

# Triadimefon Reregistration Eligibility Decision (RED) and Triadimenol Tolerance Reassessment and Risk Management Decision (TRED) Fact Sheet

## Table of Contents

### This Page:

[Pesticide Registration](#)  
[Regulatory History](#)  
[Uses](#)  
[Health Effects](#)  
[Ecological Effects](#)  
[Risk](#)  
[Risk Mitigation](#)  
[Regulatory Conclusion](#)  
[Generic Data Requirements](#)  
[For More Information](#)

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## Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers that describe the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet current human health and safety standards and can be used without posing unreasonable risks to human health and the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. For the purpose of tolerance reassessment, EPA explains the basis for its decision in a Tolerance Reassessment Eligibility Decision (TRED) document. This fact sheet summarizes the information in the RED/TRED document for the pesticide triadimefon and the tolerance reassessment for triadimenol, case number 2700 (PC Codes 109901 and 127201).

## Regulatory History

- Triadimefon and triadimenol are broad spectrum, systemic fungicides.
- Triadimenol is the primary metabolite of triadimefon and is registered separately under its own active ingredient number.
- Triadimenol was first registered after 1984 and is not subject to reregistration under the 1988 amendments to FIFRA. It is being assessed by the Agency for the purposes of a tolerance reassessment.
- Triadimefon and triadimenol belong to a group of pesticides called triazoles (or conazoles), which also includes propiconazole, another triazole fungicide subject to reregistration. However, 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.
- The registrant has agreed to delete all food uses (except pineapple) and residential turf uses. Therefore, the Reregistration Eligibility Decision document only evaluates risks from all currently supported uses of triadimefon.

## Uses

- Triadimefon is used to control various fungal diseases in fruit (pineapple) and non-food use sites such as: pine seedlings, Christmas trees, residential (sod farm) and commercial turf, ornamentals, and landscapes.
- Triadimenol is used as a seed treatment on: barley, corn, cotton, oats, rye, sorghum, and wheat. There is also an import tolerance for bananas.
- Total triadimefon use averaged 135,000 lbs ai/year with an upper-end estimate of 266,000 lbs ai/year.
- Approximately 24,000 lbs ai of triadimenol are applied annually.

## Health Effects

- The endpoint of concern for triadimefon and triadimenol is neurotoxicity, which was observed in rat, mice, and rabbit studies.
- 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.
- The Cancer Assessment Review Committee (CARC) assigned triadimefon and triadimenol a classification of Category C "possible human carcinogen." As a result, a quantitative cancer risk assessment was not appropriate and was not conducted. The human health risk assessment was based on the population adjusted dose (PAD) and margin of exposure (MOE) approaches, only.

## Ecological Effects

- Triadimefon is classified as moderately toxic to freshwater fish and invertebrates on an acute basis.
- Triadimenol is classified as slightly toxic to freshwater fish and moderately toxic to freshwater invertebrates on an acute basis.
- No triadimefon or triadimenol acute toxicity tests were submitted for estuarine/marine fish or invertebrates.
- Triadimefon and triadimenol are classified as practically non-toxic to birds on an acute basis.
- Triadimefon and triadimenol are classified as slightly toxic to mammals on an acute basis.

## Risks

- Combined acute dietary (food and water) risk estimates were calculated based on combined dietary exposure from pineapples (triadimefon) and drinking water (triadimefon from golf course application to entire golf course), seed treatment uses (triadimefon and triadimenol) and bananas (triadimenol import tolerance). Risks were below the Agency's level of concern (<100% aPAD) at the 95th 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 was 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.
- The chronic dietary risk from exposure to food and drinking water was below the Agency's level of concern, at 18% of the cPAD for the U.S. population and 57% of the cPAD for non-nursing infants, the most highly exposed population subgroup.
- Inhalation risks for residential handlers were below the level of concern for all residential uses of triadimefon. However, combined dermal and inhalation risks were above the level of concern (MOEs < 1000) for mixing, loading, and applying triadimefon with a hose-end sprayer to greenhouse ornamentals.
- In the majority of occupational scenarios where data are available, combined dermal and inhalation risks were below the level of concern at baseline (long-sleeve shirt, long pants, shoes, socks, no respirator) or baseline plus chemical-resistant gloves. However, there were 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.
- Acute and chronic RQs for birds and mammals exceeded the level of concern.
- Risks (RQs) did not exceed the level of concern for freshwater fish, freshwater invertebrates, and aquatic non-vascular plants.
- No data were available to assess the risks to estuarine/marine invertebrates, estuarine/marine fish, vascular aquatic plants, and terrestrial plants.
- The Agency's screening level ecological risk assessment for endangered species resulted in the determination that triadimefon will have no direct acute effects on threatened and endangered freshwater fish, freshwater aquatic invertebrates, and aquatic non-vascular plants. However, the assessment indicated that triadimefon has the potential for causing acute risk to endangered birds and mammals. Chronic RQs for endangered mammals exceeded the level of concern at all application rates modeled. Chronic RQs for endangered birds also exceeded the level of concern. No data were 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.

## Risk Mitigation

The following risk mitigation measures are required for triadimefon and triadimenol to address risks of concern.

### ***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.

### ***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.

### ***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.

### ***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).

### **Regulatory Conclusion**

- EPA has determined that all supported uses of triadimefon are eligible for reregistration, provided that: 1) required product-specific data are submitted; 2) risk mitigation measures outlined in the decision document are adopted; and 3) label amendments are made to reflect these measures.
- The following uses of triadimefon are being voluntarily cancelled by the registrant: all food uses (apples, pears, grapes, and raspberries), except pineapple, and residential turf use. The Agency will take regulatory action under FFDCA to revoke the associated tolerances.
- 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. However, product-specific and generic data are required to be submitted.

### **Generic Data Requirements**

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 the decision document:

#### **Human Health Effects - Triadimefon**

<b>Guideline Study Name</b>	<b>New Harmonized Test Guideline No.</b>
Developmental Neurotoxicity Study (DNT)	870.6300

### Ecological Effects - Triadimefon

Guideline Study Name	New Harmonized Test Guideline No.
Estuarine/Marine Fish LC50	850.1015
Estuarine/Marine Mollusk EC50	850.1025
Estuarine/Marine Shrimp EC50	850.1035
Seedling Emergence	850.4225
Vegetative Vigor	850.4250
Aquatic Vascular Plant Growth	850.4400

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 the decision 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 the decision document.

### Product Chemistry - Triadimenol

Guideline Study Name	New Harmonized Test Guideline No.
Stability	830.6313
pH ( H <sub>2</sub> O solutions)	830.7000
Ultraviolet/visible Absorption	830.7050
Partition Coefficient (N-octanol/water)	830.7550 830.7560 OR 830.7570
Water Solubility	830.7840 OR 830.7860

### Toxicology- Triadimenol

Guideline Study Name	New Harmonized Test Guideline No.
Acute neurotoxicity study	870.6100
Subchronic neurotoxicity Study	870.6200

## 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.

Top of page

## For More Information

Electronic copies of the Triadimefon RED and Tolerance Reassessment for Triadimenol and all supporting documents are available in the Agency's electronic docket on the internet at <http://www.regulations.gov> under docket number EPA-HQ-OPP-20050258 and EPA-HQ-OPP- 2006-0038, respectively.

For more information about EPA's pesticide reregistration program, the Triadimefon RED, or reregistration of individual products containing triadimefon and triadimenol, please contact the Special Review and Reregistration Division (7508C), Office of Pesticide Programs, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is <http://npic.orst.edu>. [EXIT Disclaimer](#)