

US EPA ARCHIVE DOCUMENT

# EPA R.E.D. FACTS

## Thiram

### 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 which were 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, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act 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 the safety standard of the FQPA and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0122, thiram.

### Use Profile

Thiram is a non-systemic fungicide used to prevent crop damage in the field and to protect harvested crops (apples, peaches, and strawberries) from deterioration in storage or transport. It is also used as a seed protectant (e.g. small seeded vegetables, large seeded vegetables, cereal grains and other seeds, coniferous seeds, cotton seed, ornamental seeds, and soybeans) and to protect turf from fungal diseases. In addition, thiram is used as an animal repellent to protect crops from damage by rabbits, rodents, and deer. Formulations include dust, wettable powder, water dispersable granule, flowable concentrate, dry flowable, soluble concentrate, and ready-to-use liquid. Thiram is applied to seeds prior to planting both by commercial seed treaters and on-farm applicators.

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Approximately 165,000 pounds of thiram are applied to 35,000 acres of strawberries, apples, and peaches annually. Approximately 631,000 pounds of thiram are used to treat approximately 1.3 billion pounds of seed annually.

### **Regulatory History**

Thiram has been registered in the United States since 1948 for use as a non-systemic, protectant dithiocarbamate fungicide. During the second phase of reregistration, the Agency conducted a review of the scientific data base underlying pesticide registrations and identified missing or inadequate studies. Subsequent Data Call-Ins (DCIs) were issued in 1991 and 1995 for thiram.

### **Human Health Assessment**

#### **Toxicity**

Thiram exhibits low to moderate acute toxicity via the oral (Toxicity Category III) and dermal (Toxicity Category III) routes of exposure. Thiram is considered to be moderately toxic via the inhalation route of exposure (Toxicity Category II). It is a moderate eye irritant (Toxicity Category II), a slight dermal irritant (Toxicity Category IV) and a moderate skin sensitizer.

Thiram is a neurotoxicant and can also act as a developmental toxicant. The neurotoxic effects of thiram seen in laboratory animals include lethargy and reduced motor activity. Developmental effects seen in laboratory animals include severe fetal malformations. In carcinogenicity studies in rats and mice, thiram did not demonstrate any significant evidence of carcinogenic potential.

#### **Dietary Exposure (Food and Water)**

People may be exposed to residues of thiram through the diet. Tolerances or maximum residue levels have been established for apples, peaches, and strawberries. The registrant voluntarily agreed to halt after December 31, 2004, the distribution or sale of any thiram product bearing a label that includes uses on strawberries, unless and until EPA has determined certain conditions are satisfied. Please refer to the Dietary Risk Mitigation section for further discussion.

EPA has assessed the dietary risk posed by thiram. Acute risks from aggregate exposures are not of concern due to removal of strawberries from the label, a voluntary request for cancellation of apple uses, and requests for voluntary cancellation of most residential uses. Models have been used to estimate ground and surface water concentrations. The Agency concludes with reasonable certainty that aggregate exposure to food and drinking water will not result in an unacceptable acute, short-term, or chronic risk.

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## Occupational and Residential Risk

**Residential Risk.** Thiram will no longer be available for sale or use by homeowner applicators. As such, all residential risks were calculated related to the non-residential turf uses that include golfing for adults and toddler exposures in areas that can be treated with thiram by certified pesticide applicators. Margins of-Exposure (MOEs) for golfers are not of concern to the Agency, and therefore no risk mitigation measures are required to address this scenario. To protect children from potential exposure to thiram treated turf and to further protect from exposure to ornamentals treated with thiram as a deer repellent, the Agency is requiring mitigation measures outlined below.

**Occupational Risk.** The Agency calculated the potential exposure and risk to pesticide handlers from 28 major occupational exposure scenarios. Worker risk is measured by an MOE, which determines how close the occupational exposure comes to the No-Observed-Adverse-Effect-Level (NOAEL) taken from an animal study. A MOE of 100 or greater, for both the dermal and inhalation route is considered to be protective for thiram.

Occupational exposure and risk estimates were conducted using maximum application rates and high-end assumptions. The results of the worker exposure assessment indicate that most potential exposure scenarios result in MOEs greater than or equal to the target MOE of 100 for dermal and inhalation for all of the seed crops treated with thiram products being actively sold in the U.S.

Workers can also be exposed to thiram residues by entering previously treated areas to perform activities. The Restricted Entry Interval (REI) is used by the Agency to manage risks for postapplication workers doing activities that require contact with treated surfaces. The REI is the amount of time required after application before residues decline to a level so entry into the treated area and engaging in any task or activity would not result in exposures which are of concern. Current labels for thiram specify an REI of 24 hours. Current REIs are protective for most crops, however risks for reentry workers are of concern for very high exposure activities. The number of days required for MOEs to reach the Agency's level of concern MOE of 100 is two days for peach thinning on the East coast. Risks are a concern for high exposure activities such as transplanting and hand weeding sod (MOEs>100 at 12-21 days). The Agency has no concern with maintaining the current REI of 24 hours because the apple use has been voluntarily cancelled, and the MOE for peaches is almost 100 (i.e., 94 after 24 hours).

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## FQPA Considerations

No Special FQPA Safety Factor is necessary to protect the safety of infants and children because there is no quantitative or qualitative evidence of increased susceptibility following in utero or postnatal exposure in any of the developmental or reproductive studies, and the toxicity endpoints selected are protective of pre/postnatal toxicity following acute and chronic exposures.

Thiram is classified as “not likely to be carcinogenic to humans ” according to the EPA *Draft Proposed Guidelines for Carcinogen Risk Assessment* (July 2, 1999).

## Environmental Assessment

### Environmental Fate

Thiram is expected to be sufficiently mobile and persistent in some cases to reach surface waters in concentrations high enough to impact aquatic life.

### Ecological Effects

Mammals and birds in the field may be exposed to thiram by ingesting treated seeds or by other routes, such as incidental ingestion of contaminated soil, dermal contact with treated seed surfaces and soil during activities in the treated areas, inhalation of pesticide vapor and contaminated particulate, and ingestion of drinking water contaminated with the pesticide.

The ecological risk assessment for birds shows risks for reproductive effects to birds. There is a chronic effect to mammals including endangered species, and for fish and aquatic invertebrates including endangered species. Risk quotients range from 0.1 to 28. The Agency’s assessment suggested that a number of endangered species may potentially be impacted by thiram; however, this RED includes only risk mitigation for the Attwater’s Prairie Chicken (*Tympanuchus cupido attwateri*). The mitigation measures contained in the RED address the Agency’s ecological risks of concern.

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. As discussed above, Agency estimates of exposure indicate risks of reproductive effects to endangered species of birds. The foliar and turf uses of thiram may pose an acute risk to endangered fish and invertebrate species, and a chronic risk to endangered mammalian species. However, based on the ecological risk assessment conducted for thiram and implementation of the mitigation procedures described in the RED, EPA has determined that thiram will

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have no effect on the Attwater Prairie Chicken. Relating to any additional endangered species concerns, these findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Based on information provided by the U.S. Fish and Wildlife Service, the endangered species profile, and communications with refuge managers, the Attwater's Prairie Chicken (*Tympanuchus cupido attwateri*) may be at risk for consuming thiram-treated seed.

### **Risk Mitigation     Dietary Risk Mitigation**

The Agency has worked with the registrant, Taminco, Inc. (Taminco), to reduce potential exposure to thiram from treated strawberries and apples. Subsequently, Taminco has requested voluntary cancellation of thiram use on apples and will amend its registration to remove strawberries from its label pending receipt, review, and acceptability of additional data (a strawberry processing study and a Developmental Neurotoxicity Study). The percent of the aPAD considering dietary contributions from strawberries and peaches only is 273. Without strawberries, the percent of the aPAD is reduced to 9.

To further reduce dietary concerns, the Agency has determined that the following label changes for specific scenarios are appropriate and required for reregistration eligibility:

- "Treated [Seed, Bulbs, Seed Pieces] - Do Not Use for Food, Feed, or Oil Purposes."

### **Drinking Water Risk Mitigation**

As previously discussed above, the acute, short-term and chronic risks from aggregate exposures are not of concern to the Agency and no further mitigation is necessary.

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## Residential Risk Mitigation

To protect children from scenarios of concern (MOE=4) for exposure to thiram treated turf) and to further protect from exposure to ornamentals treated with thiram as a deer repellent, the Agency is requiring the following label modifications:

### Deer Repellent Use:

- Use one quart of this product in 3 to 7 gallons of water for application to 1000ft<sup>2</sup>.
- Applications to ornamentals will be restricted to the following 17 Northern states and applications will occur during the winter season only (October thru March): OH, PA, NY, MI, CT, MA, IN, IL, NJ, WV, MN, WI, VT, NH, RI, DE, and MD.

### Cancellations of Turf/Other Uses:

- Turf applications to parks, athletic fields and commercial landscapes.
- All turf applications for turf grown for sale or other commercial use such as sod.
- All homeowner and retail uses on residential lawns and turf
- Residential homeowner use as a fungicide on bulbs, flower seeds, greenhouse and nursery cuttings, and pruning paints.

Through these label amendments and voluntary cancellations to remove all homeowner uses from Taminco, the Agency believes exposure to the deer repellent use will be insignificant and therefore not of concern. No additional mitigation is necessary.

## Occupational Risk Mitigation

### Handler exposure

To reduce worker exposure, the Agency has determined that the following label changes for specific scenarios are appropriate and required for reregistration eligibility:

- Mixers/Loaders/Applicators/Other Handlers (general): wear baseline (long-sleeve shirt, long pants, shoes, socks, no respirator) plus chemical resistant gloves for the following scenarios (mixer/loaders wear a chemical resistant apron):
  - liquids or dry flowables applied aerially
  - liquids, dry flowables or sprays applied via airblast



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- liquids, dry flowables or sprays applied via groundboom
  - liquids or dry flowables applied via a high pressure handwand
  - liquids or dry flowables applied for rights of way
  - liquids applied as a paint-on application
  - solid broadcast spreader
  - repellent paint brush use
  - sprinkler can
  - ready-to-use solutions
  - wettable powder paint-on
  - dry flowable paint-on
  - Mixers/loaders/applicators/other handlers (packaged seed): seed that has been treated with this product that is then packaged or bagged for future use must bear labeling that contains the restricted-entry interval (REI) information and the following text on the outside of the seed package or bag: “Persons opening this bag or loading/pouring the treated seed, must wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves.”
  - Flaggers: wear baseline (long-sleeve shirt, long pants, shoes, socks, no respirator for the following scenarios:
    - sprays applied aurally

In addition to the above mentioned PPE requirements, the registrant has agreed to the following use modifications/amendments to further address the Agency’s concerns:

- Cancellation of the aerial and hand/spoon applications
- Changing all wettable powder formulations to water soluble bag formulations.
- Cancellation of on-farm seed treatment of peanuts

The following mitigation addresses the risks of concern for high exposure activities associated with apples and sod:

- Cancellation of all turf applications for turf grown for sale or other commercial use such as sod.
- Cancellation of all apple uses.



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### Post-Application Risk Mitigation

EPA has determined that the current 24 hour REI is appropriate, and labels must contain the following language to be eligible for reregistration:

“After the [seeds, bulbs, seed pieces] have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours. Exception: Once the seeds, bulbs, seed pieces are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the [seeds, bulbs, seed pieces].”

### **Environmental Risk Mitigation**

To reduce risks to mammals, birds, and aquatic species, the Agency, in agreement with the technical registrants of thiram, has developed several mitigation requirements to address the above mentioned concerns (mitigation measures concerning strawberries are contingent upon if EPA determines that one or more of the uses on strawberries is/are not eligible for reregistration). They include:

- A statement added to the label “Treated [seeds, seed pieces, bulbs] are hazardous to fish, birds and mammals. Do not plant treated seeds or seed pieces by broadcasting to the soil surface. Ensure that all [seeds, seed pieces, bulbs] are thoroughly covered with soil, especially in turn areas. If [seeds, seed pieces, bulb] are not thoroughly incorporated by the planter during planting, additional incorporation may be required to thoroughly cover exposed [seeds, seed pieces, bulbs].”
- A statement added to the label: “This chemical is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.”
- Cancellation of thiram use on apples.
- Restriction of thiram use on golf courses to tees and greens only.
- Reduction of the winter golf course treatment from a maximum of four applications to a maximum of one application.
- Reduction of summer golf course treatment from a maximum of eight applications to a maximum of three applications.

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- Restrict the number of annual applications of thiram to golf courses to 47 pounds of active ingredient per acre (this corresponds to a 40% total reduction in thiram use on golf courses).
  - For the golf course use, increase the re-treatment interval from 7 to 14 days.
  - For strawberries, limit the maximum number of applications to five at 2.6 lbs ai/Acre.
  - For strawberries, East of the Mississippi River, limit the maximum number of applications to twelve at 2.6 lbs ai/Acre.
  - For strawberries, add a label statement to indicate that 1.3 lbs ai/Acre should be used when thiram is used in combination with other fungicides.
  - For strawberries, the label will establish a 25 foot vegetative buffer zone from water bodies.
  - For cotton, reduce the maximum treatment rate for cotton seed from 2.25 oz. ai/cwt (1406 ppm) when treated with thiram as a single active ingredient to 1.6 oz. ai/cwt (1,000 ppm) reflecting the global use rate for thiram on imported and exported cotton seed.
  - For cotton, reduce the maximum treatment rate for cotton seed for thiram in products containing multiple active ingredients to 1.0 oz. ai/cwt (625 ppm).
  - For cotton, wheat, barley, oats, and sugar beets include the statement plant seed a minimum of 1 inch deep.

Upon examining the risks and requiring the above listed mitigation measures, the Agency believes that concerns noted in Chapter 3 and above have been adequately mitigated. No further mitigation is needed at this time.

In conjunction with other local and federal agencies, EPA will continue to evaluate whether currently identified and/or additional endangered species may be impacted by exposure to thiram.

#### **Additional Data Required**

EPA requires additional generic studies for thiram to confirm its regulatory assessments and conclusions.

Most product chemistry data requirements are satisfied; however, additional data are required for Prochimie 98.5% Technical and Gustafson 97.5% Technical, and Prochimie 98.5% Technical. Please refer to Appendix E of the RED for a complete list.

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The Agency is uncertain regarding the endocrine disrupting potential of thiram and, once the appropriate testing protocols have been established for examining endocrine disruption, thiram may be subject to this battery of tests.

**Product Labeling  
Changes Required**

All thiram end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the thiram RED document.

**Regulatory  
Conclusion**

The use of currently registered products containing thiram in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Thiram products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

**For More  
Information**

To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See <http://www.epa.gov/REDs>.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the thiram RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the thiram RED, or reregistration of individual products containing thiram, please contact the Special Review and Reregistration Division (7508C), OPP, 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

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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. Their internet address is <http://npic.orst.edu>.