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Environmental Protection  
Agency

Prevention, Pesticides  
And Toxic Substances  
(7508P)

EPA 738-R-06-003  
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# **Reregistration Eligibility Decision for**

# **Triadimefon**

# **And**

# **Tolerance Reassessment for Triadimenol**

**List B**

**Case No. 2700**

Reregistration Eligibility Decision (RED) Document for  
Triadimefon  
and  
Tolerance Reassessment for Triadimenol

Approved by: \_\_\_\_\_

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## Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q <sub>1</sub> *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard



## **ABSTRACT**

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for triadimefon and the dietary and aggregate assessments for triadimenol, and is issuing its risk management reregistration decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently supported products and additional information received through the public docket.

The Agency discussed the dietary risks of concern (food + water) with the registrant, and the registrant has proposed a number of changes to its triadimefon registration including the voluntary deletion of all food (except pineapples) and residential turf use, and a reduction of application rates and frequencies. In doing so, this document has estimated exposure and risk based on these new use patterns.

After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management reregistration decision for uses of triadimefon and tolerance reassessment for triadimenol. As a result of this review, EPA has determined that triadimefon-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. Furthermore, the tolerances for triadimefon and triadimenol are considered reassessed and regulatory action under the Federal Food, Drug and Cosmetic Act ("FFDCA") will occur after the uses that do not meet the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") standard are canceled. These decisions are discussed fully in this document.

### **I. Introduction**

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 EPA. 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 risks 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 or not 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 and the FFDCA to require reassessment of all existing tolerances for pesticides in food. FQPA also requires EPA to review all tolerances in effect on August 2, 1996, by August 3, 2006. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. When a safety finding has been made that aggregate risks are not of concern and the Agency concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered

reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

As mentioned above, FFDCA requires that the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity” when considering whether to establish, modify, or revoke a tolerance. Potential cumulative effects of chemicals with a common mechanism of toxicity are considered because low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism of toxicity could lead to the same adverse health effect that would occur at a higher level of exposure to any one of these individual chemicals. Triadimefon belongs to a group of pesticides called triazoles (or conazoles), which also includes the triazole fungicide subject to reregistration, propiconazole. Triadimenol, a metabolite of triadimefon, is also a registered fungicide and is subject to tolerance reassessment. For the purpose of this reregistration eligibility decision (RED) for triadimefon and tolerance reassessment for triadimenol, EPA has concluded that triadimefon and triadimenol do not share a common mechanism of toxicity with other substances. However, the triazole fungicides share common metabolites, the triazole compounds 1,2,4-triazole (free triazole), triazole alanine, and triazole acetic acid, which are considered in this document. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

The Agency has identified triazole metabolites of toxicological concern; these include 1,2,4-triazole and the conjugates triazole alanine and triazole acetic acid. Because these metabolites are formed from all triazole pesticides, EPA has conducted a separate toxicology assessment for these compounds and concluded that the existing data are sufficient to support the reregistration of triadimefon and triadimenol. For more details on the toxicity of the free triazoles, see the August 5, 2003, documents, *TRIAZOLES – Report of the Ad Hoc HED Peer Review Committee*, *TRIAZOLES – 2<sup>nd</sup> Report of the Ad Hoc HED Peer Review Committee*, and the February 7, 2006, document, *1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid: Human Health Aggregate Risk Assessment in Support of Reregistration and Registration Actions for Triazole-derivative Fungicide Compounds*, which are available under docket number EPA-HQ-OPP-2005-0258. Because the risks associated with the free triazoles are all below the Agency’s level of concern, they are not discussed further in this document. For more information regarding the aggregate assessment of free triazoles, see the July 18, 2006, document, *Reregistration Eligibility Decision (RED) for Propiconazole*, in the Agency’s electronic docket on the internet at <http://www.regulations.gov> under docket number EPA-HQ-OPP-2005-0497.

Triadimefon and triadimenol also share a common metabolite, 1,2,4-triazole, with several triazole-derivative pharmaceutical compounds. Thus, EPA must consider the incremental impact of exposure to 1,2,4-triazole pesticide residues to individuals using triazole-derivative pharmaceutical products. To this end, EPA worked with the U.S. Food and Drug Administration (FDA), which has regulatory authority for drug products, to assess

the risks posed by 1,2,4-triazole residues that could result from concurrent exposure to triazole-derivative pharmaceutical and pesticide products. This assessment will provide the basis of safety findings reflecting the joint perspectives of FDA and EPA, and will inform a decision by both Agencies about whether appropriate measures are needed to reduce exposure from one or both sources of 1,2,4-triazole residues.

This document presents a summary of EPA's revised human health and ecological risk assessments, its reregistration eligibility decision for triadimefon and tolerance reassessment decision for triadimenol. Occupational and ecological risks from exposure to the pesticidal uses of triadimenol are not addressed in this document. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemicals. Section III gives an overview of the revised human health and environmental effects risk assessments based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's reregistration eligibility, risk management and tolerance reassessment decisions. Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related and supporting documents. The revised risk assessments for triadimefon and triadimenol are available in the Agency's electronic docket on the internet at <http://www.regulations.gov> under docket number EPA-HQ-OPP-2005-0258 and EPA-HQ-OPP-2006-0038, respectively.

## **II. Chemical Overview**

### **A. Regulatory History**

#### Triadimefon

Triadimefon is a broad spectrum, systemic fungicide used to control rust and mildew on apples, grapes, pears, pineapples, and raspberries. In addition, it is used to control various fungal diseases on non-food use sites such as pine seedlings, Christmas trees, residential and commercial turf, ornamentals, and landscapes. There are tolerances for triadimefon on apples, grapes, pears, pineapples, and raspberries. Triadimefon end-use products are marketed in the United States under the trade names Bayleton and Summit. There are nineteen active products containing triadimefon (one technical product) registered under Section 3 of FIFRA.

The registrant has agreed to delete all food (except pineapple) and residential turf uses. Therefore, this Reregistration Eligibility Decision document evaluates risks from all currently supported uses of triadimefon. The Agency will follow the FIFRA cancellation with the appropriate tolerance revocations.

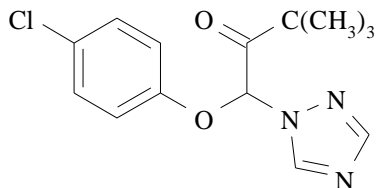
#### Triadimenol

The primary metabolite of triadimefon is triadimenol. Triadimenol, which degrades to include the metabolites KWG 1323 and KWG 1342, is also registered separately as a broad spectrum, systemic fungicide under its own active ingredient number (PC code:

127201). Triadimenol is used exclusively in the U.S. as a seed treatment for cotton and grains. As a result, it is also being assessed by the Agency for the purposes of a tolerance reassessment eligibility decision (TRED). Triadimenol was first registered after 1984 and is not subject to reregistration under the 1988 amendments to FIFRA.

## B. Chemical Identification

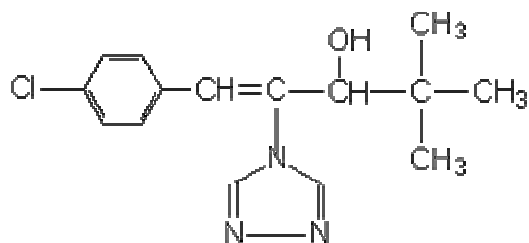
### 1. Technical Triadimefon



<b>Common Name:</b>	Triadimefon
<b>Chemical Name:</b>	1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone
<b>Chemical Family:</b>	Azole (Triazoles)
<b>Empirical Formula:</b>	C <sub>14</sub> H <sub>16</sub> ClN <sub>3</sub> O <sub>2</sub>
<b>CAS Registry Number:</b>	43121-43-3
<b>Case Number:</b>	2700
<b>OPP Chemical Code:</b>	109901
<b>Molecular weight:</b>	293.75 g/mol
<b>Trade Names:</b>	Bayleton and Summit
<b>Basic Manufacturers:</b>	Bayer CropScience, LC

Triadimefon has a melting point of 82.3 degrees Celsius, a solubility of 64 mg/L ppm in water 20 degrees Celsius and a vapor pressure of 0.2 – 0.6 mPa at 20 and 25 degrees Celsius, respectively (7.6 x 10<sup>-7</sup> mm Hg).

## 2. Triadimenol

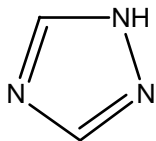


<b>Common Name:</b>	Triadimenol
<b>Chemical Name:</b>	[beta-(4-chlorophenoxy)-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol]
<b>Chemical Family:</b>	Azole (Triazoles)
<b>Empirical Formula:</b>	C <sub>14</sub> H <sub>18</sub> ClN <sub>3</sub> O <sub>2</sub>
<b>CAS Registry Number:</b>	55219-65-3
<b>Case Number:</b>	2700
<b>OPP Chemical Code:</b>	127201
<b>Molecular weight:</b>	295.77 g/mol
<b>Trade Names:</b>	Baytan
<b>Basic Manufacturers:</b>	Bayer CropScience, LC

## 3. Triazole Metabolites

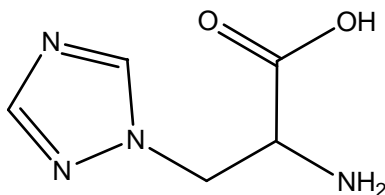
Triadimefon, triadimenol, and other triazole fungicides are metabolized in animals and plants to form compounds containing the triazole moiety, including 1,2,4-triazole (free triazole), triazole alanine, and triazole acetic acid, which are also considered in this decision. Since triazole alanine and triazole acetic acid are formed by conjunction with an amino acid, they are referred to as triazole conjugates throughout this document. Chemical information for these triazole metabolites is provided below.

**a. 1,2,4-Triazole**



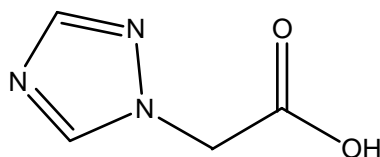
**Chemical Name:** 1,2,4-Triazole  
**Common Name(s):** 1,2,4-T; free triazole  
**CAS Number:** 288-88-0  
**PC Code:** 600074  
**Molecular Weight:** 69.07

**b. Triazole Alanine**



**Chemical Name:** Triazole Alanine (TA)  
**CAS No.:** 86362-20-1  
**PC Code:** 600011  
**Molecular Weight:** 156.15

**c. Triazole Acetic Acid**



**Chemical Name:** Triazole Acetic Acid (TAA)  
**CAS No.:** 28711-29-7  
**PC Code:** 600082  
**Molecular Weight:** 127.10

## C. Use Profile

### 1. Triadimefon

The following is information on the currently registered uses of triadimefon, including an overview of use sites and application methods. A detailed table of the uses of triadimefon eligible for reregistration is contained in Appendix A.

<b>Type of Pesticide:</b>	Broad spectrum, systemic fungicide; demethylation inhibitor (DMI).
<b>Summary of Use:</b>	Used for the systemic control of various fungal diseases in fruits, turf, pine seedlings, Christmas trees, and ornamentals.
<u>Food uses:</u>	Apples, grapes, pears, pineapples, and raspberries. (Registrant is voluntarily deleting use on apples, grapes, pears, and raspberries).
<u>Non-food uses:</u>	Pine seedlings, Christmas trees, residential and commercial turf, ornamentals, and landscapes. (Registrant is voluntarily deleting residential turf use).
<b>Formulation Type:</b>	Registered formulations include granular (G)(0.5-1% active ingredient), wettable powder (WP)(25-50% active ingredient), water soluble packets (50% active ingredient), liquid concentrate (LC)(0.88% active ingredient), and ready-to-use (RTU)(0.5% active ingredient).
<b>Registrant(s):</b>	Bayer CropScience, LP
<b>Method and Rates of Application:</b>	
<u>Application Methods:</u>	Applied via ground spray, airblast, aerial spray, chemigation, and broadcast (granular only) to apples, pears, raspberries, grapes, Christmas trees, ornamentals, pine seedlings, and turf (golf course, residential, commercial, and recreational). It is also used as a post-harvest dip for pineapples and as a seed-piece treatment prior to planting. It is also used to treat pine seeds via dip, soak, or traditional seed treatment.
<u>Application Rates:</u>	The registrant has agreed to voluntarily delete all food (except pineapple) and residential turf use.

Current maximum application rates are a 5.4 lb. ai/A treatment on turf (California only) and a 2.7 lb. ai/A treatment on turf outside of California. A maximum rate of 0.75 lbs ai/A may be used as a pre-harvest foliar treatment on apples and pears (up to 12X per season), 0.56 lbs ai/A for grapes (up to 6X per season), and 0.88 lbs ai/A for raspberries (up to 7X per season). A maximum rate of 2.0 lbs ai/A may be used for pre-harvest foliar treatment on both Christmas trees (up to 8X per season) and pine seedlings (up to 16X per season). For pineapple, a maximum rate of 0.28 lbs ai/100 gallons solutions may be applied via dip and at a maximum rate of 0.28 lbs ai/100 gallons solution via dip or spray to the whole fruit following harvest. It is also used as a pine seed soak (0.63 lbs ai/100 gal solution), and as a pine seed treatment (0.063 lbs ai/100 gal solution, one time prior to planting).

**Application Timing:** Applied pre-plant, foliar and post-harvest.

**Use Classification:** General

## 2. Triadimenol

The following is information on the currently registered uses of triadimenol, including an overview of use sites and application methods. A detailed table of the uses of triadimenol eligible for tolerance reassessment is contained in Appendix A.

**Type of Pesticide:** Systemic fungicide for seed treatment.

**Summary of Use:** Used as a seed treatment on: barley, corn, cotton, oats, rye, sorghum, and wheat. There is also an import tolerance on bananas.

**Formulation Type:** Registered formulations include emulsifiable concentrate (EC) (5% active ingredient), wettable powder (WP)(25% active ingredient), soluble concentrate (SC) (13.33% active ingredient), and flowable concentrate (FIC) (28.3 - 30% active ingredient).

**Registrant(s):** Bayer CropScience, LP

**Method and Rates of Application:**



Application Rates: The maximum use rates, adjusted for planting, range from 0.006 to 0.0375 lbs. ai/A (0.007-0.042 kg ai/ha) for one season.

Application Timing: Applied pre-plant.

**Use Classification:** General

#### **D. Estimated Usage of Pesticide**

##### **1. Triadimefon**

Screening level estimates of triadimefon use in the U.S., based on data from the years 1990 through 2000, have been provided by the Agency's Biological and Economic Analysis Division. Total use averaged 135,000 lbs ai/year with an upper-end estimate of 266,000 lbs ai/year. The largest market, in terms of total pounds ai, was seen in the turf and ornamental sector.

##### **2. Triadimenol**

Based on pesticide usage data for the years 1992 through 2001, total annual domestic usage of triadimenol averaged approximately 24,000 pounds of active ingredient (a.i.) for over 12,000,000 acres treated. Use on cotton accounted for approximately 75 % of the total pounds of a.i. applied annually. Corn and wheat accounted for approximately 20% and 5%, respectively. About 80% of U.S. acreage planted to cotton is treated with triadimenol, and less than 1 % of corn and wheat acres are treated

#### **III. Summary of Risk Assessments**

The following is a summary of EPA's human health and ecological risk findings and conclusions for triadimefon and triadimenol, as presented fully in the documents:

##### Triadimefon

- *Triadimefon. Preliminary Human Health Risk Assessment (Revised).* **February 9, 2006**
- *Triadimefon/Triadimenol: Summary of Refinements and Revisions to the Human Health Risk Assessment.* **July 10, 2006**
- *Triadimefon: Revised Acute, Probabilistic and Chronic Dietary (Food + Drinking Water) Exposure and Risk Assessments for the Triadimefon Reregistration.* **July 6, 2006**
- *Environmental Fate and Effects Chapter (Revised), Risk Assessment for Triadimefon.* **January 19, 2006**
- *Triadimefon: HED Response to Comments Received During the Public Comment Phase.* **June 20, 2006**
- *Memo: EFED Revisions to the Ecological Risk Assessment.* **August 3, 2006**

- *Triadimefon. Summary of Analytical Chemistry and Residue Data for the Reregistration Eligibility Decision (RED) Document. **November 23, 2005***
- *Triadimefon: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document. **June 30, 2006***
- *Triadimefon and Triadimenol: Aggregate Acute, Chronic, and Short-Term Risk Assessments Reflecting July, 2006 Risk Mitigation in Response to the Phase 4 Triadimefon RED. **August 1, 2006***
- *Response to Bayer Public Comments Regarding the Environmental Fate and Effects Division Triadimefon Risk Assessment. **June 1, 2006***
- *Tier 2 Drinking Water Assessment for Triadimefon and its Major Degradate Triadimenol. **August 31, 2005***

### Triadimenol

- *Triadimenol: HED Chapter of the Tolerance Reassessment Eligibility Decision (TRED) Document (Revised). **February 9, 2006***
- *Triadimenol. Acute and Chronic Dietary Exposure Assessments for the Tolerance Reassessment Eligibility Decision (TRED) Document. **November 18, 2005***

The purpose of this section is to summarize the key features and findings of the risk assessments in order to help the reader better understand the risk management decisions reached by the Agency. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety finding and regulatory decisions for triadimefon and triadimenol. Although the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket OPP-2005-0258 and OPP-2006-0038, and may also be accessed on the web at <http://www.regulations.gov>. Hard copies of these documents may be found in the OPP public docket under these same docket numbers.

#### **A. Human Health Risk Assessment**

The human health risk assessment incorporates potential exposure from all sources, which for triadimefon includes food, drinking water, residential, and occupational scenarios and for triadimenol include food and drinking water scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population.

This document summarizes risk estimates for triadimefon (including its metabolite triadimenol and degradates KWG 1342 and KWG 1732), and its metabolites 1,2,4-triazole, triazole alanine, and triazole acetic acid, which are formed from triazole compounds in animals and plants and may be found in food commodities, including animal byproducts. 1,2,4-Triazole appears to be relatively stable in the environment, and may be found in rotational crops and drinking water. A surface water monitoring study showed detections of 1,2,4-triazole in a small number of samples. Therefore, EPA has considered the risks from food, drinking water and non-occupational exposure resulting from triadimefon alone and

from the triazole metabolites from all pesticide sources. For triadimenol, since there are no residential uses, EPA considered exposure and risk from food and drinking water. In addition, EPA has also considered potential co-exposure to free triazoles resulting from pharmaceutical uses of triazole compounds. Because the risks associated with the free triazoles from all sources are all below the Agency's level of concern, they are not discussed further in this document. Additional details regarding the risks associated with the free triazoles, which includes contribution from triadimefon and triadimenol, may be found in the February 7, 2006, document, *1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid: Human Health Aggregate Risk Assessment in Support of Reregistration and Registration Actions for Triazole Derivative Fungicide Compounds*, which is available in the public docket (EPA-HQ-OPP-2005-0258).

## **1. Toxicity of Triadimefon and Triadimenol**

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects such as skin or eye damage, and lifetime or chronic effects such as cancer, developmental and/or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database for triadimefon is adequate although there are data gaps (lack of a developmental neurotoxicity study which the Agency will remedy through the DCI). In addition, the Agency has reviewed all toxicity studies submitted for triadimenol and has determined that the database is adequate. The triadimenol data base is less definite than triadimefon; however, because it is a metabolite of triadimefon the Agency believes that the use of data on triadimefon can be used for triadimenol and be protective regarding any potential risk concerns. But the Agency is requiring data to confirm this decision. However, pending the results of both the acute and subchronic neurotoxicity studies, the Agency is not requiring a developmental neurotoxicity (DNT) study for triadimenol at this time. All other studies have been submitted to support guideline requirements and a reregistration eligibility determination for all currently registered uses. For more details on the toxicity of triadimefon, see the February 9, 2006, document, *Triadimefon. Preliminary Human Health Risk Assessment (Revised)*, and the July 10, 2006, document, *Triadimefon/Triadimenol: Summary of Refinements and Revisions to the Human Health Risk Assessment*, which is available under docket number EPA-HQ-OPP-2005-0258.

### **a. Acute Toxicity Profile**

#### *Triadimefon*

Triadimefon is classified as category III for acute oral and dermal toxicity and as category IV for acute inhalation. It is also classified as category IV for eye irritation potential and category IV for skin irritation potential. In addition, triadimefon caused dermal sensitization in guinea pigs. The acute toxicity profile for technical grade triadimefon is summarized in Table 1 below. The technical acute toxicity values included in this document are only to provide background information. Additional acute toxicity data may be required to determine appropriate cautionary label language for products containing triadimefon.

**Table 1. Acute Toxicity Profile for Triadimefon**

Old Guideline No.	New Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
81-1	870.1100	Acute Oral - rat	264276	LD <sub>50</sub> = 1,470 mg/kg (Males) LD <sub>50</sub> = 1,090 mg/kg (Females)	III
81-2	870.1200	Acute Dermal - Rabbit	264276	LD <sub>50</sub> > 2,000 mg/kg	III
81-3	870.1300	Acute Inhalation - rat	41616002	LC <sub>50</sub> > 3.570 mg/L	IV
81-4	870.2400	Acute (Primary) Eye Irritation - rabbit	41782501	Slightly irritating	IV
81-5	870.2500	Acute (Primary) Dermal (Skin) Irritation - rabbit	41616004	Not an irritant	IV
81-6	870.2600	Skin (Dermal) Sensitization – guinea pig	41554001	Sensitizer	Not Applicable

Triadimenol

Triadimenol shows low toxicity for acute oral, dermal, and inhalation exposure (toxicity Category III or IV) and is not a skin sensitizer. Triadimenol is an eye irritant with irritation clearing in 21 days or longer (toxicity Category II), and is a mild dermal irritant (toxicity Category IV). The acute toxicity profile for technical triadimenol is summarized in Table 2 below.

**Table 2: Acute Toxicity Profile for Triadimenol**

Old Guideline No.	New Guideline No.	Study Type	MRID #(s)	Results	Toxicity Category
81-1	870.1100	Acute oral –rat	00125411	LD <sub>50</sub> = 689 mg/kg (males) LD <sub>50</sub> = 752 mg/kg (females)	III
81-2	870.1200	Acute dermal – rabbit	00145086	LD <sub>50</sub> > 2000 mg/kg	III
81-3	870.1300	Acute inhalation – rat	00145087	LC <sub>50</sub> > 2.58 mg/L (Limit Dose)	IV
81-4	870.2400	Acute eye irritation – rabbit	00145088	eye irritant. Irritation cleared in 21 days or longer.	II
81-5	870.2500	Acute dermal irritation – rabbit	00145088	mild skin dermal irritation	IV
81-6	870.2600	Skin sensitization-guinea pig	00125413	Not a skin sensitizer	Not Applicable

## **b. FQPA Safety Factor Considerations**

The FFDCAs as amended by the FQPA direct the Agency, in setting pesticide tolerances, to use an additional tenfold (10X) margin of safety to protect infants and children, taking into account the potential for pre- and post-natal toxicity and the completeness of the toxicology and exposure databases. The statute authorizes the Agency to reduce this tenfold FQPA safety factor (SF) only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

### Triadimefon

The current developmental and reproductive toxicity studies do not suggest that the young are more sensitive than adult animals. However, since the triadimefon database does not include a DNT study, an FQPA safety factor for database uncertainty (10X) has been retained for exposure scenarios through which exposure to children or pregnant women is expected. A DNT study is required for triadimefon and the Agency will issue a DCI for this data.

### Triadimenol

The endpoint of concern for triadimenol, like triadimefon, is neurotoxicity, which was observed in rat, mice, and rabbit studies. Evidence of increased susceptibility to offspring was not seen in available developmental toxicity studies in two species (rabbits and rats) and in a two-generation reproductive toxicity study in rats. Therefore, the Agency is not requiring a developmental neurotoxicity (DNT) study for triadimenol at this time, pending the results of the acute and subchronic neurotoxicity studies listed in section V of this document. However, the Agency is retaining the FQPA Safety Factor (10X) for database uncertainty for lack of both acute and subchronic neurotoxicity studies.

## **c. Toxicological Endpoints**

### Triadimefon

Table 3 summarizes the studies, toxicological endpoints, dose levels, and uncertainty/safety factors selected for the assessment of dietary, oral, dermal, and inhalation exposure to triadimefon. Since no appropriate acute endpoint could be determined from the triadimenol database, the triadimefon subchronic neurotoxicity study in rats was chosen for the acute reference dose (aRfD) for triadimenol, as well. In addition, the subchronic neurotoxicity study for triadimefon was also chosen for the chronic reference dose (cRfD) for triadimenol. Therefore, the endpoint of concern is neurotoxicity and is the same for both triadimefon and triadimenol.

**Table 3. Summary of Doses and Toxicological Endpoints for Triadimefon**

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Effects
Acute Dietary (general population)	NOAEL = 3.4 mg/kg/day (subchronic)  UF = 100  Acute RfD = 0.034 mg/kg/day	FQPA SF = 10X  aPAD = $\frac{\text{acute RfD}}{\text{FQPA SF}}$  aPAD = 0.0034 mg/kg/day	Subchronic neurotoxicity study in rats (MRID 44153501). LOAEL = 54.6 mg/kg/day (males) and 68.7 mg/kg/day (females) based largely on hyperactivity.
Chronic Dietary (all populations)	NOAEL = 3.4 mg/kg/day  UF = 100  Chronic RfD = 0.034 mg/kg/day	FQPA SF = 10X  cPAD = $\frac{\text{chronic RfD}}{\text{FQPA SF}}$  cPAD = 0.0034 mg/kg/day	Subchronic neurotoxicity study in rats (MRID 44153501). LOAEL = 54.6 mg/kg/day (M) and 68.7 mg/kg/day (F) based largely on hyperactivity.
Incidental Oral Short-Term (1 - 30 days)	NOAEL = 3.4 mg/kg/day  UF = 100	FQPA SF = 10X  Residential MOE = 1000	Subchronic neurotoxicity study in rats (MRID 44153501). LOAEL = 54.6 mg/kg/day (M) and 68.7 mg/kg/day (F) based largely on hyperactivity.
Dermal Short-Term (1 - 30 days) and Intermediate-Term (1 - 6 months)	Dermal NOAEL = 300 mg/kg/day  UF = 100	Residential MOE = 1000 FQPA SF = 10X  Occupational MOE = 100	21 day dermal toxicity in rats (MRID 42341501). The LOAEL= 1000 mg/kg/day based on increased reactivity and activity in the females.
Inhalation Short-Term (1 - 30 days)	NOAEL = 3.4 mg/kg/day (Inhalation absorption rate = 100%)  UF = 100	Residential MOE = 1000 FQPA SF = 10X  Occupational MOE = 100	Subchronic neurotoxicity study in rats (MRID 44153501). LOAEL = 54.6 mg/kg/day (M) and 68.7 mg/kg/day (F) based largely on hyperactivity.
Inhalation Intermediate-Term (1 - 6 months)	NOAEL = 3.4 mg/kg/day (Inhalation absorption rate = 100%)  UF = 100	Residential MOE = 1000 FQPA SF = 10X  Occupational MOE = 100	Subchronic neurotoxicity study in rats (MRID 44153501). LOAEL = 54.6 mg/kg/day (M) and 68.7 mg/kg/day (F) based largely on hyperactivity.
Cancer (oral, dermal, inhalation)	Classification: Category C (possible human carcinogen) based on statistically significant increase in thyroid adenomas in male Wistar rats and statistically significant increases in hepatocellular adenomas in both sexes of the NMRI mouse.		
UF, uncertainty factor; SF, safety factor; NOAEL, no observable adverse effect level; LOAEL, lowest observable adverse effect level; RfD, reference dose, exposure which is not expected to exceed EPA's level of concern; PAD, population adjusted dose, which is the RfD adjusted for the FQPA safety factor (SF); MOE, margin of exposure; LOC, Level of Concern, MOE at and above which the Agency does not have a risk concern. NA, Not Applicable.			

## Triadimenol

Table 4 summarizes the studies, toxicological endpoints, dose levels, and uncertainty/safety factors selected for the assessment of dietary exposure to triadimenol. The endpoint of concern is neurotoxicity (same as triadimefon).

**Table 4. Summary of Doses and Toxicological Endpoints for Triadimenol**

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Effects
Acute Dietary (general population)	NOAEL = 3.4 mg/kg/day (subchronic)  UF = 100  Acute RfD = 0.034 mg/kg/day	FQPA SF = 10X  $aPAD = \frac{\text{acute RfD}}{\text{FQPA SF}}$  aPAD = 0.0034 mg/kg/day	Subchronic neurotoxicity study in rats (MRID 44153501) for triadimefon. LOAEL = 54.6 mg/kg/day (M) and 68.7 mg/kg/day (F) based largely on hyperactivity.
Chronic Dietary (all populations)	NOAEL = 3.4 mg/kg/day  UF = 100  Chronic RfD = 0.034 mg/kg/day	FQPA SF = 10X  $cPAD = \frac{\text{chronic RfD}}{\text{FQPA SF}}$  cPAD = 0.0034 mg/kg/day	Subchronic neurotoxicity study in rats (MRID 44153501) for triadimefon. LOAEL = 54.6 mg/kg/day (M) and 68.7 mg/kg/day (F) based largely on hyperactivity.
Cancer (oral, dermal, inhalation)	Classification: Category C “possible human carcinogen” based on increased incidence of hepatocellular adenomas in females.		

## 2. Carcinogenicity

### Triadimefon

The Cancer Assessment Review Committee (CARC) assigned triadimefon a classification of "possible human carcinogen", using the criteria in the *Draft Guidelines for Carcinogen Risk Assessment (July, 1999)*. This classification is based on a statistically significant increase in thyroid adenomas in male Wistar rats and statistically significant increases in hepatocellular adenomas in both sexes of the NMRI mouse. However, the Agency concluded that a quantified carcinogenic risk assessment for triadimefon is not appropriate and risk assessment will be based on the chronic population adjusted dose (cPAD) and margin of exposure (MOE) approaches only.

### Triadimenol

The CARC has assigned triadimenol a classification of “possible human carcinogen”, using the criteria in the *Draft Guidelines for Carcinogen Risk Assessment (July, 1999)*. This classification is based on increased incidence of hepatocellular adenomas in females. However, the Agency concluded that a quantified carcinogenic risk assessment for triadimenol is not appropriate and risk assessment will be based on the chronic population adjusted dose (cPAD) and margin of exposure (MOE) approaches only.

### 3. Endocrine 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 recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis 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).

#### Triadimefon and Triadimenol

The toxicity databases for triadimefon and triadimenol did not show any estrogen, androgen, or thyroid mediated toxicity.

### 4. Dietary Exposure and Risk

The registrant has agreed to voluntarily cancel all food (apples, pears, grapes, and raspberries), except pineapple, and residential turf use for triadimefon<sup>1</sup>. Thus, these uses were not included in this dietary risk assessment. In addition, the registrant is only supporting a maximum turf rate of 2 applications of 2.7 lbs. ai/A for golf courses and sod farms. Therefore, all drinking water risk estimates were calculated using this rate.

Dietary risk assessments consider exposure to pesticide residues from both food and drinking water. In examining dietary risk, exposures from the use of triadimefon, which includes the parent and its metabolites, including triadimenol, as well as exposures from the use of triadimenol, which includes the parent and its metabolites, must be added together. This is due to the fact that both the acute and chronic PADs are based on the same study (a subchronic neurotoxicity study in rats exposed to triadimefon) and therefore must be aggregated. To estimate dietary risks from food and drinking water, EPA compares the estimated exposure to pesticide residues in food and drinking water to the acute or chronic population adjusted dose, or PAD. The PAD is the reference dose (RfD) adjusted for the FQPA safety factor. A risk estimate that is less than 100% of the acute PAD (aPAD), the dose at which an individual could be exposed over the course of a single day and no adverse health effects would be expected, does not exceed EPA’s level of concern. Likewise, a risk estimate that is less than 100% of the chronic PAD (cPAD), the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected, does not exceed EPA’s level of concern. Additional details about the dietary risk

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<sup>1</sup> Bayer no longer wishes to support these uses. The Agency will take regulatory action under FFDCFA to revoke the associated tolerances.



assessment for triadimefon and triadimenol are described in the July 6, 2006, document, *Triadimefon. Revised Acute and Chronic Dietary (Food + Drinking Water) Exposure and Risk Assessments for the Triadimefon Reregistration* and in the February 9, 2006, document, *Triadimenol: HED Chapter of the Tolerance Reassessment Eligibility Decision (TRED) Document (Revised)*.

**Acute PAD.** As discussed in Section III of this document, the Agency used the subchronic neurotoxicity study (SCN) for triadimefon to establish the acute RfD that is used for both chemicals. The endpoint of concern is neurotoxicity seen after both an acute gavage and repeated dietary exposure. The NOAEL was 3.4 mg/kg/day. The aPAD is 0.0034 mg/kg/day. Dietary risk results >100% of the aPAD are above the Agency's level of concern. Refer to Table 3 above.

**Chronic PAD.** Combined dietary risk for triadimefon and triadimenol was assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the triadimefon cPAD. Dietary risk is expressed as a percent of the cPAD, which is the chronic RfD (3.4 mg/kg/day-NOAEL) modified by an uncertainty factor of 1000 (10X for inter-species extrapolation, 10X for intra-species variability, and 10X FQPA safety factor for database uncertainty- lack of a developmental neurotoxicity study). Therefore, the cPAD for triadimefon and triadimenol is 0.0034 mg/kg/day. Dietary risk results >100% of the cPAD are above the Agency's level of concern. The cPAD was derived from a subchronic neurotoxicity study in rats, which accounted for the most sensitive species and endpoints (rat versus chronic dog study), with a LOAEL of 54.6 (male) and 68.7 (female) mg/kg/day as noted in Table 3 above.

#### **a. Dietary (Food) Risk Assessment**

The Agency conducted acute and chronic dietary exposure assessments using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998.

##### **1) Acute Dietary Food Risk**

A probabilistic (Monte-Carlo) acute dietary exposure assessment was conducted based on field trial data and 100% crop treated (%CT) at the 95<sup>th</sup> percentile. The risk assessment combined exposure for both triadimefon and triadimenol. Acute dietary (food only) risk estimates were based on field trial data for pineapples (triadimefon and triadimenol) and bananas (triadimenol), plus seed treatment uses on cotton and grain (barley, corn, oats, rye, sorghum, and wheat) from triadimenol based on a tolerance level approach and assuming 100% crop treated. The ratio of total toxic residues (TTR) to triadimefon, from available metabolism studies, was used to estimate the total residues of concern.

For food alone, acute dietary risk estimates are below the Agency's level of concern (<100% aPAD) at the 95<sup>th</sup> percentile exposure for children 1-2 years old at 32% of the aPAD, the most highly exposed population subgroup. The 95<sup>th</sup> percentile of exposure is the appropriate percentile to use given the level of refinement (i.e., unrefined) of the residue values used and that 100% of the crops are assumed to be treated. Refer to Table 5 below.

**Table 5. Results of Acute Dietary Exposure Analysis for Food Alone Using DEEM-FCID**

Population Subgroup	aPAD (mg/kg/day)	95 <sup>th</sup> Percentile	
		Exposure (mg/kg/day)	% aPAD
General U.S. Population	0.0034	0.000520	15
All Infants (< 1 year old)	0.0034	0.000828	24
Children 1-2 years old	0.0034	0.001083	32
Children 3-5 years old	0.0034	0.000923	27
Children 6-12 years old	0.0034	0.000668	20

**2) Chronic Dietary Food Risk**

Chronic dietary exposure assessments were also conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID, Version 2.03), which incorporates consumption data from USDA’s Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998.

The risk assessment combined exposure for both triadimefon and triadimenol. Chronic dietary (food only) risk estimates were based on field trial data for pineapples (triadimefon and triadimenol) and bananas (triadimenol), plus seed treatment uses on cotton and grain (barley, corn, oats, rye, sorghum, and wheat) from triadimenol using a tolerance level approach and assuming 100% crop treated.

For all supported commodities, the chronic dietary exposure to triadimefon from food (only) is below the Agency’s level of concern (<100% cPAD) for the U.S. population (6% cPAD) and all population subgroups, including children 1-2 years old (15% of the cPAD), the most highly exposed subgroup. Refer to Table 6 below.

**Table 6. Results of Chronic Dietary Exposure Analysis for Food Alone Using DEEM-FCID**

Population Subgroup	cPAD (mg/kg/day)	Food Alone	
		Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.0034	0.000194	6
All Infants (< 1 year old)	0.0034	0.000227	7
Children 1-2 years old	0.0034	0.000493	15
Children 3-5 years old	0.0034	0.000471	14
Children 6-12 years old	0.0034	0.000323	10

**b. Dietary Exposure from Drinking Water**

Surface Water Exposure

Triadimefon and triadimenol can be transported to surface water during or after application via run-off and/or erosion as well as soil leaching from ground applications. The triadimefon surface water assessment is based on Florida turf use. This scenario was chosen because it is expected to present the greatest risk to drinking water supplies. Because water monitoring data for triadimefon are limited, the Agency used screening-level models to estimate drinking water concentrations of triadimefon from surface water.

Since current labels do not limit the number of applications, EECs were calculated for a range of numbers of applications for residential and golf/sod turf. However, Bayer, the technical registrant, is only supporting a maximum turf rate of 2 applications of 2.7 lbs. ai/A for golf courses and sod farms. As a result, only those results are presented here. Since there is no limitation for application to tees, greens, and/or fairways, “entire course” values (also applies to sod farm use) were used in determining potential surface drinking water concentration(s).

A summary of the surface water concentration scenarios is presented below in Table 7. For additional information, refer to the *Tier 2 Drinking Water Assessment for Triadimefon and its Major Degradate Triadimenol*, dated August 31, 2005.

**Table 7. Estimated Concentrations of Triadimefon and its Degradate Triadimenol in Surface Drinking Water Using PRZM/EXAMS Scenarios (Turf)**

Use Scenario	Portion of Golf Course- (Treated)	Acute Concentration (ppb)	Chronic Concentration (ppb)	
			1 in 10 year annual mean (non-cancer) (ppb)	30-year overall mean (cancer) (ppb)
2 applications 14 day interval 2.75 lbs ai/A (1 oz/1000 ft <sup>2</sup> )	Entire Course	100.8	24.94	4.071

Groundwater Exposure

As an initial screen, the concentrations expected in ground water for the use of triadimefon were estimated using the SCI-GROW model (Tier 1 Ground Water Computer Model). In addition, groundwater monitoring studies were supplied by the registrant, Bayer CropScience. Although SciGrow should typically over-estimate expected ground water concentrations, in this case the model actually underestimated the SciGrow predicted value in at least one instance. A ground water monitoring study in New Jersey, which reflected suggested turf uses, showed a peak groundwater concentration of 25 ppb, while the SciGrow estimate for similar usage yielded an estimate of only 5 ppb. Therefore, the potential for ground water triadimefon contamination may be greater than supposed. Although the ground water monitoring values were lower than surface water modeled values, there may be an

unforeseen risk to private shallow ground water wells used for drinking water in areas where triadimefon is applied. This may be further exacerbated by the fact that, unlike surface water, which is generally treated prior to use, private well water may be used in the home with no pre-treatment. However, although the Agency recognizes the potential for groundwater contamination, surface water estimates in this case are considered protective for ground and/or drinking water contributions. For more information on drinking water risks and representative calculations, see the Water Exposure/Risk Pathway section of the revised human health risk assessment, dated February 9, 2006.

### **c. Dietary Risk from Drinking Water**

Drinking water exposure to pesticides can occur through ground and surface water contamination. In assessing drinking water risks, EPA considers acute (one-day) and chronic (long-term) exposure, and uses modeling and monitoring data, if available, to estimate those exposures. Given the limited use patterns of triadimenol (seed treatment) and the amount of pesticide available on a per acre basis, drinking water exposures resulting from the use of triadimefon in both surface and ground water are much greater. Consequently, the Agency is using the exposure values from the use of triadimefon in its assessments which is protective of any drinking water exposure from the use of triadimenol. Estimated environmental drinking water concentrations (EDWCs) for triadimefon were calculated using the PRZM-EXAMS model. The assessment also accounted for triadimenol as the primary degradate in water. The PRZM-EXAMS assessment considers 100% of the golf course was treated and that the watershed was 100% golf course. Based on these conservative assumptions, the Agency is regulating at the 95 percentile. The distribution of estimated residues of triadimefon and triadimenol were incorporated directly into the acute dietary assessment.

Triadimefon transforms into triadimenol in the natural environment, particularly in shallow subsurface soil and is moderately mobile and persistent. Triadimefon on or near the soil surface or on vegetation may be subject to runoff and/or erosion into surface water bodies used as drinking water supplies. Triadimefon and triadimenol may also leach into groundwater when triadimefon is applied in areas with well-drained soil, high rainfall (and/or irrigation) rates, and shallow water tables. Once it reaches groundwater, triadimenol is likely to degrade more slowly than the parent compound. Both parent and degradate are stable to hydrolysis and have fairly long half-lives in soil and water. The Agency modeled surface drinking water values which are higher than groundwater estimates, and are therefore protective for dietary risk analyses.

#### **1) Acute Dietary Water Risk**

The Agency believes it is appropriate to use the 95<sup>th</sup> percentile as the level of concern (LOC) for drinking water because the drinking water assessment is conservative. The following factors provide the rationale for this approach: 1) the Agency assumes that 100 percent of the watershed is in golf courses (100 percent cropped area (PCA)), and therefore 100% of the watershed is turf treated with triadimefon; 2) residue estimates were modeled using PRZM-EXAMS, which usually results in higher water concentration values than would monitoring data; 3) the dose spacing between the NOAEL and LOAEL in the

guideline acute and subchronic neurotoxicity studies is fairly large; and 4) the entire golf course is assumed to be treated.

Acute dietary (water only) risk estimates were based on a FL golf course scenario for triadimefon. The acute dietary exposure to triadimefon from water (only) is below the Agency’s level of concern (<100% cPAD) for the U.S. population (24% aPAD) and all population subgroups, including all infants (< 1 year old) (85% of the aPAD), the most highly exposed subgroup (See Table 8).

**Table 8. Results of Acute Dietary Exposure Analysis for Water (only) Using DEEM-FCID**

Population Subgroup	aPAD (mg/kg/day)	95 <sup>th</sup> Percentile	
		Exposure (mg/kg/day)	% aPAD
General U.S. Population	0.0034	0.000812	24
All Infants (< 1 year old)	0.0034	0.002904	85
Children 1-2 years old	0.0034	0.001235	36
Children 3-5 years old	0.0034	0.001148	34
Children 6-12 years old	0.0034	0.000789	23

## 2) Chronic Dietary Water Risk

Chronic dietary (water only) risk estimates were based on this scenario incorporating both triadimefon and its degradate triadimenol to determine risk values. The chronic dietary exposure to triadimefon from water (only) is below the Agency’s level of concern (<100% cPAD) for the U.S. population (12% cPAD) and all population subgroups, including non-nursing infants (49% of the cPAD), the most highly exposed subgroup (See Table 9).

**Table 9. Results of Chronic Dietary Exposure Analysis for Water (only) Using DEEM-FCID**

Population Subgroup	cPAD (mg/kg/day)	95 <sup>th</sup> Percentile	
		Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.0034	0.000414	12
Infants (non-nursing)	0.0034	0.001681	49
Children 1-2 years old	0.0034	0.000615	18
Children 3-5 years old	0.0034	0.000575	17
Children 6-12 years old	0.0034	0.000397	12

## 5. Residential (Non-dietary) Exposure and Risk

### Triadimefon

The registrant has agreed to voluntarily delete residential turf use based on exposure to toddlers.

### Triadimenol

There are no residential uses of triadimenol products.

Currently, triadimefon products are marketed for homeowner use on residential lawns, landscape ornamentals, and trees. Triadimefon-containing products are also marketed for use by professional applicators (Pest Control Operators, or PCOs) on residential turf, on golf courses, other turf such as recreational/commercial areas, and on ornamental plantings. Based on these uses, triadimefon is assessed for the residential handler, and for post-application dermal contact for adults, youths, and for toddler's post-application incidental oral exposure that may occur from turf contact. Residential exposure may occur during and after application at homes, or after applications at golf courses, parks, schools, or other turf sites. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE > 1000 does not exceed the Agency's Level of Concern). For more information on residential exposure and risk, refer to the document, *Triadimefon: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated June 30, 2006.

#### **a. Residential Handler Risk**

The anticipated use patterns and current labeling indicate several residential handler exposure scenarios based on the types of equipment and techniques that can be used to make triadimefon applications. The quantitative short-term exposure/risk assessment developed for residential handlers is based on these scenarios. Intermediate-or long-term exposures are not likely because of the intermittent nature of applications by homeowners.

*(Mixer/Loader/Applicators):*

- (1) Liquid Formulations: Low Pressure Handwand (ORETF data for ornamentals)
- (2) Wettable Powder Formulations: Low Pressure Handwand (PHED data)
- (3) Liquid Concentrates with Hose-End Sprayer (Residential ORETF data -- ornamental shrubs)
- (4) Wettable Powders with Hose-End Sprayer (Residential ORETF data -- liquid concentrate application to ornamentals)
- (5) Liquid Concentrates with a Tree Injector (no data)
- (6) Loading/Applying Granulars via Push Type Spreader (ORETF data)
- (7) Loading/Applying Granulars via Belly Grinder (PHED data)

Inhalation risks for residential handlers are not a concern for all residential uses of triadimefon. Combined dermal and inhalation risks for residential handlers are not a concern (MOEs >1000) for the following scenarios:

- (1) Mixing/loading/applying liquid and wettable powder formulations to outdoor and greenhouse flowers, trees, and shrubs with a low pressure handwand;
- (2) Loading/applying granulars via push type spreader and belly grinder.

However, combined risks remain a concern (MOEs < 1000) for mixing/loading/applying liquid concentrates/ wettable powders with a hose-end sprayer to greenhouse ornamentals. Short-term risks for residential handlers are presented below in Table 10, which only represents those scenarios that exceed the Agency's level of concern (MOE < 1000).

**Table 10. Triadimefon Residential Handler Risks**

Exposure Scenario	Crop or Target	App Rate <sup>a</sup> (lb ai /gallon)	Area Treated Daily <sup>b</sup> (gallons)	Baseline Unit Exposure		MOEs		
				Dermal <sup>c</sup> (mg/lb ai)	Inhalation <sup>d</sup> (mg/lb ai)	Baseline Dermal	Baseline Inhalation	Baseline Dermal + Baseline Inhalation MOE
<b>Mixer/Loader/Applicator</b>								
Mixing/ Loading/ Applying Liquid Concentrates with Hose-End Sprayer	Greenhouse ornamentals (shrubs, trees)	0.00938	100	39	1.6	490	160000	490
Mixing/ Loading/ Applying Liquid Concentrates with Hose-End Sprayer	Greenhouse ornamentals (flowering)	0.00938	100	34	0.82	560	310000	560
Mixing/ Loading/ Applying Wettable Powders with Hose-End Sprayer	Greenhouse ornamentals (flowering)	0.00625	100	34	0.82	850	460000	850

Exposure Scenario	Crop or Target	App Rate <sup>a</sup> (lb ai /gallon)	Area Treated Daily <sup>b</sup> (gallons)	Baseline Unit Exposure		MOEs		
				Dermal <sup>c</sup> (mg/lb ai)	Inhalation <sup>d</sup> (mg/lb ai)	Baseline Dermal	Baseline Inhalation	Baseline Dermal + Baseline Inhalation MOE
<p>a Application rates are the maximum application rates determined from EPA registered labels for triadimefon.</p> <p>b Amount handled per day values are EPA estimates of acres, square feet, or cubic feet treated or gallons applied based on Exposure SAC, SOP #9 Standard Values for Daily Acres Treated in Agriculture, and industry sources, and EPA estimates.</p> <p>c Baseline Dermal: Long-sleeve shirt, long pants, no gloves.</p> <p>d Baseline Inhalation: no respirator.</p>								

**b. Residential Post-application Exposure and Risks**

The Agency uses the term “post-application” to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Triadimefon can be used in many areas that can be frequented by the general population including residential areas (e.g., home lawns and gardens). As a result, individuals can be exposed by entering these areas if they have been previously treated.

Exposures were calculated by considering the potential sources of exposure (e.g., dislodgeable foliar residues (DFRs) on ornamental plants) for both triadimefon and triadimenol, then calculating dermal and non-dietary ingestion exposures and risks. Individuals of varying ages can potentially be exposed to triadimefon when they are in areas that have been previously treated. Post-application exposure scenarios were developed for each residential setting where triadimefon can be used. The scenarios that were assessed are dermal exposure to adults, dermal exposure to youths, and dermal and incidental oral exposure to toddlers from those uses which remain where there is a potential for post-application exposure.

Risk Summary:

Risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of the body burden to the toxicological endpoint of concern. Risks to adults and youths are below the Agency’s level of concern (See Table 11 & 12 below).



**Table 11. Adult Residential Risk Estimates for Post-application Exposure to Triadimefon (including Triadimenol)**

Exposure Scenario	Route of Exposure	Formulation	Application Rate (lb ai/acre)	MOE at Day 0
<b>Outdoors – with default transferable residues</b>				
Home Garden (Ornamentals)	Dermal	Spray	0.25	4,800
Golfer	Dermal	Spray/Granular	1.3 (Bayer max residential)	12,000

**Table 12. Youth Residential Risk Estimates for Post-application Exposure to Triadimefon (including Triadimenol)**

Exposure Scenario	Route of Exposure	Formulation	Application Rate (lb ai/acre)	MOE at Day 0
<b>Outdoors – with default transferable residues</b>				
Home Garden (Ornamentals)	Dermal	Spray/Granular	0.25	13,000
Golfer	Dermal	Spray/Granular	1.3 (Bayer max residential)	7,800

The registrant has agreed to voluntarily cancel all residential turf use and include a pre-transplant interval of 17 days to sod farms in order to address any potential concerns for post-application exposure to toddlers.

Additional details regarding the residential exposure and risk assessments for triadimefon may be found in the following documents: *Triadimefon. Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated June 30, 2006.

## 6. Aggregate Exposure/Risk from Triadimefon and Triadimenol

The FQPA amendments to the FFDCFA, section 408(b)(2)(A)(ii)) require the Agency to determine “that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information.” Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-

occupational sources of exposure. When aggregating exposure and risk from various sources, the Agency considers the route and duration of exposure.

Acute (Food and Water)

The Agency believes it is appropriate to use the 95<sup>th</sup> percentile as the level of concern (LOC) for the entire golf course because it is a highly conservative approach. The following factors provide the rationale for this approach: 1) the Agency assumes that 100 percent of the watershed is in golf courses (100 percent cropped area (PCA)), and therefore 100% of the watershed is turf treated with triadimefon; 2) residue estimates were modeled using PRZM-EXAMS, which usually results in higher water concentration values than would monitoring data; 3) the dose spacing between the NOAEL and LOAEL in the guideline acute and subchronic neurotoxicity studies for triadimefon are fairly large; and 4) the Agency assumes that the entire golf course is treated.

Combined acute dietary (food and water) risk estimates from pineapples (triadimefon) and drinking water (triadimefon from golf course application to entire golf course) plus seed treatment uses and banana import tolerance (triadimenol) are below the Agency’s level of concern (<100% aPAD) at the 95<sup>th</sup> percentile of exposure (assuming 2 applications per year for turf at 2.7 lbs ai/A). The dietary exposure for acute food and drinking water is 33% of the aPAD for the U.S. population and 94% of the aPAD for all infants less than one year old, the most highly exposed population subgroup. A summary of acute dietary risk estimates (food + drinking water) is presented below in Table 13.

**Table 13. Triadimefon and Triadimenol Results of Acute Dietary Exposure Analysis for Food + Drinking Water From the Golf Course (entire) Use Scenario Using DEEM-FCID**

Population Subgroup	aPAD (mg/kg/day)	95 <sup>th</sup> Percentile	
		Exposure (mg/kg/day)	% aPAD
General U.S. Population	0.0034	0.001106	33
All Infants (< 1 year old)	0.0034	0.003190	94
Children 1-2 years old	0.0034	0.001959	58
Children 3-5 years old	0.0034	0.001765	52
Children 6-12 years old	0.0034	0.001210	36

Chronic (Food and Water)

Combined chronic dietary (food and water) risk estimates were derived from pineapples and drinking water (entire golf course-triadimefon) plus seed treatment uses and bananas import tolerance from triadimenol. Drinking water exposures are based on using the 1 in 10 year annual mean concentration assuming 2 applications per year for turf at 2.7 lbs ai/A. The dietary exposure for chronic food and drinking water is below the Agency’s level of concern and is 18% of the cPAD for the U.S. population and 57% of the cPAD for non-

nursing infants, the most highly exposed population subgroup. A summary of chronic dietary risk estimates (food + drinking water) is presented below in Table 14.

**Table 14. Triadimefon Results of Chronic Dietary Exposure Analysis for Food + Drinking Water From the Golf Course (entire) Using DEEM-FCID**

Population Subgroup	cPAD (mg/kg/day)	95 <sup>th</sup> Percentile	
		Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.0034	0.000607	18
Infants (non-nursing)	0.0034	0.001952	57
Children 1-2 years old	0.0034	0.001108	33
Children 3-5 years old	0.0034	0.001047	31
Children 6-12 years old	0.0034	0.000720	21

Short-term (Food + Water + Residential)

The exposure attributable to residential uses of triadimefon were not initially aggregated with dietary sources of exposure (food plus drinking water) because at that time the dietary and residential exposure pathways separately exceeded the Agency’s level of concern. The registrant agreed to voluntarily delete residential turf uses and all food uses (except pineapple) so that the aggregate risks are within acceptable levels. Taking into consideration the agreement to request deletion of these uses and mitigation requiring a 17-day post-application, pre-transplant interval for sod farms, risks will be below the Agency’s level of concern.

Aggregate exposures to toddlers, youths, and adults could occur from triadimefon uses on golf courses and in residential settings from turf transplanted from sod farms. The Agency assessed short-term aggregate risks to adults and toddlers by calculating an aggregate risk MOE assuming background (chronic) exposure to triadimefon and triadimenol residues from dietary (food and water) sources. The chronic exposure from drinking water considers treatment of an entire golf course. Short-term aggregate risk, calculated as an MOE, is 1100 for toddlers (from the turf use), and 1300 for adults and for youths (from the golf course use). None of these estimates exceed the Agency’s level of concern.

Aggregate exposures could also occur for adults making applications to residential ornamentals. Using this scenario and assuming an application rate of 0.005 to 0.0025 lb. ai/gallon with the highest exposure scenario that is still below the Agency’s level of concern (mixing/loading/applying wettable powders with a low pressure handwand to greenhouse ornamentals), aggregate (food + water + residential) risk is below the Agency’s level of concern (MOE = 1300).

The combined risk assessment for exposures to toddlers following the application of sod farm turf transplanted to a residential lawn are not a concern (MOEs > 1000) at day 17 following application to sod farms at the 2.7 lbs ai/A rate. Therefore, the labels for these

products must be restricted to not allow transplantation earlier than the 17<sup>th</sup> day after treatment.

#### Intermediate-term and Chronic (Food + Water + Residential)

Intermediate-term and chronic residential exposures to triadimefon are not expected because of the intermittent nature of applications in residential settings. Therefore, intermediate-term chronic aggregate risk assessments were not conducted.

### **7. Pesticide and Pharmaceutical Co-Exposure Assessment for The Triazole Metabolites**

FFDCA Section 408 requires EPA to consider potential sources of exposure to a pesticide and related substances in addition to the dietary sources expected to result from a pesticide use subject to a tolerance (legal limit for pesticide residue levels) in food or feed commodities. In determining whether to maintain a pesticide tolerance, EPA must “determine that there is a reasonable certainty of no harm...” in accordance with FFDCA, Section 408(b)(2)(A)(ii). The FDA regulates human drugs for safety and effectiveness under FFDCA section 505 and may approve use of a drug in humans notwithstanding the possibility that some individual patients may experience adverse side effects. EPA does not believe that, for purposes of the section 408 dietary risk assessment, it is compelled to treat a pharmaceutical patient the same as a non-patient, or to assume that combined exposures to pesticide and pharmaceutical residues that lead to a physiological effect in the patient constitutes “harm” under the meaning of section 408 of the FFDCA.

Rather, EPA believes that an appropriate way to consider the metabolite 1,2,4-triazole resulting from pharmaceutical use of triazole-derivative drugs would be to consider the additional contribution that non-occupational pesticide exposure would have to a pharmaceutical patient exposed to the same compound. Where the additional pesticide exposure has no more than a minimal impact on the pharmaceutical patient, EPA can make a “reasonable certainty of no harm” finding for the pesticide tolerances of that compound under FFDCA Section 408. If the potential impact on the pharmaceutical user as a result of co-exposure from pesticide use is more than minimal, then EPA would not be able to conclude that dietary residues were safe, and would need to discuss with FDA appropriate measures to reduce exposure from one or both sources.

As previously mentioned, triadimefon may share a common metabolite, 1,2,4-triazole, with triazole-derivative pharmaceutical compounds. Thus, EPA consulted with FDA on triazole drugs that could metabolize to 1,2,4-triazole and the Agencies concluded that only one compound, anastrozole, a chemotherapy drug used to treat breast cancer, had this metabolic pathway in humans. Because anastrozole is used at very small doses in a limited population of patients, EPA conducted a conservative screening-level assessment to determine whether the combined metabolites from triazole pesticide uses and anastrozole would adversely impact pharmaceutical users. EPA concluded that, using upper-bound estimates for metabolites of anastrozole, the combined metabolite exposure is below the Agency’s level of concern. Because EPA is able to reach this conclusion with a screening-level assessment, the Agency has not conducted a more refined co-exposure assessment for

pharmaceutical uses as described above. Therefore, EPA concludes that the potential dietary pesticide exposure to triazole pesticide residues in food and water will result in no harm to a patient being treated with anastrozole. Please see the May 19, 2006, memo from FDA and the July 18, 2006, EPA document summarizing EPA and FDA discussions on potential free triazole metabolites of triazole derivative drugs, (both available in the public docket for triadimefon, EPA-HQ-OPP-2005-0258) for additional information.

## **8. Cumulative Risk Assessment**

Section 408(b)(2)(D)(v) of the FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” Other substances are considered to account for the possibility that low-level exposures to multiple chemical substances that cause a common effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to each individual substance. For the purposes of this reregistration eligibility decision, EPA has concluded that triadimefon and triadimenol do not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external review of the data supporting a common mechanism of toxicity for a number of chemical classes. Triadimefon, triadimenol, and the other triazole fungicides share the common metabolites 1,2,4-triazole, triazole alanine, and triazole acetic acid, which are considered in this RED.

## **9. Occupational Risk**

The registrant has agreed to voluntarily delete all uses on apples, pears, grapes, raspberries, and residential turf. Occupational post-application exposure and risk assessment for agricultural uses of triadimefon indicates that risks are not a concern at day 0 (i.e., 12 hours after application) for all use sites and all post-application activities.

Workers can be exposed to a pesticide through various routes/pathways. There is potential for exposure to triadimefon in occupational scenarios from handling triadimefon products during the application process (i.e., mixer/loaders, applicators, flaggers, and mixer/loader/applicators), and a potential for post-application worker exposure from entering into areas previously treated with triadimefon. In addition, there is potential exposure to workers who treat seed with triadimefon in commercial and nursery settings and to persons who plant treated seed. Occupational risk for all of these potentially exposed populations is measured by a MOE, which determines how close the occupational exposure comes to a dose level or NOAEL.

Occupational risk is assessed for exposure at the time of application (termed “handler” exposure) and following application (termed post-application exposure). Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose. Post-application risk is assessed for activities such as scouting, irrigating, pruning, and harvesting, and is based primarily on dermal exposure estimates. Note that occupational risk estimates are intended

to represent pesticide workers, and on this basis assumptions are made concerning acres treated per day and the seasonal duration of exposure.

Triadimenol is only being reviewed for tolerance reassessment purposes. Currently registered uses do not involve occupational exposures. Therefore, no worker risk assessment was completed.

For more information on the assumptions and calculations of potential risk of triadimefon to workers, refer to the documents entitled: *Triadimefon. Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document*, dated June 30, 2006; and the *memorandum: Triadimefon/Triadimenol: Summary of Refinements and Revisions to the Human Health Risk Assessment*, dated July 10, 2006.

### a. Occupational Toxicity

Table 15 below provides a listing of the toxicological endpoints used in the triadimefon occupational risk assessment.

**Table 15. Toxicological Endpoints for the Triadimefon Occupational Risk Assessment**

Exposure Scenario	Dose Used in Risk Assessment, UF	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Short-Term (1 - 30 days)	Dermal NOAEL = 300 mg/kg/day  UF = 100	Occupational MOE = 100	21 day dermal toxicity in rabbits. The LOAEL= 1000 mg/kg/day based on increased reactivity and activity in the females.
Dermal Intermediate-Term (1 - 6 months)	Dermal NOAEL = 300 mg/kg/day  UF = 100	Occupational MOE = 100	21 day dermal toxicity in rabbits. The LOAEL= 1000 mg/kg/day based on increased reactivity and activity in the females.
Inhalation Short-Term (1 - 30 days)	NOAEL = 3.4 mg/kg/day (Inhalation absorption rate = 100%)  UF = 100	Occupational MOE = 100	Subchronic neurotoxicity study in rats. LOAEL = 54.6/68.7 mg/kg/day based largely on hyperactivity.
Inhalation Intermediate-Term (1 - 6 months)	NOAEL = 3.4 mg/kg/day (Inhalation absorption rate = 100%)  UF = 100	Occupational MOE = 100	Subchronic neurotoxicity study in rats. LOAEL = 54.6/68.7 mg/kg/day based largely on hyperactivity.
Cancer (oral, dermal, inhalation)	Classification: Category C (possible human carcinogen) based on statistically significant increase in thyroid adenomas in male Wistar rats and statistically significant increases in hepatocellular adenomas in both sexes of the NMRI mouse.		

## **b. Occupational Handler Exposure**

Occupational handler risk estimates have been assessed for both short- and intermediate-term exposure durations. Due to the use patterns for triadimefon, long-term exposures are not expected. Since the endpoints and points of departure (PODs) are identical to assess short and intermediate exposure, these risk estimates represent both durations of exposure.

Occupational handler assessments are conducted using increasing levels of protection. The Agency typically evaluates all exposures with minimal protection and then considers additional protective measures using a tiered approach in an attempt to obtain an adequate MOE. The lowest tier is represented by the baseline clothing scenario (i.e., single layer clothing, socks, and shoes), followed by increasing levels of risk mitigation such as personal protective equipment (PPE) and engineering controls (EC). In the case of triadimefon, exposure to pesticide handlers is likely during the occupational use of the pesticide in a variety of occupational environments. The anticipated use patterns and current labeling indicate several occupational exposure scenarios based on the types of equipment and techniques that can potentially be used for triadimefon applications. Based on the use patterns, twenty-seven major occupational handler exposure scenarios (non-seed treatment) were identified. In addition, six major exposure scenarios were identified for pine seed treatment. The following exposure scenarios were used to develop the risk assessment for occupational handlers.

*(Non-seed treatment)*

### Mixer/Loaders:

- (1a) Liquid Formulations to support Aerial Applications (PHED)
- (1b) Liquid Formulations to support Groundboom Applications (PHED)
- (1c) Liquid Formulations to support LCO Handgun Applications (PHED)
- (1d) Liquid Formulations to support Airblast Applications (PHED)
- (2a) Wettable Powders to support Aerial Applications (PHED)
- (2b) Wettable Powders to support Chemigation Applications (PHED)
- (2c) Wettable Powders to support Groundboom Applications (PHED)
- (2d) Wettable Powders to support LCO Handgun Applications (PHED)
- (2e) Wettable Powders to support Airblast Applications (PHED)
- (2f) Wettable Powders to support Rights-of-Way Applications (PHED)
- (3a) Water Dispersible Granules to support Aerial Applications (PHED)
- (3b) Water Dispersible Granules to support Chemigation Applications (PHED)
- (3c) Water Dispersible Granules to support Groundboom Applications (PHED)
- (3d) Water Dispersible Granules to support LCO Handgun Applications (PHED)
- (4a) Loading Granulars to support Aerial Applications (PHED)
- (4b) Loading Granulars to support Tractor Drawn Spreader Applications (PHED)

### Applicators:

- (5) Aerial Spray Applications (PHED)
- (6) Aerial Granular Applications (PHED)
- (7) Groundboom Spray Applications (PHED)

- (8) Airblast Spray Applications (PHED)
- (9) Handgun Spray Applications (PHED)
- (10) Rights of Way Spray Applications (PHED)
- (11) Tractor-Drawn Spreader Granule Applications (PHED)

Flaggers:

- (12) Flagging for Aerial Spray Applications (PHED)
- (13) Flagging for Aerial Granular Applications (PHED)

Mixer/Loader/Applicators:

- (14) Liquid Formulations: Low Pressure Handwand Sprayer (ORETF)
- (15) Wettable Powder Formulations: Low Pressure Handwand Sprayer (PHED)
- (16) Water Dispersible Granules with Low Pressure Handwand (using ORETF data for liquid formulations as a surrogate)
- (17) Liquid Formulations: Handgun Sprayer (ORETF)
- (18) Wettable Powders with a Handgun Sprayer (ORETF)
- (19) Water Soluble Bags with Handgun Sprayer (ORETF)
- (20) Dry Flowables Concentrates with a Handgun Sprayer (ORETF)
- (21) Liquid Formulations: High Pressure Sprayer (PHED)
- (22) Water Dispersible Granules: High Pressure Handwand (PHED: liquid concentrates)
- (23) Wettable Powders: High Pressure Handwand (PHED: liquid concentrates)
- (24) Liquids with an Tree Injector (no data)
- (25) RTU: Briquette (no data)
- (26) Liquid Formulations: Dip (no data)
- (27) Loading/Applying Granulars via Push Type Spreader (ORETF)

*(Pine seed treatment)*

- (S-1) on-nursery loading/applying with hopper or planter box seed treatment,
- (S-2) on-nursery loading/planting previously treated seeds,
- (S-3) on-nursery loading/applying wettable powders using cement mixer equipment (using PHED mixing/loading WP data),
- (S-4) on-nursery loading/applying dry flowables using cement mixer equipment (using PHED mixing/loading DF data),
- (S-5) on-nursery drying/raking/bagging treated seed,
- (S-6) loading and applying wettable powder formulations with commercial seed-treatment equipment,
- (S-7) commercial sewer stitching bags of seed,
- (S-8) bagging and otherwise handling treated seeds with commercial equipment, and
- (S-9) multiple commercial seed treatment activities.

**c. Occupational Handler Risk Summary**

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle triadimefon during the usual use patterns associated with the pesticide's use.



In all non-seed treatment scenarios, combined dermal and inhalation MOEs meet or exceed the level of concern of 100 at some level of risk mitigation (personal protective equipment or engineering controls). In the majority of scenarios where data are available, combined dermal and inhalation risks are not a concern at baseline (long-sleeve shirt, long pants, shoes, socks, no respirator) or baseline plus chemical-resistant gloves. However, there are risk concerns requiring additional dermal or inhalation protection (e.g. a respirator or engineering controls) for several of the scenarios involving mixing/loading/applying wettable powder (See Table 16).

In all the in-nursery seed treatment scenarios where data are available, combined dermal and inhalation MOEs meet or exceed the required level of concern of 100 at baseline or baseline plus chemical-resistant gloves. For commercial seed treatment, combined dermal and inhalation risks meet or exceed the required MOE of 100 with baseline PPE.

**Table 16. Combined Dermal plus Inhalation Handler Risks for Agricultural and Commercial Uses**

Exposure Scenario	Crop or Target	App Rate (lb ai/acre) <sup>a</sup>	Area Treated Daily (acre) <sup>b</sup>	Combined MOEs <sup>i</sup>								
				Baseline <sup>c</sup> Dermal + Baseline Inh	Single layer w/ gloves <sup>d</sup> Dermal + Baseline Inh	Double layer w/ gloves <sup>e</sup> Dermal + Baseline Inh	Single layer w/gloves Dermal + 80% R <sup>f</sup> Inh	Single layer w/ gloves Dermal + 90% R <sup>g</sup> Inh	Double layer w/ gloves Dermal + 80% R Inh	Double layer w/ gloves Dermal + 90% R Inh	Eng Control <sup>h</sup> Dermal + Inh	
<b>Mixer/Loader</b>												
Mixing/Loading Liquid Concentrates for Injection	ornamentals (shade trees, woody shrubs)	0.000026 lb ai/inch of trunk	inch of trunk	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
Mixing/Loading Wettable Powders for Aerial Applications	Christmas trees	0.25	350	30	60	61	250					
	turf (sod farm)	2.7 (except CA)	350	2.7	5.6	5.6	23	38	24	42	680	
	pine seedlings	0.5	350	15	30	30	130					
Mixing/Loading Wettable Powders for Chemigation Applications	turf (sod farm)	2.7 (except CA)	350	2.7	5.6	5.6	23	38	24	42	680	
Mixing/Loading Wettable Powders for Groundboom Applications	azaleas	0.005 lb ai/gallon	16000 gallons	32	66	67	270					
	turf (sod farm)	2.7	80	12	24	25	100					
	turf (golf course)	2.7	40	24	49	49	200					

Exposure Scenario	Crop or Target	App Rate (lb ai/acre) <sup>a</sup>	Area Treated Daily (acre) <sup>b</sup>	Combined MOEs <sup>i</sup>								
				Baseline <sup>c</sup> Dermal + Baseline Inh	Single layer w/ gloves <sup>d</sup> Dermal + Baseline Inh	Double layer w/ gloves <sup>e</sup> Dermal + Baseline Inh	Single layer w/gloves Dermal + 80% R <sup>f</sup> Inh	Single layer w/ gloves Dermal + 90% R <sup>g</sup> Inh	Double layer w/ gloves Dermal + 80% R Inh	Double layer w/ gloves Dermal + 90% R Inh	Eng Control <sup>h</sup> Dermal + Inh	
Mixing/Loading Wettable Powders to Support Rights-of-way sprayer	turf (golf course and sod farms)	2.7	80	12	24	25	100					
<b>Applicator</b>												
Applying Sprays via Aerial Equipment	Christmas trees	0.25	350	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	20000
	turf (sod farm)	2.7	350	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	1900
	pine seedlings	0.5	350	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	10000
Applying Granulars via Aerial Equipment	turf (sod farm)	2.6	350	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	200
<b>Mixer/Loader/Applicator</b>												
Mixing/Loading /Applying Wettable Powders with Low Pressure Handwand (PHED)	turf (golf course, sod farms)	2.7	5	No Data	15	15	53	79	58	92		Not Feasible
	pine seedlings	0.5	5	No Data	78	81	290					Not Feasible

Exposure Scenario	Crop or Target	App Rate (lb ai/acre) <sup>a</sup>	Area Treated Daily (acre) <sup>b</sup>	Combined MOEs <sup>i</sup>								
				Baseline <sup>c</sup> Dermal + Baseline Inh	Single layer w/gloves <sup>d</sup> Dermal + Baseline Inh	Double layer w/gloves <sup>e</sup> Dermal + Baseline Inh	Single layer w/gloves Dermal + 80% R <sup>f</sup> Inh	Single layer w/gloves Dermal + 90% R <sup>g</sup> Inh	Double layer w/gloves Dermal + 80% R Inh	Double layer w/gloves Dermal + 90% R Inh	Eng Control <sup>h</sup> Dermal + Inh	
Mixing/Loading /Applying Liquids with an Injector	ornamentals (shade trees, woody shrubs)	0.000075 lb ai/1 inch of trunk circumference	inch of trunk circumference	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible
Mixing/Loading /Applying RTU Briquette	pine seedlings	0.00019 lb ai/seedling	seedlings	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	Not Feasible
Mixing/Loading /Applying Dip	pine seed (nurseries)	0.0000625 lb ai/gallon	100 gallons	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data
	pineapple (post-harvest)	0.0028 lb ai/gallon	100 gallons	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data	No Data

a Application rates are the maximum application rates determined from EPA registered labels for triadimefon.

b Amount handled per day values are HED estimates of acres treated per day based on Exposure SAC SOP #9 "Standard Values for Daily Acres Treated in Agriculture," industry sources, and HED estimates.

c Baseline = No gloves and no respirator (i.e., long sleeve shirt, long pants, shoes and socks).

d Single layer w/gloves is baseline attire plus chemical-resistant gloves.

e Double layer w/gloves is coveralls worn over long-sleeve shirt and long pants, plus chemical-resistant gloves (with headgear).

f 80% Respirator is quarter-face dust/mist respirator (that provides an 80% protection factor).

g 90% Respirator is half-face dust/mist respirator (that provides a 90% protection factor).

h Engineering control is closed mixing/loading system, enclosed cab, or enclosed cockpit.

i Combined MOEs = 1/[(1/Dermal MOE) + (1/Inhalation MOE)]

As noted above, there are no available data to assess the following: 1) mixing/loading/ applying liquids with a tree injector to ornamental trees and woody shrubs; 2) mixing/loading/applying dips to pineapples (pre-plant and post-harvest) and pine seed (nursery applications); 3) drying/raking/bagging treated pine seed; and 4) ready-to-use (RTU) briquette applications to pine seedlings. Therefore, the Agency is requiring the use of gloves to mitigate potential dermal exposure for these uses described above.

#### **d. Occupational Post-application Risk Summary**

Triadimefon is currently labeled for use on grapes, turf (including residential, golf course and sod farm turf), ornamentals, apples, pears, Christmas trees, pine seedlings, and raspberries. Because of the use pattern, a wide array of individuals can potentially be exposed by working in areas that have been previously treated. However, the registrant has agreed to voluntarily delete all uses on apples, pears, grapes, raspberries, and residential turf.

The Agency has used the most up-to-date information available to complete the post-application risk assessment for triadimefon. Several data gaps exist, such as a lack of triadimefon-specific post-application studies and lack of transfer coefficients for certain crop activities. However, the existing database is adequate to assess post-application risk.

Occupational risks were calculated using a MOE, which is a ratio of the daily dose to the toxicological endpoint of concern. Post-application risks diminish over time because triadimefon residues eventually dissipate in the environment. Therefore, risks were calculated over time based on changing residue levels. Occupational post-application exposure and risk assessment for agricultural uses of triadimefon indicates that risks are not a concern at day 0 (i.e., 12 hours after application) for all use sites and all post-application activities. MOEs for occupational post-application risk range from 220 for transplanting, weeding (hand), harvesting (hand), and harvesting (mechanical) at the 2.7 lbs. ai/A rate on sod farms and golf course turf.

### **10. Human Incident Data**

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), California Department of Pesticide Regulation (CDPR), the Agency's Office of Pesticide Program's Incident Data System (IDS), the National Pesticide Information Center (NPIC), the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR) for poisoning incident data on triadimefon/triadimenol.

Data provided by the PCC reported nine incidents of occupational exposure to triadimefon and 46 non-occupational exposures from 1993 through 2003. Of the 46 non-occupational exposures, 13 occurred in children under six years of age. Of the total 20 cases with medically determined outcome, 11 reported minor medical outcome. From a total of 55 exposures to triadimefon, just four were seen in a health care facility and none required hospitalization. A review of symptoms revealed almost exclusively irritation effects (including rash and erythema) to skin, mouth, throat, and eyes. In addition, there were four

cases reporting headache and two reported cough. No other significant symptoms were reported.

The majority of triadimefon incidents (92%) reported by CDPR occurred prior to 1990. Most of the triadimefon cases (73%) involved use on grapes which is a labor intensive crop involving high exposure to foliar residues. Foliar residues accounted for half of the illnesses and nearly half of the systemic illnesses. Skin, eye irritation, and rash were among the most common topical symptoms. The most common systemic effects included nausea, headache, sneezing, congestion, difficulty breathing and other allergic-type reactions. In addition, there were three reports of vomiting. Furthermore, the registrant has voluntarily agreed to delete all food (apples, grapes, pears, and raspberries) uses.

Reports submitted to the IDS indicate incidents from various sources. The NPIC is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others. Triadimefon was not reported on the list of the top 200 chemicals with incidents reported to NPIC. Triadimefon was associated with one case out of a total of 5,899 cases reported to NIOSH SENSOR between 1998 and 2003. However, this case was a duplicate of a CDPR case, which had already been reported.

Conclusion: Both California and Poison Control Center data show a pattern of irritative, but usually minor, symptoms from exposure to triadimefon. Irritation to skin, eyes, and respiratory passage occur readily among unprotected handlers (applicators and mixer/loaders) and among those who have substantial contact with foliage such as grape harvesters and tenders. Additionally, it should be noted that triadimefon is a skin sensitizer, and as such, may contribute to allergic-type reactions. Furthermore, the registrant has voluntarily agreed to delete all uses on apples, grapes, pears, and raspberries.

## **B. Environmental Fate and Effects Risk Assessment**

Triadimefon has the following registered uses, which result in environmental exposures: applications to fruits (apples, grapes, pears, and raspberries) turf, pine seedlings, Christmas trees, and ornamentals. However, the registrant has agreed to voluntarily delete all use on apples, grapes, pears, raspberries, and residential turf. A summary of the Agency's environmental risk assessment for triadimefon is presented below. More detailed information associated with the environmental risk from the use of triadimefon can be found in the *Environmental Fate and Ecological Risk Assessment (Revised) for Triadimefon*, dated January 19, 2006 and *Response to Bayer Public Comments Regarding the Environmental Fate and Effects Division Triadimefon Risk Assessment*, dated June 1, 2006. These documents may be accessed in the OPP Public Docket (docket number EPA-HQ-OPP-2005-0258) at <http://www.regulations.gov>.

## 1. Environmental Fate and Transport

Triadimefon is stable to hydrolysis but degrades by photolysis in water with a half-life of 7.6 hours. In aerobic sandy loam soil, parent triadimefon degraded with a half life of 5.6 days, and in anaerobic sandy loam soil the half life was 23.1 days. In anaerobic aquatic environments, triadimefon had a half-life of 217 days. The primary degradate identified in environmental fate studies (aerobic/anaerobic soil and anaerobic aquatic) was triadimenol. The other degradates identified in these studies were: p-chlorophenol (photolysis water/soil), 4-chlorophenoxy-1,2,4-triazol-1-yl-methane (aerobic soil), and 1H-1,2,4-triazole (aerobic soil).

The environmental fate assessment was based on an evaluation of total triadimefon toxic residues, which includes both parent and the degradate triadimenol. Since approximately 75% of parent triadimefon degraded to triadimenol within 60 days post-application, for the purpose of modeling, physical characteristics that reflected combined properties of both compounds in proper relative proportions were used. Thus, for example, the aerobic soil half-life for total residues used in modeling was 240 days.

Both triadimefon and triadimenol were shown to be moderately soluble, and are therefore capable of being transported dissolved in water as surface runoff or as leachate to groundwater. The adsorption coefficients ( $K_{oc}$ ) for triadimefon and triadimenol were 387 L/kgoc and 365 L/kgoc (average of four soils), respectively. Triadimenol appears to be even more prone to leaching than triadimefon. This may be due partly to its formation in the aerobic subsurface, where subsequent rain or irrigation events can leach it deeper into the soil. However, due to its moderate mobility and adsorption characteristics, triadimefon is capable of persisting and accumulating in a variety of environmental conditions. Therefore, triadimefon is likely to be of greater concern for surface water runoff issues, but triadimenol is of greater concern for groundwater and apt to be more persistent than parent triadimefon in most settings.

## 2. Ecological Exposure and Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing estimated environmental concentrations (EECs), based on environmental fate characteristics and pesticide use data, by ecotoxicity values for various wildlife and plant species. RQs are then compared to levels of concern (LOCs), and when the RQ exceeds the level of concern for a particular category, the Agency presumes a risk of concern to that category. See Table 17 for the Agency's LOCs. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed. To the extent feasible, the Agency seeks to reduce environmental concentrations in an effort to reduce the potential for adverse effects to non-target organisms.

**Table 17. EPA’s Levels of Concern and Associated Risk Presumptions**

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants (Terrestrial/Aquatic/Semi-Aquatic)
<b>Acute Risk</b> - there is potential for acute risk.	0.5	0.5	1
<b>Acute Endangered Species</b> - endangered species may be adversely affected.	0.1	0.05	1
<b>Chronic Risk</b> - there is potential for chronic risk.	1	1	N/A

For a more detailed explanation of the ecological risks posed by the use of triadimefon, refer to the “*Environmental Fate and Effects Division Revised Risk Assessment for Triadimefon*”, dated January 19, 2006.

**a. Aquatic Organism Exposure and Risk**

**1) Fish, Invertebrate, and Aquatic Plant Toxicity**

Freshwater and Estuarine/Marine Fish

Toxicity studies conducted using technical triadimefon demonstrate that it is slightly to moderately toxic to freshwater fish under acute exposure with LC<sub>50</sub> values ranging from 4.1 ppm to 28 ppm (rainbow trout) and 10 ppm to 24.7 ppm (bluegill sunfish). Likewise, two freshwater toxicity studies were also conducted for the major triadimefon degradate, triadimenol. The freshwater fish acute toxicity values (LC<sub>50</sub>) for triadimenol indicate that triadimenol is slightly toxic on an acute basis.

Tables 18 and 19 summarize the data that support the acute toxicity endpoints used in assessing the risks to freshwater fish. No triadimefon or triadimenol estuarine/marine fish acute toxicity tests were submitted to the Agency.

**Table 18. Acute Toxicity Endpoints for Freshwater Fish (Triadimefon)**

Test Species/	% a.i.	96-hr LC <sub>50</sub> (ppm)	Toxicity Classification	MRID No. Author/Year
Cold water fish (Rainbow trout, <i>Oncorhynchus mykiss</i> )	96.8	4.1	Moderately toxic	43256201 Bowers/1994

**Table 19. Acute Toxicity Endpoints for Freshwater Fish (Triadimenol)**

Test Species/	% a.i.	96-hr LC <sub>50</sub> (ppm)	Toxicity Classification	MRID No. Author/Year
Warm water fish (Bluegill sunfish, <i>Lepomis macrochirus</i> )	92	14	Slightly toxic	071469 Lamb/1981



For chronic toxicity, a freshwater fish early life-stage test using technical triadimefon showed that the most sensitive species is the rainbow trout, with a NOAEL of 41 ppb (0.041 ppm). However, no chronic freshwater fish toxicity data were available for the degradate triadimenol. In addition, no triadimefon or triadimenol estuarine/marine fish chronic toxicity tests were submitted. Table 20 summarizes the data for the chronic toxicity endpoints used in assessing the risks to freshwater fish.

**Table 20. Early Life-Stage Chronic Toxicity Endpoints for Freshwater Fish (Triadimefon)**

Group (Test Species)	% a.i.	NOAEL (ppm)	LOAEL (ppm)	Endpoints Affected	MRID No. Author/Year
Cold water fish (Rainbow trout, <i>Oncorhynchus mykiss</i> )	93	0.041	0.116	Growth	251243 Carlisle/1983

Freshwater and Estuarine/Marine Invertebrates

Toxicity studies conducted using technical triadimefon demonstrate that it is slightly to moderately acutely toxic to freshwater invertebrates, with LC<sub>50</sub> values ranging from 1.6 to 11.3 ppm. Freshwater invertebrate acute toxicity tests were also performed for the degradate triadimenol, resulting in an LC<sub>50</sub> value of 2.5 ppm (moderately toxic). Table 21 summarizes the data that support the acute toxicity endpoints used in assessing the risks to aquatic invertebrates. No triadimefon or triadimenol estuarine/marine invertebrate acute toxicity tests were submitted to the Agency.

**Table 21. Acute Toxicity Endpoints for Freshwater Invertebrates**

Test Species/ Flow-through	% a.i.	48-hr LC <sub>50</sub> (ppm)	Toxicity Classification	MRID No. Author/Year
<b>Triadimefon</b>				
Invertebrate (Waterflea, <i>Daphnia magna</i> )	Tech.	1.6	Moderately toxic	231311 Lamb/1997
<b>Triadimenol</b>				
Invertebrate (Waterflea, <i>Daphnia magna</i> )	92	2.5	Moderately toxic	071469 Lamb/1981

A freshwater early life stage aquatic toxicity test using technical triadimefon is available for daphnia magna with a NOAEL of 0.052 ppm (decreased adult length). Table 22 summarizes the data for the chronic toxicity endpoint used in assessing the risks to freshwater invertebrates. No triadimenol freshwater invertebrate chronic toxicity data was submitted, and no triadimefon or triadimenol estuarine/marine invertebrate chronic toxicity tests were submitted.

**Table 22. Early Life-Stage Chronic Toxicity Endpoints for Freshwater Invertebrates**

Group (Test Species)	% a.i.	NOAEL (ppm)	LOAEL (ppm)	Endpoints Affected	MRID No. Author/Year
<b>Triadimefon</b>					
Invertebrate (Waterflea, <i>Daphnia magna</i> )	94.2	0.052	0.119	Adult length	41922102 Gagliano/1991

### Non-target Aquatic Plants

An aquatic plant toxicity study was performed for triadimefon on the technical formulated product on green algae, resulting in an EC<sub>50</sub> value of 1.71 ppm. The EC<sub>50</sub> value for triadimenol was 3.7 ppm. No studies were performed on vascular aquatic plant species. Table 23 summarizes the data for the plant toxicity endpoints used in assessing the risks to aquatic plants.

**Table 23. Toxicity Endpoints for Aquatic Plants (Nonvascular)**

Species	% a.i.	EC <sub>50</sub> (ppm)	EC <sub>05</sub> or NOAEC (ppm)	MRID No. Author/Year
<b>Triadimefon</b>				
Green algae <i>Scenedesmus subspicatus</i>	91.5	1.71	0.1	00159558 Heimbach/1985
<b>Triadimenol</b>				
Green algae <i>Scenedesmus subspicatus</i>	94.9	3.7	0.32	266051 Mobay/1986

## 2) Fish and Invertebrate Exposure

This assessment assumes exposure to both the parent triadimefon as well as triadimenol for aquatic organisms. OPP generally uses computer simulation models to estimate exposure of aquatic organisms, such as plants, fish, aquatic-phase amphibians, and invertebrates, to a pesticide. These models calculate estimated environmental concentrations (EECs) in surface water using laboratory data that describe the rate at which the pesticide breaks down and how it moves into the environment. The Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM-EXAMS) model is initially used to calculate high-end estimates of surface water concentrations of pesticide in a generic pond. This model was used to generate EECs of total triadimefon (parent + triadimenol) in surface water. The User's Manual and PRZM-EXAMS model description can be consulted for additional information at: [www.epa.gov/offefed1/models/water/index.htm](http://www.epa.gov/offefed1/models/water/index.htm). No EECs are generated in instances where no toxicity was observed at concentrations above the active ingredient's water solubility or at or above the recommended limit concentration for a particular type of study.

The Agency used PRZM-EXAMS (Exposure Analysis Modeling System) modeling to derive tier II estimated environmental concentrations (EECs) for triadimefon in surface water. Unlike the drinking water assessment described in the human health risk assessment section of this document, the ecological water resource assessment does not include the Index

Reservoir (IR) and Percent-Crop Area (PCA) factor refinements. The IR and PCA factors represent a drinking water reservoir, not the variety of aquatic habitats, such as ponds adjacent to treated fields, relevant to a risk assessment for aquatic animals. The assumptions used represent pesticide transport in surface water in a standard pond (10,000-m<sup>2</sup> pond, 2-m deep), with the assumption that the small field (10-ha agricultural field) is cropped at 100%. Therefore, the EEC values used to assess exposure to aquatic organisms are not the same as the values used to assess human dietary exposure from drinking water sources.

Several scenarios chosen to represent different U.S. regions and uses were modeled for each use and can be found in the environmental fate and effects assessment for triadimefon. The turf scenarios gave the maximum EECs, and so were chosen for regulatory purposes. The EEC values used to assess exposure to aquatic organisms can be found in the *Environmental Fate and Ecological Risk Assessment (Revised) for Triadimefon*, dated January 19, 2006.

### 3) Fish and Invertebrate Risk

#### Fish, Aquatic Invertebrates, and Aquatic Plants

There would be no LOC exceedances for fish, aquatic invertebrates, or aquatic non-vascular plants for Bayer’s newly proposed turf maximum application rate of 2 applications of 2.7 lbs. ai/A at 14 day intervals. There were no studies available to assess risk to aquatic vascular plants (See Table 24).

**Table 24. Aquatic Organism RQ calculations**

Crop App. rate (# of apps., and interval between apps.)	Peak EEC (ppb)	Acute Risk Quotients			Chronic Risk Quotients			
		Freshwater Fish LC <sub>50</sub> = 4100 ppb	Freshwater Invert. LC <sub>50</sub> = 1600 ppb	Aquatic non-vascular plants EC50 = 17000 ppb	60 Day EEC	21 Day EEC	Freshwater Fish NOEAC = 41 ppb	Freshwater Invertebrate NOEAC = 52 ppb
FL turf 2.7 lbs. a.i./acre (2 app., 14 day intervals)	40.65	<LOC	<LOC	<LOC	27.2	33.36	< LOC	< LOC

### 4) Non-target Aquatic Plants

Risks were below the Agency’s level of concern for non-target aquatic non-vascular plants. No toxicity data were available to assess risks to non-target aquatic vascular plants.

**b. Terrestrial Organism Exposure and Risk**

**1) Bird and Mammal Toxicity**

Birds

Triadimefon is classified as practically non-toxic to birds with acute oral LD<sub>50</sub> values exceeding the highest dose tested (>4000 mg ai/kg bw) and (>2000 mg ai/kg bw) via an 8-day and 14-day test, respectively. With dietary LC<sub>50</sub> values between >4640 ppm to >10,000 ppm triadimefon is classified as practically non-toxic on a subacute dietary basis.

Avian single dose oral toxicity studies were also performed on the major degradate triadimenol. The acute oral (LD<sub>50</sub>) toxicity of triadimenol to bobwhite quail exceeded the highest dose tested (>2000 mg ai/kg) (MRID 126276). Additionally, a triadimenol subacute dietary study was performed with mallard ducks, and no mortality or signs of toxicity were seen at any doses (LC<sub>50</sub> >5000 ppm; MRID 00126277). The results of both studies demonstrate that triadimenol is practically nontoxic to birds on an acute oral and subacute dietary basis. Table 25 summarizes the data that support the acute and subacute toxicity endpoints used in assessing the risks to birds for both triadimefon and its degradate triadimenol.

**Table 25. Acute Toxicity to Birds**

Endpoint	Chemical	Environment/Species	Toxicity Value Used in Risk Assessment	Reference	Toxicity Classification
Acute Toxicity to Birds	Triadimefon	Bobwhite quail	LD <sub>50</sub> = >2000 mg ai/kg bw	MRID 41895901	Practically non-toxic
	Triadimenol	Bobwhite quail	LD <sub>50</sub> = >2000 mg ai/kg bw	MRID 071469	Practically non-toxic
Subacute Toxicity to Birds	Triadimefon	Bobwhite quail	LC <sub>50</sub> = 8392 ppm	MRID 00050066	Practically non-toxic
	Triadimenol	Mallard duck	LC <sub>50</sub> >5000 ppm	MRID 00126277	Practically non-toxic

For chronic toxicity, avian reproduction toxicity tests were performed using technical triadimefon resulting in a NOAEL of 20 ppm ai (bobwhite quail). In addition, avian reproduction toxicity tests were also performed for the degradate triadimenol with a NOAEL of 100 ppm ai (mallard duck). Table 26 summarizes the data for the chronic toxicity endpoints used in assessing the risks to birds.

**Table 26. Chronic Toxicity to Birds**

Species	% a.i.	NOAEL (ppm ai)	LOAEL (ppm ai)	LOAEL Endpoints	MRID No. Author/Year
<b>Triadimefon</b>					
Northern	93	20	100	Eggs cracked, decrease in	110430 Lamb/1982

bobwhite				fertile eggs, decrease in viable embryos, hatchling, 14-day old survivors	
<b>Triadimenol</b>					
Mallard duck	97	100	500	Eggs laid, decrease in viability, hatchability, 14-day survivors	40283102 Carlisle/1984

### Mammals

Triadimefon is classified as slightly toxic to mammals on an acute basis with LD<sub>50</sub> values of 1470 mg/kg (males) and 1090 mg/kg (females). Acute toxicity tests showed LD<sub>50</sub> values of 689 mg/kg (males) and 752 mg/kg (females) for the degradate triadimenol, classifying it as slightly toxic to mammals (see Table 27).

**Table 27. Summary of Acute Toxicity Endpoints for Mammals**

Endpoint	Chemical	Species	Toxicity Used in Risk Assessment (Most sensitive Endpoints)	Reference:	Classification
Acute Toxicity to Mammals	Triadimefon	Rat	LD <sub>50</sub> = 1090 mg/kg (females)	MRID 00264276	Acceptable
	Triadimenol	Rat	LD <sub>50</sub> = 689 mg/kg (males)	MRID 00125411	Acceptable

Chronic toxicity data for mammals from the 2-generation rat reproduction study testing triadimefon indicate decreased pup weights and viability in the F<sub>1</sub> and F<sub>2</sub> generations and decreased litter size in the F<sub>2</sub> generation with an offspring NOAEL of 50 ppm ai. In addition, chronic toxicity tests for the degradate triadimenol showed decreased pup weights with a NOAEL of 100 ppm ai and a LOAEL of 500 ppm ai (see Table 28).

**Table 28. Summary of Chronic Toxicity Endpoints for Mammals**

Species	Test Type/Classification	Toxicity Values Used in Risk Assessment	Affected Endpoints	MRID No.
<b>Triadimefon</b>				
Laboratory Rat ( <i>Rattus norvegicus</i> )	2-generation reproduction	Offspring NOAEL = 50 ppm Offspring LOAEL = 1800 ppm	Decreased pup weight and viability.	00155075 92188019 92188320
<b>Triadimenol</b>				
Laboratory Rat ( <i>Rattus norvegicus</i> )	2-generation reproduction	Parental NOAEL = 100 ppm Parental LOAEL = 500 ppm Offspring NOAEL =	Decreased body weights and weight gain  Decreased pup	00151248

Species	Test Type/ Classification	Toxicity Values Used in Risk Assessment	Affected Endpoints	MRID No.
		100 ppm Offspring LOAEL = 500 ppm	weight	

## 2) Bird and Mammal Exposure

Pesticide residues on food items are estimated based on the assumption that terrestrial organisms are exposed to a single pesticide residue in a given exposure scenario. Application methods for liquid triadimefon formulations include ground spray, aerial spray, and chemigation. Additionally, granular triadimefon is broadcast on residential lawns and turf (no soil incorporation).

The Agency assessed exposure to terrestrial organisms first predicting the amount of triadimefon residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. Estimated exposure concentrations for terrestrial animals (via spray applications) were determined by using the standard screening-level exposure model, TREX (v.1.2) (US EPA, 2005), which calculates pesticide residues on each type of food item on a daily interval for one year. Also, registrant supported golf course use rates and application intervals were used (2 applications @ 2.7 lbs. ai/A).

For a single application there is a linear relationship between the amount of pesticide applied and the amount of pesticide residue present on a given food item. These relationships for the various food items are determined from the Kenaga nomogram, which is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994). In addition to incorporating the nomogram relationship, TREX also includes pesticide degradation in the estimation of EECs.

## 3) Bird and Mammal Risk

### Birds

There are acute and chronic LOC exceedances for birds. The turf maximum application rate of 2 applications of 2.7 lbs. ai/A at 14 day intervals results in acute RQ LOC exceedances that are 0.14 for short grass only and chronic RQ LOC exceedances that range from 4 to 57. Table 29 shows the avian acute and chronic risk quotients for turf use of triadimefon. An avian acute assessment was not conducted for granular applications because definitive avian LD<sub>50</sub> values were not available for triadimefon (no mortalities or signs of toxicity were seen in the study at the highest exposure level).

**Table 29. Avian Dietary-Based Acute and Chronic RQs for turf uses of Triadimefon (based on NOAEC of 20 mg/kg diet) based on upper-bound Kenaga values.**

Use (Application Rate)	Food Items	Upper Bound EEC (mg/kg)	Acute Dietary-Based RQ (EEC/LC50)	Chronic Dietary-Based RQ (EEC/NOAEC)
Turf (2.7 lbs. a.i./A, 2 applications, 14 day interval)	Short grass	1139	0.14	57
	Tall grass	522	0.06	26
	Broadleaf plants/small insects	641	0.08	32
	Fruits, pods, seeds, large insects	71	0.01	4

Mammals

For spray application, there are mammalian acute LOC exceedances (LOC > 0.5) for small and medium (15 and 35g) mammals which consume short grass treated with 2 applications @ 2.7 lbs. ai/A with a 14-day interval. Endangered species LOCs are exceeded (LOC > 0.1) for all weight classes of mammals assessed. Acute RQs are summarized below in Table 33.

The predicted triadimefon granular EEC values resulting from residential application at a rate of 2.7 lbs. ai/A (2 applications, 14-day interval) is 28.12 mg/ft<sup>2</sup> (See Table 30).

**Table 30. Mammalian Dose-based Acute RQs for turf uses of Triadimefon (based on Triadimenol LD<sub>50</sub> of 689 mg/kg in rats) based on upper-bound Kenaga values.**

Spray Application							
Use	Body Weight (g)	Adjusted LD <sub>50</sub>	Mammalian Dose-based Acute Risk Quotients				
			Short grass	Tall grass	Broadleaf plants/ small insects	Fruits/pods/ large insects	Seeds
Turf (2.7 lbs. ai/A, 2 applications, 14 day interval)	15	1514	0.72	0.33	0.40	0.04	0.01
	35	1225	0.61	0.28	0.34	0.04	0.01
	1000	530	0.33	0.15	0.18	0.02	0.00
Granular Application							
Use	Body Weight (g)	Mg a.i./sq ft	Adjusted LD <sub>50</sub>	Risk Quotient			
Turf (2.7 lbs. ai/A, 2 applications, 14 day interval)	15	28.12	1514	1.24			
	35	28.12	1225	0.66			
	1000	28.12	530	0.05			

In addition, there are LOC exceedances of mammalian chronic risks ranging from 1.42 to 23 for the turf maximum application rate of 2 applications of 2.7 lbs. a.i./A at 14 day intervals (See Table 31).

**Table 31. Mammalian Dietary-based Chronic RQs for selected uses of non-granular Triadimefon (based on triadimefon rat NOAEL of 50mg/kg diet) and upper-bound Kenaga values.**

Use	Dietary-based Chronic Risk Quotients			
	Short Grass	Tall Grass	Broadleaf plants	Fruits/pods/ large insects/seeds
Turf (2.7 lbs. ai/A, 2 applications, 14 day interval)	22.78	10.44	12.81	1.42

Additional/Potential Dietary Risks to Birds and Mammals

Based on the use of a fugacity-based (equilibrium partitioning) approach, an estimation of the concentration of triadimefon and its degradates in earthworms were calculated in order to determine the possible contribution of earthworm (and other terrestrial invertebrate) consumption to mammal and avian risk. The calculated earthworm tissue concentrations of triadimefon/triadimenol suggest that ingestion of earthworms by birds and mammals based on dietary dose (triadimefon NOAEC = 20 mg/kg diet and NOAEL = 2.5 mg/kg bw, respectively) could be another exposure pathway contributing to chronic risk, although the low earthworm concentrations would necessitate consumption of a large number of worms.

**4) Non-target Terrestrial Plants**

Non-target Terrestrial Plants

No guideline studies evaluating the toxicity of triadimefon to terrestrial plants have been submitted to the Agency. However, although several other studies within the Agency’s database were not suitable for use in determining toxicity endpoints, they can be interpreted qualitatively to demonstrate *potential* terrestrial plant risk from triadimefon. One such study is summarized below.

The regrowth of Kentucky bluegrass was inhibited following treatment of triadimefon. The same study showed a height decrease in kidney bean plants. Although the study did not provide adequate information to quantitatively calculate RQ values for non-target terrestrial plants, the results suggest that triadimefon may have negative effects on both monocot and dicot non-target terrestrial plants. Please refer to the environmental fate and effects risk assessment for more detailed information.

Based on the supported maximum 2 applications for the golf course use pattern for a maximum single application of 2.7 lbs. a.i./acre, there would be no LOC exceedances for non-vascular aquatic plants.



## **5) Non-target Insects**

EPA currently does not quantify risks to terrestrial non-target insects; therefore, risk quotients are not calculated for these organisms. Based on the acute contact toxicity study to honeybees, the LD<sub>50</sub> for triadimefon is >25 ug ai/bee (MRID 42307804), which classifies it as practically non-toxic to honeybees. No data were available for the degradate triadimenol.

### **3. Ecological Incidents**

A review of the Ecological Incident Information System (EIIS) was completed on April 21, 2005. No incidents involving triadimefon or its metabolite triadimenol were reported.

### **4. Endangered Species**

The Agency's screening level ecological risk assessment for endangered species results in the determination that triadimefon will have no direct acute effects on threatened and endangered freshwater fish, and freshwater aquatic invertebrates. However, the assessment indicates that triadimefon has the potential for causing risk to endangered birds, mammals, and non-target plants. Further, potential indirect effects to any species dependent upon a species that experiences effect cannot be precluded from use of triadimefon. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act.

## **IV. Risk Management, Reregistration, and Tolerance Reassessment Decision**

### **A. Determination of Reregistration Eligibility and Tolerance Reassessment**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing triadimefon as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing triadimefon.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient triadimefon. Based on a review of these data and on public comments on the Agency's assessments for triadimefon, the Agency has sufficient information on the human health and ecological effects to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing triadimefon are eligible for reregistration provided that: (i) required product-specific data are submitted; (ii) risk mitigation measures outlined in this document are adopted (including requests for deletion of certain uses); and (iii) label

amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of triadimefon that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of triadimefon, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of triadimefon, the Agency has determined that triadimefon products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a 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 the use of triadimefon. If all changes outlined in this document are implemented, then all current risks for triadimefon will be adequately mitigated for the purposes of this determination under FIFRA. Additionally, once an endangered species assessment is completed, further changes to these registrations may be necessary, as explained in Section IV..D.4 of this document. Once the uses that result in risks of concern are deleted and a cancellation order is issued, the Agency will take the appropriate regulatory action under FFDCA to revoke the associated tolerances.

Triadimenol, a metabolite of triadimefon, is also a registered fungicide. Triadimenol was first registered after 1984 and is not subject to reregistration under the 1988 amendments to FIFRA. Triadimenol is, however, subject to tolerance reassessment under the FFDCA, as amended by FQPA. Based on its evaluation of combined exposures from the uses of triadimefon, triadimenol, and their metabolites, the Agency has determined that the tolerances for triadimefon and triadimenol are considered to be reassessed under FFDCA.

## **B. Public Comments and Responses**

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for triadimefon. EPA released its preliminary risk assessments for triadimefon and triadimenol for public comment on February 16, 2006, for a 60-day public comment period (Phase 3 of the public participation process). During the public comment period on the risk assessments, which closed on April 17, 2006, the Agency received comments from a public citizen, nursery and forestry cooperatives, the U.S. Triazole Task Force, and the technical registrant Bayer CropScience. These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket for triadimefon (EPA-HQ-OPP-2005-0258) and for triadimenol (EPA-HQ-OPP-2006-0038) in the EPA's electronic docket at <http://www.regulations.gov>.

## **C. Regulatory Position under the FFDCA**

### **1. Food Quality Protection Act Findings**

#### **a. "Risk Cup" Determination**

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to triadimefon and triadimenol are within acceptable levels. In other words, EPA has concluded that the tolerances for triadimefon and triadimenol will meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to triadimefon and triadimenol from all possible sources. Furthermore, if the registrant does not cancel the uses agreed to or make the mitigation changes necessary to meet the safety determination, the Agency will take the appropriate regulatory action.

**b. Determination of Safety to U.S. Population**

The Agency has determined that the established tolerances for triadimefon and triadimenol, with amendments and changes as specified in this document, will meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCFA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of triadimefon and triadimenol. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of triadimefon and triadimenol and their free triazole degradates.

As discussed in Section III, the aggregate risks from triadimefon and triadimenol from food, drinking water, and residential exposure are not of concern, provided the mitigation measures described in this document are implemented through amendments to existing registrations. Furthermore, aggregate risks from the free triazoles (1,2,4-triazole, triazole acetic acid, and triazole alanine) are not of concern. The aggregate risk assessment for the free triazoles considers all currently registered uses of all triazole fungicides.

**c. Determination of Safety to Infants and Children**

EPA has determined that the established tolerances for triadimefon and triadimenol, with amendments and changes as specified in this document, will meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCFA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of triadimefon and triadimenol residues in this population subgroup.

**d. 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 endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis 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 to include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA 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).

#### **e. Cumulative Risks**

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” Other substances are considered to account for the possibility that low-level exposures to multiple chemical substances that cause a common effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to each individual substance. For the purposes of this regulatory decision, EPA has concluded that triadimefon and triadimenol do not share a common mechanism of toxicity with other substances. The Agency reached this conclusion after a thorough internal review and external review of the data supporting a common mechanism of toxicity for a number of chemical classes. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA’s Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA’s website <http://www.epa.gov/pesicides/cumulative/>.

### **2. Tolerance Summary for Triadimefon**

Tolerances of triadimefon in/on plant and livestock commodities (40 CFR § 180.410) are presently expressed in terms of residues of triadimefon and its metabolites containing chlorophenoxy and triazole moieties (expressed as the parent compound).

#### **a. Tolerances Currently Listed Under 40 CFR §180.410**

Tolerances are established for residues of triadimefon [1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone] and its metabolites containing chlorophenoxy and triazole moieties (expressed as the parent compound) in/on various plant and animal commodities [40 CFR §180.410]. The established tolerances for residues in plant and animal commodities [40 CFR §180.410(a)] range from 0.04 ppm (milk, hog, and poultry commodities) to 145 ppm (grass seed cleanings). A tolerance with regional registration is established for triadimefon and its metabolites in/on raspberries at 2.0 ppm [40 CFR

§180.410(c)]. However, all triadimefon tolerances (except pineapple) will be proposed for revocation.

Residues of triadimenol (and its butanediol metabolite KWG 1342), from use of triadimenol *per se*, are regulated separately under 40 CFR §180.450. In addition, 40 CFR §180.3(d)(13) specifies that where tolerances are established for residues of both 1-(4-chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazole-1-yl)-2-butanone (triadimefon) and  $\beta$ -(4-chlorophenoxy)- $\alpha$ -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol (triadimenol) including its butanediol metabolite, 1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol (KWG1342), in or on the same raw agricultural commodity and its products thereof, the total amount of such residues shall not yield more residue than that permitted by the higher of the two tolerances. Currently, triadimefon and triadimenol do not share any uses, so 40 CFR §180.3(d)(13) should be deleted. A tolerance summary for triadimefon is presented in Table 32.

**Table 32. Tolerance Summary for Triadimefon**

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments
<b>Tolerances Established Under 40 CFR §180.410(a)</b>			
Apple	1	Revoke	Bayer is voluntarily deleting this use.
Apple, wet pomace and Apple, dry pomace	4	Revoke	Bayer is voluntarily deleting this use.
Barley, milled fractions (except flour)	4	Revoke	Currently, Bayer does not have any registered uses of triadimefon on barley.
Beet, sugar	0.5	Revoke	Currently, Bayer does not have any registered uses of triadimefon on sugar beets.
Beet, sugar, tops	3		
Cattle, fat	1	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any cattle feed items.
Cattle, meat	1	Revoke	40 CFR §180.6(a)(3) It is not possible to establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Cattle, meat byproducts	1	Revoke	
Chickpea, seed	0.1	Revoke	Currently, Bayer does not have any registered uses of triadimefon on chickpea plants.
Cucurbits	0.3	Revoke	Currently, Bayer does not have any registered uses of triadimefon on chickpea plants.
Eggs	0.04	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any poultry feed items.  40 CFR §180.6(a)(3) It is not possible to establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Goat, fat	1	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any goat feed items.  40 CFR §180.6(a)(3) It is not possible to

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments
Goat, meat	1	Revoke	establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Goat, meat byproducts	1	Revoke	
Grape	1	Revoke	Bayer is voluntarily deleting this use.
Grape, wet pomace and Grape, dry pomace	3	Revoke	No longer considered significant livestock feed items.
Grape, raisin, waste	7		
Grass, forage	0.2	Revoke	Currently, Bayer does not have any registered uses of triadimefon on pasture or rangeland.
Grass, seed screenings	145		
Grass, straw, grown for seed	105		
Hog, fat	0.04	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any hog feed items. 40 CFR §180.6(a)(3) It is not possible to establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Hog, meat	0.04		
Hog, meat byproducts	0.04		
Horse, fat	1	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any horse feed items. 40 CFR §180.6(a)(3) It is not possible to establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Horse, meat	1		
Horse, meat byproducts	1		
Milk	0.04	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any cattle feed items. 40 CFR §180.6(a)(3) It is not possible to establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Nectarine	4	Revoke	Currently, Bayer does not have any registered uses of triadimefon on nectarine.
Pear	1	Revoke	Bayer is voluntarily deleting this use.
Pineapple, fresh	3	2	Re-evaluation of data from field trials shows lower residues are expected. <i>[Pineapple]</i>
Poultry, fat	0.04	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any poultry feed items. 40 CFR §180.6(a)(3) It is not possible to establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Poultry, meat	0.04		
Poultry, meat byproducts	0.04		

Commodity	Current Tolerance (ppm)	Reassessed Tolerance (ppm)	Comments
Raspberry	2	Revoke	Bayer is voluntarily deleting this use. 40 CFR §180.410(c) A tolerance with regional registration is established for triadimefon and its metabolites in/on raspberries.
Sheep, fat	1	Revoke	Currently, Bayer does not have any registered uses of triadimefon on any sheep feed items. 40 CFR §180.6(a)(3) It is not possible to establish with certainty whether finite residues will be incurred but there is no reasonable expectation of finite residues.
Sheep, meat	1		
Sheep, meat byproducts	1		
Wheat, forage	15	Revoke	Currently, Bayer does not have any registered uses of triadimefon on wheat.
Wheat, grain	1		
Wheat, milled fractions (except flour)	4		
Wheat, straw	5		

#### b. Codex Harmonization

No Codex maximum residue levels (MRLs) have been established for triadimefon.

The Codex Alimentarius Commission (Codex) has established several MRLs for triadimenol in/on various raw agricultural commodities. The Codex MRLs are expressed in terms of triadimenol per se. The MRLs have been established to accommodate triadimenol residues resulting from the use of triadimefon and/or triadimenol. Compatibility cannot be achieved with the Codex MRLs because these levels are expressed in terms of triadimenol only; the U.S. tolerances for plant commodities are expressed in terms of triadimefon, KWG 1342, and KWG 1732 in/on cereal grains and cotton and triadimenol and KWG 1342 in/on bananas..

#### c. Residue Analytical Methods – Plants/Livestock

The reregistration requirements for residue analytical methods are fulfilled. Adequate methods are available for data collection and for the enforcement of tolerances for residues of triadimefon *per se* in/on plant commodities. Since there is no reasonable expectation of residues in poultry, enforcement methods for the determination of triadimefon residues in livestock commodities are not needed.

*Plant Commodities.* Two methods of gas chromatography with mass spectrometry detection (GC/MS) are listed in the Pesticide Analytical Manual (PAM Vol. II) for enforcement of tolerances in plant and livestock commodities. The methods use a single moiety detection in which residues are converted to p-dichlorophenol, derivatized with dinitrofluorobenzene, and reported as triadimefon equivalents. The GC/MS method is no

longer adequate due to the recommended tolerance expression revisions. However, a GC method using a nitrogen phosphorus detector (NPD; Report No. 80488) is available for determination of residues of triadimefon, triadimenol, KWG 1323, and KWG 1342, and it is adequate for the enforcement of a pineapple tolerance. The reported method limit of quantitation (LOQ) is 0.01 ppm for each analyte. The limit of detection (LOD) was not reported.

*Livestock Commodities.* The Pesticide Analytical Manual (PAM) Vol. II lists the two GC/MS methods described above (Methods I and II) for the determination of triadimefon and its free and conjugated metabolites in livestock commodities. Method I (Report No. 69531) is appropriate for livestock tissues and milk and Method II (Report No. 80265) is appropriate for livestock tissues and eggs. The reported LOQ is 0.05 and the LOD is 0.01 ppm for both methods.

*Multiresidue Methods.* The 10/99 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that triadimefon is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method; Protocol D); recovery of triadimefon is small (<50%) using Multiresidue Methods Sections 303 (Mills, Onley, and Gaither; Protocol E, nonfatty) and 304 (Mills, fatty food). Triadimefon metabolites triadimenol and KWG 1323 are completely recovered using Section 302. Triadimenol, KWG 1323, and metabolite KWG 1732 are not recovered using Sections 303 and 304.

### **3. Tolerance Summary for Triadimenol**

The current tolerance expression for residues of triadimenol resulting from direct application to primary crops is adequate. The Agency has determined that the tolerance expression for residues in/on cereal grains (barley, corn, oats, rye, and wheat) and cotton commodities should include only triadimenol and its metabolites KWG 1342, and KWG 1732. However, the tolerance expression for residues in/on bananas should include only triadimenol and its metabolite KWG 1342. A summary of triadimenol tolerance reassessments is presented in Table 33.

#### **a. Tolerances Currently Listed Under 40 CFR §180.450**

Tolerances are established for residues of triadimenol and its butanediol metabolite, 4-(4-chlorophenoxy)-2,2-dimethyl-4-(1H-1,2,4-triazol-1-yl)-1,3-butanediol (calculated as triadimenol) in/on various plant commodities. The established tolerances in plant commodities range from 0.01 (sorghum grain and fodder) to 2.5 ppm (green forage of oats, rye, and wheat). Tolerances are currently established for residues of triadimenol and its metabolites containing the chlorophenoxy moiety (calculated as triadimenol) in livestock commodities at 0.01 ppm (milk and poultry commodities) and 0.1 ppm (fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep).

#### Tolerances Needed Under 40 CFR §180.450(a):

Triadimenol is registered for use on barley, corn, cotton, oats, rye, sorghum, wheat,



and bananas as an import tolerance only; however, there are no existing tolerances associated with barley (hay), oat (hay), wheat (hay), and cotton (gin byproducts). Therefore, tolerances will need to be established for these crops.

Tolerances Under 40 CFR §180.450(b):

The reregistration requirements for data depicting the magnitude of triadimenol residues of concern in meat, milk, poultry, and eggs have been fulfilled. Acceptable ruminant and poultry feeding studies have been submitted and evaluated. Triadimenol is not registered for use as a direct livestock treatment. The nature of the residue in livestock is adequately defined for the current uses. The Agency has concluded that the supported uses on barley, corn, cotton, oats, rye, and wheat result in a 40 CFR §180.6(a)(3) situation for ruminant commodities (i.e., there is no reasonable expectation of finite residues in ruminant commodities). Therefore, additional data on the transfer of residues to meat, milk, poultry, and eggs are not required and all tolerances for triadimenol residues in livestock commodities should be revoked pending results from the requested corn and wheat metabolism studies. If, however, foliar uses or registration on additional major livestock feed items are requested, then triazole and phenyl-labeled livestock metabolism studies would be required. Such data may, in turn, trigger the need for magnitude of the residue (feeding) studies in livestock.

**Table 33. Tolerance Summary for Triadimenol**

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
<b>Tolerances Established Under 40 CFR §180.450(a)</b>			
Banana (Whole) <sup>1</sup>	0.2	0.2	
Barley, grain	0.05	TBD <sup>2</sup>	
Barley, straw	0.2	TBD <sup>2</sup>	
Corn, forage	0.05	TBD <sup>2</sup>	[Corn, field, forage] [Corn, sweet, forage]
Corn, fresh (including sweet), (K+CWHR)	0.05	TBD <sup>2</sup>	[Corn, sweet, K+CWHR]
Corn, grain	0.05	TBD <sup>2</sup>	[Corn, field, grain] [Corn, pop, grain]
Corn, stover	0.05	TBD <sup>2</sup>	[Corn, field, stover] [Corn, pop, stover] [Corn, sweet, stover]
Cotton, forage	0.02	Revoke	No longer considered a significant livestock feed item.
Cotton, undelinted seed	0.02	TBD <sup>2</sup>	
Oat, grain	0.05	TBD <sup>2</sup>	
Oat, forage	2.5	TBD <sup>2</sup>	
Oat, straw	0.2	TBD <sup>2</sup>	
Rye, forage	2.5	TBD <sup>2</sup>	
Rye, grain	0.05	TBD <sup>2</sup>	
Rye, straw	0.1	TBD <sup>2</sup>	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ [Correct Commodity Definition]
<b>Tolerances Established Under 40 CFR §180.450(a)</b>			
Sorghum, forage, hay	0.05	Revoke	Use is not being supported.
Sorghum, grain	0.01	Revoke	Use is not being supported.
Sorghum, grain, stover	0.01	Revoke	Use is not being supported.
Wheat, forage	2.5	TBD <sup>2</sup>	
Wheat, grain	0.05	TBD <sup>2</sup>	
Wheat, straw	0.2	TBD <sup>2</sup>	
<b>Tolerances Established Under 40 CFR §180.450(b)</b>			
Cattle, fat	0.1	Revoke	Available data indicate that tolerances for cattle commodities are not required.
Cattle, meat	0.1		
Cattle, meat byproducts	0.1		
Egg	0.01	Revoke	Available data indicate that a tolerance for egg is not required.
Goat, fat	0.1	Revoke	Available data indicate that tolerances for goat commodities are not required.
Goat, meat	0.1		
Goat, meat byproducts	0.1		
Hog, fat	0.1	Revoke	Available data indicate that tolerances for hog commodities are not required.
Hog, meat	0.1		
Hog, meat byproducts	0.1		
Horse, fat	0.1	Revoke	Available data indicate that tolerances for horse commodities are not required.
Horse, meat	0.1		
Horse, meat byproducts	0.1		
Milk	0.01	Revoke	Available data indicate that a tolerance for milk is not required.
Poultry, fat	0.01	Revoke	Available data indicate that tolerances for poultry commodities are not required.
Poultry, meat	0.01		
Poultry, meat byproducts	0.01		
Sheep, fat	0.1	Revoke	Available data indicate that tolerances for sheep commodities are not required.
Sheep, meat	0.1		
Sheep, byproducts	0.1		
<b>Tolerances To Be Proposed Under 40 CFR §180.450(a)</b>			
Barley, hay	None established	TBD <sup>2</sup>	
Cotton, gin byproducts	None established	TBD <sup>2</sup>	
Oat, hay	None established	TBD <sup>2</sup>	
Wheat, hay	None established	TBD <sup>2</sup>	

<sup>1</sup>40 CFR §180.450(a) states that there are no U.S. registrations for bananas (whole).

<sup>2</sup>TBD = To be determined. Additional data are required. Note that while additional data are needed, there are no dietary risks associated with these tolerances and EPA considers them reassessed.

#### D. Regulatory Rationale under FIFRA

The Agency has determined that triadimefon is eligible for reregistration, in compliance with FIFRA, and the associated tolerances are considered reassessed, provided that: 1) required product-specific and generic data are submitted; 2) risk mitigation measures (including requests to delete certain uses) outlined in this document are adopted; and 3) label amendments are made to reflect these measures. As stated above, the Agency will take steps to revoke the tolerances associated with the uses that are being deleted.

Risks for currently registered uses of triadimenol are below the Agency's level of concern, and no further mitigation is required. The tolerances for triadimenol are considered reassessed. Product-specific and generic data are required to be submitted, as specified in section V.

The following is a summary of the rationale for managing risks associated with the use of triadimefon. Where labeling revisions are required, specific language is set forth in the summary tables of Chapter V of this document.

## **1. Human Health Risk Management**

### **a. Dietary (Food and Water) Risk Mitigation**

Bayer, the sole technical registrant, has agreed to voluntarily delete all triadimefon food uses, except for pre-plant and post-harvest use on pineapples. Food uses to be deleted include apples, pears, grapes, and raspberries (in both commercial and residential settings). In order to reduce potential drinking water exposure to triadimefon, use on turf will be restricted to golf courses and sod farms, only, with a maximum single application rate of 2.7 lbs ai/A, and a maximum yearly rate of 5.4 lbs ai/A. With the above use deletions and restrictions, aggregate (food and water) risks are below the Agency's level of concern.

### **b. Residential Risk Mitigation**

The following residential uses will remain as labeled use sites for triadimefon:

- Outdoor ornamental flowers, shrubs, and trees;
- Greenhouse ornamental flowers, shrubs, and trees.

Bayer, the sole technical registrant, has agreed to request voluntary deletions of the residential turf use to address post-application and aggregate risks to toddlers. In addition, a 17-day post-application, pre-harvest interval is required for sod farm turf, to address potential risks to toddlers exposed to sod farm turf transplanted to a residential setting.

In order to address risks to residential handlers making applications to ornamentals, the following mitigation measures are required:

- Package all wettable powder products in water-soluble bags;
- Prohibit application with hose-end sprayers in residential greenhouses;

- Reduce the application rate for all outdoor ornamental applications to a maximum of 0.0025 lbs ai/gallon (for certain use sites, rates will remain lower than this maximum).

Currently, the number of applications that can be made to golf course turf is not specified on product labels. Golf course use will be restricted to a maximum single application rate of 2.7 lbs ai/A, and a maximum yearly rate of 5.4 lbs ai/A. Although aggregate risks to golfers (youths and adults) do not currently exceed the Agency's level of concern, this mitigation measure will further reduce exposure to golfers.

### **c. Occupational Risk Mitigation**

The following commercial and agricultural uses will remain as labeled use sites for triadimefon:

- Golf course turf
- Sod farm turf
- Outdoor ornamental flowers, shrubs, and trees
- Greenhouse ornamental flowers, shrubs, and trees
- Roses
- Azaleas, for control of pine-twisting rust only
- Pines, including Christmas trees
- Pine seedlings
- Pine seed (in-nursery and commercial)
- Pineapples (pre-plant and post-harvest dip)

Bayer, the sole registrant has requested that use on apples, pears, grapes, raspberries, and all turf other than golf course and sod farm turf be voluntarily deleted, reducing handler exposure. For golf courses and sod farms, a maximum single application rate of 2.7 lbs ai/A, and a maximum yearly rate of 5.4 lbs ai/A are required, further reducing handler exposure. Golf course applications will be restricted to turf less than 2.5 inches in height, which will limit application to golf course roughs.

In order to address risks to occupational handlers mixing, loading, and applying triadimefon, the mitigation listed below is required:

- (1) Require all wettable powder products to be packaged in water-soluble bags (an engineering control).
- (2) Require closed cockpits for aerial applications.
- (3) Require chemical-resistant gloves for occupational handlers performing the following activities:
  - Mixing and loading all formulations (liquids, wettable powders, dry flowables)
  - Loading granulars;

- Making applications with handheld equipment;
- Any activities which involve contact with treated seed (including drying, raking, bagging, and sewing bags);
- Mixing, loading, and applying when using a tree-injection unit;
- Applying a ready-to-use briquette to pine seedlings.

(4) Require both chemical resistant gloves and a chemical resistant apron for occupational handlers performing the following activities:

- Dipping pineapples (pre-plant, and post-harvest);
- Dipping pine seed (for on-nursery applications).

With the above engineering controls and personal protective equipment, risks to residential handlers are below the Agency's level of concern.

#### **d. Aggregate Risk Mitigation for Triazole Metabolites**

Acute, short- and intermediate-term, and chronic aggregate risks for degradates 1,2,4-triazole, triazole alanine, and triazole acetic acid are below the Agency's level of concern. The Agency considered the contribution of acute and chronic dietary risks from food and drinking water as well as residential handler and post-application exposures in the aggregate risk assessment for the free triazoles. Therefore, no further mitigation is necessary at this time.

### **2. Environmental Risk Mitigation**

A number of the mitigation measures described above will reduce exposure and risks to mammals and birds. These include:

- Deleting all outdoor food uses of triadimefon (pears, apples, grapes, and raspberries);
- Limiting turf application rates to a maximum single application rate of 2.7 lbs ai/A, and a maximum yearly rate of 5.4 lbs ai/A (reduced from no limit on the number of applications);
- Prohibiting use on residential turf (only application to golf course and sod farm turf will continue);
- Limiting golf course applications to turf that is less than 2.5 inches in height (this will reduce application to golf course roughs, which are usually 3 or more inches in height).

### **3. Other Labeling**

In order to be eligible for reregistration, various use and safety information will be required in the labeling of all end-use products containing triadimefon. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

### **4. Endangered Species Program**

The Agency's screening level ecological risk assessment for endangered species results in the determination that triadimefon will have no direct acute effects on threatened and endangered freshwater fish, and freshwater aquatic invertebrates. However, the assessment indicates that triadimefon has the potential for causing acute risk to endangered birds, mammals, and non-vascular aquatic plants. Chronic RQs for endangered mammals exceed the level of concern at all application rates modeled. Chronic RQs for endangered birds also exceed the level of concern. No data are available to assess the risks to estuarine/marine invertebrates, estuarine/marine fish, vascular aquatic plants, and terrestrial plants. Therefore, risks cannot be precluded on these species at this time.

Further, potential indirect effects to any species dependent upon a species that experiences effect cannot be precluded from use of triadimefon. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act.

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 address these impacts. The Endangered Species Act requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will consider the risk mitigation measures that are being implemented as a result of this regulatory decision.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of triadimefon; other measures to mitigate any potential impact; or consultations with the Fish and Wildlife Service or the National Marine Fisheries Service as necessary. If the Agency determines that use of triadimefon "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species-specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to triadimefon at levels of concern. EPA is not requiring specific triadimefon label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

## **V. What Registrants Need to Do**

The use of currently registered products containing triadimefon in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment provided that the risk mitigation measures and label changes (including use

deletions) outlined in this document are implemented. Therefore, all remaining uses of these products are eligible for reregistration. These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products that contain other ingredients in addition to triadimefon will be reregistered when all of their other active ingredients are also reregistered.

A. For triadimefon technical grade active ingredient products, the registrant needs 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. Any time extension and/or waiver requests with a full written justification.

**Within the time limit specified in the generic DCI:**

1. Citations of any existing generic data that address data requirements or submit new generic data responding to the DCI.

Please contact John W. Pates, Jr. at (703) 308-8195 with questions regarding generic reregistration.

By U.S. Mail:

Document Processing Desk (DCI/SRRD)  
John W. Pates, Jr.  
U.S. EPA (7508P)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)  
John W. Pates, Jr.  
Office of Pesticide Programs (7504P)  
Room S-4900  
One Potomac Yard  
Arlington, VA 22202

B. For end-use products containing the active ingredient triadimefon, the registrant needs 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) 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) a 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 33 of this document;
- (4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);
- (5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- (6) the product-specific data responding to the PDCI.

Please contact Veronica Dutch at (703) 308-8047 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)  
 Veronica Dutch  
 US EPA (7508P)  
 1200 Pennsylvania Ave., NW  
 Washington, DC 20460

By express or courier service only:

Document Processing Desk (PDCI/PRB)  
 Veronica Dutch  
 Office of Pesticide Programs (7504P)  
 Room S-4900  
 One Potomac Yard  
 Arlington, VA 22202

**A. Manufacturing Use Products**

**1. Generic Data Requirements for Triadimefon**

The generic data base supporting the reregistration of triadimefon for the above eligible uses has been reviewed and determined to be substantially complete. However, the following data requirements are necessary to confirm the reregistration eligibility decision documented in this RED:

**Human Health Effects**

<b>Guideline Study Name</b>	<b>New OPPTS Guideline No.</b>	<b>Old Guideline No.</b>
Developmental Neurotoxicity Study (DNT)	870.6300	83-6

**Ecological Effects**

<b>Guideline Study Name</b>	<b>New OPPTS Guideline No.</b>	<b>Old Guideline No.</b>
Estuarine/Marine Mollusk EC50	850.1025	72-3 B
Estuarine/Marine Shrimp EC50	850.1035	72-3 C
Estuarine/Marine Fish LC50	850.1075	72-3 A



Seedling Emergence	850.4225	123-1 A
Vegetative Vigor	850.4250	123-1 B
Aquatic Vascular Plant Growth	850.4400	123-2

## 2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in the labeling table, which will be issued separately.

### B. End-Use Products

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

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant 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 measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 34.

### C. Data Requirements for Triadimenol

There are data that must be submitted to support the continuing registration of triadimenol. These data are not expected to change the regulatory conclusions for triadimenol described in this document. A generic DCI will be issued and will require development and submission of these listed data in order to confirm the conclusions outlined in this document.

#### Product Chemistry

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Stability	830.6313	63-13
pH ( H <sub>2</sub> O solutions)	830.7000	63-12
Ultraviolet/visible Absorption	830.7050	None
Partition Coefficient (N-octanol/water)	830.7550	63-11
	830.7560 OR	

<b>Guideline Study Name</b>	<b>New OPPTS Guideline No.</b>	<b>Old Guideline No.</b>
	830.7570	
Water Solubility	830.7840 OR 830.7860	63-8

#### **Toxicology**

<b>Guideline Study Name</b>	<b>New OPPTS Guideline No.</b>	<b>Old Guideline No.</b>
Acute neurotoxicity study	870.6100	81-7
Subchronic neurotoxicity Study	870.6200	82-7

#### **Residue Chemistry**

- Separate metabolism studies with triazole-14C and phenyl-14C labeled triadimenol applied as a seed treatment to wheat and corn must be conducted to confirm residues of concern.
- Storage stability data for triadimenol, KWG 1342, and KWG 1732 in/on field corn, sweet corn, cotton, and wheat processed commodities are required pending the results from the requested metabolism studies. Storage stability data for KWG 1732 in/ on wheat forage, hay, and straw are required pending the results from the requested metabolism studies.
- Crop field trial data depicting residues of triadimenol, KWG 1342, and KWG 1732 in/on field corn (forage, grain, stover), sweet corn (forage, kernel plus cob with husks removed, grain, and stover), cotton (undelinted seed and gin byproducts), and wheat (forage, grain, hay, and straw) grown from seed treated at the maximum rate are required pending the results from the requested metabolism studies.
- A wheat processing study conducted with triadimenol applied to wheat as a seed treatment should be submitted once the requested corn or wheat metabolism studies have been submitted and reviewed.
- Limited field rotational crop studies for triadimenol must be submitted pending the results from the requested metabolism studies.

#### **D. Labeling Changes Summary Table**

For triadimefon to be eligible for reregistration, all triadimefon labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 34 describes how language on the labels should be amended.

**Table 34. Labeling Changes Summary Table**

<b>Summary of Labeling Changes for Triadimefon</b>		
<b>Description</b>	<b>Amended Labeling Language</b>	<b>Placement on Label</b>
<b>Manufacturing Use Products</b>		
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>Only for formulation into a <i>fungicide</i> for the following use(s): golf course turfgrass, sodfarm turfgrass, outdoor- and greenhouse-grown ornamentals (trees, shrubs, flowering plants, including roses), azaleas (for control of pine-twisting rust only), pine trees (including Christmas trees), pine seedlings, pine seeds, and pineapple (preplant dip and postharvest dip only), “</p> <p>“This product can not be formulated into end-use products with directions for use in residential or commercial settings on apples, grapes, pears, raspberries, azaleas (except to control pine-twisting rust only), or turfgrass (except for turfgrass on golf courses or sodfarms).”</p> <p>“This product can not be formulated into liquid concentrate end-use products with directions for use on azaleas, pine seedlings, pine seeds, or pineapple.”</p> <p>“This product can not be formulated into dry flowable end-use products with directions for use on pine trees, pine seedlings, or pineapple.”</p> <p>“This product can be formulated into granular end-use products with directions for use only on golf course turfgrass or sodfarm turfgrass.”</p>	Directions for Use
	<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 U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards	<p>“Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.”</p>	Precautionary Statements immediately following the User Safety Recommendations

End Use Products Intended for Occupational Use (WPS and NonWPS)

<p>PPE Requirements Established by the RED<sup>1</sup> for liquid concentrate end-use 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, applicators, flaggers, and other handlers must wear: &gt; Long sleeved shirt and long pants, &gt; Shoes plus socks, and &gt;Chemical resistant gloves, such as (<i>registrant insert correct chemical-resistant materials</i>) when mixing/loading or when applying using handheld equipment or handheld nozzles.”</p> <p>“See engineering controls for additional requirements.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED<sup>1</sup> for dry flowable end-use products</p> <p>Note: if the end-use product does not have directions for use as a seed treatment, then the phrase “or when handling treated seed (including spreading, drying, raking, bagging, and sewing seed bags)” may be dropped.</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, applicators, flaggers, and other handlers must wear: &gt; Long sleeved shirt and long pants, &gt; Shoes plus socks, and &gt;Chemical resistant gloves, such as (<i>registrant insert correct chemical-resistant materials</i>) when mixing/loading, when applying using handheld equipment or handheld nozzles, or when handling treated seed (including spreading, drying, raking, bagging, and sewing seed bags).”</p> <p>“See engineering controls for additional requirements.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED<sup>1</sup> for wettable powder end-use 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>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

End Use Products Intended for Occupational Use (WPS and NonWPS)

<p><i>Note: all wettable powder products must be in water soluble packets to be eligible for reregistration.</i></p> <p>Note: if the end-use product does not have directions for use as a seed treatment, then the phrase “or when handling treated seed (including spreading, drying, raking, bagging, and sewing seed bags)” may be dropped.</p> <p>Note: if the end-use product does not have directions for use as a dip treatment, then the phrases “participating in dip applications” may be dropped.</p>	<p>“Mixers, loaders, applicators, flaggers, and other handlers must wear:</p> <ul style="list-style-type: none"> <li>&gt; Long sleeved shirt and long pants,</li> <li>&gt; Shoes plus socks,</li> <li>&gt; Chemical resistant gloves, such as (<i>registrant insert correct chemical-resistant materials</i>) when mixing/loading, when using handheld equipment or handheld nozzles, when participating in dip applications, or when handling treated seed (including spreading, drying, raking, bagging, and sewing seed bags), and</li> <li>&gt; Chemical-resistant apron, when mixing/loading, when participating in dip applications, or cleaning spills or equipment.”</li> </ul> <p>“See engineering controls for additional requirements.”</p>	
<p>PPE Requirements Established by the RED<sup>1</sup> 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, applicators, flaggers, and other handlers must wear:</p> <ul style="list-style-type: none"> <li>&gt; Long-sleeved shirt and long pants,</li> <li>&gt; Shoes plus socks, and</li> <li>&gt; Chemical resistant gloves, such as (<i>registrant insert correct chemical-resistant materials</i>) when loading.”</li> </ul> <p>“See engineering controls for additional requirements.”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

End Use Products Intended for Occupational Use (WPS and NonWPS)

<p>PPE Requirements Established by the RED<sup>1</sup> for ready-to-use briquette 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>“Applicators and other handlers must wear: &gt; Long-sleeved shirt and long pants, &gt; Shoes plus socks, and &gt; Chemical resistant gloves, such as (<i>registrant insert correct chemical-resistant materials</i>). “</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>PPE Requirements Established by the RED<sup>1</sup> for tree-injection products</p> <p>Note: if the tree-injection product is ready-to-use, the words “mixers, loaders” may be dropped</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, applicators and other handlers must wear: &gt; Long-sleeved shirt and long pants, &gt; Shoes plus socks, and &gt; Chemical resistant gloves, such as (<i>registrant insert correct chemical-resistant materials</i>).”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</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.”</p> <p>“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: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>

End Use Products Intended for Occupational Use (WPS and NonWPS)		
<p>Engineering Controls for liquid, dry flowable , or granular formulations that contain directions for use for sodfarm turfgrass</p>	<p>“Engineering Controls”</p> <p>“Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR170.240(d)(6)]. Pilots must wear the PPE required on this labeling for applicators.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)</p>
<p>Engineering Controls for wettable powders packaged in water-soluble packets. <i>All wettable powders must be in water soluble packets to be eligible for reregistration.</i></p>	<p>“Engineering Controls”</p> <p>“Water soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4). Mixers and loaders using water soluble packets must:</p> <ul style="list-style-type: none"> <li>-wear the personal protective equipment required on this labeling for mixers and loaders, and</li> <li>-be provided, have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown: <ul style="list-style-type: none"> <li>&gt;chemical resistant footwear and</li> <li>&gt;a NIOSH-approved respirator equipped with: <ul style="list-style-type: none"> <li>-- a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or</li> <li>-- any N, R, P, or HE filter.”</li> </ul> </li> </ul> </li> </ul> <p>“Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR170.240(d)(6)]. Pilots must wear the PPE required on this labeling for applicators.”</p>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)</p>
<p>User Safety Recommendations</p>	<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 under: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>

End Use Products Intended for Occupational Use (WPS and NonWPS)		
Environmental Hazards	<p>“ ENVIRONMENTAL HAZARDS”</p> <p>“Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean water mark. Do not contaminate water when disposing of equipment washwater or rinsate.”</p> <p>“Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to organisms in neighboring areas.”</p> <p>“This product may contaminate water through runoff. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product.”</p> <p>“This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.”</p>	Environmental Hazards
<p>Restricted-Entry Interval (for labels with WPS uses)</p> <p>Note: the prohibition for sodfarms may be dropped if the end-use product does not contain directions for use on sodfarms</p>	<p>“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.”</p> <p>“Harvesting or transplanting turfgrass grown on sodfarms is prohibited for 17 days following application.”</p>	Directions for Use, Agricultural Use Requirements Box
Early Reentry Personal Protective Equipment established by the RED (for labels with WPS uses)	<p>“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:</p> <ul style="list-style-type: none"> <li>&gt; coveralls,</li> <li>&gt; shoes plus socks, and</li> <li>&gt; chemical-resistant gloves made of any waterproof material.”</li> </ul>	Place in the Directions for Use In Agricultural Use Requirements box, immediately following the REI
Entry Restriction for NonWPS uses	<p><b><i>Entry Restriction for non-WPS uses applied as a spray (does not include tree-injection uses):</i></b></p> <p>“Do not enter or allow others to enter until sprays have dried.”</p>	If no WPS uses on the label, place the statements in the Directions for Use Under General Precautions



End Use Products Intended for Occupational Use (WPS and NonWPS)		
	<p><b>Entry Restriction for non-WPS uses applied dry (does not include ready-to-use briquette uses):</b></p> <p>“Do not enter or allow others to enter until dusts have settled.”</p> <p><b>Entry Restriction for non-WPS uses applied as a granular and when watering-in is required:</b></p> <p>“Do not enter or allow others to enter the treated area (except those involved in watering-in) until watering-in is complete and the surface is dry.”</p>	<p>and Restrictions.</p> <p>If WPS uses are also on the labeling, place these statements in a NonAgricultural Use Requirements box as specified in PR Notice 93-7 and 93-11.</p>
General Application Restrictions (for labels with WPS uses)	<p>“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”</p>	Place in the Directions for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	<p><b>All Products/Formulations Containing Triadimefon</b></p> <p>Delete all directions for use for the following use-patterns:</p> <ul style="list-style-type: none"> <li>&gt; apples</li> <li>&gt; grapes</li> <li>&gt; pears</li> <li>&gt; raspberries</li> <li>&gt; residential or commercial turfgrass (except for turfgrass on golf courses or sodfarms).</li> </ul> <p>Include the following statement: “Application to trees that bear fruit or nuts is prohibited. Applications are permitted on nonbearing fruit or nut trees only.”</p>	Directions for Use
Spray Drift	<p><u>“Spray drift requirements”</u></p> <p>(1) For groundbloom and aerial applications, use only medium or coarser spray nozzles according to ASABE (S572) definition for standard nozzles. Aerial applicators must consider flight speed and nozzle orientation in determining droplet size.</p>	

**End Use Products Intended for Occupational Use (WPS and NonWPS)**

	<p>(2) Make aerial or ground applications when the wind velocity is 3 to 10 mph. Do not apply when the wind speed is greater than 10 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application.</p> <p>(4) Do not make aerial or ground applications into temperature inversions.</p> <p>(5) For groundboom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy.</p> <p>(6) For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in tree applications, spray must be directed into the canopy.</p> <p>(7) For aerial applications, do not release spray at a height greater than 10 feet above the ground or plant canopy.</p> <p>(8) For aerial applications, the outermost nozzles must not exceed 60% of the wingspan or 80% of the rotor blade diameter.</p> <p>(9) When aerial applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind.”</p>	
<p><b>Application Restrictions for Turfgrass Uses</b></p> <p>(Note: The maximum allowable application rate per application or per year must be listed as pounds or gallons of formulated product per acre, not solely as pounds active ingredient per acre.)</p>	<p>“Use on turfgrass is limited to sodfarm turf and golf course turf only. Use on turfgrass is prohibited on all other residential and commercial sites.”</p> <p>Maximum application rate is 2.7 lb ai/A  Maximum annual application rate is 5.4 lb ai/A  Minimum retreatment interval is 14 days.</p> <p>“Aerial application and chemigation to turf are permitted on sodfarm turfgrass only.”</p> <p>“Application to golf courses, including tees, greens, fairways, and roughs, is permitted only if the turfgrass is 2.5 inches or less in height.”</p>	<p>Directions for Use associated with turfgrass use directions</p>

End Use Products Intended for Occupational Use (WPS and NonWPS)		
	“Harvesting or transplanting turfgrass grown on sodfarms is prohibited for 17 days following application.”	
Application Restrictions for Azaleas	“Use on azaleas is limited to applications to control pine-twisting rust disease.”	Directions for Use associated with azalea use directions
Application Restrictions for Ornamentals and Pine Trees, including Christmas trees	“Chemigation is permitted for use on ornamentals and pine trees, including Christmas trees.”	
Application Restrictions for Ornamentals at Residential Sites  Note: The maximum allowable application rate must be listed as pounds or gallons of formulated product per acre, not solely as pounds active ingredient per gallon.)	“The maximum application rate for ornamentals (including azaleas) at residential sites is 0.0025 lb ai/gal.”	Directions for Use associated with ornamental use directions
End Use Products Intended Primarily for Use by Homeowners		
Environmental Hazards	<p>“ ENVIRONMENTAL HAZARDS”</p> <p>“Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.”</p> <p>“Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to organisms in neighboring areas.”</p> <p>“This product may contaminate water through runoff. This product has a high potential for runoff for</p>	Precautionary Statements

End Use Products Intended for Occupational Use (WPS and NonWPS)		
	<p>several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product.”</p> <p>“This chemical has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.”</p>	
Application Restrictions	<p><b>All products:</b></p> <p>“Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application.”</p>	<p>Directions for Use under General Precautions and Restrictions</p> <p>Statements must be in the color red and in all caps.</p>
Entry Restrictions	<p><b>Products Applied as a Liquid (except tree-injection uses):</b></p> <p>“Do not allow people or pets to enter the treated area until sprays have dried.”</p>	Directions for Use under General Precautions and Restrictions
Directions for Use	“Do not apply this product to lawns or other turfgrass.”	Directions for Use section
<p>Directions for Use on Ornamentals</p> <p>Note: The maximum allowable application rate must be listed as pounds or gallons of formulated product per acre, not solely as pounds active ingredient per gallon.)</p>	<p>“Applications with hose-end sprayers are permitted only for outdoor use on ornamentals. Use of hose-end sprayer equipment in residential greenhouses is prohibited.”</p> <p>“The maximum application rate for ornamentals is 0.0025 lb ai/gal.”</p>	Directions for Use section associated with the directions for ornamental uses
Other Application Restrictions (Risk Mitigation)	<p><b>All Products/Formulations Containing Triadimefon</b></p> <p>Delete all directions for use for the following use-patterns:</p>	Directions for Use

End Use Products Intended for Occupational Use (WPS and NonWPS)

- > apples
- > grapes
- > pears
- > raspberries
- > residential or commercial turfgrass

Include the following statement: "Application to trees that bear fruit or nuts is prohibited. Applications are permitted on nonbearing fruit or nut trees only."

<sup>1</sup> 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.

<sup>2</sup> The registrant must drop the N type filter from the respirator statement if the pesticide product contains or is used with oil.

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.

## VI. Appendices

**Appendix A: Use Patterns Subject to Reregistration for Triadimefon**

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
<i>(Food Uses)</i>					
<b>Pineapples</b> (post-harvest or pre-plant crowns)					
Pre-plant and Post-harvest dip, spray	WP	0.0028 lbs ai/gallon	1	Not Specified (NS)	All wettable powder products must be packaged in water soluble bags.
<i>(Non-food Uses)</i>					
<b>Azaleas</b> (for control of pine twisting rust, only)					
Chemigation, groundboom, low- pressure handwand, high pressure handwand	WP DF	0.005 lbs ai/gallon	8	NS	All wettable powder products must be packaged in water soluble bags.
<b>Christmas trees</b>					
Aerial, flagging, airblast	WP	0.25 lbs ai/A	8	NS	A closed cockpit is required for aerial applications (all formulations).  All wettable powder products must be packaged in water soluble bags.
<b>Golf Course Turf</b>					

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Groundboom, LCO handgun, low-pressure handwand, and handgun sprayer  Flagging, tractor-drawn spreader	LC WP DF  G	2.7 lbs ai/A	2  (at max. single app. rate)	14	Use is restricted to golf course and sod farm turf, only.  A maximum annual application rate of 5.4 lbs ai/A is allowed.  Applications are restricted to turf less than 2.5 inches in height. This applies to the entire golf course, including tees, greens, fairways, and roughs.  All wettable powder products must be packaged in water soluble bags.
<b>Greenhouse Ornamentals</b> (including flowers, shrubs, and trees)					
Low-pressure handwand, handgun sprayer, high-pressure handwand	WP  LC	0.00625 lbs ai/gallon  0.00938 lbs ai/gallon	8	N/S  NS	Prohibit residential (consumer) hose-end sprayer applications in greenhouses.  All wettable powder products must be packaged in water soluble bags.
<b>Ornamentals</b> (including flowers, shrubs and trees)					
Low-pressure handwand, handgun sprayer, high-pressure handwand  Low-pressure handwand, chemigation, groundboom, high-pressure handwand	LC  WP DF	0.0023 lbs ai/gallon  0.0025 lbs ai/gallon	8	NS  NS	Residential (consumer) use limited to ornamentals, <u>only</u> .  Professional hose-end sprayer applications are allowed.  All wettable powder products must be packaged in water soluble bags.
<b>Ornamentals</b> (including shade trees and woody shrubs)					



Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Tree injection unit (ready-to-use micro injection unit, or unit requiring product dilution)	LC	0.000026 lbs ai/ inch of trunk circumference	6	NS	
<b>Pines (including Christmas trees)</b>					
Low-pressure handwand and handgun sprayer	LC	0.0023 lbs ai/gallon	8	NS	
<b>Pine Seed (on-nursery applications)</b>					
Dip	WP	0.0000625 lbs ai/gallon		NS	All wettable powder products must be packaged in water soluble bags.
Planter box, hopper box, cement mixer,	WP	0.0013 lbs ai/A	1	NS	
Cement mixer	DF	0.00136 lbs ai/A		NS	
<b>Pine Seed (commercial applications)</b>					
Commercial loading/applying, commercial bagging of treated seed, commercial bag sewing, and multiple commercial activities	WP	0.0013 lbs ai/lb	1	NS	All wettable powder products must be packaged in water soluble bags.
<b>Pine Seedlings</b>					
Aerial, flagging, airblast, groundboom, low-pressure handwand, handgun sprayer	WP	0.5 lbs ai/A	4	NS	A closed cockpit is required for aerial application.
By hand	Ready-to-use briquette	0.000019 lbs ai/seedling	1	NS	All wettable powder products must be packaged in water soluble bags.
<b>Roses</b>					

Site Application Type Application Timing Application Equipment	Formulation	Max. Single Application Rate (ai)	Max. # Apps.	Minimum Retreatment Interval (Days)	Use Limitations
Low-pressure handwand, handgun sprayer, high-pressure handwand	LC WP	0.00029 lbs ai/gallon	8	NS	All wettable powder products must be packaged in water soluble bags.
<b>Sod Farm Turf</b>					
Aerial, chemigation, flagging, groundboom, LCO handgun, low-pressure handwand, and handgun sprayer  Aerial, flagging, tractor-drawn spreader	WP DF  G	2.7 lbs ai/A	2 (at max. single app. rate)	17	A closed cockpit is required for aerial applications (all formulations).  A maximum annual application rate of 5.4 lbs ai/A is allowed.  All wettable powder products must be packaged in water soluble bags.

## Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

### GUIDE TO APPENDIX B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within the case 2700 covered by this RED/TRED. It contains generic data requirements that apply to triadimefon/triadimenol in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.
2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
  - A. Terrestrial food
  - B. Terrestrial feed
  - C. Terrestrial non-food
  - D. Aquatic food
  - E. Aquatic non-food outdoor
  - F. Aquatic non-food industrial
  - G. Aquatic non-food residential
  - H. Greenhouse food
  - I. Greenhouse non-food
  - J. Forestry
  - K. Residential
  - L. Indoor food
  - M. Indoor non-food
  - N. Indoor medical
  - O. Indoor residential
3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MIRD) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

## APPENDIX B-1

<b>Data Supporting Guideline Requirements for the Reregistration of Triadimefon</b>				
<b>REQUIREMENT</b>			<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b><u>PRODUCT CHEMISTRY</u></b>				
<b><u>New Guideline Number</u></b>	<b><u>Old Guideline Number</u></b>			
830.1550	61-1	Product Identity and Composition	All	CSF ('96)
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	00098119, 42307801
830.1620	61-2B	Description of Production Process	All	00098119, 42307801
830.1650	61-2B	Description of Formulation Process	All	00098119, 42307801
830.1670	61-2B	Formation of Impurities	All	40477401
830.1700	62-1	Preliminary Analysis	All	00098120, 44166001
830.1750	62-2	Certification of limits	All	44166001, CSF ('96)
830.1800	62-3	Enforcement Analytical Method	All	42307802
830.6302	63-2	Color	All	41616001
830.6303	63-3	Physical State	All	41616001
830.6304	63-4	Odor	All	41616001
830.6313	63-13	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	All	42307803
830.6314	63-14	Oxidation/Reduction: Chemical Incompatibility	All	Not Applicable; N/A
830.6315	63-15	Flammability	All	N/A
830.6316	63-16	Explosibility	All	N/A
830.6317	63-17	Storage Stability	All	N/A
830.6319	63-19	Miscibility	All	N/A
830.6320	63-20	Corrosion Characteristics	All	N/A
830.7000	63-12	pH	All	41616001
830.7050	None	UV/Visible Absorption	All	N/A
830.7100	63-18	Viscosity	All	41616001

## Data Supporting Guideline Requirements for the Reregistration of Triadimefon

REQUIREMENT			USE PATTERN	CITATION(S)
830.7200	63-5	Melting Point	All	41616001
830.7220	63-6	Boiling Point	All	N/A
830.7300	63-7	Relative Density	All	41616001
830.7370	63-10	Dissociation Constants in Water	All	N/A
830.7550 830.7560 or 830.7570	63-11	Octanol/Water Partition Coefficient	All	42307803
830.7840 or 830.7860	63-8	Water solubility: column elution method; shake flask method	All	41616001
830.7950	63-9	Vapor Pressure	All	42307801
<b>ECOLOGICAL EFFECTS</b>				
850.2100	71-1	Avian Acute Oral Toxicity		00071469, 41895901
850.2200	71-2A	Avian Dietary Toxicity - Quail		00071469, 00050066
850.2200	71-2B	Avian Dietary Toxicity - Duck		00126277
850.2300	71-4	Avian Reproduction –Avian chronic tests on the Mallard Duck and Bobwhite Quail		00110430, 00110431, 40283102, 42342301
850.2400	71-3	Mammal Acute/ Chronic Toxicity- Rat		00125411, 00151248, 00155075, 00264276, 92188019, 92188320
850.1010	72-2A	Invertebrate Toxicity		00071469, 00231311, 254693, 41922101
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk		<b>Data Gap</b>
850.1035 850.1045	72-3C	Estuarine/Marine Toxicity – Shrimp EC50		<b>Data Gap</b>
850.1075	72-3A	Estuarine/Marine Fish LC50		<b>Data Gap</b>
850.1075	72-1A	Fish Toxicity- Bluegill		00071469, 43304301
850.1075	72-1C	Fish Toxicity- Rainbow Trout		00071469, 43256201
850.1300	72-4A	Freshwater Fish- Early Life Stage		00251243, 41922103

## Data Supporting Guideline Requirements for the Reregistration of Triadimefon

REQUIREMENT			USE PATTERN	CITATION(S)
850.1500	72-5	Life Cycle Fish		N/A
850.1735	None	Freshwater Acute Invertebrate Toxicity		00071469, 00231311, 00246736, 41922102
850.4100	122-1A	Terrestrial Toxicity; Seedling Emergence		N/A
850.4150	122-1B	Terrestrial Plant Toxicity; Vegetative Vigor		N/A
850.5400	122-2	Aquatic Plant Growth		00159558, 00266051
850.4225	123-1A	Seed Germination and Seedling Emergence (Tier 2)		<b>Data Gap</b>
850.4250	123-1B	Vegetative Vigor (Tier 2)		<b>Data Gap</b>
850.4400	123-2	Aquatic Vascular Plant Growth (Tier2)		<b>Data Gap</b>
850.3020	141-1	Honey Bee Acute Contact		05001991, 42307804
850.3030	141-2	Honey Bee Residue on Foliage		N/A
<b>TOXICOLOGY</b>				
870.1100	81-1	Acute Oral Toxicity		00125411, 00264276, 43936101
870.1200	81-2	Acute Dermal Toxicity-Rat		00145086, 00264276
870.1300	81-3	Acute Inhalation Toxicity-Rat		41616002
870.2400	81-4	Primary Eye Irritation-Rabbit		41782501
870.2500	81-5	Primary Skin Irritation- Rabbit		41616004
870.2600	81-6	Dermal Sensitization- Guinea pig		41554001
870.6100	82-5A	90-Day Neurotoxicity- Hen		44153501
870.6300	83-6	Developmental Neurotoxicity Study		00089023; <b>Data Gap</b>
870.3100	82-1A	90-Day Feeding - Rat		00048624
870.3100	82-1A	30-Day Oral Toxicity- Rat		00048627
870.3150	82-1B	90-Day Feeding (Non-rodent)- Dog		00048625, 00060226
870.3200	82-2	21-Day Dermal Toxicity- Rat		42341501
870.3700	83-3A	Developmental Toxicity - Rat		00089023, 00149336, 92188018

## Data Supporting Guideline Requirements for the Reregistration of Triadimefon

REQUIREMENT			USE PATTERN	CITATION(S)
870.3700	83-3B	Developmental Toxicity - Rabbit		41446201, 42089601
870.3800	83-4	2-Generation Reproduction - Rat		00155075, 92188019, 92188020 The reproductive study in the rat is acceptable/ non-guideline in conjunction with the 3-generation study (MRID 00032541)
870.3800	83-4	Reproduction and fertility effects (3-Gen)- Rat		00032541 The reproductive study in the rat is acceptable/ non-guideline in conjunction with the multi-generation reproduction study (MRID 00155075)
870.4100	83-1B	Chronic Toxicity - Dog		00032539, 00126261
870.4200	83-2B	Carcinogenicity- Mice		40752101, 40865101
870.4300	83-5	2-year Combined Chronic/Oncogenicity- Rat		42153901
870.5100	84-2	Mutagenicity-Gene Mutation- bacterial		00126264, 00099413
870.5395	84-2	Micronucleus Assay		00048637
870.5450	84-2	Cytogenetics Dominant Lethal Assay		00048628
870.5550	84-2	Unscheduled DNA Synthesis Assay		00159343
870.6200	81-8	Acute Neurotoxicity Screening Battery- Rat		43495509, 43936101
870.6200	82-7	Subchronic Neurotoxicity Screening Battery- Rat		44153501
870.7485	85-1	General Metabolism- Rat		00033057, 42409101
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2400	133-3	Dermal Passive Dosimetry Exposure		43125401
875.2500	133-4	Inhalation Passive Dosimetry Exposure		43125401
None	231	Estimation of Dermal Exposure at Outdoor Sites		45654503

## Data Supporting Guideline Requirements for the Reregistration of Triadimefon

REQUIREMENT			USE PATTERN	CITATION(S)
None	232	Estimation of Inhalation Exposure at Outdoor Sites		45654503
<b>ENVIRONMENTAL FATE</b>				
None	160-5	Chemical Identity		N/A
835.2120	161-1	Hydrolysis		41922101
835.2240	161-2	Photodegradation - Water		42112901
835.2410	161-3	Photodegradation - Soil		00044169, 42820401
835.2370	161-4	Photodegradation - Air		N/A
835.4100	162-1	Aerobic Soil Metabolism		42242701, 42224104, 41686102,
835.4200	162-2	Anaerobic Soil Metabolism		41686101, 42401201
835.4400	162-3	Anaerobic Aquatic Metabolism		41686101, 42401201
835.4300	162-4	Aerobic Aquatic Metabolism		42224104
835.1240	163-1	Leaching/Adsorption/Desorption		41616008, 42356601
835.1410	163-2	Laboratory Volatilization		N/A
835.8100	163-3	Volatility- Field		N/A
835.6100	164-1	Terrestrial Field Dissipation		42242701, 41686103, 41686104
835.6200	164-2	Aquatic Field Dissipation		N/A
835.6300	164-3	Forestry Dissipation		N/A
860.1950	165-4	Bioaccumulation in Fish		41619901
None	165-5	Bioaccumulation- Aquatic Nontarget		41619901
835-7100	166-1	Ground Water- Small Scale Prospective		N/A
840.1100	201-1	Spray Droplet Size Spectrum		N/A
840.1000	201-4	Background for Pesticide Aerial Drift (Evaluation)		N/A
840.1200	202-1	Spray Drift Field Deposition (Evaluation)		N/A
<b>RESIDUE CHEMISTRY</b>				



**Data Supporting Guideline Requirements for the Reregistration of Triadimefon**

REQUIREMENT			USE PATTERN	CITATION(S)
860.1200	171-3	Directions for Use		N/A
860.1300	171-4A	Nature of Residue - Plants		42123401, 42123402, 42123403, 42798901, 42853401, 92188025-33
860.1300	171-4B	Nature of Residue - Livestock		42123404, 42856801, 42864901, 43418301-02, 92188034-39
860.1340	171-4C	Residue Analytical Method - Plants		43870101, 44041002, 92188040-43
860.1340	171-4D	Residue Analytical Method - Livestock		43418303, 92188044-48
860.1360	171-4M	Multiresidue Methods		41976601, 43705401
860.1380	171-4E	Storage Stability Data- Plant and Livestock		41976602, 42857401, 44038901, 44041001, 92188051-53, 43462401
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg		92188054-57
860.1500	171-4K	Crop Field Trials		92188060-65, 92188070, 92188073-75, 42342303-08, 41809401
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed		42346601, 43948601, 92188064-65, 92188069, 43284401, 42013201, 92188074
860.1850	165-1	Confined Accumulation in Rotational Crops Study		42613301
860.1900	165-2	Field Accumulation in Rotational Crops Study		N/A

## APPENDIX B-2

Data Supporting Guideline Requirements for the Reregistration of Triadimenol				
REQUIREMENT			USE PATTERN	CITATION(S)
<b><u>PRODUCT CHEMISTRY</u></b>				
<u>New Guideline Number</u>	<u>Old Guideline Number</u>			
830.1550	61-1	Product Identity and Composition	All	N/A
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	N/A
830.1620	61-2B	Description of Production Process	All	N/A
830.1650	61-2B	Description of Formulation Process	All	N/A
830.1670	61-2B	Formation of Impurities	All	N/A
830.1700	62-1	Preliminary Analysis	All	N/A
830.1750	62-2	Certification of limits	All	N/A
830.1800	62-3	Enforcement Analytical Method	All	N/A
830.6302	63-2	Color	All	N/A
830.6303	63-3	Physical State	All	N/A
830.6304	63-4	Odor	All	N/A
830.6313	63-13	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	All	<b>Data Gap</b>
830.6314	63-14	Oxidation/Reduction: Chemical Incompatibility	All	N/A
830.6315	63-15	Flammability	All	N/A
830.6316	63-16	Explosibility	All	N/A
830.6317	63-17	Storage Stability	All	N/A
830.6319	63-19	Miscibility	All	N/A
830.6320	63-20	Corrosion Characteristics	All	N/A
830.7000	63-12	pH	All	Not available; <b>Data Gap</b>
830.7050	None	UV/Visible Absorption	All	Not Available; <b>Data Gap</b>
830.7100	63-18	Viscosity	All	N/A

## Data Supporting Guideline Requirements for the Reregistration of Triadimenol

REQUIREMENT			USE PATTERN	CITATION(S)
830.7200	63-5	Melting Point	All	00125399
830.7220	63-6	Boiling Point	All	N/A
830.7300	63-7	Relative Density	All	00125399
830.7370	63-10	Dissociation Constants in Water	All	Not available
830.7550 830.7560 or 830.7570	63-11	Octanol/Water Partition Coefficient	All	Not available; <b>Data Gap</b>
830.7840 or 830.7860	63-8	Water solubility: column elution method; shake flask method	All	00125399; <b>Data Gap</b>
830.7950	63-9	Vapor Pressure	All	00125399
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity		00125411
870.1200	81-2	Acute Dermal Toxicity-Rat		00145086
870.1300	81-3	Acute Inhalation Toxicity-Rat		00145087
870.2400	81-4	Primary Eye Irritation-Rabbit		00145088
870.2500	81-5	Primary Skin Irritation- Rabbit		00145088
870.2600	81-6	Dermal Sensitization- Guinea pig		00125413
870.3100	82-1A	90-Day Oral Toxicity- Rat		00127769, 42192701
870.3150	82-1B	90-Day Oral Toxicity (Non-rodent )- Dog		00125420
870.3150	82-1B	6 months oral toxicity (Non-rodent)- Dog		00151247
870.3200	82-2	15-Day Dermal Toxicity- Rabbit		00151246
870.3465	82-4	21-Day Inhalation Toxicity- Rat		00125421
870.3700	83-3A	Prenatal Developmental Toxicity - Rat		40307804, 40887702, 41498401
870.3700	83-3B	Developmental Toxicity - Rabbit		40307805, 40887703, 42365001

## Data Supporting Guideline Requirements for the Reregistration of Triadimenol

REQUIREMENT			USE PATTERN	CITATION(S)
870.3800	83-4	2-Gen. reproduction and fertility effects - Rat		00151248
870.4100	83-1B	Chronic Toxicity - Dog		00150484, 00159012
870.4200	83-2B	Carcinogenicity- Mice		00126259, 44740901
870.4300	83-5	Combined Chronic/Carcinogenicity- Rat		00126260
870.5100	84-2	Bacterial system, mammalian activation-Gene Mutation		00126264
870.5300	84-2	<i>In Vitro</i> Mammalian Cell Gene Mutation		00126269
870.5450	84-2	Cytogenetics Dominant Lethal Assay		00126266
870.5500	84-2	Other Genotoxicity DNA Damage		00126271
870.5550	84-2	Other Genotoxicity Unscheduled DNA Synthesis		00126271
870.5900	84-2	Other Effects <i>In Vitro</i> Sister Chromatid Exchange Assay		40815901
870.6100	81-7	Acute Neurotoxicity Study		<b>Data Gap</b>
870.6200	82-7	Subchronic Neurotoxicity Study		<b>Data Gap</b>
Other	none	Other Studies; Central Nervous Effects- Mice		00145083
<b>RESIDUE CHEMISTRY</b>				
860.1200	171-3	Directions for Use		N/A
860.1300	171-4A	Nature of Residue - Plants		42123401-03, 42798901, 42853401, 92188025-33
860.1300	171-4B	Nature of Residue - Livestock		42123404, 42856801, 42864901, 43418301-02, 92188034-39
860.1340	171-4C	Residue Analytical Method - Plants		43870101, 44041002, 92188040-43
860.1340	171-4D	Residue Analytical Method - Livestock		43418303, 92188044-48
860.1360	171-4M	Multiresidue Methods		40969801, 41976601, 43705401

**Data Supporting Guideline Requirements for the Reregistration of Triadimenol**

<b>REQUIREMENT</b>			<b>USE PATTERN</b>	<b>CITATION(S)</b>
860.1380	171-4E	Storage Stability Data- Plant and Livestock		41976602, 42857401, 44038901, 44041001, 92188051-53, 43462401
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry /Egg		92188054-57
860.1500	171-4K	Crop Field Trials		00125407-09, 40615201, 41051401, 41242801, 42696308-09, 42712101
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed		44519801-03
860.1850	165-1	Confined Accumulation in Rotational Crops Study		42613301
860.1900	165-2	Field Accumulation in Rotational Crops Study		N/A

## Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding Federal Holidays, from 8:30 am to 4 pm.

The docket contains the risk assessments and related documents as of August 30, 2006. The availability announcement will be published in the Federal Register. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the internet at the following site: [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration). The following list details all documents related to the Triadimefon/Triadimenol (RED/TRED).

### Health Effects Documents:

1. DP Barcode 329823 and D328572. Jin Kim, Tara Chandgoyal and Jonathan Becker. July 18, 2006. Characterization of Triadimefon Use on Golf Courses, Turf, Pine Seed and Seedling Treatment, and Pineapple.
2. DP Barcode D314778. Yvonne Barnes and Sheila Piper. July 6, 2006. Triadimefon: Revised Acute, Probabilistic and Chronic Dietary (Food + Drinking Water) Exposure and Risk Assessments for the Triadimefon Reregistration.
3. DP Barcode D331455. Yvonne Barnes and Sheila Piper. August 1, 2006. Triadimefon + Triadimenol: Aggregate Acute, Chronic, and Short-Term Risk Assessments Reflecting July, 2006 Risk Mitigation in Response to the Phase 4 Triadimefon RED.
5. DP Barcode D328262. Rich Griffin. June 20, 2006. Triadimefon: HED Response to Comments Received During the Public Comment Phase.
6. DP Barcode D330611. Rich Griffin. July 10, 2006. Triadimefon/Triadimenol: Summary of Refinements and Revisions to the Human Health Risk Assessment.
7. DP Barcode D314814 and D315040. Shanna Recore. June 30, 2006. Triadimefon: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document.
8. Meeting Summary. Kimberly Nesci. EPA/FDA Joint Teleconference on July 11, 2006 to Discuss 1,2,4 Triazole (Free Triazole) as a Common Metabolite of Triazole Derivative Fungicides and Anastrozole, a Drug.
9. Sam Ary. Triadimefon. Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document.

10. DP Barcode D321636. Sam Ary. August 31, 2005. Triadimefon. Registrants Response to Residue Chemistry Data Requirements. Magnitude of Triadimefon Residues of Concern in Apple Processed Commodities.
11. DP Barcode D314778. Sam Ary. November 23, 2005. Triadimefon. Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision (RED) Document.
12. DP Barcode D315115. Yvonne Barnes. November 22, 2005. Triadimefon: Summary of Product Chemistry Data for Reregistration Eligibility Decision (RED) Document.
13. DP Barcode D 326678. Rich Griffin. February 9, 2006. Triadimefon. Preliminary Human Health Risk Assessment (Revised).
14. DP Barcode D314742. Sam Ary. November 23, 2005. Triadimefon. Summary of Analytical Chemistry and Residue Data for the Reregistration Eligibility Decision (RED) Document.
15. DP Barcode D314928. Sam Ary. November 18, 2005. Triadimenol Acute and Chronic Dietary Exposure Assessments for the Tolerance Reassessment Eligibility Decision Document.
16. DP Barcode D314891. Sam Ary. November 17, 2005. Triadimenol. Summary of Analytical Chemistry and Residue Data for the Tolerance Reassessment Eligibility Decision Document.
17. DP Barcode D326716. Christina Jarvis. January 24, 2006. Triadimenol HED Chapter of the Tolerance Reassessment Eligibility Decision Document (Revised).
18. DP Barcode D322336. Sam Ary. October 14, 2005. Triadimenol. Registrants Response to Residue Chemistry Data Requirements.
19. DP Barcode D315152. Yvonne Barnes. November 22, 2005. Summary of Product Chemistry Data for Tolerance Reassessment Document.
20. DP Barcode D322240. Jack Arthur. December 9, 2005. Occupational and Residential Exposure/Risk Assessment of 1,2,4-Triazole.
21. DP Barcode D 322238. Michael Doherty. November 1, 2005. 1,2,4-Triazole. Acute and Chronic Dietary Exposure Assessments to Support Reregistration and Registration Actions for Triazole-derivative Fungicides.

22. DP Barcode D322239. Michael Doherty. December 20, 2005. Triazole Alanine and Triazole Acetic Acid. Acute and Chronic Dietary Exposure Assessments to Support Reregistration and Registration Actions for Triazole-derivative Fungicides.
23. DP Barcode D322215. Michael Doherty. February 7, 2006. 1,2,4-Triazole, Triazole Alanine, triazole Acetic Acid: Human Health Aggregate Risk Assessment in Support of Reregistration and Registration Actions for Triazole-derivative Fungicide Compounds.
24. Kathleen Raffaele. Triazoles- 2<sup>nd</sup> Report of the *Ad Hoc* HED Peer Review Committee.

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6. DP Barcode D329271. James Hetrick. June 15, 2006. Response to Triazole Task Force Comments on the FQPA Drinking Water Assessment for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), and Triazole acetic acid (TAA).

Other Documents:

1. Memorandum. John A. Lazor. EPA 1,2,4 Triazole Consult Response.



**Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision (Bibliography) for Triadimefon and Triadimenol**

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92188069	Leslie, W. (1990) Mobay Corporation Phase 3 Reformat of MRID 00128337. Triadimefon (BAYLETON 50WP Formulation) - Magnitude of the residues in Unprocessed Sugar Beets and Sugar Beet processed Products: Project Nos. (82811, 84211, 84212); Mobay Report No. 100116. Prepared by MOBAY CORPORATION. 56 p.
92188070	Leslie, W. (1990) Mobay Corporation Phase 3 Reformat of MRID 00067381 and Related MRIDs 00109463. Triadimefon (BAYLETON 25WP Formulation) - Magnitude of the Residues on Chick Peas (Project Nos. 68905, 68906, 68907, 68908, 68909, 80723, 80930, 80931); Mobay Report No. 100117. Prepared by MOBAY CORPORATION. 55 p.
92188073	Leslie, W. (1990) Mobay Corporation Phase 3 Reformat of MRID 00128337. Triadimefon (BALETON 50WP) - Magnitude of the Residues on Sugar Beets: (Project Nos. 81198, 81199, 82205, 82206, 82207, 82800, 82801, 82802, 82812, 82813, 82814, 82815, 82816, 82817, 82818); Mobay Report No. 10115. Prepared by MOBAY CORPORATION. 204 p.
92188074	Leslie, W. (1990) Mobay Corporation Phase 3 Reformat of MRID 00098114 and Related MRIDs 00149329, 00061736. Triadimefon (BAYLETON 50WP Formulation) - Magnitude of the Residues on Wheat: (Report Nos. 80494, 80495, 80530, 80542, 80545, 80546, 80547, 80550, 80551, 80552, 80553, 82821, 82874, 84208, 82822, 82824); Mobay Report No. 100111. Prepared by MOBAY CORPORATION. 219 p.
92188075	Leslie, W. (1990) Mobay Corporation Phase 3 Reformat of MRID 00072532 and Related MRIDs 00149342. Triadimefon (BAYLETON 50WP Formulation) - Magnitude of the Residues on Seed Grass: Project Report Nos. (80670, 80673, 80674, 80675, 80676, 82848, 82854, 82855, 82856, 82857, 82858); Mobay Report 100114. Prepared by MOBAY CORPORATION. 121 p.
92188320	Bayer Ag Institute of Toxicology; Two Generation Study with Rats; Report No.: 12712, Report Author: Dr. R. Eiben (Also under MRIDs 00155075, 92188019 and TRID Number 470102-011).

MRID	Citation Reference
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None	Crofton, KM. 1996. A structure- activity relationship for the neurotoxicity of triazole fungicides. <i>Toxicol. Lett</i> 84 (3): 155-159.
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None	Crofton, KM., Boneck, VM., and MacPhail, RC. 1989. Evidence for monoaminergic involvement in triadimefon- induced hyperactivity, <i>Psychopharmacology</i> 97, 326-330.
None	Crofton, KM., Howard, JL., Moser, VC., Gill, MW., et al. 1991. Interlaboratory comparison of motor activity experiments: implications for neurotoxicological assessments. <i>Neurotoxicol. Teratol.</i> 13 (6): 599- 609.
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None	Goetz, A.K., Blystone, C., Ren, H., Schmid, J.E., Nichols, H.P., Bao, W., Best, D.S., Narotsky, M.G., Wolf, D.C., Rockett, J.C., and Dix, D.J. (2005) Reproductive Effects of Exposure to Conazole Fungicides in the Male Rat. <i>The Toxicologist</i> . Abstract No 2148.
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None	Hester, S., Thai, S.-F., Wolf, D., Ward, W., and Nesnow, S. (2005) Comparison of Gene Expression Profiles from Rats Fed Acute Levels of Three Toxicologically Different Conazoles. <i>The Toxicologist</i> . Abstract No. 2149.
None	Ikaidi, MU., Akunne, HC., and Soliman, KE. 1997. Behavioral and neurochemical effects of acute and repeated administration of triadimefon in the male rat. <i>Neurotoxicology</i> 18(3): 771-80.
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MRID	Citation Reference
None	Toxicity for Conazole Fungicides. <i>The Toxicologist</i> . Abstract No. 2150.
None	Sun G, Thai SF, Tully DB, Lambert GR, Goetz AK, Wolf DC, Dix DJ, Nesnow S: Propiconazole-induced cytochrome P450 gene expression and enzymatic activities in rat and mouse liver. <i>Tox Lett</i> 155: 277-287, 2004; and abstracts from the 2005 SOT meeting,
None	Walker, QD and Mailman, RB. 1996. Triadimefon and triadimenol: effects on monoamine uptake and release. <i>Toxicol. Appl. Pharmacol.</i> 139 (2): 227- 233.
None	Ward, W., Delker, D., Hester, S., Thai, S-F., Allen, J., Jones, C., Wolf, D., and Nesnow, S. (2005) Comparison of Hepatic Gene Expression Profiles from Mice Exposed to Three Toxicologically Different Conazoles. <i>The Toxicologist</i> . Abstract No. 2147.
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## **Appendix E. Generic Data Call-In**

**Appendix E.**

The generic data call-in will be posted at a later date.

## **Appendix F. Product Specific Data Call-In**

**Appendix F.**

The product specific data call-in will be posted at a later date.

## **Appendix G: Batching of Triadimenol/Triadimefon Products**

### **EPA'S BATCHING OF TRIADIMENOL/TRIADIMEFON PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION**

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must

select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Seven products were found which contain Triadimenol as the active ingredient. These products have been placed in a no batch group in accordance with the active and inert ingredients and type of formulation

Batching Instructions for Triadimenol:

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

No Batch	EPA Reg. No.	Percent Active Ingredient
	264-742	25.00
	264-743	98.30
	264-760	28.30
	264-939	Triademinol: 5.00 Tetramethylthiuram disulfide: 15.30
	264-941	30.00
	264-980	Triademinol: 13.33 Azoxystrobin: 8.00 Metalaxyl: 40.00
	2935-459	30.00

Fifty one products were found which contain Triadimefon as the active ingredient. These products have been placed in seven batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions for Triadimefon:

Batch 3A: Products in this Batch may cite studies conducted on products in Batch 3.

Batch 6: Each product in this Batch must conduct a primary eye irritation study using the fertilizer with the highest percentage of nitrogen.

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

Batch 1	EPA Reg. No.	Percent Active Ingredient
	264-737	50.0
	264-740	50.0
	432-1294	50.0
	432-1360	50.0
	432-1367	50.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	432-1293	25.0
	432-1309	25.0
	432-1316	25.0
	432-1317	25.0

Batch 3	EPA Reg. No.	Percent Active Ingredient
	4-342	1.0
	432-1295	1.0
	432-1336	1.0
	961-354	1.0
	8378-55	1.0
	9198-111	1.0
	10404-58	1.0
	28293-278	1.0
	32802-41	1.0
	34704-802	1.0

Batch 3A	EPA Reg. No.	Percent Active Ingredient
	4-362	0.50
	432-1296	0.50
	869-224	0.50
	829-288	0.50
	961-353	0.50
	7401-432	0.50
	8378-54	0.50
	8660-199	0.78



	9198-112	0.50
	9198-187	0.59
	28293-280	0.50
	32802-42	0.50
	72155-47	0.50

Batch 4	EPA Reg. No.	Percent Active Ingredient
	432-1297	0.88
	829-289	0.88
	72155-48	0.88

Batch 5	EPA Reg. No.	Percent Active Ingredient
	869-222	0.88
	2724-691	0.88

Batch 6	EPA Reg. No.	Percent Active Ingredient
	961-388	0.10
	961-389	0.05
	9198-190	0.62
	10404-65	0.50

No Batch	EPA Reg. No.	Percent Active Ingredient
	264-736	97.70
	264-757	Triadimefon: 2.10 Sulfur: 53.70
	432-1300	22.00
	432-1412	Triadimefon: 8.33 Trifloxystrobin: 41.67
	432-1445	43.00
	432-1446	Triadimefon: 20.86 Trifloxystrobin: 4.17
	9198-169	Triadimefon: 16.00 Metalaxyl: 16.00
	9198-197	Triadimefon: 1.59 Thiram: 40.76
	64014-3	0.88
	72155-46	1.00

**H. List of Registrants Sent this Data Call-In**

United States Environmental Protection Agency Washington, D.C. 20460 <b>LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE</b> Case # and Name: 2700, Triadimefon					
Co. Number	Company Name	Agent for	Address	City and State	Zip
264	BAYER CROPSIECNCE		2 T.W. Alexander Drive	Research Triangle Park	NC 27709

## Appendix I. List of Available Related Documents and Electronically Available Forms

**Pesticide Registration Forms are available at the following EPA internet site:**

<http://www.epa.gov/opprd001/forms/>.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

### Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)
2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at [williams.nicole@epamail.epa.gov](mailto:williams.nicole@epamail.epa.gov).

The following Agency Pesticide Registration Forms are currently available via the internet: at the following locations:

8570-1	Application for Pesticide Registration/Amendment	<a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a> .
8570-4	Confidential Statement of Formula	<a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a> .
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	<a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a> .
8570-17	Application for an Experimental Use Permit	<a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a> .
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	<a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a> .
8570-27	Formulator's Exemption Statement	<a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a> .
8570-28	Certification of Compliance with Data Gap Procedures	<a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a> .
8570-30	Pesticide Registration Maintenance Fee Filing	<a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a> .
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	<a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a> .

8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a> .
8570-35	Data Matrix (in PR Notice 98-5)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf</a> .
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a> .
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	<a href="http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf</a> .

**Pesticide Registration Kit**

[www.epa.gov/pesticides/registrationkit/](http://www.epa.gov/pesticides/registrationkit/).

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
  - a. 83-3 Label Improvement Program--Storage and Disposal Statements
  - b. 84-1 Clarification of Label Improvement Program
  - c. 86-5 Standard Format for Data Submitted under FIFRA
  - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
  - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
  - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
  - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
  - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at [http://www.epa.gov/opppmsd1/PR\\_Notices](http://www.epa.gov/opppmsd1/PR_Notices).

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
  - b. EPA Form No. 8570-4, Confidential Statement of Formula

- c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)
- a. Registration Division Personnel Contact List
- I.
- b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - c. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
  - f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
  - g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site
2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)  
5285 Port Royal Road  
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.
4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: [ace.orst.edu/info/nptn](http://ace.orst.edu/info/nptn).

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

### **Documents Associated with this RED**

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

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.