not required to support the currently proposed uses of trichlorfon.

## b. Ecological Effects Risk Assessment

### (1) Exposure to Terrestrial Animals

Birds and mammals may ingest trichlorfon granules directly and may ingest food (vegetation, seeds, insects) contaminated with trichlorfon residues. The risk assessment is based on the use of trichlorfon granular formulation on turf, which is the use with greatest potential exposure to wildlife. The exposure assessment is based on a single application to turf at the maximum label rate for the granular of 3.75 oz of product per 1000 square feet (i.e. at a rate of 8.17 lb ai/A or 87.07 mg/ft<sup>2</sup> applied as a granular broadcast or foliar spray). [The granular bait formulation was not evaluated due to a lack of data. However, the registrant has agreed to voluntarily cancel the lawn uses of the bait formulation, thus eliminating the need for the bait specific risk assessment.]

The exposure estimate for direct ingestion of granules is 87.07 mg ai/ft<sup>2</sup> for birds and mammals. The exposure estimate for ingestion of trichlorfon residues on feed items is based on the standard evaluation procedure (USEPA, 1986, 540/9-85-001):

- for short grass (comparable to turf) the EEC is given in mg/L by multiplying the application rate (in lb ai/A) times 240, i.e.  $EEC = 8.17 \times 240 = 1960.8$  ppm; this represents the worst case scenario for exposure. The value of 240 is the expected concentration of pesticide on food (in ppm) when applied at a rate of 1 lb ai/A.
- for residues on seeds and insects the EEC is the application rate multiplied by about 12 ppm per lb/A applied, i.e.  $EEC = 8.17 \times 12 \approx 100$  ppm.

Multiple applications are permissible with trichlorfon on turf, but are not directly addressed in the following terrestrial hazard assessment. The potential for repeated exposure is taken into consideration when evaluating the overall risk of trichlorfon.

#### (a) Risk to Birds

**Acute Toxicity Findings:** Based on acute oral and subacute dietary testing, trichlorfon is highly toxic to practically non-toxic to birds. LD<sub>50</sub> values of 22.4 to 123 mg/kg, based on the technical material, were obtained representing seven species; LC<sub>50</sub> values of 720 to >5000 mg/L were obtained representing four species. An LD<sub>50</sub> value of 99 mg/kg was determined for bobwhite using a formulated product (42.4% active ingredient), indicating moderate toxicity.

**Acute Risk from Ingestion of Granules:** Granular pesticides are a significant problem for birds, which may ingest pesticide granules along with normal grit. Risk quotient values ( $RQ=EEC/LD_{50}$ ) range from 1.28 to 21.1, corresponding to LD<sub>50</sub> estimates from 22.4 mg/kg to 123 mg/kg, and an EEC of 8.17 lb ai/A (87.07 mg/ft<sup>2</sup>). For acute risk to birds the Agency

generally accepts an RQ of 0.5 or greater as exceeding the Level of Concern (LOC). Therefore, the use of granular trichlorfon on turf is expected to result in acute risk to birds. [This does not include a risk analysis for the bait formulation, see III. C. 1. b.(1) above.]

**Acute Risk from Residues on Feed:** Acute risk is expected to birds that are exposed to dietary residues on turf. Based on an LC<sub>50</sub> value of 720 ppm (for bobwhite) and an EEC of 1960.8 ppm (for short grass) the RQ is 2.72, which exceeds the acute LOC of 0.5.

**Chronic Risk from Residues on Feed:** The avian reproduction Lowest Observable Effect Levels (LOELs) for trichlorfon are 30 ppm for the bobwhite and 78 ppm for the mallard duck. The EECs from the use of trichlorfon on turf are 1961 ppm for short grass and 100 ppm for insects and seeds. The risk quotients (RQ = EEC/LOEL) are 65 and 3.3 for bobwhite, and 25 and 1.3 for the mallard. For chronic risk to birds, the Agency generally accepts an RQ of 1.0 or greater as exceeding the Level of Concern. Therefore, chronic hazard to birds is expected from the turf use of trichlorfon.

#### (b) Risk to Mammals

Acute and chronic risk to mammals is based on potential ingestion of granules and/or contaminated food items. [This does not include a risk analysis for the bait formulations, see Avian risk analysis above for more details.] A rat acute oral study resulted in an LD<sub>50</sub> value of 400 mg/kg, which suggests that mammals are less sensitive to trichlorfon than birds.

**Acute Risk from Ingestion of Granules:** Based on the LD<sub>50</sub> of 400 mg/kg and an EEC 8.17 lb ai/A (87.07 mg/ft<sup>2</sup>) the risk quotient is 2.13, which is greater than the LOC (0.5).

**Acute Risk from Residues on Feed:** An LC<sub>50</sub> estimate was is determined for this scenario, as no acute dietary mammalian data were available. An estimate was obtained by dividing the LD<sub>50</sub> by the fraction of body weight that an animal will consume in a day. For a 200 g rat that consumes 10 g food per day, the LC<sub>50</sub> is 8000 mg/L (= 400×200/10). The corresponding RQ is 0.25 (= 1961/8000) which does not exceed the LOC of 0.5.

**Chronic Risk:** A 3-generation rat reproduction study resulted in reproductive and maternal NOELs of 300 mg/L and a LOEL of 1000 mg/L. The EEC for short grass (1961 ppm) exceeds the LOEL, but the EEC for insect and seeds (100 ppm) does not.

#### (c) Risk to Nontarget Insects

Trichlorfon is practically non-toxic to honeybees and therefore based on this data, the Agency does not have a concern for exposed non-target beneficial insects.

## (2) Risk to Aquatic Animals

EEC values, risk quotients and LOC's are displayed in the table following; exceeded levels of concern are indicated by shading. Exposure assessment for aquatic organisms is based on application to turf at the maximum label rate of 3.75 oz product per 1000 square feet, or 8.17 lb ai/A. EECs were calculated using the simulation models PRZM 1.0 and EXAM 2.94.

The values displayed assess risk to marine and estuarine animals based on toxicity measurements for freshwater animals. There is considerable uncertainty in these findings, and chronic toxicity measurements are needed for marine/estuarine animals. The development of the tabled values is described in greater detail subsequently, along with some discussion of variation among species.

Levels of concern are exceeded for *acute* risk to *freshwater, marine, and estuarine fish and invertebrates*. *Chronic* levels of concern are exceeded for *freshwater invertebrates* but *not for freshwater fish*.

**Table 13.**

Level of Concern Determination for Aquatic Animals						
Habitat	Invertebrate/ Fish	Acute/ Chronic	Toxic Concentration ( $\mu\text{g/L}$ ) <sup>a</sup>	EEC( $\mu\text{g/L}$ )	RQ = (EEC/Toxic Level)	LOC <sup>f</sup>
Freshwater	Invertebrates	Acute	0.18	224 <sup>c</sup>	1244	0.5 <sup>g</sup>
		Chronic	0.0071	54 <sup>d</sup>	7606	1
	Fish	Acute	230	224 <sup>c</sup>	0.97	0.5 <sup>g</sup>
		Chronic	135	24.7 <sup>e</sup>	0.18	1
Estuarine/ Marine	Invertebrates	Acute	0.36	224 <sup>c</sup>	622	0.5 <sup>g</sup>
		Chronic	0.0071 <sup>b</sup>	54 <sup>d</sup>	7606 <sup>b</sup>	1
	Fish	Acute	300	224 <sup>c</sup>	0.75	0.5 <sup>g</sup>
		Chronic	135 <sup>b</sup>	24.7 <sup>e</sup>	0.18 <sup>b</sup>	1

a EC<sub>50</sub>, LC<sub>50</sub>, or MATC (see text), for the most sensitive species tested.

b Toxicity value based on freshwater animals.

c 96-hour EEC

d 21-day EEC

e 60-day EEC

f There is a concern for risk if the RQ is equal to or larger than the LOC.

g LOC value for high risk; LOC = 0.1 for restricted use, 0.05 for endangered species.

## (a) Toxicity Summary for Aquatic Organisms

The available toxicity measurements for aquatic organisms are shown in the table above.

Toxicity tests have been conducted with trichlorfon technical on 12 species of freshwater fish and 10 species of freshwater invertebrates. For fish, LC<sub>50</sub> estimates ranged from 0.23 mg/L for bluegill sunfish to 110 mg/L for fathead minnow, indicating that trichlorfon technical ranges from highly toxic to practically non-toxic to freshwater fish. For invertebrates, EC<sub>50</sub>'s ranged from 0.18 µg/L for *Daphnia pulex* to 7800 µg/L for crayfish; however, ten of eleven studies resulted in EC<sub>50</sub> estimates indicating very high toxicity (EC<sub>50</sub> ≤ 0.1 mg/L).

A freshwater fish early life stage test showed that trichlorfon technical causes adverse effects to rainbow trout growth and survival at levels greater than 110 µg/L. A life cycle study with *Daphnia magna* showed that growth, survival, and reproduction were impaired from trichlorfon at levels greater than 5.6 ng/L.

For marine and estuarine species, studies using trichlorfon technical resulted in LC<sub>50</sub>'s ranging from 0.36 µg/L for pink shrimp to >1.0 mg/L for spot, indicating very high to moderate toxicity.

Acute toxicity testing with formulated products (8-80% active ingredient) was performed with 3 species of fish and 2 species of invertebrates. For fish, the LC<sub>50</sub> values ranged from 0.78 mg/L for rainbow trout to 100 mg/L for bluegill sunfish indicating high to slight toxicity. For invertebrates tested with an 80% formulation, LC<sub>50</sub>'s of 12 µg/L for stonefly and 17 µg/L for scud resulted, indicating high toxicity.

## (b) Aquatic Exposure

Exposure assessment is based on application to turf at the maximum label rate of 3.75 oz product per 1000 square feet, or 8.17 lb ai/A. The resulting estimated environmental concentrations (EEC's) are displayed in the previous table. The EEC values correspond to different durations of exposure: initially (immediately following a runoff event) and for durations of 96 hours, 21 days, and 60 days.

In the exposure scenario, trichlorfon was applied on May 1, June 1, and July 1, to a 10 hectare grass covered field draining into a body of water with no outlet, with surface area 1 hectare and depth 2 meters. Spray drift from ground spray was 1% of applied active ingredient. The EECs were calculated so that there is an estimated 10% probability of the EEC being exceeded at the site in a given year, by the concentration averaged over a time interval of particular duration (96 hrs, 21 days, or 60 days). For example, there is an

estimated 10% probability that the 60 day EEC will be equaled or exceeded in a particular year by the average concentration over 60 consecutive days, for the use site.

A high exposure scenario was specified in the model using input data from a turf farm in Columbia County NY, in Major Land Resource Area (MLRA) 144B. Year to year variation in meteorological variables for MLRA 144B was taken into account by relying on a record of 36 years of data from weather station W14745 (Concord, NH). The site receives on average about 93 cm of precipitation each year, of which about 19% becomes runoff. The expected volume of runoff is greater than that of 90% of turf use sites. The soil is Sharkey clay. Data for the Sharkey clay was taken from the PRZM database and the 1987 National Resources Inventory. Soil Conservation Service curve numbers were generated based on the hydrologic group and the plant cover (Wischmeier and Smith, 1972). Additional details of the scenario and model parameters are specified in the EFED/EFGWB modelling summary.

### **(c) Acute Risk to Aquatic Organisms**

Acute adverse effects are expected to occur to freshwater fish from the turf use of trichlorfon. The lowest available  $LC_{50}$  measurement for a freshwater fish is 230  $\mu\text{g/L}$  for bluegill sunfish. That value corresponds to a risk quotient of 0.97 which exceeds the LOC. Risk quotients also exceed the LOC based on rainbow trout, cutthroat trout, and brook trout.

Adverse effects are expected to occur to a variety of freshwater invertebrates from the turf use of trichlorfon. The lowest  $EC_{50}$  value for freshwater invertebrates (0.18  $\mu\text{g/L}$  for water flea) results in a risk quotient of 1244, which greatly exceeds the LOC of 0.5. The second highest  $EC_{50}$  value (40  $\mu\text{g/L}$  for scud) also results in a risk quotient greater than the LOC. The  $EC_{50}$  value for crayfish (7800  $\mu\text{g/L}$ ) results in a risk quotient below the LOC, but that species is obviously much less sensitive to trichlorfon than the other species tested.

LOCs are exceeded for marine and estuarine fish and invertebrates. Risk quotients for estuarine and marine organisms range from 622 (pink shrimp) to 0.75 (Atlantic salmon) and >0.3 (spot). All species tested, with the exception of spot, result in risk quotients exceeding the LOC.

### **(d) Chronic Risk to Aquatic Organisms**

The potential for chronic risk to aquatic organisms is determined by comparing the MATC value (geometric mean of the NOEC and LOEC) to the appropriate EEC (21-day for invertebrate life cycle and 60-day for fish early life). The 21-day EEC from ground application is 54  $\mu\text{g/L}$ , and the 60-day EEC is 24.7  $\mu\text{g/L}$ . The risk quotient for fish, based on the early life stage MATC of 135  $\mu\text{g/L}$ , is 0.18, which does not exceed the LOC of 1.0. The risk quotient for invertebrates, based on the mean life cycle MATC of 0.0071  $\mu\text{g/L}$  is 7606 for ground application, which greatly exceeds the LOC of 1.0.

Based on these results there are chronic risk concerns for aquatic invertebrates (freshwater, marine, and estuarine). The results do not indicate a concern for chronic risk for freshwater fish. The results also do not indicate a chronic risk for marine and estuarine fish; however, that finding is based on toxicity measurements from freshwater animals and so there is substantial uncertainty regarding that finding. Data are required in order to confirm the risk assumptions made for marine/estuarine fish.

### (3) Risk to Plants

Hazard to nontarget plants (aquatic, semiaquatic, or terrestrial) is not expected from the use of trichlorfon.

### (4) Risk to Endangered Species

**Terrestrial:** *Acute and chronic* LOCs are exceeded for *non-endangered* species (birds and mammals), and therefore are also exceeded for endangered species.

**Aquatic:** *Acute* LOCs are exceeded for *non-endangered* species (freshwater, estuarine, and marine fish and invertebrates), and therefore are also exceeded for endangered species. By the same reasoning, *chronic* levels of concern are exceeded for aquatic *invertebrates* (freshwater, marine, and estuarine). Chronic levels of concern are not exceeded for fish.

## 2. Environmental Fate

The following categories of information are treated in this section: a review of studies conducted to fulfill the environmental fate data requirements for registration; qualitative characterization of environmental fate properties of trichlorfon based on synthesis of information from studies reviewed; information from detections of trichlorfon and dichlorvos in ground water. (Dichlorvos is a trichlorfon degradate and also a registered pesticide active ingredient.)

Aquatic organisms will be exposed to trichlorfon in runoff and/or spray drift from treated fields. Quantitative assessment of that exposure is summarized in the Ecological Effects Risk Assessment.

### a. Environmental Chemistry, Fate and Transport Data

**Hydrolysis:** Trichlorfon appears to be stable under acid conditions: the half-life was 31 minutes at pH 9 and 34 hours at pH 7, but was 104 days at pH 5. Degradates identified and percent of applied radioactivity, at pH 5, 7, and 9 respectively, were DDVP (1.4% to 2.1%; 1.3% to 25.5%; 2.1% to 52.3%), desmethyl DDVP (2.4% to 10.5%; 1.5% to 11.9%; 1.0% to 10.5%), and dichloroacetaldehyde (0.7% to 7.7%; 3.5% to 22.7%; 0%) (MRID 00148974).

**Photodegradation in Water:** Trichlorfon at 25 mg/L degraded in pH 5 sterile water with a half-life of 110 days indicating that the compound is stable to photolysis in water. In the dark control the half-life was 115 days. This corresponds with the 104 day hydrolytic half-life. Identified degradates included DDVP (1.3 to 5.1%), desmethyl DDVP (3.4 to 8.9%), and dichloroacetaldehyde (1.1 to 8.0%) (MRID 00148975).

**Photodegradation in Soil:** Trichlorfon at 65 mg/L did not degrade appreciably when applied to the surface of a silt loam soil. There was very little difference in measured half-lives between irradiated and non-irradiated samples: half-life estimates were 13 to 20 days for irradiated samples and 10 to 13 days for non-irradiated samples. Degradates detected 20 days after treatment, and percentages of applied radioactivity (for irradiated and non-irradiated samples, respectively) were desmethyl DDVP (34.9% and 49.3%), DDVP (24.5% and 37.0%), unextracted residues (6.3% and 8.0%), and volatiles (1.2% and 0.1%).

In another soil photolysis study, half-lives were reported to be 8.8 days for irradiated soil samples and 10.5 days for non-irradiated soil samples. DM-DDVP comprised 48% to 54.4% of applied radioactivity, DDVP 3.1% to 9.8%, unextractables 0.2% to 6.4%, and volatilized compounds 0.1% to 10.9% (MRID 00157859).

**Aerobic Soil Metabolism:** Measurements of trichlorfon indicated rapid degradation; two hours after application only 88% of the applied radioactivity remained as the active ingredient. Small amounts of desmethyl TCF [methyl (2,2,2-trichloro-1-hydroxyethyl) phosphonate] and DCA (dichloroacetic acid) were formed. Half-life was estimated at 6.4 days (MRID 42243701).

Metabolism of trichlorfon produced three acidic metabolites: DCA, TCA (trichloroacetic acid), and HDCP (1-hydroxy-2,2-dichlorovinyl phosphate). DCA formed and decreased rapidly, reaching a maximum concentration of 23% in approximately 3 days and decreasing to 0% in 14 days or less. TCA reached a maximum concentration of 2% in 7 days and decreased to 0% in 120 days or less. HDCP reached a maximum concentration of 11% in approximately 65 days and at the 120 day sampling time represented 21% of applied radioactivity. Carbon dioxide was approximately 64%. Bound residues increased from 3% on Day 0 to 10% at Day 7, and remained constant at 10% to 11% for the rest of the study. Further extraction of the soil-bound residues by acid reflux released less than 5%, which was not characterized further (MRID 42243701).

In other studies, the half-life estimates ranged from 1 to 27 days depending on the soil type. In two silt loam soils that were sterilized prior to application of trichlorfon, the half-life was 20.5 days to over 40 days, compared to 4.5 to 10 days under non-sterile conditions. This suggests that microbial activity is responsible for degradation in non-sterile soils. The major degradate was desmethyl DDVP (MRID 00098625).



**Anaerobic Soil Metabolism:** Trichlorfon degraded rapidly (half-life 1.8 days) in an anaerobic sandy loam soil. This rapid degradation following flooding was probably caused by hydrolysis, and not by anaerobic soil metabolism alone, given that trichlorfon hydrolyses rapidly. (The hydrolysis study indicates a half-life at environmental pH between 2 hours or less and 34 hours.) The low  $K_d$  values (0.25 to 0.51) support the conclusion that trichlorfon would partition into the water phase and be degraded by hydrolysis.

Carbon dioxide was 73% of applied radioactivity after 63 days. Minor metabolites included glyoxylic acid, dichloroacetic acid, and DDVP (dimethyl 2,2-dichlorovinyl phosphate). DDVP was not over 1%, and was not detectable 3 after flooding (MRID 42243701).

**Aerobic Aquatic Metabolism:** Trichlorfon was applied at 1.0 mg/L to samples of pond water and incubated for 24 hours. At pH 5.0 trichlorfon did not degrade significantly. At pH 8.5 trichlorfon degraded rapidly to DDVP and could not be detected after 8 hours. DDVP concentrations peaked at 0.56 mg/L after 8 hours of incubation and declined to 0.39 mg/L after 24 hours (MRID 40338602).

**Leaching and Adsorption/desorption:** In column leaching studies, trichlorfon residues aged for 4 days (i.e., for one half-life) were mobile: over 93% of applied radioactivity was in the leachate of sand, sandy loam, silt loam, and silty clay loam soil, leached with 25 inches of water.  $K_d$  values for the four soil types ranged from 0.41 to 0.59. About 57% to 96% of the radioactivity recovered in the leachate represented parent trichlorfon, DDVP was 0.40% to 34%, and desmethyl DDVP was 3.2% to 7% (MRID 40279302).

**Laboratory Volatility:** Trichlorfon was applied to a sand soil and incubated in a continuous air-flow apparatus for 14 days. After incubation, 1% of applied radioactivity was trapped in methanol as volatile organic compounds, 13% was trapped in NaOH as carbon dioxide, and 84% remained in the soil (MRID 40279302).

**Terrestrial Field Dissipation:** A terrestrial field dissipation study was conducted on four plots in California. At three plots the reported application rate was not confirmed by analysis of samples collected immediately after application. No meaningful conclusions can be reached regarding the dissipation of trichlorfon in those plots because only about 0.73% to 3.4% of the applied trichlorfon was recovered. The fourth plot can be regarded as providing supplemental information. In that plot 53.7% of the total residues were identified as parent trichlorfon. The half-life was determined to be less than 0.2 days. No residues of trichlorfon or DDVP were found below 6 inches depth in any sampling intervals, although irrigation was applied over the time that residues were detected, i.e. to 7 days after application. At least two residue-free depths were identified below the depths that contained trichlorfon residues (MRID 42322501). An acceptable field dissipation must be submitted.

**Confined Crop Accumulation:** Trichlorfon was applied at 30 lb ai/A and crops were planted 30, 120, and 250 days after application. Residues ranged from 0.009 to 0.024 mg/L for kale, from 0.018 to 0.624 mg/L for red beets, and from 0.005 to 0.52 mg/L for wheat. Identification of degradates was difficult because of low concentration of residues and poor extractability of residues in plant samples (MRID 403338602).

**Droplet Size Spectrum and Field Drift:** Data have not been submitted and are required as confirmatory data.

## **b. Environmental Fate Assessment**

**Synthesis of Reviewed Environmental Fate Studies:** Studies submitted to the Agency provide sufficient information for a preliminary qualitative characterization of environmental fate properties of trichlorfon.

Potential for contamination of surface and ground water by trichlorfon and trichlorfon degradates (particularly DDVP) cannot be adequately assessed because acceptable field dissipation data is not available. Potential to leach is suggested by findings of high mobility in soil:  $K_d$  estimates of 0.25 to 0.50 were obtained for soils with texture varying from sand to silty clay and organic matter content 0.5% to 5.1%.

Risk of contamination of surface and ground water may be moderated by rapid degradation of trichlorfon in soil and water. It appears that hydrolysis and aerobic metabolism are the main routes of dissipation in both soil and water. The major degradate in both soil and water is DDVP (dimethyl 2,2-dichlorovinyl phosphate), with desmethyl DDVP also reported as a degradate in soil. DDVP is itself a registered pesticide active ingredient.

Trichlorfon was found to degrade rapidly in non-sterile aerobic soils (half-life approximately 1 to 27 days) but was stable in a sterile soil (half-life over 40 days). Studies in pond water and sterile water indicate more rapid degradation at lower pH (higher acidity). In pond water, trichlorfon degraded rapidly at pH 8.5 and room temperature (99% of applied active ingredient degraded in 2 hours), but was stable when held at pH 5.0 for 2 hours. In sterile water trichlorfon hydrolyzed rapidly at pH 7 and 9 (half-life 31 minutes at pH 9 and 34 hours at pH 7) but at pH 5 the half-life was 104 days.

The available data, from field studies that were not completely acceptable, suggested that trichlorfon and DDVP may have little potential to contaminate ground water because they degrade rapidly in soil. Acceptable field studies are needed.

**Detections and Measurements of Trichlorfon in Ground Water:** The EPA Pesticides in Ground Water Database indicates that trichlorfon has been reported at concentrations 10 µg/L and higher in 12 of 179 wells in Georgia. However, these data are not useful for regulatory purposes because of analytical uncertainties surrounding the detections. There were no

detections of trichlorfon in 280 wells sampled in California, and no detections of DDVP in 188 wells sampled in California, Hawaii, and Indiana.

**Exposure to Aquatic Organisms:** Aquatic organisms will be exposed to trichlorfon in runoff and drift from treated sites. The resulting risk is characterized in Ecological Effects Risk Assessment based on Tier 2 exposure calculations using the PRZM and EXAM models.

#### **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 ingredient 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 trichlorfon. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing trichlorfon. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of trichlorfon, and lists the submitted studies that the Agency used to make its determination.

The data identified in Appendix B were sufficient to allow the Agency to assess the currently supported uses of trichlorfon, and to determine that trichlorfon can be used without resulting in unreasonable adverse effects to humans and the environment provided certain risk mitigation measures are implemented. Nonfood uses, except sod farms and domestic lawn use of the bait formulations, are being supported by the registrant. All food uses are not being supported. The corresponding food use tolerances will be proposed for revocation, except those currently established for cattle meat, cattle fat and cattle meat by-products which are being supported for import purposes. 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, etc. and the data identified in Appendix B. Although the Agency has found that most nonfood uses of trichlorfon currently registered are eligible for reregistration, 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 trichlorfon, 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 trichlorfon, the Agency has sufficient information on the health effects of trichlorfon and on its potential for causing adverse effects in fish and wildlife and the environment. Where the potential for adverse effects was identified, the Agency and the registrant agreed upon risk mitigation measures. The Agency has determined that all trichlorfon products, labeled for non-food uses as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing trichlorfon are eligible for reregistration if labeling and other changes specified in this document are implemented. Eligible uses are limited to indoor and outdoor uses on nonfood and nonfeed sites. The use of trichlorfon on sod farms and the use of trichlorfon bait formulations on residential lawns have been voluntarily cancelled by the effected registrants. Also, the use of the bait formulations in indoor residential areas is prohibited unless prepackaged in child resistant bait stations.

## **2. Eligible and Ineligible Uses**

The Agency has determined that only indoor and outdoor non-food and non-feed uses of trichlorfon are eligible for reregistration. These include golf courses; turf and ornamentals (except sod and turf farms and also the use of bait formulations on residential lawns); animal premises and kennels (non-livestock contact areas); mound treatment for ants to non-food and non-feed areas; nonfood contact areas of food processing plants, grocery markets, commercial and industrial premises; residential areas (bait formulations are prohibited from indoor residential use unless housed in prepackaged child resistant bait stations). The terrestrial food and feed crop uses have been voluntarily cancelled and request for voluntary cancellation has been received for the dermal livestock treatment. The sod and turf farm use resulted in high risk exposures for mixers, loaders and applicators and was voluntarily cancelled by the registrant. Potential exposure to children and pets from the residential uses of the bait formulations were a concern. The registrant with the residential bait uses on their label has voluntarily cancelled the residential lawn use and has agreed to limit indoor residential use of the bait to prepackaged child resistant bait stations. Data are being generated to reassess the tolerances for cattle products to support their continuing import; all other tolerances will be proposed for revocation.

## **B. Regulatory Position**

The following is a summary of the regulatory positions and rationales for trichlorfon. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

## 1. Tolerance Reassessment

The tolerances listed in [40 CFR §180.198] and [40 CFR §186.2325] are for residues of trichlorfon in/on raw agricultural commodities, animal products, and feed commodities. Voluntary cancellation of all food/feed uses was finalized in November 1995. The dermal pour-on cattle treatment is in the process of being cancelled. The Agency is proposing to revoke all tolerances for trichlorfon except those for cattle meat, cattle fat and cattle meat by-products. The registrant is not supporting the domestic use of the cattle treatment but will support the tolerances needed to continue the importation of cattle meat, cattle fat and meat by-products. In order to reassess these tolerances additional residue data are required and will be submitted within 24 months. The Agency has determined that the current tolerances of 0.1 ppm are protective of the public health for the estimated three year period of data generation and review. Tolerances will be reassessed when the additional residue data are available. This reassessment will be used to determine appropriate levels for tolerances with no U.S. registration. If the data are not submitted within two years the Agency will propose revocation of the cattle tolerances.

**Table 14. Tolerance Reassessment Summary for Trichlorfon**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments
<b>Tolerances listed under 40 CFR §180.198</b>			
Alfalfa	60	Revoke	
Alfalfa, hay	90	Revoke	
Artichokes	0.1 (N)	Revoke	
Bananas (NMT 0.2 ppm will be present after the peel is removed)	2	Revoke	
Barley, forage	50	Revoke	
Barley, grain	0.1 (N)	Revoke	
Barley, straw	1	Revoke	
Beans, dried	0.1 (N)	Revoke	
Beans, lima (reflecting 0.1 ppm (N) in or on the shelled beans)	12	Revoke	
Beans, lima vine hay	12	Revoke	
Beans, lima vines	12	Revoke	
Beans, snap	0.1 (N)	Revoke	

<b>Commodity</b>	<b>Current Tolerance (ppm)</b>	<b>Tolerance Reassessment (ppm)</b>	<b>Comments</b>
Beans, vines	1	Revoke	
Beets	0.1 (N)	Revoke	
Beets, sugar	0.1 (N)	Revoke	
Beets, sugar, tops	12	Revoke	
Birdsfoot trefoil, hay	90	Revoke	
Blueberries	0.1	Revoke	
Brussels sprouts	0.1 (N)	Revoke	
Cabbage	0.1 (N)	Revoke	
Carrots	0.1 (N)	Revoke	
Cattle, fat	0.1 (N)		Data to reassess submitted in 24 months, or revocation proposed.
Cattle, mbyp	0.1 (N)		“ ”
Cattle, meat	0.1 (N)		“ ”
Cauliflower	0.1 (N)	Revoke	
Citrus fruit	0.1 (N)	Revoke	
Clover	60	Revoke	
Clover, hay	90	Revoke	
Collards	0.1 (N)	Revoke	
Corn, fodder	30	Revoke	
Corn, forage	30	Revoke	
Corn, fresh (including sweet K + CWHR)	0.1 (N)	Revoke	
Corn, grain	0.1 (N)	Revoke	
Cottonseed	0.1 (N)	Revoke	
Cowpeas	0.1 (N)	Revoke	
Cowpeas, vines	1	Revoke	
Flax, straw	1	Revoke	

<b>Commodity</b>	<b>Current Tolerance (ppm)</b>	<b>Tolerance Reassessment (ppm)</b>	<b>Comments</b>
Flaxseed	0.1 (N)	Revoke	
Goats, fat	0.1 (N)	Revoke	
Goats, mbyp	0.1 (N)	Revoke	
Goats, meat	0.1 (N)	Revoke	
Grass, pasture	60	Revoke	
Grass, pasture, hay	90	Revoke	
Grass, range	240	Revoke	
Grass, range, hay	240	Revoke	
Horses, fat	0.1 (N)	Revoke	
Horses, mbyp	0.1 (N)	Revoke	
Horses, meat	0.1 (N)	Revoke	
Lettuce	0.1 (N)	Revoke	
Milk	0.01(N)	Revoke	
Oats, forage	50	Revoke	
Oats, grain	0.1 (N)	Revoke	
Oats, straw	1	Revoke	
Peanuts	0.05 (N)	Revoke	
Peanuts, vine hay	4	Revoke	
Peanuts, vine hulls	4	Revoke	
Peppers	0.1 (N)	Revoke	
Pumpkins	0.1 (N)	Revoke	
Safflower seed	0.1 (N)	Revoke	
Sheep, fat	0.1 (N)	Revoke	
Sheep, mbyp	0.1 (N)	Revoke	
Sheep, meat	0.1 (N)	Revoke	
Tomatoes	0.1 (N)	Revoke	
Wheat, forage	50	Revoke	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comments
Wheat, grain	0.1 (N)	Revoke	
Wheat, straw	1	Revoke	
<b>Tolerances listed under 40 CFR §180.2325</b>			
Dried Citrus Pulp	2.5	Revoke	

## 2. Restricted Use Classification

Trichlorfon is not currently classified as a Restricted Use pesticide and the Agency is not requiring any change in this classification.

## 3. Reference Dose and Cancer Classification

**Reference Dose:** A reference dose of 0.002 mg/kg/day was established based on the results of a ten year chronic feeding study in monkeys in which the LOEL was 0.2 mg/kg/day. An uncertainty factor of 100 was used based on the lack of a NOEL and to take into consideration inter-species extrapolation and intra-species variability.

**Cancer Classification:** Trichlorfon has been classified as a Group E chemical - no evidence of carcinogenicity for humans based on available data.

## 4. 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 restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. 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.

## 5. Labeling For Non-Food Uses

In order to maintain use of trichlorfon in animal premises, barns etc., as a non food use, labels must bear a statement prohibiting use in food or feed handling areas or where livestock may gain access. Specific label language is found in Section V.



## **6. Child Resistant Packaging**

In order to maintain use of trichlorfon bait formulations in indoor residential areas, the bait must be in prepackaged child-resistant bait stations. If the bait is not housed in child-resistant packaging, the label must clearly state that the product is not for use in indoor residential areas. Specific language is found in Section V.

## **7. Spray Drift Advisory**

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation to develop the best spray drift management practices. The Agency is now requiring interim measures that must be placed on product labels/labeling as specified in Section V. Once the Spray Drift Task Force completes their studies, submits data, and the Agency evaluation is completed, there may be further refinements in spray drift management practices.

## **8. Ecological Effects**

The Agency has identified concerns for avian and aquatic species exposed to trichlorfon when applied to turf sites. The Agency and the registrant agreed upon mitigation measures that will greatly reduce the potential exposure to these organisms. These measures include: prohibition of aerial application, prohibition of residential lawn use with bait formulations, buffer strips from aquatic habitats, mandatory watering-in that will reduce potential run-off to aquatic habitats as well as reduce exposure to avian species through ingestion of granules or vegetative residues.

Aquatic levels of concern were exceeded by a large margin. However, the Agency is confident that the mitigation efforts that have been established will minimize aquatic exposure. The mandatory watering-in for turf and golf course uses will cause trichlorfon to move into the soil, where trichlorfon is most efficacious, and degrades rapidly. The buffer strips from aquatic habits will minimize any run-off that could occur after the watering-in. These measures coupled with the drastically reduced acreage (eliminating sod farm and food/feed uses) will minimize aquatic exposure.

Reproductive concerns for avian species (specifically, impaired egg shell thickness) exposed to trichlorfon from turf applications have been addressed by consideration of a study performed by Miles Inc. for the registration of an insecticide with a similar use pattern (MRID No. 434665-02). The research indicated that species of concern (i.e. mallards, Canada geese on golf courses and turf farms) apparently would not be exposed to trichlorfon (specifically insecticides used for grub treatment) during the period of egg formation in the early Spring months because the efficacious application time of trichlorfon is late Spring to early Summer. Specific labeling language is found in Section V.

## 9. Surface Water Advisory

Since trichlorfon can contaminate surface water through ground spray and run-off, a surface water advisory is required. Specific language is found in Section V of this document.

## 10. Occupational/Residential Labeling Rationale/Risk Mitigation

### The Worker Protection Standard

**Scope of the WPS:** The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food and feed crops). Uses within the scope of the WPS also include uses on plants and uses on the soil or planting medium the plants are (or will be) grown in. At this time some of the registered uses of trichlorfon are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some uses are outside the scope of the WPS. Those that are outside the scope of the WPS may include the following uses (these are not trichlorfon specific):

- on livestock or other animals, or in or around animal premises,
- on plants grown for other than commercial or research purposes, which may include plant inhabitations, home fruit and vegetable gardens, and home greenhouses,
- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit. (However, pesticides used on sod farms are covered by the WPS),
- in a manner not directly related to the production of agricultural plants, including, for example, control of pests in manure and garbage dump sites, in poultry and red-meat packing plants, in inedible product areas of commercial, industrial, institutional and food processing/preparation/handling/storage.

**Compliance With the WPS:** Any product whose labeling can be reasonably interpreted to permit use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7

and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

- After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by the primary registrant or any supplementally registered distributor.
- After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by any person.

### **Personal Protective Equipment/Engineering Controls for Handlers**

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.
2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):
  - In the RED for that active ingredient, EPA may establish minimum or “baseline” handler PPE requirements that pertain to all or most end-use products containing that active ingredient.
  - These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.
  - The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over

a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

**Occupational-Use Products:** EPA has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for trichlorfon. The addition of baseline PPE is necessary to adequately reduce risk to an acceptable level for three scenarios. (1) To adequately mitigate risk to mixers and loaders handling soluble powder formulations, such handlers must wear a single layer of body protection and chemical-resistant gloves. (2) To adequately mitigate risk to commercial mixers/loaders/applicators handling the bait formulations using a cup or watering can, such handlers must wear a single layer of body protection and chemical resistant gloves. (3) To adequately mitigate risk to commercial mixer/loader/applicators handling the granular formulations using push-type granular spreaders, such handlers must wear a double layer body protection and chemical-resistant gloves.

The addition of maximum PPE (double layer body protection, chemical-resistant gloves, and a dust/mist filtering respirator) is insufficient to adequately mitigate risk to homeowner or commercial mixer/loader/applicators applying granular formulations using chest-mounted rotary spreaders (“belly-grinders”). No currently available engineering controls are considered feasible for such a formulation and application technique. The registrant has proposed to voluntarily prohibit the use of chest-mounted rotary spreader application equipment.

The addition of maximum PPE is also insufficient to adequately mitigate the risk to mixers and loaders handling soluble powder formulations to support large-area (more than 40 acres per day; ie., sod and turf farms) applications. Also, engineering controls -- water soluble packaging -- is infeasible for trichlorfon for the soluble powder formulations. There was no sufficient mitigation for handlers and/or applicators associated with aerial applications. The registrant has proposed voluntary cancellation of the sod farm use and will prohibit the aerial application of trichlorfon.

**WPS and NonWPS Uses:** Since potential handler exposure is similar for WPS and nonWPS uses, the requirements for active-ingredient-based minimum (baseline) PPE applies to both WPS and nonWPS occupational uses of trichlorfon (specified in Section V). These requirements must be followed in the labeling of all applicable trichlorfon end-use products intended primarily for occupational use.

**Homeowner-Use Products:** EPA has determined that the risks are unacceptable for homeowners applying the granular formulation using chest mounted rotary spreader granular applicators. That risk could be adequately mitigated by requiring the homeowners to wear chemical-resistant gloves. However, EPA is reluctant to require

personal protective equipment for homeowners, except in special circumstances. Furthermore, EPA believes the use of chest mounted rotary spreader application equipment by homeowners is uncommon. Therefore, upon recommendation of EPA the registrant is voluntarily prohibiting the use of chest mounted rotary spreader application equipment for granular end-use products intended primarily for homeowner use. The Agency has concerns for exposure to children and pets from normal homeowner use of the bait formulations and is therefore requiring that these products be sold in prepackaged child-resistant bait stations when intended for indoor use. Also, upon recommendation of the Agency the registrants have agreed to voluntarily cancel the domestic lawn use of the bait formulations.

EPA is not establishing minimum (baseline) handler PPE for trichlorfon end-use products that are intended primarily for homeowner use, because the Agency has determined that the risks for homeowner mixers/loaders/applicators (other than chest mounted rotary spreader application) are acceptable without the addition of PPE.

## **Post-Application/Entry Restrictions**

### **Occupational-Use Products (WPS Uses)**

**Restricted-Entry Interval:** Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REI's) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

The WPS REI in effect until now was 24 hours. This was an interim REI placed on trichlorfon products by PR Notice 93-7. EPA notes that the 24-hour interim WPS REI was established because trichlorfon, at that time, was classified as toxicity category II for eye irritation potential. Trichlorfon has since been reclassified as a toxicity category III for eye irritation.

EPA is retaining the REI of 24 hours for all occupational-use products that contain trichlorfon and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). The Agency acknowledges that considering solely the acute toxicity of trichlorfon an REI of 12 hours may be appropriate. However, in light of the slow environmental degradation of trichlorfon, and a lack of reentry data, the Agency will retain the 24 hour REI. The Agency is requiring reentry data for trichlorfon and will reevaluate the REI when the data are available.

**Early-Entry PPE:** The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category.

During the reregistration process, EPA considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If EPA determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient. In any case, the minimum (baseline) early-entry PPE for all WPS products is coveralls, chemical-resistant gloves, and shoes plus socks.
2. If EPA determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

Due to the lack of post-application exposure data, the toxicity concerns (dermal NOEL of 100), and the high application rates. EPA is establishing PPE for dermal protection that is more stringent than the PPE that would otherwise be established on the basis of the acute toxicity category of the active ingredient. Since trichlorfon is classified as toxicity category III for eye irritation potential, no protective eyewear is required for early entry.

**WPS Notification Statement:** Under the WPS, the labels of some pesticide products must require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of “double notification.” EPA has determined that double notification is not required for trichlorfon end-use products.

### **Occupational-Use Products (NonWPS Uses)**

Since EPA has concerns about post-application exposures to persons after nonWPS occupational uses of trichlorfon, it is establishing entry restrictions for all nonWPS occupational uses of trichlorfon end-use products. For specific requirements, refer to Section V of this document.

### **Homeowner-Use Products**

Since EPA has concerns about post-application exposures to persons after homeowner applications of trichlorfon, it is establishing entry restrictions for all homeowner uses of trichlorfon end-use products. For specific requirements, refer to Section V of this document.

#### **11. Skin Sensitization**

Trichlorfon is classified as a skin sensitizer, therefore EPA is requiring a cautionary statement in the “Hazards to Humans and Domestic Animals” section of the Precautionary Statements on the labeling of all end-use products.

#### **12. Other Labeling Requirements**

The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing trichlorfon. For the specific labeling statements, refer to Section V of this document.

### **V. ACTIONS REQUIRED OF 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 following data are required as confirmatory:

#### **Occupational Residential Exposure:**

- 231 & 232 mixer/loader/applicator exposure data are required for residential turfgrass sites using a hydraulic low pressure handwand (specifically, commercial applicators using hand held sprayers on residential sites)
- 132-1, 133-3, 133-4 exposure data for post-application entry into greenhouses and on residential turf

#### **Ecological Effects:**

- 72-3(b) Acute Toxicity for Estuarine/Marine Organisms - Mollusk
- 72-4 Aquatic invertebrate life-cycle - Estuarine/marine

#### **Environmental Fate:**

- 164-1 Field Dissipation
- 201-1 Droplet Size
- 201-2 Field Drift

#### **Residue Chemistry:**

In order to reassess the tolerances for cattle meat, cattle fat, and cattle meat by-products to support the continued import of cattle products from cattle treated with trichlorfon, the following residue data are required:

- 171-4(b) Nature of the Residue; livestock metabolism
- 171-4(c) Residue analytical method - animals
- 171-4(e) Storage stability
- 171-4(j) Magnitude of the Residue; meat/milk/poultry/eggs

### **2. Labeling Requirements for Manufacturing-Use Products**

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

“Only for formulation into an insecticide for the following use(s): \_\_\_ (fill blank only with these uses that are being supported by MP registrant).”



An MP registrant may, at his/her discretion, add one of the following statements to an MP label under “Directions for Use” to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user groups:

- (a) “This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).”
- (b) “This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).”

## **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. Labeling Requirements for End-Use Products**

#### **PPE/Engineering Control Requirements for Pesticide Handlers**

For **sole-active-ingredient** end-use products that contain trichlorfon, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

#### **Products Intended Primarily for Occupational Use (WPS and nonWPS)**

**Minimum (Baseline) PPE/Engineering Control Requirements:** At this time there are no engineering control requirements, such as closed systems, currently required on labeling for trichlorfon products. EPA is not establishing active-ingredient-based minimum (baseline) engineering control requirements for trichlorfon end-use products that are intended primarily for occupational use.

EPA is establishing minimum (baseline) PPE for some occupational uses of trichlorfon.

For soluble powder formulations:

Mixers and loaders must wear:

- long-sleeve shirt and long pants,
- chemical-resistant gloves\*, and
- shoes plus socks,

Applicators and other handlers (other than mixers and loaders) must wear:

- long-sleeve shirt and long pants,
- shoes plus socks.

For granular formulations:

Applicators and other handlers must wear:

- coveralls over long-sleeve shirt and long pants,
- chemical-resistant gloves\*, and
- chemical-resistant footwear.

For ready-to-use bait formulations:

Applicators and other handlers must wear:

- long-sleeve shirt and long pants,
- chemical-resistant gloves\*, and
- shoes plus socks.

\*For the glove statement, use the statement established for trichlorfon through the instruction in Supplement Three of PR Notice 93-7.

**Determining PPE Requirements for End-use Product Labels:** The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

**Placement in Labeling:** The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

## **Products Intended Primarily for Homeowner Use**

**Minimum (Baseline) PPE Requirements:** EPA is not establishing active-ingredient-based minimum (baseline) handler PPE for trichlorfon end-use products that are intended primarily for homeowner use.

**Determining PPE Requirements for End-Use Product Labels:** Any necessary PPE for each trichlorfon end-use product intended primarily for homeowner use will be established on the basis of the end-use product's acute toxicity category.

**Placement in Labeling:** The personal protective equipment requirements, if any, must be placed on the end-use product labeling immediately following the precautionary statements in the labeling section "Hazards to Humans (and domestic animals)."

## **Entry Restrictions**

For **sole-active-ingredient** end-use products that contain trichlorfon the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

### **Products Intended Primarily for Occupational Use: WPS Uses**

**Restricted-entry Interval:** A 24-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all trichlorfon end-use products.

"Exception: if the product is soil-injected or soil-incorporated (including watering-in), the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated."

**Early-entry Personal Protective Equipment (PPE):** The PPE required for early entry is:

- coveralls over long-sleeve shirt and long pants,
- chemical-resistant gloves,
- shoes plus socks,

**Placement in labeling:** The REI and the PPE required for early entry must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

### **Products Intended Primarily for Occupational Use: NonWPS uses**

**Entry Restrictions:** The Agency is establishing the following entry restrictions for nonWPS occupational uses of trichlorfon end-use products:

- For liquid applications:  
“Do not enter or allow others to enter the treated area until sprays have dried.”
- For granular applications:  
“Do not allow people or pets to enter the treated area (except those involved in the watering) until the watering-in is complete and the surface is dry.”
- For bait applications:  
There are no entry restrictions.

**Placement in labeling:**

**If WPS uses are also on label** - Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

**If no WPS uses are on the label** - Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading “Entry Restrictions.”

**Products Intended Primarily for Homeowner Use**

**Entry restrictions:** The Agency is establishing the following entry restrictions for all homeowner uses of trichlorfon end-use products:

- For liquid applications:  
“Do not allow people or pets to enter the treated area until sprays have dried.”
- For granular applications:  
“Do not allow people or pets to enter the treated area (except those involved in the watering) until the watering-in is complete and the surface is dry.”

**Placement in labeling:** Place the appropriate entry restrictions in the Directions for Use, under the heading “Entry Restrictions.”

**Other Labeling Requirements**

**Products Intended Primarily for Occupational Use**

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

### **Application Restrictions for All Formulations:**

- “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.”
- “Aerial application is prohibited.”

### **Application Restrictions for Granular Formulations Only:**

- “Apply with push-type granular spreaders only. Chest-mounted rotary spreader (“belly-grinder”) application equipment is prohibited.”

### **User Safety Requirements:**

{Registrant: select this if coveralls are required for pesticide handlers on the end-use product label: }

- Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

{Registrant: select this always: }

- “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.”

### **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.”

### **Skin Sensitizer Statement:**

- “This product may cause skin sensitization in some people.”

### **Engineering Controls:**

- “When handlers use closed systems, or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS.”

### **Products Intended Primarily for Home Use**

#### **Application Restrictions:**

- “Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application.”
- “Do not apply this product using “chest mounted rotary-type spreader” application equipment.”

#### **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.”

{Select this only if gloves and/or protective eyewear are required for homeowner users:}

- “Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. Keep and wash protective clothing and equipment separately from other laundry.”

#### **Skin Sensitizer Statement:**

- “This product may cause skin sensitization reactions in some people.”

## **Environmental Hazard Statements**

All labels must have standard language, including:

- “Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.”
- “Do not contaminate water by cleaning of equipment or disposal of wastes.”
- “Do not apply when turf grass areas are water logged or the soil is saturated with water (ie. will not irrigate).”
- “Avoid run-off or puddling of irrigation water following application.”

### **Soluble Powders:**

- “Do not apply when average wind speeds are greater than 15 mph.”
- “Apply product using spray nozzles which produce a coarse droplet size, such as flood jet nozzles or lawn care gun.”

### **For Golf Course Use:**

- “Do not apply within 25 feet of lakes, reservoirs, rivers, permanent streams, marshes natural ponds, or estuaries.”
- “Post-application watering-in is required.”

### **For All Other Turf/lawn Uses:**

- “Post-application watering-in is required.”

## **Premise Precautions**

All products labeled for use in **livestock premise or areas** must include the following:

- “Remove animals before using products as a premise spray treatment in barns.”
- “Do not treat areas such as drinking cup, mangers, or troughs where livestock feed.”
- “Do not contaminate water, food, feedstuffs, food or feed handling equipment, or milk or meat handling equipment.”

- “Do not apply bait or spray to areas accessible to animals.”

All products labeled for use in **indoor residential or commercial establishments** must include:

- “For use in non-food/non-feed areas.”
- “Do not contaminate food/feed or food/feed handling equipment.”
- “Do not use in the food/feed areas of food/feed handling establishments. Do not use in edible product areas of food or feed processing plants, restaurants or other areas where food or feed is commercially prepared for processed. Do not use in restaurant serving areas while food is exposed.”

All bait formulation products that are **not housed in child-resistant packaging** must include the following:

- “Not for Indoor Residential Use.” and
- “Not for Lawn/Turf Use.”

All products labeled for use as a **mound treatment for Texas Harvest Ants** must include the following:

- “Apply only by hand-broadcast.”
- All products containing the site “area treatment” must be modified to “nonfood/nonfeed areas.”

### **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 trichlorfon 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**

































































## GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Trichlorfon covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Trichlorfon 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 Trichlorfon

REQUIREMENT	USE PATTERN	CITATION(S)
<b>PRODUCT CHEMISTRY</b>		
<b><u>Product Chemistry for Reg. No. 3125-9</u></b>		
61-1	Chemical Identity	ALL 00152133, 42835201, 44024701
61-2A	Start. Mat. & Mnfg. Process	ALL 00152133, 42835201
61-2B	Formation of Impurities	ALL 42835201
62-1	Preliminary Analysis	ALL 00148973, 42835202, 44027402
62-2	Certification of limits	ALL 00152133, 42835202
62-3	Analytical Method	ALL 00148973, 42835202
63-2	Color	ALL 00152133
63-3	Physical State	ALL 00152133
63-4	Odor	ALL 00152133
63-5	Melting Point	ALL 00152133
63-6	Boiling Point	ALL N/A
63-7	Density	ALL 00152133, 42835203, 44027403
63-8	Solubility	ALL 00152133
63-9	Vapor Pressure	ALL 00152133, 41535301
63-10	Dissociation Constant	ALL 00152133
63-11	Octanol/Water Partition	ALL 00147436

## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

REQUIREMENT	USE PATTERN	CITATION(S)
63-12	pH	00152133
63-13	Stability	00152133, 42835203
63-14	Oxidizing/Reducing Action	00152133
63-15	Flammability	N/A
63-16	Explodability	00152133
63-17	Storage stability	00152133
63-18	Viscosity	N/A
63-19	Miscibility	N/A
63-20	Corrosion characteristics	00152133, 42835203
<b><u>Product Chemistry for Reg. No. 3125-404</u></b>		
61-1	Chemical Identity	42835207
61-2A	Start. Mat. & Mnfg. Process	DATA GAP, 44024704
61-2B	Formation of Impurities	42835207, 44024704
62-1	Preliminary Analysis	42835208
62-2	Certification of limits	42835208
62-3	Analytical Method	42835208, 44024705
63-2	Color	42835209
63-3	Physical State	42835209
63-4	Odor	42835209

## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

REQUIREMENT	USE PATTERN	CITATION(S)
63-5	Melting Point	ALL 42835209
63-6	Boiling Point	ALL N/A
63-7	Density	ALL DATA GAP, 44024706
63-8	Solubility	ALL 00162307, 42835209
63-9	Vapor Pressure	ALL 00162307, 42835209, 41535302
63-10	Dissociation Constant	ALL 00162307
63-11	Octanol/Water Partition	ALL 00162307, 42835209
63-12	pH	ALL 42835209
63-13	Stability	ALL 42835209, 44027406
63-14	Oxidizing/Reducing Action	ALL DATA GAP
63-15	Flammability	ALL N/A
63-16	Explodability	ALL DATA GAP
63-17	Storage stability	ALL DATA GAP
63-18	Viscosity	ALL DATA GAP
63-19	Miscibility	ALL DATA GAP
63-20	Corrosion characteristics	ALL 4285203, 42835209
<b><u>Product Chemistry for Reg. No. 3125-371</u></b>		
61-1	Chemical Identity	ALL 00158290, 42835204
61-2A	Start. Mat. & Mnfg. Process	ALL 42835204

## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

REQUIREMENT	USE PATTERN	CITATION(S)
<b>61-2B</b>	<b>Formation of Impurities</b>	ALL 42835204
<b>62-1</b>	<b>Preliminary Analysis</b>	ALL N/A
<b>62-2</b>	<b>Certification of limits</b>	ALL 00158290, 42835205
<b>62-3</b>	<b>Analytical Method</b>	ALL 42835205
<b>63-2</b>	<b>Color</b>	ALL 42835206
<b>63-3</b>	<b>Physical State</b>	ALL 42835206
<b>63-4</b>	<b>Odor</b>	ALL 42835206
<b>63-5</b>	<b>Melting Point</b>	ALL N/A
<b>63-6</b>	<b>Boiling Point</b>	ALL N/A
<b>63-7</b>	<b>Density</b>	ALL 42835206
<b>63-8</b>	<b>Solubility</b>	ALL N/A
<b>63-9</b>	<b>Vapor Pressure</b>	ALL N/A
<b>63-10</b>	<b>Dissociation Constant</b>	ALL N/A
<b>63-11</b>	<b>Octanol/Water Partition</b>	ALL N/A
<b>63-12</b>	<b>pH</b>	ALL 42835206
<b>63-13</b>	<b>Stability</b>	ALL 43139501, 42835206
<b>63-14</b>	<b>Oxidizing/Reducing Action</b>	ALL N/A
<b>63-15</b>	<b>Flammability</b>	ALL N/A
<b>63-16</b>	<b>Explodability</b>	ALL 42835206

## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

<b>REQUIREMENT</b>		<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b>63-17</b>	<b>Storage stability</b>	ALL	DATA GAP, 42835206
<b>63-18</b>	<b>Viscosity</b>	ALL	N/A
<b>63-19</b>	<b>Miscibility</b>	ALL	N/A
<b>63-20</b>	<b>Corrosion characteristics</b>	ALL	DATA GAP
<b><u>ECOLOGICAL EFFECTS</u></b>			
<b>71-1A</b>	<b>Acute Avian Oral - Quail/Duck</b>	C, K	00073683, 0016000
<b>71-1B</b>	<b>Acute Avian Oral - Quail/Duck TEP</b>	C, K	00091969
<b>71-2A</b>	<b>Avian Dietary - Quail</b>	C, K	00034769
<b>71-2B</b>	<b>Avian Dietary - Duck</b>	C, K	00034769
<b>71-3</b>	<b>Wild Mammal Toxicity</b>	C, K	00128682
<b>71-4A</b>	<b>Avian Reproduction - Quail</b>	C, K	43119501
<b>71-4B</b>	<b>Avian Reproduction - Duck</b>	C, K	43019601
<b>72-1A</b>	<b>Fish Toxicity Bluegill</b>	C, K	40094602, 40098001
<b>72-1B</b>	<b>Fish Toxicity Bluegill - TEP</b>	C, K	40098001, 00091951
<b>72-1C</b>	<b>Fish Toxicity Rainbow Trout</b>	C, K	00091881, 00091766
<b>72-1D</b>	<b>Fish Toxicity Rainbow Trout- TEP</b>	C, K	00091766, 00091951, 0091942
<b>72-2A</b>	<b>Invertebrate Toxicity</b>	C, K	40094602, 0065497, 40228401, 40098001
<b>72-2B</b>	<b>Invertebrate Toxicity - TEP</b>	C, K	40098001
<b>72-3A</b>	<b>Estuarine/Marine Toxicity - Fish</b>	C, K	40228401

## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

REQUIREMENT		USE PATTERN	CITATION(S)
72-3B	Estuarine/Marine Toxicity - Mollusk	C, K	DATA GAP
72-3C	Estuarine/Marine Toxicity - Shrimp	C, K	40098001
72-4A	Early Life Stage Fish	C, K	42571701
72-4B	Life Cycle Invertebrate	C, K	DATA GAP (estuarine), 40452601
141-1	Honey Bee Acute Contact	C, K	00036935
141-2	Honey Bee Residue on Foliage	C, K	00060628, 05000837
141-5	Field Test for Pollinators	C, K	05004412
<b><u>TOXICOLOGY</u></b>			
81-1	Acute Oral Toxicity - Rat	C, I, K, M, O	00152315, 00005494, 00081186
81-2	Acute Dermal Toxicity - Rabbit/Rat	C, I, K, M, O	00085923, GS0104070, 00081185
81-3	Acute Inhalation Toxicity - Rat	C, I, K, M, O	00152315, 00085923, 00081185, GS0104070
81-4	Primary Eye Irritation - Rabbit	C, I, K, M, O	41571302
81-5	Primary Dermal Irritation - Rabbit	C, I, K, M, O	40306901
81-6	Dermal Sensitization - Guinea Pig	C, I, K, M, O	40654306
81-7	Acute Delayed Neurotoxicity - Hen	C, I, K, M, O	00152139
82-1A	90-Day Feeding - Rodent		N/A

## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

REQUIREMENT	USE PATTERN	CITATION(S)
<b>82-1B</b>	<b>90-Day Feeding - Non-rodent</b>	C, I, K, M, O 00148091
<b>82-2</b>	<b>21-Day Dermal - Rabbit/Rat</b>	C, I, K, M, O 40306901
<b>82-3</b>	<b>90-Day Dermal - Rodent</b>	C, I, K, M, O N/A
<b>82-4</b>	<b>90-Day Inhalation - Rat</b>	C, I, K, M, O N/A
<b>82-5A</b>	<b>90-Day Neurotoxicity - Hen</b>	C, I, K, M, O 40351201, 40879301
<b>82-5B</b>	<b>90-Day Neurotoxicity - Mammal</b>	C, I, K, M, O DATA GAP, 43871701
<b>83-1A</b>	<b>Chronic Feeding Toxicity - Rodent</b>	C, I, K, M, O 42510301, 41056201, 41973001, 00165011 00152148
<b>83-1B</b>	<b>Chronic Feeding Toxicity - Non-Rodent</b>	C, I, K, M, O 00080593, 40776001
<b>83-2A</b>	<b>Oncogenicity - Rat</b>	C, I, K, M, O 42510301, 41056201, 41973001
<b>83-2B</b>	<b>Oncogenicity - Mouse</b>	C, I, K, M, O 40782401, 40844301
<b>83-3A</b>	<b>Developmental Toxicity - Rat</b>	C, I, K, M, O 00128683, GS0104075, 00063192, 40255601
<b>83-3B</b>	<b>Developmental Toxicity - Rabbit</b>	C, I, K, M, O 00128683, GS0104075, 00063192, 41565201
<b>83-4</b>	<b>2-Generation Reproduction - Rat</b>	C, I, K, M, O 00128682, 42228301
<b>84-2A</b>	<b>Gene Mutation (Ames Test)</b>	C, I, K, M, O 00132949, 00125787, 00028625
<b>84-2B</b>	<b>Structural Chromosomal Aberration</b>	C, I, K, M, O 00123282, 00028625
<b>84-4</b>	<b>Other Genotoxic Effects</b>	C, I, K, M, O 00125787, 40277201, 00132949, 0028625
<b>85-1</b>	<b>General Metabolism</b>	C, I, K, M, O 40438101

## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

<b>REQUIREMENT</b>	<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b><u>OCCUPATIONAL/RESIDENTIAL EXPOSURE</u></b>		
<b>132-1A</b>	<b>Foliar Residue Dissipation</b>	C, I, K, M, O DATA GAP
<b>133-3</b>	<b>Dermal Passive Dosimetry Exposure</b>	C, I, K, M, O DATA GAP
<b>133-4</b>	<b>Inhalation Passive Dosimetry Exposure</b>	C, I, K, M, O DATA GAP
<b>231</b>	<b>Estimation of Dermal Exposure at Outdoor Sites</b>	C, K DATA GAP
<b>232</b>	<b>Estimation of Inhalation Exposure at Outdoor Sites</b>	C, K DATA GAP
<b><u>ENVIRONMENTAL FATE</u></b>		
<b>161-1</b>	<b>Hydrolysis</b>	C, I, K 00148974
<b>161-2</b>	<b>Photodegradation - Water</b>	C 00148975
<b>161-3</b>	<b>Photodegradation - Soil</b>	C 00157859
<b>162-1</b>	<b>Aerobic Soil Metabolism</b>	C, I, K 00098625, 42243701
<b>163-1</b>	<b>Leaching/Adsorption/Desorption</b>	C, I, K 40279302, 00029887
<b>163-2</b>	<b>Volatility - Lab</b>	C, I 40279302
<b>164-1</b>	<b>Terrestrial Field Dissipation</b>	C, K DATA GAP, 00091852, 423222501
<b>165-1</b>	<b>Confined Rotational Crop</b>	C 403338602
<b>201-1</b>	<b>Droplet Size Spectrum</b>	C, K DATA GAP
<b>202-1</b>	<b>Drift Field Evaluation</b>	C, K DATA GAP



## Data Supporting Guideline Requirements for the Reregistration of Trichlorfon

<b>REQUIREMENT</b>	<b>USE PATTERN</b>	<b>CITATION(S)</b>	
<b><u>RESIDUE CHEMISTRY</u></b>			
<b>171-4B</b>	<b>Nature of Residue - Livestock</b>	L	00005297, DATA GAP
<b>171-4D</b>	<b>Residue Analytical Method - Animal</b>	L	00091795, 00133081, 0091806, DATA GAP
<b>171-4E</b>	<b>Storage Stability</b>	L	00091791, 00091807, DATA GAP
<b>171-4J</b>	<b>Magnitude of Residues - Meat/Milk/Poultry/Egg</b>	L	00091796, 00091794, 00041262, 00091665 00091807, DATA GAP



## **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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- 00028625 Simmon, V.F. (1979) In vitro Microbiological Mutagenicity and Unscheduled DAN Syntheses Studies of Eighteen Pesticides: Report No. EPA-600/1-79-041. Unpublished study including submitter summary, received apr 3, 1980 under 279-2712; prepared by SRI International, submitted by FMC Corp., Philadelphia PA; CDL:099350-A.
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- 00034769 Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds. By U.S. Fish and Wildlife Service, Patuxent Wildlife Research Center. Washington D.C.: U.S.F.W.S. (Special Scientific Report- Wildlife No. 191; also in unpublished submission received Mar 28, 1979 under 3125-236; submitted as report number 334223a by Mobay Corp., Kansas City, Mo.; CDL: 237905-B.
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**WASHINGTON, D.C. 20460**

**OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES**

**GENERIC AND PRODUCT SPECIFIC  
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 A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain 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 7; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of 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. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

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 3-31-99).

This Notice is divided into six sections and seven 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 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
- 3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
- 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(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

## **SECTION II. DATA REQUIRED BY THIS NOTICE**

### **II-A. DATA REQUIRED**

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/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 the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes 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 (Telephone number: 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].

## 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**

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

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

The appropriate responses initially required by this Notice for generic and 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

#### 1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic 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.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (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.

#### a. 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 completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option.

Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms 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.

b. Use Deletion

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

- (i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;
- (ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and
- (iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for 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.

2. Product Specific Data Requirements

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 choose 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.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.



Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, for product specific data (contained in Attachments 2 and 3, respectively). 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 also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. 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.

a. 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 both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose 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.

b. 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.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Registrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

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

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic 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 you to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified timeframe (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. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and

Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

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 or protocols. 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

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

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 the 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 to 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 burden 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 normally will 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 '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, means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must 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 usually are 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 EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

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 also should 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 ecological effects studies, the classification generally would be a rating of “core.” 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.

### 2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 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 -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, 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.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

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, and in the generic data requirements section (III.C.1.), as appropriate.

### III-D REQUESTS FOR DATA WAIVERS

#### 1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

##### a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision,



EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and

associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must

submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

## 2. Product Specific Data

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 product specific 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:
  - i. 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.
  - ii. Fulfill the commitment to develop and submit the data as required by this Notice; or
  - iii. 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 CANCELLED 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 generally would 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 also must 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 a 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 must include completed Data Call-In Response Forms (Attachment 2) and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and 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 Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), 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

The Attachments to this Notice are:

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





# **TRICHLORFON PRODUCT SPECIFIC DATA CALL-IN CHEMICAL STATUS SHEET**

## **INTRODUCTION**

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

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 Trichlorfon. 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) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this Trichlorfon Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

## **DATA REQUIRED BY THIS NOTICE**

The additional data requirements needed to complete the database for Trichlorfon are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Trichlorfon 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 Trichlorfon 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 Barbara Briscoe at (703) 308-8177.

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

Barbara Briscoe  
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: Trichlorfon

## **TRICHLORFON GENERIC DATA CALL-IN CHEMICAL STATUS SHEET**

### **INTRODUCTION**

You have been sent this Generic Data Call-In Notice because you have product(s) containing Trichlorfon.

This Generic 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 Trichlorfon. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Trichlorfon Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

### **DATA REQUIRED BY THIS NOTICE**

The additional data requirements needed to complete the generic database for Trichlorfon are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Trichlorfon are needed. These data are needed to fully complete the reregistration of all eligible Trichlorfon products.

### **INQUIRIES AND RESPONSES TO THIS NOTICE**

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Dana Lateulere at (703) 308-8044.

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

Dana Lateulere, Chemical Review Manager  
Reregistration Branch  
Special Review and Reregistration Division (7508W)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Washington, D.C. 20460  
RE: Trichlorfon

## **Instructions For Completing The “Data Call-In Response Forms” For The Generic And Product Specific Data Call-In**

### **INTRODUCTION**

These instructions apply to the Generic and Product Specific “Data Call-In Response Forms” and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific “Data Call-In Response Forms.” Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 (“Date and Type of DCI”) on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. **DO NOT** use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

- Item 1.       **ON BOTH FORMS:** This item identifies your company name, number and address.
  
- Item 2.       **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.
  
- Item 3.       **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

**NOTE: Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** 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.”

FOR BOTH MUP and EUP products

You should also respond “yes” to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do 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.

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.

**NOTE: Item 7a and 7b are not applicable for Generic Data.**

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

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

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## **Instructions For Completing The “Requirements Status and Registrant's Response Forms” For The Generic and Product Specific Data Call-In**

### **INTRODUCTION**

These instructions apply to the Generic and Product Specific “Requirements Status and Registrant's Response Forms” and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific “Requirements Status and Registrant's Response Forms.” Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 (“Date and Type of DCI”) on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. **DO NOT** use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 30 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, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

### **Generic and Product Specific Data Call-In**

- Item 1.           **ON BOTH FORMS:** This item identifies your company name, number and address.
- Item 2.           **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

**ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

**ON THE PRODUCT SPECIFIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In 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. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

- 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 crop
- J Forestry
- K Residential



- L Indoor food
- M Indoor non-food
- N Indoor medical
- O Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Ingredient or Pure Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient
TGAI/PAIRA	Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP	Technical Grade Active Ingredient or Typical End-Use Product
MET	Metabolites
IMP	Impurities
DEGR	Degradates
*	See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

**ON THE GENERIC DATA FORM:** The time frame runs from the date of your receipt of the Data Call-In notice.

**ON THE PRODUCT SPECIFIC DATA FORM:** The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. 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 and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

**However, for Product Specific Data,** I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency 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.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. 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 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 apply as well.

**However, for Product Specific Data,** I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

- Option 4. **ON BOTH FORMS: (Submitting Existing Data)** I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.
- Option 5. **ON BOTH FORMS: (Upgrading a Study)** I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.
- Option 6. **ON BOTH FORMS: (Citing a Study)** I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

**However, for Product Specific Data,** 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 the Agency 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). If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

**FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.**

- Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

- Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.
- Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

**FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the “Requirements Status and Registrant’s Response Form” for product specific data.**

- Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. 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” form specifying 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.
- Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.
- Item 11. **ON BOTH FORMS:** Enter the date of signature.
- Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

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NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

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

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 the active ingredient trichlorfon, 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 registrants' 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.

There are 27 active products registered with the active ingredient trichlorfon, dimethyl (2,2,2-trichloro-1-hydroxyethyl)phosphonate. Of these, the three manufactured by Bayer (manufacturer number 11556) are being considered for withdrawal by the producer. Presently these are still in the batching process, and will not be withdrawn until they are removed from the active list.

The first batch are technicals, with no added inerts. These will not need testing as the RED includes validated acute toxicity information on the pure substance.

<b>Batch No.</b>	<b>Epa Reg. No.</b>	<b>% of Trichlorfon</b>	<b>Formulation Type</b>
1	3125-9	98	Solid
	3125-404	97	Solid
	11556-30	98	Solid

The products in Batch #2 have the smallest percentage of trichlorfon and similar inerts. It is possible to bridge from Batch #3 and cite data with the exception of an eye irritation study.

<b>Batch No.</b>	<b>Epa Reg. No.</b>	<b>% of Trichlorfon</b>	<b>Formulation Type</b>
2	3125-7	1	Solid
	3125-151	1	Solid

There is valid information on 3125-76, with the exception of acute inhalation toxicity study, which may be used on all products for Batch #3.

<b>Batch No.</b>	<b>Epa Reg. No.</b>	<b>% of Trichlorfon</b>	<b>Formulation Type</b>
3	655-790	5.0	Solid
	655-791	5.0	Solid
	3125-76	5.0	Solid
	3125-400	6.2	Solid



<b>Batch No.</b>	<b>Epa Reg. No.</b>	<b>% of Trichlorfon</b>	<b>Formulation Type</b>
3	3125-405	5.0	Solid
	3125-406	6.2	Solid
	8660-71	6.2	Solid
	9198-100	5.0	Solid
	9198-110	6.2	Solid
	10404-55	5.0	Solid
	10401-64	6.2	Solid
	32802-29	6.2	Solid

<b>Batch No.</b>	<b>Epa Reg. No.</b>	<b>% of Trichlorfon</b>	<b>Formulation Type</b>
4	829-203	5	Solid
	19713-220	5	Solid

PRS waived acute toxicity data on products 3125-184 and 371, and used data on the technical for toxicity grading with the addition of an eye irritation study. This approach may be used for products in Batch #5.

<b>Batch No.</b>	<b>Epa Reg. No.</b>	<b>% of Trichlorfon</b>	<b>Formulation Type</b>
5	3125-184	80	Solid
	3125-371	80	Solid
	3125-449	80	Solid
	34704-308	80	Solid
	45639-123	80	Solid

The table below shows products which were not batched because of significant differences in inert ingredients.

<b>Epa Reg. No.</b>	<b>% of Trichlorfon</b>	<b>Formulation Type</b>
10370-186	5	Solid
11556-32	8	Liquid
11556-109	8	Liquid

The following is a list of available documents for Trichlorfon 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 Barbara Briscoe at (703)-308-8177.

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 Trichlorfon.

The following documents are part of the Administrative Record for Trichlorfon 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



**Attachment 1. List of All Registrants Sent This Data Call-In (insert) Notice**





United States Environmental Protection Agency  
Washington, D.C. 20460

**Certification of Offer to Cost  
Share in the Development of Data**

Form Approved  
OMB No. 2070-0106,  
2070-0057  
Approval Expires  
3-31-99

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
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Product Name	EPA Reg. No.
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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 firms 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
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Name and Title (Please Type or Print)
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**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 section 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)



## 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.





