

Temephos RED

[Team](#) | [Terms & Abbreviations](#) | [Fact Sheet](#) | [RED Appendices](#)

TABLE OF CONTENTS

Executive Summary

I. Introduction

II. Chemical Overview

- A. Regulatory History
- B. Chemical Identification
- C. Use Profile
- D. Estimated Usage of Pesticide

III. Summary of Temephos Risk Assessment

- A. Human Health Risk Assessment
 - 1. Occupational Risk
 - a. Toxicity
 - b. Dermal Absorption
 - c. Exposure
 - d. Occupational Handler Risk Summary
 - e. Post-Application Occupational and Residential Risk
 - 2. Aggregate Risk
- B. Environmental Risk Assessment
 - 1. Environmental Fate and Transport
 - 2. Risk to Water Resources
 - 3. Risk to Aquatic Species
 - 4. Risk to Birds and Mammals

IV. Risk Management and Reregistration Decision

- A. Determination of Reregistration Eligibility
 - 1. Summary of Phase 5 Comments and Responses
- B. Regulatory Position
 - 1. FQPA Assessment
 - 2. Endocrine Disruptor Effects
 - 3. Labels
 - a. Occupational Risk
 - b. Ecological Risk Mitigation
- C. Regulatory Rationale
 - 1. Rationale for Occupational Risk Mitigation
 - 2. Rationale for Environmental Risk Mitigation
 - 3. Benefits of Temephos Use
- D. Other Labeling
 - 1. Endangered Species Statement
 - 2. Spray Drift Management

V. What Registrants Need To Do

- A. Manufacturing Use Products
 - 1. Additional Generic Data Requirements
 - 2. Labeling for Manufacturing Use Products
- B. End-Use Products

1. Additional Product-Specific Data Requirements
 2. Labeling for End-Use Products
- C. Existing Stocks
- D. Table 8: Summary of Labeling Changes for Temephos
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Executive Summary

EPA has completed its review of public comments on the revised risk assessments and is issuing its risk management decisions for temephos. The risk management and regulatory decisions outlined in this document represent the final reregistration eligibility decision for temephos. Because there are no tolerances and no likely exposure from drinking water or residential use, temephos will not be included in the cumulative assessment for organophosphate pesticides.

The revised risk assessments are based on review of the required target data base supporting the use patterns of currently registered products and new information received. The Agency invited stakeholders to provide proposals, ideas or suggestions on appropriate mitigation measures before the Agency issued its risk mitigation and eligibility decisions on temephos. After considering the revised risks, as well as mitigation proposed by Clarke Mosquito Control Company, Inc., the registrant of temephos' technical product, and comments and mitigation suggestions from other interested parties, EPA developed its risk management decision for uses of temephos that pose risks of concern. These decisions are discussed fully in this document.

Temephos is an organophosphate insecticide currently used primarily as a mosquito larvicide.

EPA considers this to be a public health use. As such, the Agency has considered the provisions of FIFRA, as amended by FQPA, related to public health pesticides in its regulatory decision, including consultation with the Department of Health and Human Services (HHS) concerning the public health risk of mosquito-transmitted diseases and the benefits of temephos use. Information received from HHS confirms EPA's evaluation of temephos as the only organophosphate with any appreciable mosquito larvicidal use. It is effective against a wide spectrum of mosquitos, including those that transmit Eastern equine encephalitis, St. Louis encephalitis, dengue fever, and West Nile virus. It is more effective than available alternatives in highly polluted water, and tidal zones. As such, it is considered to be an important management tool in mosquito abatement programs.

Use of temephos has declined in recent years, with current annual usage of about 25,000 to 40,000 lbs of active ingredient. All remaining food tolerances were revoked in 1998.

Overall Risk Summary

EPA's human health risk assessment indicates some risks of concern for some pesticide handlers and applicators who mix, load, and apply temephos for mosquito abatement. Because there are limited re-

entry activities associated with mosquito larvicide applications, post-application risk to workers is not a concern. There are no food uses and exposure from drinking water is expected to be negligible due to its use only in non-potable water (stagnant, saline, brackish and temporary water bodies). There are no residential or homeowner uses of temephos, and again, because of its limited use pattern no significant exposure is expected to children or the general population.

Temephos is not expected to have a direct impact on terrestrial animals. Risk quotients for freshwater fish only slightly exceed levels of concern; no acute toxicity data are available for marine fish species. Field monitoring data indicate little impact on birds. Aquatic invertebrates, particularly *Daphnia magna*, are extremely sensitive to temephos. Monitoring data show that populations reestablish rapidly, but diversity may be affected.

Risk Mitigation

To address risk concerns posed by the use of temephos, EPA considered the mitigation proposal submitted by the technical registrant, as well as comments and mitigation ideas from other interested parties. The Agency has concluded that a number of label amendments are necessary. Results of the risk assessments, and the label amendments necessary to mitigate those risks, are presented in this RED.

To address occupational risk concerns, additional personal protective equipment (PPE) will be needed. Closed systems for mixing and loading would also address occupational risks for these activities and this option will be provided on new labels. In addition, the registrant has agreed to remove from product labels the use of certain hand held equipment (belly grinder) with the highest risk. No data are available to assess the risk from the use of power backpack blowers to apply temephos granules to tire piles. This is a minor but critical use--the granular temephos product is uniquely formulated for penetration of large tire piles and provides residual effectiveness. EPA is requiring data to assess exposure from this use and additional PPE will be needed. A 21-day dermal toxicity study is necessary as confirmatory data. The results of this study, if submitted in a timely fashion, may allow for reconsideration of some or all of the necessary PPE and engineering controls.

To address ecological risks, certain label restrictions are needed. Temephos labels will need to specify intervals between applications, further limit use sites to ensure that drinking water sources are not treated, and limit the circumstances under which the highest application rates may be used. In addition, the registrant has agreed to include reference to EPA's endangered species web site on product labels.

Reregistration Eligibility

For the mosquito, midge, gnat, punkie, and sandfly larvicidal use of temephos the Agency has determined that, with the adoption of all of the label amendments noted in this document, these uses are eligible for reregistration.

The Agency is issuing this Reregistration Eligibility Decision (RED) for temephos, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any necessary label changes for products containing temephos. There is no additional comment period for this RED and the time frames for compliance with the necessary changes outlined in this document are shorter than those given in previous REDs. As part of the process discussed by the TRAC, which sought to open up the process to interested parties, the Agency's risk assessments for temephos have already been subject to numerous public comment periods, and a further comment period for temephos was deemed unnecessary. The Phase 6 of the pilot process did not include a public comment period; however, for some chemicals, the Agency may provide for another comment period, depending on the content of the risk management decision. With regard to complying with the requirements in this document, the Agency has shortened this time period so that the risks identified herein are mitigated as quickly as possible. Because there are no food or residential uses, and drinking water is unlikely to be contaminated with temephos, no further cumulative assessment will be needed.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database 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" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment of all existing tolerances. The Agency had decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity. Temephos belongs to a group of pesticides called organophosphates,

which share a common mechanism of toxicity - they all affect the nervous system by inhibiting cholinesterase. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document presents a brief summary of the Agency's revised human health and ecological risk assessments, and final reregistration eligibility decision for temephos. Based on the current limited use pattern, no cumulative assessment will be necessary for temephos.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was composed of representatives from industry, environmental groups, and other interested parties. The TRAC identified the following science policy issues it believed were key to the implementation of FQPA and tolerance reassessment:

- Applying the FQPA 10-Fold Safety Factor
- Whether and How to Use "Monte Carlo" Analyses in Dietary Exposure Assessments
- How to Interpret "No Detectable Residues" in Dietary Exposure Assessments
- Refining Dietary (Food) Exposure Estimates
- Refining Dietary (Drinking Water) Exposure Estimates
- Assessing Residential Exposure
- Aggregating Exposure from all Non-Occupational Sources
- How to Conduct a Cumulative Risk Assessment for Organophosphate or Other Pesticides with a Common Mechanism of Toxicity
- Selection of Appropriate Toxicity Endpoints for Risk Assessments of Organophosphates
- Whether and How to Use Data Derived from Human Studies

The process developed by the TRAC calls for EPA to provide one or more documents for public comment on each of the policy issues described above. Each of these issues is evolving and in a different stage of refinement. Some issue papers have already been published for comment in the Federal Register and others will be published shortly.

In addition to the policy issues that resulted from the TRAC process, the Agency issued on Sept. 29, 2000, a Pesticide Registration Notice (PR 2000-9) that presents EPA's approach for managing risks from organophosphate pesticides to occupational users. The Worker PR Notice describes the Agency's baseline approach to managing risks to handlers and workers who may be exposed to organophosphate pesticides, and the Agency expects that other types of chemicals will be handled similarly. Generally, basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or protective clothing, as well as increased reentry intervals will be necessary for most uses where current risk assessments indicate a risk and such protective measures are feasible. The policy also states that the Agency will assess each pesticide individually, and based upon the risk

assessment, determine the need for specific measures tailored to the potential risks of the chemical. The measures included in this RED are consistent with the Worker Pesticide Registration Notice.

This document consists of six sections. Section I. contains the regulatory framework for reregistration/tolerance reassessment as well as descriptions of the process developed by TRAC for public comment on science policy issues for the organophosphate pesticides and the worker risk management PR notice. Section II. provides a profile of the use and usage of the chemical. Section III. gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV. presents the Agency's reregistration eligibility and risk management decisions. Section V. summarizes necessary label changes based on the risk mitigation measures outlined in Section IV. Section VI. provides information on how to access related documents. Finally, the Appendices lists Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page <http://www.epa.gov/pesticides/reregistration/status.htm>, and in the public docket.

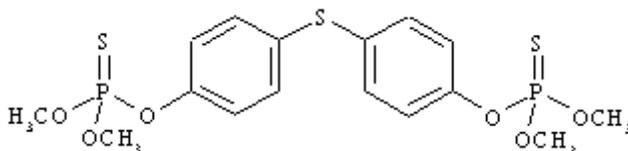
II. Chemical Overview

A. Regulatory History

Temephos was first registered in the United States in 1965 by American Cyanamid Company for a number of uses including citrus fruits, pet collars, and mosquito control. A Registration Standard was issued in August, 1981. In response to EPA's 1991 Data Call-In, American Cyanamid dropped all uses except the mosquito larvicide use in non-potable waters and requested a low volume minor use waiver for relief from the data requirements associated with that use. EPA found the waiver justified on economic grounds and waived some of the requirements. In 1997, the temephos technical registration was transferred to Clarke Mosquito Control Products, Inc. The Agency has revoked all food tolerances for temephos. See the Federal Register (63 FR 5910) published on February 5, 1998.

B. Chemical Identification

Temephos:



- Common Name: Temephos
- Chemical Name: Phosphorothioic acid, O,O'-(thiodi-4,1-phenylene) bis (O,O'-dimethyl) phosphorothioate;
- Phosphoric acid, O,O'-(thiodi,1,4-phenylene) O,O,O',O'-tetramethyl ester

- Chemical Family: Organophosphate
- Trade Name: Abate®
- Case Number: 0006
- CAS Registry Number: 3383-96-8
- OPP Chemical Code: 059001
- Molecular Formula: C₁₆H₂₀O₆P₂S₃
- Molecular Weight: 446.46
- Vapor Pressure: 7.17 x 10⁻⁸ (torrs); 9.5 x 10⁻⁶ Pa at 25C
- Physical State: Crystalline Solid
- Henry's Law Constant: 1.47 x 10⁻⁶ atm.m⁻³.mol⁻¹
- Boiling Point: Not applicable
- Melting Point: 30.0 - 30.5 C
- Solubility: 30 g/L at 25°C
- Kow: 80,900 (log Kow = 4.91)
- Basic Manufacturer: Clarke Mosquito Control Products, Inc.

C. Use Profile

The following information is based on the currently registered uses of temephos:

Type of Pesticide: Insecticide

Summary of Use Sites: Public Health: Mosquito larvicide

Target Pests: Aquatic larvae of mosquitos, midges, gnats, punkies, and sandflies

Formulation Types Registered: Granular and emulsifiable concentrate

Method and Rates of Application:

Equipment -Helicopters and fixed wing aircraft, backpack power blowers, backpack sprayers, horn blower, right-of-way sprayers, belly grinder, and spoon.

Use Rate -Maximum application rate for the granular product is 0.5 lbs/ai/A; typical application rate for granular products ranges from 0.1 to 0.3 lbs/ai/A; the granular tire treatment is applied at a rate of 0.05 lbs/ai/100 sq. ft. Maximum application rate for the emulsifiable concentrate (EC) is 1.5 fl. oz./A (0.0469 lbs/ai/A); typical application rate for the EC is 0.5 to 1.0 fl. oz./A. (0.0156 to 0.0313 lbs/ai/A).

Timing -No intervals are given on current labels. Multiple applications per season are permitted. Rate and frequency depend on the organic content of the water being treated, climatic conditions, infestation levels, and other regional and site-specific factors.

Use Classification: General

D. Estimated Usage of Pesticide

This section presents the best estimates available for the uses of temephos, based on available pesticide usage information for 1987 through 1998. A full listing of all uses of temephos with the corresponding use and usage data for each site, has been completed and is in the "Quantitative Use Assessment" (QUA) document, which is available in the public docket and on the Agency's website. It should be noted that the QUA contains usage information for sites that are no longer registered. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. Historically, as much as 100,000 lbs ai were used annually. For a better understanding of current usage, EPA has also consulted survey information from the American Mosquito Control Association (AMCA). Approximately 25,000 to 40,000 lbs ai of temephos are currently used annually, according to Agency and registrant estimates. Although temephos is used in many areas of the US, Florida and New Jersey are the states with most usage.

III. Summary of Temephos Risk Assessment

Following is a summary of EPA's revised human health and ecological risk findings and conclusions for the organophosphate pesticide temephos, as fully presented in the documents, "TEMEPHOS: Revised HED Chapter for the Reregistration Eligibility Decision (RED) Document," dated September 29, 1999 and the EFED "Reregistration Eligibility Document for Temephos," dated October 4, 1999. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to better understand the conclusions reached in the assessments.

These risk assessments for temephos were presented at a October 13, 1999, Stakeholders Meeting in Orlando, Florida, which was followed by an opportunity for public comment on risk management for this pesticide. The risk assessments presented here form the basis of the Agency's risk management and eligibility decision for temephos only.

A. Human Health Risk Assessment

EPA issued its preliminary risk assessments for temephos in September, 1998 (Phase 3 of the TRAC process). In response to comments and studies submitted during Phase 3, the risk assessments were updated and refined. Major revisions to the preliminary human health risk assessment include incorporation of a 38% dermal absorption factor based on a literature study provided by the registrant and correction of the maximum application rate for the emulsifiable concentrate--the preliminary assessment had assumed 0.5 lbs/ai/A; the correct rate is 0.0469 lbs/ai/A.

Only an occupational (mixer, loader, and applicator) risk assessment was conducted for temephos. The Agency believes that it is unlikely that significant postapplication exposures would occur based on the low application rate, the short duration spent by the worker in a treated area, and the low exposure activities performed by the worker.

Because of its limited use pattern, no residential, dietary, or drinking water exposures are likely and thus no risk assessments were warranted. Use sites include outdoor non-food and non-domestic aquatic areas such as non-potable water (stagnant, saline, brackish and temporary water bodies), waters high in organic content, highly polluted water, including moist areas, woodland pools, shallow ponds, edges of lakes, swamps, marshes, tidal waters, intertidal zones, catch basins, and tire piles. These use sites are typically unusable as sources of drinking water. Because of the areas in which temephos is aerially applied (e.g., tidal marshes) and the presumed large droplet size of the spray, the Agency believes it is unlikely that significant exposure via spray drift would occur. However, because of the diversity of sites on which temephos may be used, the Agency is concerned that bystander spray drift exposure may occur in some situations. Although temephos may be used in areas that may occasionally be visited by the general population (e.g., temporary pools along the side of the road, standing water in discarded tires), the Agency believes that postapplication exposure would be minimal. This belief is based on the relatively low application rate, the likelihood of a brief duration spent in such environments, and the probability of low exposure activities in these areas.

FQPA Safety Factor

The FQPA Safety Factor Committee determined that the 10X for temephos should be retained solely because of the inadequacy of the toxicology data base which precluded an evaluation of potential enhanced susceptibility to infants and children. However, an FQPA safety factor for the protection of infants and children from exposure to temephos was not used in the risk assessment because presently there are no registered food, drinking water, or residential uses, and thus there are no concerns for potential exposures of infants and children to temephos. For these reasons, only occupational risk assessments were conducted for temephos, and, as a matter of policy, the FQPA factor is not considered in occupational assessments. For additional information see "Report of the Hazard Identification Assessment Review Committee," dated May 12, 1998, available in the public docket and on the Internet.

1. Occupational Risk

In general, occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. For temephos, occupational handlers include: personnel of mosquito abatement districts (MADs) and personnel of companies under contract to MADs, and other state and local public health authorities.

The Agency believes that it is unlikely that significant postapplication exposures to temephos would occur either to workers or by-standers based on the relatively low application rate, the limited use pattern, the short duration spent by the worker or bystanders in the types of areas treated, and the low exposure activities, such as sampling, performed by the re-entry worker. Thus, no post-application assessment has been conducted.

Risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). Generally, MOEs greater than 100 are not of concern.

a. Toxicity

The toxicity of a chemical is integral to assessing the occupational risk. All risk calculations are based on the most current toxicity information available for temephos. A valid 21-day dermal toxicity study was not available to assess temephos. The toxicological endpoints, and other factors used in the occupational risk assessments for temephos are discussed in more detail below.

The toxicology database for temephos has several data gaps. Most of the available studies were conducted in the 1960's and 1970's and do not meet the current requirements of Subdivision F Guidelines. However, the Agency has reviewed all toxicity studies submitted and has determined that available data are adequate to support the reregistration of temephos for non-food, non-residential, low-volume, minor use.

Temephos has relatively low to moderate acute toxicity compared to other organophosphate insecticides. Temephos is moderately acutely toxic by the oral and dermal route, and has low toxicity through inhalation. Signs of toxicity observed in animals treated with high doses of temephos are typical of acute toxicity signs induced by cholinesterase (ChE) inhibition which include; hypoactivity, labored breathing, rough coat, chromodacryorrhea, salivation, muscle spasms and tremors. Temephos is slightly irritating to eyes but is not a skin irritant or a dermal sensitizer.

Table 1. Summary of Acute Toxicity Data for Temephos

Guideline#	Study Type	MRID	Results	Toxicity Category
870.1100	Acute Oral (Rats)	000019021	LD ₅₀ = 444 mg/kg	II
870.1200	Acute Dermal (Rabbits)	140124 1906/1907	LD ₅₀ = 1850 mg/kg (Males) LD ₅₀ = 970 mg/kg (Females)	II II
870.1300	Acute Inhalation	00101656	LC ₅₀ > 1.3 mg/L	III

870.2400	Primary Eye Irritation	001907	Corneal opacity 72 hrs	III
870.2500	Primary Skin Irritation	140124	PIS = 1.4	IV
870.2600	Dermal Sensitization	00157836	Not a sensitizer	

Note: The information in this table is based on studies used to support the original registrations of temephos products. These data may not be acceptable by current guideline standards. New acute toxicity data will be necessary and reviewed as a result of the PDCI that accompanies this RED.

A complete assessment of the neurotoxic potential of temephos cannot be made since acute and subchronic neurotoxicity studies in rats are not available. Nevertheless, temephos belongs to the class of organophosphorus insecticides which exert their toxic action by inhibiting cholinesterase in the peripheral and central nervous systems and therefore, neurotoxicity is implied in this class of chemicals.

Temephos is not considered to be a reproductive or developmental toxicant. Additional data are necessary to confirm this assessment. Since there are no current registered food or residential uses, there are no concerns for potential exposure to infants and children.

Temephos is not classified as a carcinogen. The only study available for this assessment was a 2-year chronic study in rats, in which the highest dose (15 mg/kg/day) did not induce tumor formation. In addition, several *in vitro* mutagenicity studies were considered not adequate to evaluate the genotoxic potential of temephos. Because this chemical is for non-food use only, a chronic/carcinogenicity study in another species is not necessary.

A NOAEL of 0.3 mg/kg/day was selected for the short-term, intermediate-term, and long-term or chronic occupational risk assessments. This endpoint is based on inhibition of cholinesterase in the red blood cells of rats of both sexes at 0.9 mg/kg/day (LOAEL) in a 90-day feeding study. The toxic effect was observed within one week after initiation of treatment, and thus is considered to be appropriate for a short term (1-7 day) assessment. Use of this same endpoint for the chronic assessment is supported by similar doses and endpoints seen in another subchronic toxicity study in rats, as well as a chronic study in dogs where red blood cell and plasma cholinesterase inhibition occurred from one week onward.

No short, intermediate or chronic inhalation study is available. Therefore, the oral NOAEL of 0.3 mg/kg/day was also used to estimate inhalation risk and to perform a combined dermal and inhalation assessment.

Further details on the toxicity of temephos can be found in the September 29, 1999 Human Health Risk Assessment. The studies and endpoints used for the occupational risk assessment are outlined in Table 2.

b. Dermal Absorption

No acceptable guideline dermal absorption studies are available for temephos. A rabbit dermal study was conducted, however this study was not considered adequate. Dermal rabbit studies can be expected to underestimate the toxicity of sulfur-containing organophosphates, such as temephos, because rabbit blood has high concentrations of arylesterases, a class of enzymes which detoxify the compounds before they can be converted to the activated form in the liver. For this reason, the rat is the preferred species for dermal studies for many organophosphates.

During Phase 3 of the OP process, the registrant submitted a published dermal absorption study of temephos (MRID 44756801) conducted by the Department of the Army. EPA has reviewed the study, and determined that a dermal absorption factor of 38% is appropriate for use in the revised assessment.

The registrant and other commenters questioned the Agency choice of 38% dermal absorption in the rat, since the Army study had also estimated lower dermal absorption values for dogs and rabbits. EPA's conclusion of 38% dermal absorption was calculated using experimentally derived values from the submitted non-guideline study using the rat. While the rat was not intended as a model of dermal absorption to predict penetration through the human skin, the rat has been extensively used for metabolic and toxicological studies and allows for consistency and comparisons from study to study and the Agency believes it is reasonable to use the rat as the preferred species for dermal absorption studies. Furthermore, in this case, the Agency's does not believe it is appropriate to compare relative dermal absorption across species because there is considerable species variation in dermal penetration and subsequent responses to toxicants due to inherent physiological differences.

Table 2. Summary of Toxicological Endpoints and Other Factors Used in the Human Occupational Risk Assessments for Temephos

Assessment	Dose	Endpoint	Study	Absorption factor
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Short-term dermal	NOAEL = 0.3 mg/kg/day	RBC ChE inhibition at 0.9mg/kg/day at week one	90-day oral Feeding Study in Rats	38%
Intermediate- term dermal	NOAEL = 0.3 mg/kg/day	RBC ChE inhibition at 0.9mg/kg/day	90-day oral Feeding Study in Rats	38%
Long-term dermal	NOAEL= 0.3 mg/kg/day	RBC ChE inhibition at 0.9mg/kg/day	90-day oral Feeding Study in Rats	38%
Inhalation--any time period	NOAEL= 0.3 mg/kg/day	RBC ChE inhibition at 0.9mg/kg/day	90-day oral Feeding Study in Rats	100%

c. Exposure

No chemical-specific exposure data were available for temephos, so risks to pesticide handlers were assessed using data from the Pesticide Handlers Exposure Database (PHED). The standard assumption of 70 kg was used for average body weight. Temephos-specific usage data were available from the American Mosquito Control Association and individual MADs to characterize the typical application rates and daily areas treated, which EPA used to calculate volume of pesticide handled for their risk estimates. The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments. Although available usage data indicate that maximum application rates are used only infrequently, they have also been taken into account in the assessment because they are allowed on current temephos labels, and registrants wish to retain those high rates for use under certain critical conditions. PHED unit exposure values, although derived from agricultural use, are currently the best available estimates of exposure for mosquito control operations. Some PHED unit exposure values are high quality while others represent low quality, but are the best available data. The quality of the data used for each scenario assessed is discussed in the Human Health Assessment document for temephos, which is available in the public docket and on the Agency's website.

Anticipated use patterns and application methods, range of application rates, and daily acres treated were derived from current labeling and information supplied by stakeholders. The maximum application rate specified on current temephos labels for granular formulations is 0.5 lbs/ai/A; typical application rate for granular products ranges from 0.1 to 0.3 lbs/ai/A; the granular tire treatment is applied at a rate of 0.05 lbs/ai/100 sq. ft. Maximum application rate for the emulsifiable concentrate (EC) is 1.5 fl. oz./A (0.0469 lbs/ai/A); typical application rate for the EC is 0.5 to 1.0 fl. oz./A (0.0156 to 0.0313 lbs/ai/A).

Occupational handler exposure assessments are conducted by the Agency using different levels of personal protection. The Agency typically evaluates all exposures with minimal protection and then adds additional protective measures using a tiered approach to obtain an appropriate MOE (i.e., going from minimal to maximum levels of protection). The lowest tier is represented by the baseline exposure scenario, followed by, if required (i.e., MOEs are less than 100), increasing levels of risk mitigation (personal protective equipment and engineering controls). The current labels for temephos require no protective equipment [not even baseline work clothes, with the exception of the label for the granular tire treatment product (EPA registration #8329-30) which requires handlers to wear safety goggles]. Information from stakeholders indicates that typical practice is to wear baseline work clothes and usually gloves, even though these requirements are not yet on product labels. The levels of protection that formed the basis for calculations of exposure from temephos activities include:

Baseline: Long-sleeved shirt and long pants, shoes and socks.

Current Label: No PPE is required on current labels except goggles which are required on the granular formulation used to treat tire piles. The current label scenario was not assessed but MOEs would be less than the baseline values given in Table 3.

Maximum PPE: Cloth coveralls over long-sleeved shirt and long pants, chemical resistant gloves, chemical resistant footwear plus socks, chemical resistant headgear for overhead exposures, and a respirator if risk is driven by inhalation. Inhalation is a minor contributor to temephos exposure.

Engineering controls: Engineering controls such as a closed cab truck or closed cockpit for application scenarios, or a closed mixing/loading system such as a mechanical transfer system for emulsifiable concentrate or a packaged based system (e.g., a lock and load type system for granulars). Some engineering controls are not applicable for certain scenarios (e.g., for hand held application methods there are no known devices that can be used to routinely lower the exposures). EPA is not aware of any closed loading systems for granular application by aircraft.

Dermal exposure is the primary route of concern. Risk from inhalation exposure would be minimal, based on the lack of toxic effects near or above the limit dose in an acute inhalation toxicity study. Occupational handlers can be exposed to temephos on a short term, intermediate term, and long term (chronic) basis. Information from the registrant and user community indicates that workers could be

exposed up to five days per week for the 6 warm months and 2-3 times per week for the rest of the year. Typical exposures may be less and vary by region.

The Agency believes that it is unlikely that significant postapplication exposures to temephos would occur either to workers or by-standers based on the relatively low application rate, the limited use pattern, the short duration spent by the worker or bystanders in the types of areas treated, and the low exposure activities performed by the re-entry worker. Thus no post-application assessments have been conducted.

d. Occupational Handler Risk Summary

The representative treatment scenarios considered for mixers, loaders, and applicators are listed below:

Mixer/Loader

- (1) mixing / loading emulsifiable concentrate for aerial application;
- (2) mixing / loading emulsifiable concentrate for rights-of-way sprayer;
- (3) loading granulars for aerial application;

Applicator

- (4) applying emulsifiable concentrate using fixed-wing aircraft;
- (5) applying emulsifiable concentrate using helicopters;
- (6) applying emulsifiable concentrate using rights-of-way sprayer;
- (7) applying granulars using fixed-wing aircraft;
- (8) applying granulars using helicopters;

Flagger

- (9) flagging during aerial application of emulsifiable concentrate sprays;
- (10) flagging during aerial application of granulars;

Mixer/Loader/Applicator

- (11) mixing / loading / applying emulsifiable concentrate with a backpack sprayer;
- (12) loading / applying granulars with a power backpack blower;
- (13) loading / applying granulars with belly grinder; and
- (14) applying granulars by spoon (by hand used as a surrogate).

The personal protective equipment (PPE) assumed for each scenario is listed below:

- (1, 2, 3) Cloth coveralls over long pants, long sleeved shirt, chemical resistant gloves, organic vapor respirator.
- (4, 5, 7, 8) Single layer of clothing. (Double layer clothing is not feasible for pilots. The added bulk and restricted movement are considered safety hazards.)

(6, 9, 10, 11, 13, 14) Cloth coveralls over long pants, long sleeved shirt, chemical resistant gloves, organic vapor respirator.
 (12) No data are available to assess exposure from power backpack blowers.

The engineering controls for each scenario are listed below:

(1, 2, 3) Closed mixing and loading systems.
 (4, 5, 7, 8) Closed cockpit.
 (6) Engineering controls were not considered for rights-of-way sprayer applications. EPA assumes that these types of applications involve an individual on the back of a tank truck directing the pesticide spray with a hose.
 (9, 10) Closed cab vehicle.
 (11, 12, 13, 14) Applications by backpack sprayer, backpack power blower, spoon, and belly grinder are not amenable to closed systems.

Data from PHED for helicopter application of sprays and granulars are based on a very limited number of replicates. Instead of assessing this exposure scenario using inadequate data, EPA assumes that the estimates for helicopters are similar to those for fixed-wing applications.

Combined dermal and inhalation risks were calculated for all exposure scenarios based on the PPE and/or engineering controls described above. For temephos, the same NOAEL was chosen for short, intermediate and long term assessments. Because of the variability in usage, EPA has calculated MOEs with both typical and maximum application rates and acres treated. The resulting range of MOEs are presented in Table 3.

Table 3. Temephos Mosquito Control Uses: Remaining Risk Concerns (combined dermal & inhalation MOEs)

			Short, Intermediate, and Long-term MOEs		
Scenario	Acres	Rate (lbs/ai/A)	Baseline	Max PPE	Engineering Control
Mixer / Loader Exposure					
(1) Mixing/ loading emulsifiable	350	0.0469	1.2	190	380

concentrate for aerial application	700	0.0469	0.58	97	190
	700	0.0313	0.8	126	254
(2) Mixing/loading emulsifiable concentrate for right-of-way sprayer	40	0.0469	10	1,700	3,300
(3) Loading granulars for aerial application	350	0.5	25	82	1,200
	700	0.5	12	41	610
	700	0.25	25	82	1,200
Applicator Exposure					
(4) Applying emulsifiable concentrate using fixed-wing aircraft	350	0.0469	--	--	650
	700	0.0469	--	--	330
	700	0.0313	--	--	434
(5) Applying emulsifiable concentrate using a helicopter	No adequate data are available; MOEs are assumed to be similar to scenario (4) above.				
(6) Applying emulsifiable concentrate using right-of way	40	0.0469	22	100	--

sprayer					
(7) Applying granulars using fixed wing aircraft	350	0.5	--	--	63
	700	0.5	--	--	31
	700	0.25	--	--	63
(8) Applying granulars using a helicopter	No adequate data are available for this scenario; MOEs are assumed to be similar to scenario (7) above.				
Flagger Exposure					
(9) Flagging for liquid sprays	350	0.0469	280	330	14,000
	700	0.0469	140	170	7,000
(10) Flagging for granulars	350	0.5	99	190	4,900
	700	0.5	49	96	2,500
	700	0.25	98	190	4,900
Mixer /Loader / Applicator Exposure					

(11) M/L/A sprays with a backpack sprayer	5	0.0469	91	150	--
	5	0.0313	136	225	--
(12) Loading / applying granulars with a power backpack blower	No exposure data are available to assess this use; MOEs are assumed to be similar to scenario #13, below.				
(13) Loading / applying granulars with a belly grinder	5	0.5	2.2	2.7	--
	5	0.25	4.4	5.4	--
(14) Applying granulars by spoon (by hand used as a surrogate)	0.023	0.5	66	120	--
	0.023	0.25	132	240	--

e. Post-Application Occupational and Residential Risk

As mentioned earlier, the Agency believes that it is unlikely that significant postapplication exposures to temephos would occur either to workers or by-standers based on the relatively low application rate, the limited use pattern, the short duration spent by the worker or bystanders in the types of areas treated, and the low exposure activities performed by the re-entry worker. Thus, no post-application assessments have been conducted.

2. Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure from both food and drinking water sources, and residential exposures. Because people are not expected to be exposed to temephos from any of these sources, an aggregate assessment has not been conducted.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the Environmental Fate and Effects assessment, entitled "Reregistration Eligibility Document for Temephos", dated October 4, 1999, and "Response to Public Comments on Ecological Risk Assessment for Temephos," dated October 5, 1999, which is Attachment 1 to the "Response to Public Comments on the Preliminary Risk Assessments for the Organophosphate Pesticide Temephos," both are available in the public docket and on the Internet.

Major revisions have been made since the preliminary risk assessment was completed. Both the registrant, Clarke Mosquito Control Company Inc. and Lee County Florida Mosquito Control District submitted temephos-specific literature studies and field studies to address the many data gaps that had been identified in the preliminary assessment. While these studies, for the most part, were not adequate to satisfy guideline requirements, they contained much useful information that allowed EPA to conduct a more thorough revised ecological assessment.

1. Environmental Fate and Transport

The presence of microorganisms in aquatic environments and exposure to sunlight are likely to be the predominant means of transformation/dissipation of temephos. In the absence of microorganisms or sunlight, temephos does not dissipate significantly in water. The potential effect of sunlight on temephos is decreased by the presence of dense vegetation which may commonly shade temephos treated waters.

Temephos can bind strongly to soils and sediments and is unlikely to volatilize from either under most conditions. However, temephos could potentially volatilize slowly from shallow water. Transformation products of temephos, such as temephos sulfoxide, temephos sulfone, temephos sulfide and sulfone phenols do not bind to soil as strongly as temephos and are, therefore, more likely to migrate to and remain dissolved in the water.

Temephos, being a hydrophobic chemical and thus more likely to bind to fatty substances, has the potential to bioconcentrate. Temephos bioaccumulated in fish exposed to temephos for 28 days. However, more than 75% of the temephos was eliminated after 14-days of non-exposure.

The major transformation products of temephos are temephos sulfoxide and temephos sulfone. Temephos sulfide and sulfone phenols have also been identified in water/sediments under anaerobic and aerobic conditions. The only major degradate of temephos identified in irradiation-exposed samples was temephos sulfoxide.

The low solubility of 0.030 mg/L and the relatively high K_{oc} of 16, 250 might suggest that some laboratory sediment toxicity testing should be performed. However, measurements of residues in sediment from field studies submitted by the registrant generally concluded that temephos tends to

rapidly adsorb to organic media and further degrade to low or undetectable concentrations. The most recent field study, which monitored temephos in sediments over a three year period, (1995-1997) did not detect temephos in the sediment after 24 hours. As a result of these field data, a sediment toxicity study will not be necessary at this time.

2. Risk to Water Resources

Temephos is applied directly to non-potable, stagnant, saline, brackish and polluted waters. Exposure to temephos and its degradation products is limited to these aquatic environments, where mosquito breeding occurs. These waters are unsuitable as a source of drinking water. Even if temephos were applied to water used as a source of drinking water, e.g., reservoirs and ox-bow lakes, dilution and residence time would reduce exposures to temephos at the drinking water intake. Temephos degrades relatively rapidly in natural water. Model concentrations indicate that there is little effect of repeat applications on peak concentrations of temephos; however, longer-term concentrations in woodland pools increase when temephos treatments recur at intervals of 7 or 15 days. In estuarine environments where tidal flushing occurs repeat applications are not expected to result in accumulation of temephos.

Temephos is not likely to reach ground water that would be used for drinking water due to its relatively short half-life in natural waters and the lack of transport in typical temephos use areas-- because temephos is a larvicide, it is formulated to remain on the water's surface where larvae are located. It was therefore determined that there was no need to further evaluate temephos occurrence in ground water or surface water used for drinking.

Several commenters noted that temephos is used in some countries to treat drinking water. Since temephos is not used in potable water in the United States and this use is not supported for reregistration, the Agency has not conducted a drinking water risk assessment.

3. Risk to Aquatic Species

To estimate potential ecological risk EPA integrates the results of exposure and ecotoxicity using the risk quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

Fish

Temephos is categorized as slightly to moderately toxic to freshwater fish on an acute basis. No data are available to characterize toxicity to marine fish species. The Risk Quotients derived from the current freshwater fish acute toxicity studies exceed the levels of concern for the emulsifiable concentrate formulation only for restricted use and endangered species, the risk quotients for the granular formulation do not exceed the levels of concern. EPA has no data on acute toxicity of any marine fish species. Acute risk quotients for freshwater fish based on a rainbow trout LC50 of 3490 ppb, (study performed with the TGAI) and a granular application rate of 0.5 lbs/ai/A are given below. Calculations assume aerial or ground applications to an intermittent pond of 15 or 30 centimeter depth.

Table 4. Temephos Acute Risk Quotients for Rainbow Trout (TGAI with Granular App. Rate)

Rate (# of applications)	Acute RQ (EEC/LC50) 15 cm 30 cm	
	15 cm	30 cm
0.5 (1)	0.01 0.01	0.01
0.5 (2) @ 7 day intervals	0.01 0.01	0.01
0.5 (2) @ 15 day intervals	0.01 0.01	0.01
0.5 (2) @ 90 day intervals	0.01 0.01	0.01

Acute risk quotients for freshwater fish based on a rainbow trout LC50 of 158 ppb, (study performed with a EC formulated product) and a maximum application rate of 0.047 lbs/ai/A are given below. Calculations assume aerial or ground applications to an intermittent pond of 15 or 30 centimeter depth.

Table 5. Temephos Acute Risk Quotients for Rainbow Trout (EC Formulated Product)

Rate (# of applications)	Acute RQ (EEC/LC50)	
	15 cm	30 cm

0.047 (1)	0.31	0.15
0.047 (2) @ 7 day intervals	0.32	0.16
0.047 (2) @ 15 day intervals	0.32	0.16
0.047 (2) @ 90 day intervals	0.31	0.15

The Agency had some concern for chronic risk to fish because temephos labels allow repeated applications to water. LC₅₀ values of less than 1 ppm have been demonstrated for both aquatic invertebrates and fish. However, a number of field studies have been submitted which show that even after ten applications of the granular Abate® 2G formulation no chronic effects to fish were observed. Growth retarding effects in fish were observed in one study after 4 applications of the liquid Abate® 4E formulation, but because details of the studies were not given, the Agency does not have a high level of confidence in the results of this study. Review of the extensive field data that were submitted during Phase 3 addresses the concern for chronic risk to fish; no further data will be necessary at this time.

Aquatic Invertebrates

Temephos is "highly toxic" to "very highly toxic" to freshwater and marine/estuarine aquatic invertebrates. The emulsifiable concentrate appears to be much more toxic than the granular formulation in laboratory studies, however this conclusion is based on a single valid study with a 5% granular formulation. Acute risk quotients for freshwater invertebrates based on a stonefly *Pteronarcis spp.* LC50 of 10 ppb, (study performed with the TGAI) and a maximum granular application rate of 0.5 lbs/ai/A are given below. Calculations assume aerial or ground applications to an intermittent pond of 15 or 30 centimeter depth.

Table 6. Temephos Acute Risk Quotients for Stonefly (TGAI with Granular App. Rate)

Rate (# of applications)	Acute RQ (EEC/LC50)	
	15 cm	30 cm

0.5 (1)	4.88	2.44
0.5 (2) @ 7 day intervals	5.04	2.52
0.5 (2) @ 15 day intervals	5.00	2.50
0.5 (2) @ 90 day intervals	4.88	2.44

Acute risk quotients for freshwater invertebrates based on a *Daphnia magna* LC50 of 0.011 ppb, (study performed with a EC formulated product) maximum application rate of 0.047 lbs/ai/A are given below. Calculations assume aerial or ground applications to an intermittent pond of 15 or 30 centimeter depth.

Table 7. Temephos Acute Risk Quotients for *Daphnia magna* (EC Formulated Product)

Rate (# of applications)	Acute RQ (EEC/LC50)	
	15 cm	30 cm
0.047 (1)	4,436	2,218
0.047 (2) @ 7 day intervals	4,581	2,290
0.047 (2) @ 15 day intervals	4,545	2,272
0.047 (2) @ 90 day intervals	4,436	2,218

Some field data for freshwater invertebrates show that non-target aquatic invertebrate populations tend to reestablish their original population levels (i.e. numbers) within three weeks after application,

however, other field data show that recovery patterns (i.e. species diversity) are altered. Additionally, as shown in the above table laboratory studies show *Daphnia magna* to be extremely sensitive resulting in risk quotients being exceeded by many orders of magnitude for the emulsifiable concentrate.

Chronic risk to the estuarine environment was difficult to characterize due to the lack of marine/estuarine invertebrate chronic data. The risk quotients on the acute data based on the TGA1 did not greatly exceed the levels of concern. However, levels of concern are greatly exceeded for the EC formulated product. Although no acceptable chronic studies have been submitted for marine/estuarine invertebrates, a number of field studies have been submitted which have demonstrated that adverse effects to aquatic ecosystems are minimized when temephos is used at the lower (0.0313 lbs/ai/A) application rate.

4. Risk to Birds and Mammals

Because Temephos is only applied directly to water, it is not expected to have a direct impact upon terrestrial animals. No acute risk quotients have been calculated, however, EPA has modeled the possibility of terrestrial animals being exposed to temephos via drinking water using an avian species (Mallard duck). Results of the modeling indicate that the amount of temephos that the duck would be exposed to through normal water intake is much less than the potentially lethal concentration, and thus not of concern.

Additionally, due to the tendencies for temephos to bioconcentrate, a piscivorous bird scenario was modeled to assess the risk to fish-eating birds. This assessment was based on the comparison of the bioconcentration factor (BCF) and resulting residues in fish viscera, to an avian subacute dietary LC₅₀. It was concluded that residue levels are expected to be lower than the avian subacute dietary LC₅₀. This assessment indicates that only endangered species RQs may be exceeded in the 15 cm pond depth scenario.

There are no guideline data on the potential chronic effects of the intake of food by waterfowl or upland game birds. However field data that have been submitted for review indicate that there is very little, if any, impact on birds. Therefore, EPA will not require a chronic bird study at this time. In addition, since birds are not expected to be affected by direct applications to water and no effects were noted in the field data, EPA will not require acute testing on the formulated product.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions 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 necessary to support reregistration of products containing temephos active ingredients.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticides containing the active ingredient temephos of organophosphates as a class. Based on a review of these data and public comments on the Agency's assessments for the active ingredient temephos, EPA has sufficient information on the human health and ecological effects of temephos to make a reregistration eligibility decision. Because temephos has no dietary or residential exposure concerns, it is not subject to further cumulative assessment for other organophosphates. This RED identifies risk reduction measures that are necessary to allow the continued use of temephos. Appendix B. identifies the generic data requirements that the Agency reviewed as part of its determination, and lists the submitted studies that the Agency found acceptable.

Based on its current evaluation of temephos alone, the Agency has determined that temephos products, unless amended and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should the registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of temephos. For temephos, if all changes outlined in this document are incorporated into the labels, then the risks associated with current use patterns will be mitigated.

1. Summary of Phase 5 Comments and Responses

When making its reregistration decision, the Agency took into account all comments received during Phase 5 of the OP public participation process. After the Stakeholder meeting in Orlando in October of 1999, 33 comments were received in EPA's public docket for temephos. Of these, 31 were from officials of mosquito abatement districts and other government agencies, and of those 22 were from Florida, 5 from Illinois, 3 from Louisiana and 1 from Mississippi. These generally supported the continued use of temephos and attested to the benefits of its use. One comment was received from a public interest group, Sarasota/Manatee Citizens Rally Against Malathion (SCRAM). One comment was received from Wellmark International, a registrant of methoprene products. These comments in their entirety are available in the docket. A brief summary of the comments and the Agency response is noted here.

Comment: Many stakeholders felt that EPA should place greater weight on the benefits of temephos use.

Response: EPA acknowledges the public health benefits of temephos use to control mosquito larvae and has considered these benefits in its regulatory decision. See Section IV. C.3 below for a complete discussion of the FQPA provisions dealing with public health uses.

Comment: Several stakeholders were concerned about the potential for heat stress with additional protective equipment, since temephos is used primarily during the hottest time of the year.

Response: EPA is also concerned about heat stress and has considered this issue carefully in development of the Worker Protection Standard. In the case of temephos, double-layer clothing is needed for mixing and loading emulsifiable concentrate, loading granulars for aerial application, and for applications with a right-of way sprayer. In all cases closed mixing, loading and closed cabs are also an option. Also, route specific (dermal) toxicity data is necessary. Should these data indicate lower risks than the current assessment, EPA will revisit the PPE recommendations. See also Section IV. C.1 for a discussion of considerations related to heat stress.

Comment: Several stakeholders commented that the requirement on current labels to consult State Fish and Game Agencies before applying temephos products to waters or wetlands was counter productive. In many states, Fish and Game agencies have no regulatory oversight of mosquito control programs and are confused by such calls. Further, mosquito control agencies still must develop management plans with the relevant State and Federal agencies (including approval of pesticides to be used) when conducting operations on State and Federally owned lands.

Response: The language on current labels is obsolete and must be deleted. See PR Notice 88-1. This language was initially intended to address endangered species concerns. Registrants of temephos have agreed to include EPA's endangered species web site address on their product labels, so that users have access to all existing county bulletins.

Comment: The SCRAM comment urged EPA to eliminate the use of temephos for mosquito larviciding, citing its effects on non-target organisms and the availability of safer alternatives.

Response: Some alternatives to temephos pose less risk to humans than temephos. However, all available larvicides have some impact on non-target aquatic organisms. Furthermore, there are certain situations where available alternatives do not achieve adequate control. See Section IV. C.3 below for a more complete discussion of alternatives.

Comment: Wellmark International took exception to EPA's reference to temephos use in managing resistance to methoprene. They noted that the only documented resistance to methoprene had been in a strain of *Aedes taeniorhynchus* mosquitos in Lee County, Florida. Attached to their comment were abstracts from a literature search documenting resistance to temephos in the Caribbean, South America, Asia, Middle East, Europe, and North America.

Response: EPA and HHS acknowledge that resistance to temephos has developed in some parts of the world, due to its widespread use to control the vectors of dengue and malaria, and also perhaps due to its use at less than optimal rates. Nonetheless, it is the only OP with any significant larvicide use in the US, and as such, is an important tool for integrated control of mosquitos.

B. Regulatory Position

1. FQPA Assessment

No aggregate or cumulative assessments, as required by FQPA, have been conducted for temephos. This chemical has no food uses, is not likely to be found in drinking water, and is not used in or around homes or areas that children frequent. All tolerances for temephos have been revoked.

2. Endocrine Disruptor Effects

EPA is required under the FFDCFA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCFA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, temephos may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

3. Labels

Label amendments are needed for temephos products. Provided the following risk mitigation measures are incorporated in their entirety into labels for temephos-containing products, the Agency finds that all currently registered uses of temephos except application by belly grinder, would be eligible for reregistration. The regulatory rationale for each of the mitigation measures outlined below is discussed immediately after this list of mitigation measures. Specific label language is given in Table 8: Summary of Labeling Changes for Temephos in Section V.

a. Occupational Risk Mitigation

To address risk to mosquito abatement workers who mix, load and apply temephos products, the following measures will be necessary:

- For mixing and loading emulsifiable concentrate for aerial application and rights-of-way sprayers labels will contain the following options:

-baseline work clothes, chemical resistant gloves, chemical resistant apron + closed mixing and loading system (Note: A dry coupling device for current containers would be adequate.)

-or-

-double layer clothing (baseline work clothes + cloth coveralls), chemical resistant gloves, chemical resistant apron, and chemical resistant footwear plus socks.

- For loading granulars for aerial application labels will provide the following options:

-double layer clothing (baseline work clothes + cloth coveralls), chemical resistant gloves, chemical resistant footwear plus socks, and a dust/mist respirator.

-or-

(Note: When closed loading systems become available, EPA will work with the registrant to develop labels reflecting the appropriate reduced PPE, i.e. - baseline work clothes, chemical resistant gloves + closed loading system).

- For applying granulars and emulsifiable concentrate using fixed-wing aircraft or helicopters:

-baseline work clothes + closed cockpit.

- For applying emulsifiable concentrate using rights-of-way sprayer:

-baseline work clothes + closed cab truck

-or-

-double layer clothing (baseline work clothes + cloth coveralls), chemical resistant gloves.

- For flaggers during aerial application of liquid sprays and granulars:

-baseline work clothes and chemical-resistant headgear.

- For mixing / loading / applying sprays with a backpack sprayer or loading and applying granulars with a backpack power blower for applications other than tire piles:

-baseline work clothing and chemical resistant gloves.

- For loading and applying granulars with a power backpack blower to tire piles:
 - double layer clothing (baseline work clothes + cloth coveralls), chemical resistant gloves, chemical resistant footwear plus socks, and a dust/mist respirator.
- All granular product labels must prohibit application with a belly grinder.
- For applying granulars by spoon (by hand):
 - double layer clothing (baseline work clothes + cloth coveralls), chemical resistant gloves, and chemical resistant footwear plus socks.

(Note: The need for protective eye wear, such as goggles or a face mask, will be assessed on a product specific basis.)

b. Ecological Risk Mitigation

- Use sites must be limited to: non-potable water (stagnant, saline, brackish and temporary water bodies), waters high in organic content, highly polluted water, including moist areas, woodland pools, shallow ponds, edges of lakes, swamps, marshes, tidal waters, intertidal zones, catch basins, and tire piles.
- Limit applications to public health officials, personnel of mosquito abatement districts and similar government agencies, or personnel under contract to these entities.
- Limit use of the high application rates only to non-potable waters high in organic matter content, areas demonstrated to have resistant mosquitos, habitats having deep water or dense surface cover and where monitoring has confirmed a lack of control at typical rates.
- Establish application intervals of 7 days unless monitoring indicates that larval populations have reestablished, or weather, or flooding conditions have rendered initial treatments ineffective.
- Provide EPA's web site address on labels for information on endangered species.
- Augment current environmental hazard statement to reflect the high acute toxicity to non-target aquatic invertebrates, shrimp and crabs.

C. Regulatory Rationale

The following is a characterization of the risks and a summary of the rationale for the mitigation measures outlined in the previous section.

1. Rationale for Occupational Risk Mitigation

Consistent with the PRN 2000-9, the registrants of temephos have agreed to protective equipment and engineering controls to the extent feasible. For all handler and applicator scenarios, MOEs are near or over 100 except: loading granulars for aerial application (MOEs range from 41-82, depending on amount handled (acres treated) and application rate); and applying granulars using fixed-wing aircraft and helicopter (MOEs range from 31-63, depending on acres treated and application rate). EPA believes that the risk represented by these ranges are not of concern given the off-setting public health benefits of temephos, the protective assumptions inherent in the Agency's assessment, and the

fact that all available protective measures are being implemented, along with the development of key confirmatory data to reduce uncertainty associated with current risk estimates.

Reliable usage data provided by the American Mosquito Control Association, individual mosquito abatement districts, and other sources, indicate that the high application rates and high acreage numbers represented by the low end of the MOE range, are seldom used, and even less frequently do these "worst case" conditions occur together. PHED aerial exposure data used in the temephos assessments are based on small acreage and extrapolated to larger areas. Moreover, available exposure data are based on agricultural applications that may not be the most accurate reflection of actual exposure for the mosquito larvicide applications. There are no adequate data available to estimate exposure from helicopter applications. Additional refinement of the toxicity endpoint(s) will be possible with the route-specific dermal toxicity data which will be required in this RED. Current toxicity data show only RBC ChE inhibition, no brain inhibition or clinical signs. No incidents of worker exposure or poisoning have been reported to EPA or other agencies that collect incident data.

The Agency has no exposure data to evaluate the risk from loading and applying granulars with a power backpack blower. Because of the high application rate (equivalent to about 20 lbs/ai/A) and the type of application equipment, EPA anticipates that exposure could be high. The registrant has agreed to maximum PPE. Exposure data to characterize this use will be required along with this RED.

The power backpack blower application to tire piles is a minor but critical use. It represents <1% of all temephos use. The temephos product used for this application is uniquely formulated for penetration of large tire piles and residual action (30 days or more). It is more effective and longer lasting than alternatives for this use.

Heat Stress

In the course of developing mitigation for temephos, the registrant and other commenters raised the issue of heat stress to workers from additional protective equipment, such as cloth coveralls and respirators. This issue has been dealt with extensively in implementation of the Worker Protection Standard. Numerous publications and information on the recognition and management of heat stress can be found on EPA's site at www.epa.gov/pesticides/safety/workers/. The Agency is concerned about the potential for added heat stress, and for nearly all temephos uses, has provided users with options to the double layer of clothing. In general, the Agency supports the development and use of closed mixing and loading equipment and enclosed application equipment as noted in PRN 2000-9. In the case of temephos, emulsifiable concentrate formulation products would be readily adaptable to inexpensive coupling devices that would reduce exposure to handlers. Furthermore, information provided by registrants and other stakeholders, indicates that mixing and loading activities for mosquito control operations are intermittent in nature and would not require long periods of continuous use of PPE. Finally, it should be noted that the registrant must develop route-specific

dermal toxicity data. If these data indicate lower risk to workers than currently estimated, PPE requirements may be revised.

2. Rationale for Environmental Risk Mitigation

All currently available mosquito larviciding techniques present some risk to non-target aquatic species and the aquatic ecosystem. Although temephos presents relatively low risk to birds and terrestrial species, available information suggests that it is more toxic to aquatic invertebrates than alternative larvicides. For that reason, label amendments are warranted that limit the use of temephos to areas where less hazardous alternatives would not be effective. These include limiting use sites, specifying interval between applications, and limiting the use of the high application rates. Based on information from stakeholders, these measures, to a large extent represent current practice, but are not reflected on current labels. Current risk estimates show acute risk quotients exceeded by 5-fold for stonefly and by many orders of magnitude for *Daphnia magna*. These RQs were calculated with maximum application rates and application intervals ranging from 7-90 days. Non-guideline field studies demonstrate that adverse effects to aquatic ecosystems are minimized when temephos is used at the lower application rate of 1 fl. oz. per acre (0.0313lbs/ai/A).

EPA believes that the risk represented by these risk quotients are not of concern given the off-setting public health benefits of temephos use, the low volume of temephos use, the absence of wildlife exposure incidents related to temephos, and the documented low frequency of use at the high application rate.

3. Benefits of Temephos Use

The FQPA amendments to FIFRA require EPA to balance the risks of a public health pesticide use against the risk to the public of the diseases carried by the pests that these compounds control. The statute further requires, among other things, that EPA consult with the Secretary of Health and Human Services (HHS) prior to taking final action to suspend or cancel a public health pesticide's registration. Although EPA is not proposing to cancel or suspend any temephos uses, the Agency has sought comments from HHS on the benefits of temephos use in controlling public health pests.

In a letter dated April 13, 1999, HHS notes that temephos is an inexpensive, valuable tool for managing many mosquito species, including container-breeders like *Aedes albopictus* and *Aedes aegypti*. The former species has been implicated as a carrier of Eastern equine encephalitis, a highly lethal disease in humans and horses in the United States.

Pest species and disease incidences vary from state to state and year to year. Targeted species include potential and actual vectors of St. Louis encephalitis, Venezuelan equine encephalitis, Eastern equine encephalitis, LaCrosse encephalitis, Western equine encephalitis, malaria, yellow fever, West Nile virus, and dengue. Species that are actual and potential vectors of the above diseases in

widespread areas of the US and that are targeted by temephos include *Aedes aegypti*, *A. albopictus*, *A. triseriatus*, *A. sollicitans*, *A. taeniorhynchus*, *Anopheles quadrimaculatus*, and *Culex pipiens*. A significant number of cases of St. Louis encephalitis and Eastern equine encephalitis surface in the US annually. These diseases are significant because of their high mortality rate among humans. West Nile virus is a new disease with several fatal human cases in 1999 and 2000 which seems to be spreading southward from the northeastern US. Incidences of malaria and dengue have been increasing in Central and South America. Dengue is regularly reported from Puerto Rico and other Caribbean islands and indigenous cases have recently been reported from Texas. While none of the cases of malaria reported in the US recently were from indigenous sources, there is a threat that local mosquitoes will become infected and begin transmitting it. Because malaria microbes have recently developed resistance to several antimalarial drugs, the hazards of malaria once it is in the human population have increased. Temephos has been successfully used to reduce populations of the vectors of the above diseases.

Alternatives to temephos include methoprene, *Bacillus thuringiensis israelensis* Bti, *Bacillus sphaericus* (Bs), *Lagenidium giganteum* (Laginex), pyrethrins, malathion, oil, monomolecular films, and diflubenzuron. Temephos is generally used in rotation with one or more of the alternatives to prevent the development of resistance to any one product. Temephos is critical for US larviciding operations because it is effective in polluted water, has a long residual, is available in several use-specific formulations, has a different mode of action than alternatives, may be used on any size (growth stage) larvae, and has contact toxicity against all target species.

Abate® has emulsifiable concentrate and granular formulations that are tailored to specific uses. The emulsifiable concentrate is effectively applied aerially mainly by helicopter to open tidal water areas in Florida inaccessible by roads. The granular is available as a heavy sand granule with rapid release, a slow-release composite granule, and a corncob slow-release granule. The sand granular form is effective where dense canopies overhanging flood water must be penetrated. Composite granules or pellets are amenable to power backpack sprayers or horn seeders used in areas where trucks can not go and they are also applied by helicopter. The corncob granule is specially formulated to penetrate tire piles many of which are accessible only on foot with backpack blowers.

Abate® is the third most widely used larvicide after methoprene and Bti. Methoprene is a growth regulator with the limitations of being effective only on larvae at a certain growth stage, some resistance problems, and having some formulation problems in the past. Bti has the limitation that it must be ingested by small larvae and is not effective in polluted water. Laginex is a live organism with a short shelf life and unreliable efficacy. Pyrethrins are not used much because they have a short residual and are very costly. Diflubenzuron has little use because it is expensive, must be used only on small larvae, and lacks specificity. Oils and monomolecular films are useful for pupiciding but leave an undesirable sheen on water. Malathion is not used for larviciding, primarily because of its widespread use as an adulticide. The only product specifically designed for application to tire piles is Abate® 5% Tire Treatment.

Larviciding is a part of mosquito integrated pest management programs that include monitoring of mosquito larvae and adults and mosquito-borne diseases, source reduction, habitat modification, use of biocontrol agents such as mosquitofish, public education, adulticiding and pupiciding, and rotation of pesticides. In general, larviciding is the choice for control if source reduction, habitat modification, and biocontrol are insufficient for control. Adulticiding is usually the last choice for control. Control of the immature stages of the mosquito before adults have a chance to emerge and disperse (or become infected with a pathogen) is more effective and economical than widespread application of adulticides, although complete control is seldom achieved with larviciding alone.

Although resistance to temephos has been demonstrated in some areas of the world, it is the only remaining organophosphate larvicide with any appreciable use in the United States. As such, it is an important tool in managing resistance to the few alternatives available. HHS noted that alteration in the registration status or availability of temephos in the United States would likely have a major negative impact on the ability to control dengue and yellow fever throughout the world. For a complete discussion of benefits see, "BEAD Analysis of Public Health Benefits of Temephos for Mosquito Control Use" dated October 4, 2000 which is available in the docket and on the Internet.

D. Other Labeling

In order to remain eligible for reregistration, other user and safety information needs to be placed on the labeling of all end-use products containing temephos. For the specific labeling statements, refer to Section V. of this document.

1. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. At present, the program is being implemented on an interim basis as described in a Federal Registry notice (54 FR 27984-28008, July 3, 1989), and providing information to pesticide users to help them protect these species on a voluntary basis. As currently planned, but subject to change as the final program is developed, the final program will call for label modifications referring to limitations on pesticide uses, typically as depicted in county-specific bulletins or by other site-specific mechanisms as specified by state partners. The final program, which will be altered from the interim program, will be described in a future *Federal Register* notice. The Agency is not requiring label modifications at this time through the RED. The registrants of temephos have voluntarily agreed to put EPA's endangered species web site address on product labels for informational purposes only. Any requirements for product use modification will occur in the future under the Endangered Species Protection Program.

2. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is proposing interim mitigation measures for aerial applications that should be placed on product labels/labeling as specified in Section V. of this document. The Agency has completed its evaluation of the new data base submitted by the Spray Drift Task Force, a membership of US pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate. In the interim, labels should be amended to include the following spray drift related language.

For products that are applied outdoors in liquid sprays (except mosquito adulticides), regardless of application method, the following must be added to the labels:

"Do not allow this product to drift."

For outdoor liquid or granular products that are applied aerially, further label language is necessary for spray drift management. Specific label language is outlined in Table 8. of this document.

V. What Registrants Need To Do

In order to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in Section IV. and V., which include, among other things, submission of the following:

A. For temephos technical grade active ingredient products. registrants need to submit the following items.

Within 90 days from receipt of the generic data call-in (DCI):

- (1) Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
- (2) Submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

- (1) Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Dirk Helder at (703) 305-4610 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:

Document Processing Desk (DCI/SRRD)
Dirk Helder-CRM
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)
Dirk Helder-CRM
US EPA (7508C) Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. For products containing the active ingredient temephos, registrants need to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

- (1) Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
- (2) Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

- (1) Two copies of the confidential statement of formula (EPA Form 8570-4);
- (2) Completed original application for reregistration (EPA Form 8570-1); Indicate on the form that it is an "application for reregistration";
- (3) Five copies of the draft label incorporating all label amendments outlined in Table 8. of this document;
- (4) Completed form certifying compliance with data compensation requirements (EPA Form 8570-31);
- (5) If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

The product-specific data responding to the PDCI.

Please contact Frank Rubis, at (703) 308-8184 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:

Document Processing Desk (PDCI/PRB)
Frank Rubis-CRM
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service only:

Document Processing Desk (PDCI/PRB)
 Frank Rubis-CRM
 Office of Pesticide Programs (7508C)
 Room 266A, Crystal Mall 2
 1921 Jefferson Davis Highway
 Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of temephos has been reviewed and determined to be adequate to support the reregistration eligibility of the mosquito larvicide use. The following confirmatory data are necessary:

Ecological:

Old Guideline Number	New Guideline Number	Study Title
72-3 (a)	850.1075	Estuarine/Marine Toxicity - Fish, TEP EC

Human Health:

Old Guideline Number	New Guideline Number	Study Title
81-7	870.6100	Acute Delayed Neurotoxicity - Hen
82-2	870.3200	21-Day Dermal - Rat ⁽¹⁾ (with blood cholinesterase measurements at earlier time points within the first 7 days and at 14 days)
83-3 (a)	870.3700	Teratogenicity - Rat ⁽²⁾ Study is Reserved)
231	875.1100	Estimation of Dermal Exposure - Outdoor

		Occupational--Applying granulars by power backpack blower
232	875.1300	Estimation of Inhalation Exposure - Outdoor Occupational--Applying granulars by power backpack blower

EPA has worked closely with the registrant of temephos and other stakeholders to reassess the data requirements for this chemical in light of its low volume and minor use. Because of the many good quality, but non-guideline, ecological field monitoring studies available, EPA has waived many guideline requirements. The remaining estuarine fish acute toxicity study is necessary because there is likely exposure to estuarine species, and these basic toxicity data are not currently available from literature sources. Life cycle data on daphnia magna and shrimp are not being required at this time. The registrant has agreed to precautionary labeling related to the toxicity of temephos to aquatic species.

One study, the 21-day dermal toxicity in the rat with interim ChE measurements, would address three guidelines-"Neurotoxicity Screening Battery-Acute" (870.6200/81-8), "21-Day Dermal" (82-2), and "90-Day Neurotoxicity" (82-5 (b)). Based on available data, we believe that the onset of effects with temephos is relatively early, and that response remains constant with longer exposures. The interim measurements in the dermal toxicity study will enable EPA to confirm the dose-response relationship and refine the hazard assessment with route-specific data. A developmental toxicity study in a second species may also be necessary for non-food chemicals if significant exposure is expected.

A Data Call-In Notice (DCI) was sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947 and August 18, 1999 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies. EPA has waived the developmental neurotoxicity study for temephos based on the low volume of use, the lack of food uses and the low potential for any other exposure to children. Requirements for acute, and subchronic neurotoxicity studies can be addressed by the 21-day dermal toxicity study as noted above.

The only exposure data necessary at this time is for the power backpack blower scenario, because this method appears to be unique to temephos. Additional exposure data will likely be necessary for temephos to better characterize risk to workers and by-standers. Because the need for these data applies to all chemicals used in mosquito control, EPA is currently evaluating the most efficient and cost-effective approach for generating this information.

2. Labeling for Manufacturing Use Products

To remain in compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies.

The MP labeling should bear the labeling contained in Table 8. at the end of this section.

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

A product-specific data call-in, outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV. Specific language to incorporate these changes is specified in the Table 8. at the end of this section.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 24 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 the registrant may distribute and sell temephos products bearing old labels/labeling for 12 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell temephos products for 24 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements applicable to products they sell or distribute.

D. Table 8: Summary of Labeling Changes for Temephos

In order to be eligible for reregistration, registrants will need to amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 8: Summary of Labeling Changes for Temephos		
Description	Amended Labeling	Placement on Label
Manufacturing Use Products		
Required on all Manufacturing Use Products	"Only for formulation into an insecticide for the following use: mosquito, gnat, midge, punkie, and blackfly larvicide."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	<p>"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 US EPA submission requirements regarding support of such use(s)."</p> <p>"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 US EPA submission requirements regarding support of such use(s)."</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to aquatic organisms such as stone flies, water fleas, and shrimp. Non-target aquatic organisms in waters treated with this product may be killed. Some populations reestablish rapidly, but diversity	Precautionary Statements

	<p>may be affected. Avoid use of maximum application rate in ecologically sensitive areas. Do not contaminate water by cleaning of equipment or disposing of wastes."</p>	
<p>End Use Products</p>		
<p>PPE Requirements Established by the RED (3) for emulsifiable concentrate /liquid products</p>	<p>"Personal Protective Equipment (PPE)"</p> <p>"Some materials that are chemical-resistant to this product are" (<i>registrant inserts correct chemical-resistant material</i>). "If you want more options, follow the instructions for category" [<i>registrant inserts A,B,C,D,E,F,G,or H</i>] "on an EPA chemical-resistance category selection chart."</p> <p>"Mixers, loaders, and applicators involved in hand-held spray applications must wear:</p> <p>Long-sleeved shirt and long pants, Shoes and socks, Chemical resistant gloves"</p> <p>"Aerial applicators and flaggers must wear:</p> <p>Long-sleeved shirt and long pants, Shoes and socks, Chemical resistant headgear (flaggers only)"</p> <p>"All other mixers, loaders, applicators and other handlers must wear:</p> <p>Cloth coveralls over long-sleeved shirt and long pants, Chemical-resistant gloves, Chemical resistant footwear plus socks,</p> <p>Chemical-resistant headgear (if overhead</p>	<p>Precautionary Statements: Following Hazards to Humans and Domestic Animals</p>

	<p>exposure)"</p> <p>"In addition, mixers, loaders and cleaners of equipment must wear:</p> <p>Chemical-resistant apron"</p>	
<p>PPE Requirements Established by the RED (3) for granular products</p>	<p>"Personal Protective Equipment (PPE)"</p> <p>"Some materials that are chemical-resistant to this product are" (<i>registrant inserts correct chemical-resistant material</i>). "If you want more options, follow the instructions for category" [<i>registrant inserts A,B,C,D,E,F,G, or H</i>] "on an EPA chemical-resistance category selection chart."</p> <p>"Loaders and applicators involved in backpack blower application to sites other than tire piles must wear:</p> <p>Long-sleeved shirt and long pants, Shoes and socks, Chemical resistant gloves"</p> <p>"Aerial applicators and flaggers must wear:</p> <p>Long-sleeved shirt and long pants, Shoes and socks, Chemical resistant headgear (flaggers only)"</p> <p>"All other loaders, applicators and other handlers must wear:</p> <p>Cloth coveralls over long-sleeved shirt and long pants, Chemical-resistant gloves, Chemical resistant footwear plus socks, Chemical-resistant headgear (if overhead exposure)"</p> <p>"In addition loaders and cleaners of equipment</p>	<p>Precautionary Statements: Following PPE and User Safety Requirements</p>

	<p>must wear:</p> <p>Chemical resistant apron"</p> <p>"In addition loaders supporting aerial applications and loaders/applicators using a backpack power blower on tire pile sites must wear:</p> <p>A NIOSH-approved dust mist filtering respirator with NSHA/NIOSH approval number prefix TC-21C* or a NIOSH-approved respirator with any N, R, P, or HE filter"</p> <p>Note: The registrant must drop the N filter from the respirator statement if the pesticide product contains or is used with oil.</p>	
<p>User Safety Requirements</p>	<p>"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."</p>	<p>Precautionary Statements: Following the PPE requirements</p>
<p>Engineering Controls for emulsifiable concentrate/liquid products</p>	<p>"Engineering Controls"</p> <p>"When mixers and loaders use a closed system designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people <i>AND</i> the system is functioning properly and is used and maintained in accordance with the manufacturer's written operating instructions, the handlers:</p> <p>-- may wear long-sleeve shirt and long pants,</p>	<p>Precautionary Statements: Following PPE and User Safety Requirements</p>

shoes plus socks, chemical-resistant gloves and chemical-resistant apron, instead of the PPE necessary for mixers and loaders in the PPE section of this labeling,

-- must wear protective eye wear if the system operates under pressure, and

-- must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, all PPE necessary for mixers and loaders in the PPE section of this labeling."

"Pilots must use an enclosed cockpit and must wear chemical resistant gloves when entering or leaving an aircraft contaminated by pesticide residues. Used gloves must be stored in a closed chemical resistant container, such as a plastic bag, to prevent contamination of the inside of the cockpit."

"When ground applicators and flaggers use an enclosed cab that has a nonporous barrier that totally surrounds the occupants and prevents contact with pesticides outside the cab, they:

-- may wear a long-sleeve shirt and long pants, shoes, and socks, instead of the PPE necessary for such applicators and flaggers in the PPE section of this labeling, and

-- must be provided and must have immediately available for use in an emergency the handler PPE specified for applicators or flaggers when they must exit the cab in the treated area and,

-- must take off any PPE that was worn in the treated area before reentering the cab, and

	-- must store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."	
Engineering Controls for Granular Products	<p>"Engineering Controls"</p> <p>"Pilots must use an enclosed cockpit and must wear chemical resistant gloves when entering or leaving an aircraft contaminated by pesticide residues. Used gloves must be stored in a closed chemical resistant container, such as a plastic bag, to prevent contamination of the inside of the cockpit."</p>	Precautionary Statements: Following PPE and User Safety Requirements
User Safety Recommendations	<p>"User Safety Recommendations"</p> <p>"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."</p> <p>"Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."</p> <p>"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."</p>	<p>Precautionary Statements: Following Engineering Controls</p> <p>(Must be placed in a box.)</p>
Environmental Hazards	"This product is toxic to aquatic organisms such as stone flies, water fleas, and shrimp. Non-target aquatic organisms in waters treated with this product may be killed. Some populations reestablish rapidly, but diversity may be affected. Avoid use of maximum	Precautionary Statements immediately following the User Safety Recommendations

	<p>application rate in ecologically sensitive areas. Do not contaminate water by cleaning of equipment or disposing of wastes."</p> <p>"For information on endangered species consult EPA's web site: www.epa.gov/espp/"</p>	
<p>General Application Restrictions</p>	<p>"This product may be applied only to non-potable water, standing water, moist areas, woodland pools, shallow ponds, edges of lakes, swamps, marshes, tidal waters, intertidal zones of sandy beaches, waters high in organic content, highly polluted water, catch basins and tire piles."</p> <p>"This product may be applied only by public health officials, personnel of mosquito abatement districts and other similar government agencies or personnel under contract to these entities."</p> <p>"Maximum application rates may be used only in waters high in organic matter content, mosquito habitats having deep water or dense surface cover, and where monitoring has confirmed a lack of control at typical rates."</p> <p>"This product may not be reapplied within 7 days of the date of the initial application unless monitoring indicates that larval populations have reestablished, or weather conditions have rendered initial treatments ineffective."</p> <p>"This product may be applied as a spot treatment to non-potable water, lakes, and ponds for control of midge larvae when monitoring indicates threshold levels have been exceeded."</p>	<p>Place in the Direction for Use directly above the Agricultural Use Box</p>

<p>Spray Drift Restrictions for Outdoor Products Applied as a Liquid</p>	<p>"Do not allow this product to drift."</p>	<p>Directions for Use in General Precautions and Restrictions</p>
<p>Spray Drift language for products applied aerially</p>	<p>"Aerial Spray Drift Management"</p> <p>"Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."</p>	<p>Directions for Use</p>
<p>Drift Language for products applied aerially</p>	<p>"The following drift management requirements must be followed to avoid off-target drift movement from aerial applications. These requirements do not apply to applications using dry formulations.</p> <ol style="list-style-type: none"> 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor. 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees. <p>Where states have more stringent regulations, they should be observed.</p> <p>The applicator should be familiar with and take into account the information covered in the <u>Aerial Drift Reduction Advisory Information</u>."</p>	<p>Directions for Use</p>

<p>Drift Language for products applied aerially</p>	<p>"Aerial Drift Reduction Advisory"</p> <p>"This section is advisory in nature and does not supercede the mandatory label requirements."</p> <p>"INFORMATION ON DROPLET SIZE"</p> <p>"The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (see Wind, Temperature, and Humidity, and Temperature Inversions)."</p>	<p>Directions for Use</p>
<p>Drift Language for products applied aerially</p>	<p>"CONTROLLING DROPLET SIZE"</p> <p>"Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets."</p> <p>"Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure."</p> <p>"Number of nozzles - Use the minimum number of nozzles that provide uniform coverage."</p> <p>"Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other</p>	<p>Directions for Use</p>

	<p>orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential."</p> <p>"Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift."</p>	
Drift Language for products applied aerially	<p>"BOOM LENGTH"</p> <p>"For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width."</p>	Directions for Use
Drift Language for products applied aerially	<p>"APPLICATION HEIGHT"</p> <p>"Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is necessary for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind."</p>	Directions for Use
Drift Language for products applied aerially	<p>"SWATH ADJUSTMENT"</p> <p>"When applications are made with a crosswind, the swath will be displaced downward. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the</p>	Directions for Use

	aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)."	
Drift Language for products applied aerially	<p>"WIND"</p> <p>"Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential.</p> <p>NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift."</p>	Directions for Use
Drift Language for products applied aerially	<p>"TEMPERATURE AND HUMIDITY"</p> <p>"When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry."</p>	Directions for Use
Drift Language for products applied aerially	<p>"TEMPERATURE INVERSIONS"</p> <p>"Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited</p>	Directions for Use

	cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing."	
Drift Language for products applied aerially	"SENSITIVE AREAS" "The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, non-target bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas)."	Directions for Use

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.

Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

1 The 21-day dermal toxicity study in the rat with interim ChE measurements would be used to address three guidelines--"Neurotoxicity Screening Battery-Acute" (870.6200 / 81-8), "21-Day Dermal" (82-2), and "90-Day Neurotoxicity" (82-5 (b)).

2 The developmental (teratogenicity) study in a second species may be required depending on the outcome of the 21-day dermal study. Because temephos has no food uses, this study may be waived if data demonstrate low potential for exposure.

3 PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.