

## ANNEXE 3





United States  
Environmental Protection  
Agency

Prevention, Pesticides  
and Toxic Substances  
(7508P)

EPA 738R-06-027  
July 2006

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# Reregistration Eligibility Decision (RED) for Propiconazole

**REREGISTRATION ELIGIBILITY**

**DECISION**

**for**

**Propiconazole**

Case No. 3125

List C

Approved by:

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Debra Edwards, Ph.D.  
Director, Special Review and  
Reregistration Division

July 18, 2006

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Date

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## **ABSTRACT**

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for propiconazole and is issuing its risk management 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 registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of propiconazole that pose risks of concern. As a result of this review, EPA has determined that propiconazole-containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

### **I. Introduction**

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). Reregistration involves a thorough review of the scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the “no unreasonable adverse effects” criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA and the Federal Food, Drug, and Cosmetic Act (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 of 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, FQPA requires EPA to 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 chemicals causing a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any one of these individual chemicals. Propiconazole belongs to a group of pesticides called triazoles (or conazoles), which also includes the triazole fungicides subject to reregistration, triadimefon and triadimenol. For the purpose of this reregistration eligibility decision (RED), EPA has concluded that propiconazole does not share a common mechanism of toxicity with other substances. However, the triazole fungicides share common metabolites, the free triazole compounds 1,2,4-triazole, triazole

<b>Table 1. National Agricultural Usage of Propiconazole – Highest Use Sites</b>			
<b>Crop</b>	<b>Average Annual Amount Used (lbs. a.i.)</b>	<b>Average Annual Total Area Treated (A)</b>	<b>Average Annual Percent Crop Treated</b>
Dry Beans/Peas	560	5,300	51
Filberts	1,500	8,500	19
Peaches	12,000	110,000	31
Peanuts	48,000	810,000	73
Pecans	38,000	410,000	18
Prunes	4,400	40,000	18
Rice	58,000	420,000	55
Sweet Corn	15,000	140,000	11
Wheat, Spring	57,000	780,000	56
Wheat, Winter	91,000	940,000	62

EPA Source Data and USDA NASS (2000-2004)

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

The following is a summary of EPA’s human health and ecological effects risk assessments for propiconazole, as presented fully in the following documents:

- *Propiconazole: Phase 4, HED Chapter of the Re-registration Eligibility Decision Document (RED)*. June 28, 2006
- *Revised Drinking Water Assessment of Propiconazole*. June 7, 2006
- *Propiconazole: Revised Occupational and Residential Exposure Assessment of the Antimicrobial Uses to Support the Reregistration Eligibility Decision (RED) Document*. February 1, 2006.
- *Propiconazole: Amendment to the Propiconazole Reregistration Eligibility Decision (RED) Document for Children’s Postapplication Exposure Treated Structures*. June 20, 2006
- *Environmental Fate and Effects Division Revised RED for the Reregistration of Propiconazole*. June 30, 2006

Risks for 1,2,4-triazole, triazole alanine, and triazole acetic acid are considered in this RED because they are common metabolites of propiconazole and other triazole fungicides. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments.

The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to reach the safety finding and regulatory decision for propiconazole. Although the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket OPP-2005-0497 and may also be accessed on the website [www.regulations.gov](http://www.regulations.gov). Hard copies of these documents may be found in the OPP public docket under this same docket number.



## A. Human Health Risk Assessment

EPA released its preliminary risk assessments for propiconazole, 1,2,4-triazole, triazole alanine, and triazole acetic acid for public comment on February 15, 2006 for a 60-day public comment period (Phase 3 of the public participation process). The preliminary risk assessments may be found in the OPP public docket at the address given above and on the website [www.regulations.gov](http://www.regulations.gov). In response to comments received and new studies submitted during Phase 3, the risk assessments were updated and refined. The human health risk assessment for propiconazole was revised on June 28, 2006, to incorporate comments and additional studies submitted by the registrant. In addition, the Agency is considering late comments on the 1,2,4-triazole risk assessment which may allow EPA to refine the risk assessments for the free triazoles. However, because these risk assessment refinements are not expected to alter the conclusions of the propiconazole RED, they are not incorporated into this decision document. The Agency's use of human studies in the propiconazole risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

Revised risk assessments for propiconazole may be found in the OPP dockets under docket number OPP-2005-0497. Major revisions to the risk assessment include the following:

- Revision of estimated drinking water concentrations (EDWCs) used in the dietary risk assessment;
- Incorporation of new drinking estimates, new food residue estimates for rice and processed commodities, and the revised FQPA safety factor into the dietary risk assessment; and
- Consideration of post-application residential risk associated with use of propiconazole as a wood preservative on dimensional lumber.

The human health risk assessment incorporates potential exposure from all sources, which include food, drinking water, residential (if applicable), and occupational 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. The Agency's human health assessment is protective of all U.S. populations, including infants and young children.

This document summarizes risk estimates for both propiconazole and its free triazole metabolites 1,2,4-triazole, triazole alanine, and triazole acetic acid. Propiconazole and the other triazole fungicides metabolize to these 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 aggregate or combined risks from food, drinking water and non-occupational exposure resulting from propiconazole alone and from the free triazoles from all sources. In addition, EPA has also considered potential co-exposure to free triazoles resulting from pharmaceutical uses of triazole compounds. The aggregate risk from all sources of the free triazoles must be considered to reassess the tolerances for propiconazole in accordance with FQPA. Because the risks associated with the free triazoles are all below the Agency's level of concern, they are not addressed in as much detail as the risks from propiconazole. Additional details regarding the risks associated with the free triazoles may be found in the February 3, 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-2005-0497).

## **1. Toxicity of Propiconazole and the Free Triazoles**

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 effects, or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for propiconazole and has determined that the toxicological database is complete, reliable, and sufficient for reregistration. For more details on the toxicity of propiconazole, see the January 27, 2006 document, *Propiconazole – Hazard Characterization Assessment for the Reregistration Eligibility Decision*, which is available under docket number EPA-HQ-OPP-2005-0497.

As previously mentioned, 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 propiconazole. 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* and *TRIAZOLES – 2<sup>nd</sup> Report of the Ad Hoc HED Peer Review Committee*, which is available under docket number EPA-HQ-OPP-2005-0497.

### **a. Acute Toxicity Profile for Propiconazole**

Propiconazole is classified as category III for acute oral and dermal toxicity and as category IV for acute inhalation toxicity. It is classified as category III for eye irritation potential and category IV for skin irritation potential. Propiconazole caused dermal sensitization in guinea pigs. The acute toxicity profile for technical grade propiconazole is summarized in Table 2 below. These data are presented only to provide background information on the active ingredient and may not be appropriate for product reregistration. Additional acute toxicity data may be required to determine appropriate cautionary label language for products containing propiconazole. Acute toxicity data are not presented for the free triazoles because they do not occur in pesticide products, and thus are not considered in product labeling.

<b>Table 2. Acute Toxicity Profile for Propiconazole</b>				
<b>Guideline</b>	<b>Study Type</b>	<b>MRID</b>	<b>Results</b>	<b>Toxicity Category</b>
870.1100	Acute Oral – Rat	00058591	LD <sub>50</sub> = 1517 mg/kg	III
870.1200	Acute Dermal - Rabbit	0058596	LD <sub>50</sub> ≥ 4000 mg/kg	III
870.1300	Acute Inhalation	41594801	LC <sub>50</sub> ≥ 5.84 mg/L	IV
870.2400	Primary Eye Irritation	00058598	Corneal Opacity reversed in 72 hours	III
870.2500	Primary Skin Irritation	00058598	Non- irritant	IV
870.2600	Dermal Sensitization	44949501	Sensitizer	N/A
LD <sub>50</sub> or LC <sub>50</sub> - Median Lethal Dose or Concentration, statistically derived single dose or concentration that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). N/A - not applicable.				

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

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), directs the Agency to use an additional ten fold (10X) safety factor (SF) to account for potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA authorizes the Agency to modify the 10X FQPA SF only if reliable data demonstrate that the resulting level of exposure would be safe for infants and children.

##### *Propiconazole*

The Agency has reviewed the toxicology database for propiconazole and concluded that it is adequate to characterize any potential for prenatal or postnatal risk for infants and children. The requirement for a developmental neurotoxicity study in propiconazole was waived because no effects were seen in a submitted acute neurotoxicity study. In light of the existing toxicology database for propiconazole, EPA concluded that there is low concern for pre- and/or postnatal toxicity resulting from exposure to propiconazole and that there are no residual uncertainties. Because there was no evidence of increased susceptibility, the FQPA SF for propiconazole *per se* was reduced to 1X. This SF also considers the completeness of the exposure database for food, drinking water, and residential exposure. The FQPA SF reflects the Agency's confidence that the risk assessment for each potential exposure scenario includes all metabolites and degradates of concern and will not result in an underestimate of dietary or residential risks to infants and children.

##### *Free Triazoles*

1,2,4-Triazole. EPA has reviewed the available toxicology studies for 1,2,4-triazole and determined that the database is sufficient to conduct an FQPA assessment and adequate to characterize prenatal and postnatal effects. From the existing toxicity data, the Agency has concluded that there are low residual concerns and no residual uncertainties with regard to pre- and/or postnatal toxicity of

1,2,4-triazole. However, EPA has retained a 10X FQPA SF based on nervous system effects and database uncertainties, including data gaps for the acute and developmental neurotoxicity studies. (A developmental neurotoxicity study is required for 1,2,4-triazole.) The Agency believes that the exposure estimates for 1,2,4-triazole will not result in an underestimation of either dietary or residential risks to infants and children.

*Triazole Conjugates (Triazole Alanine and Triazole Acetic Acid).* For the triazole conjugates, triazole alanine and triazole acetic acid, the toxicology database is incomplete to characterize increased potential increased susceptibility to pre- and postnatal effects. However, the available rat developmental toxicity and two-generation reproduction studies for these conjugates showed increased qualitative and quantitative susceptibility of the offspring. Therefore, the 10X FQPA SF is retained for increased susceptibility and database uncertainties (data gaps for rabbit developmental toxicity studies with triazole alanine and triazole acetic acid, a chronic rat study with triazole alanine, and a combined 90-day/subchronic neurotoxicity rat study for triazole acetic acid). Although increased qualitative and quantitative susceptibility of the offspring was seen in the developmental toxicity and two-generation reproduction studies in rats, the currently selected dietary, residential, and occupational endpoints are all based on no observed adverse effects levels (NOAELs) that are protective of these adverse effects. Additionally, no evidence of neurotoxicity was seen in the available toxicology database, so a developmental neurotoxicity study is not being required at this time. The Agency believes that the exposure estimates for the triazole conjugates will not result in an underestimation of either dietary or residential risks to infants and children.

### c. Toxicological Endpoints

*Propiconazole.* The toxicological endpoints used in the human health risk assessment for propiconazole are listed in Table 3 below, as well as the estimated dermal and inhalation absorption factors used in the risk assessment. The Agency estimated that 40% of an applied dose of propiconazole is absorbed through the skin, based on a rat dermal absorption study. For inhalation exposure, EPA used a default factor of 100% absorption. The uncertainty factors (UF) and safety factors used to account for interspecies extrapolation, intraspecies variability, and special susceptibility of infants and children (FQPA SF) are also described in Table 3.

<b>Exposure Scenario</b>	<b>Dose, Uncertainty Factors (UF)</b>	<b>FQPA Safety Factor (SF) and Level of Concern</b>	<b>Study and Toxicological Endpoint for Risk Assessment</b>
Acute Dietary (Females age 13-50)	NOAEL = 30 mg/kg/day  UF =100  Acute RfD = 0.3 mg/kg/day	FQPA SF = 1  $aPAD = \frac{\text{acute RfD}}{\text{FQPA SF}}$  = 0.3 mg/kg/day	Developmental Toxicity Study - Rats. Increased incidence of rudimentary ribs, cleft palate malformations (0.3%) unossified sternbrae, as well as increased incidence of shortened and absent renal papillae at LOAEL of 90 mg/kg/day.

<b>Table 3. Toxicological Doses and Endpoints for Propiconazole for Use in Human Health Risk Assessments</b>			
<b>Exposure Scenario</b>	<b>Dose, Uncertainty Factors (UF)</b>	<b>FQPA Safety Factor (SF) and Level of Concern</b>	<b>Study and Toxicological Endpoint for Risk Assessment</b>
Acute Dietary (General Population including infants and children)	NOAEL = 30 mg/kg/day UF = 100 Acute RfD = 0.3 mg/kg/day	FQPA SF = 1  aPAD = $\frac{\text{acute RfD}}{\text{FQPA SF}}$  = 0.3 mg/kg/day	Acute Neurotoxicity Study - Rats. Clinical toxicity: piloerection, diarrhea, tip toe gait at LOAEL of 100 mg/kg/day.
Chronic Dietary (All populations)	NOAEL = 10 mg/kg/day UF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1  cPAD = $\frac{\text{chronic RfD}}{\text{FQPA SF}}$  = 0.1 mg/kg/day	24 Month Oncogenicity Study - Mice. Liver toxicity; increased liver weight in males, and increase in liver lesions (masses/raised areas/swellings/nodular areas). LOAEL is 50 mg/kg/day.
Short-Term Incidental Oral (1-30 days)	NOAEL= 30 mg/kg/day UF = 100	FQPA SF = 1  Residential LOC for MOE is 100.	Acute Neurotoxicity Study - Rats. Clinical toxicity: piloerection, diarrhea, tip toe gait at LOAEL is 100 mg/kg/day.
Intermediate-Term Incidental Oral (1 - 6 months)	NOAEL= 10 mg/kg/day UF = 100	FQPA SF = 1  Residential LOC for MOE is 100.	24 Month Oncogenicity Study - Mice. Liver toxicity; increased liver weight in males, and increase in liver lesions (masses/raised areas/swellings/nodular areas) ). LOAEL is 50 mg/kg/day.
Short-Term Dermal (1 - 30 days) (general population including infants and children)	Oral NOAEL= 30 mg/kg/day UF = 100  (Dermal absorption rate = 40%)	FQPA SF = 1  Residential LOC for MOE is 100.  Occupational LOC for MOE is 100.	Acute Neurotoxicity Study - Rats. Clinical toxicity: piloerection, diarrhea, tip toe gait at LOAEL of 100 mg/kg/day.
Intermediate- (1 - 6 months) and Long-Term Dermal (>6 months)	Oral NOAEL= 10 mg/kg/day UF = 100  (Dermal absorption rate = 40%)	FQPA SF = 1  Residential LOC for MOE is 100.  Occupational LOC for MOE is 100.	24 Month Oncogenicity Study - Mice. Liver toxicity; ncreased liver weight in males and increase in liver lesions (masses/raised areas/swellings/nodular areas).

<b>Table 3. Toxicological Doses and Endpoints for Propiconazole for Use in Human Health Risk Assessments</b>			
<b>Exposure Scenario</b>	<b>Dose, Uncertainty Factors (UF)</b>	<b>FQPA Safety Factor (SF) and Level of Concern</b>	<b>Study and Toxicological Endpoint for Risk Assessment</b>
Short-Term Inhalation (1 - 30 days)	Oral NOAEL= 30 mg/kg/day  UF = 100  (Inhalation absorption rate = 100%)	FQPA SF = 1  Residential LOC for MOE is 100.  Occupational LOC for MOE is 100.	Acute Neurotoxicity Study - Rats. Clinical toxicity: piloerection, diarrhea, tip toe gait at LOAEL of 100 mg/kg/day. LOAEL is 50 mg/kg/day.
Intermediate-Term (1 - 6 months) and Long-Term Inhalation (>6 months)	Oral NOAEL= 10 mg/kg/day  UF = 100  (Inhalation absorption rate = 100%)	FQPA SF = 1  Residential LOC for MOE is 100;  Occupational LOC for MOE is 100.	24 Month Oncogenicity Study - Mice. Liver toxicity (increased liver weight in males and increase in liver lesions (masses/raised areas/swellings/nodular areas)). LOAEL is 50 mg/kg/day.
Cancer (Oral, dermal, inhalation)	Classified as a Group C, possible human carcinogen, RfD used for risk characterization because the chronic RfD is protective of any potential carcinogenic effects.		
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.			

*Free Triazoles.* The toxicological endpoints used in the assessment for the free triazoles are presented 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 docket EPA-HQ-OPP-2005-0497. The toxicological endpoints used in the human health risk assessments for 1,2,4-triazole and the conjugates triazole alanine and triazole acetic acid are summarized in Tables 4 and 5, respectively. Because the available data on the conjugates are limited, the Agency has assumed that all conjugates (i.e., triazole alanine and triazole acetic acid) are toxicologically equivalent. For both dermal and inhalation exposure, EPA assumed that 100% of applied dose is absorbed.

<b>Table 4. Toxicological Doses and Endpoints for 1,2,4-Triazole for Use in Human Health Risk Assessments</b>			
<b>Exposure Scenario</b>	<b>Dose, Uncertainty Factors (UF)</b>	<b>FQPA Safety Factor (SF) and Level of Concern</b>	<b>Study and Toxicological Endpoint for Risk Assessment</b>
Acute Dietary (females age 13-49)	NOAEL = 30 mg/kg/day UF=100 Acute RfD = 0.3 mg/kg/day	FQPA SF = 10 aPAD = $\frac{\text{acute RfD}}{\text{FQPA SF}}$ = 0.03 mg/kg/day	Developmental Toxicity study – rabbits. LOAEL is 45 mg/kg based on urinary tract malformations in fetuses
Acute Dietary (general population including infants and children)	NOAEL = 30 mg/kg UF=100 Acute RfD = 0.3 mg/kg/day	FQPA SF = 10 aPAD = $\frac{\text{acute RfD}}{\text{FQPA SF}}$ = 0.03 mg/kg/day	Developmental Toxicity study – rabbits. LOAEL is 45 mg/kg based on clinical signs and mortality in does starting on Gestation Day 6 or 7
Chronic Dietary (all populations)	LOAEL = 15 mg/kg/day UF =300 Chronic RfD = 0.05 mg/kg/day	FQPA SF =10 cPAD = $\frac{\text{chronic RfD}}{\text{FQPA SF}}$ = 0.005 mg/kg/day	Reproductive Toxicity study – rats. LOAEL is 15 mg/kg/day based on decreased body weight in adult males, decreased body weight and brain weight in offspring; no NOAEL established for this study (hence additional 3X UF).
Incidental Oral Short-term (1-30 days)	NOAEL = 30 mg/kg/day UF=100	FQPA SF = 10 Residential LOC for MOE is 1000.	Developmental Toxicity study – rabbits. LOAEL is 45 mg/kg/day based on clinical signs and mortality in does starting on Gestation Day 6 or 7.
Incidental Oral Intermediate- or Long-term (30 days to 6 months)	LOAEL = 15 mg/kg/day UF = 300	FQPA SF = 10 Residential LOC for MOE is 3000.	Reproductive Toxicity study – rats. LOAEL is 15 mg/kg/day based on decreased body weight in adult males, decreased body weight and brain weight in offspring; no NOAEL established for this study (hence additional 3X UF)..
Dermal Short-term (1-30 days)	NOAEL = 30 mg/kg/day UF = 100	FQPA SF = 10 Residential LOC for MOE is 1000.	Developmental Toxicity study – rabbits. LOAEL is 45 mg/kg/day based on clinical signs and mortality in does starting on Gestation Day 6 or 7.
Dermal Intermediate- or Long-term (30 days to 6 months)	LOAEL = 15 mg/kg/day UF = 300	FQPA SF = 10 Residential LOC for MOE is 3000.	Reproductive Toxicity study - rats. LOAEL is 15 mg/kg/day based on decreased body weight in adult males, decreased body weight and brain weight in offspring; no NOAEL established for this study (hence additional 3X UF).

<b>Exposure Scenario</b>	<b>Dose, Uncertainty Factors (UF)</b>	<b>FQPA Safety Factor (SF) and Level of Concern</b>	<b>Study and Toxicological Endpoint for Risk Assessment</b>
Inhalation Short-term (1 - 30 days)	NOAEL = 30 mg/kg/day UF = 100	FQPA SF = 10 Residential LOC for MOE is 1000	Developmental Toxicity study – rabbits. LOAEL is 45 mg/kg/day based on clinical signs and mortality in does starting on Gestation Day 6 or 7
Inhalation Intermediate- or Long-term (30 days to 6 months)	LOAEL = 15 mg/kg/day UF = 300	FQPA SF = 10 Residential LOC for MOE is 3000.	Reproductive Toxicity study - rats. LOAEL is 15 mg/kg/day based on decreased body weight in adult males, decreased body weight and brain weight in offspring; no NOAEL established for this study (hence additional 3X UF).
Cancer (oral, dermal, inhalation)	Not Classified for potential carcinogenicity. Any potential cancer effects would be covered using the chronic RfD.		
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.			

<b>Exposure Scenario</b>	<b>Dose, Uncertainty Factors (UF)</b>	<b>FQPA Safety Factor (SF) and Level of Concern</b>	<b>Study and Toxicological Endpoint for Risk Assessment</b>
Acute Dietary (females 13-49)	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1 mg/kg/day	FQPA SF = 10 $aPAD = \frac{\text{acute RfD}}{\text{FQPA SF}}$ = 0.1 mg/kg/day	Prenatal Developmental Toxicity – rat  LOAEL is 300 mg/kg/day based on increased incidence of skeletal findings (unossified odontoid process).
Acute Dietary (general population, including infants and children)	None	None	No appropriate dose and endpoint could be identified for these population groups.
Chronic Dietary (all populations)	NOAEL = 90 mg/kg/day UF = 100 Chronic RfD = 0.9 mg/kg/day	FQPA SF = 10 $cPAD = \frac{\text{chronic RfD}}{\text{FQPA SF}}$ = 0.09 mg/kg/day	90-Day Oral Toxicity – rat  LOAEL is 370/400 mg/kg/day (M/F) based on decreased leukocyte counts in males and decreased triglycerides in females.
Incidental Oral (all durations)	NOAEL = 90 mg/kg/day UF = 100	FQPA SF = 10 Residential LOC for MOE is 1000.	90-Day Oral Toxicity – rat  LOAEL is 370/400 mg/kg/day (M/F) based on decreased leukocyte counts in males and decreased triglycerides in females.



<b>Table 5. Toxicological Doses and Endpoints for the Triazole Conjugates for Use in Human Health Risk Assessments</b>			
<b>Exposure Scenario</b>	<b>Dose, Uncertainty Factors (UF)</b>	<b>FQPA Safety Factor (SF) and Level of Concern</b>	<b>Study and Toxicological Endpoint for Risk Assessment</b>
Dermal (all durations)	NOAEL = 90 mg/kg/day  UF = 100  (dermal absorption rate = 100%)	FQPA SF = 10  Residential LOC for MOE is 1000.  Occupational LOC for MOE is 100.	90-Day Oral Toxicity – rat  LOAEL is 370/400 mg/kg/day (M/F) based on decreased leukocyte counts in males and decreased triglycerides in females.
Inhalation (all durations)	NOAEL = 90 mg/kg/day  UF = 100  (inhal. absorption rate = 100%)	FQPA SF = 10  Residential LOC for MOE is 1000.  Occupational LOC for MOE is 100.	90-Day Oral Toxicity – rat  LOAEL is 370/400 mg/kg/day (M/F) based on decreased leukocyte counts in males and decreased triglycerides in females.
Cancer (oral, dermal, inhalation)	Not Classified for potential carcinogenicity. Any potential cancer effects would be covered using the chronic RfD.		
UF, uncertainty factor; FQPA SF, FQPA safety factor; NOAEL, no observed adverse effect level; LOAEL, lowest observed adverse effect level; RfD, reference dose; PAD, population adjusted dose (a = acute, c = chronic); MOE, margin of exposure; LOC, level of concern; NA, Not Applicable.			

## 2. Carcinogenicity

*Propiconazole.* The Agency classified propiconazole as a Group C, possible human carcinogen, based on increased hepatocellular adenomas, combined adenomas/carcinomas, and hepatocellular carcinomas in male mice in a chronic oral feeding study. However, animals in the high dose group for this study showed excessive toxicity; furthermore, the high dose exceeded the Maximum Tolerated Dose determined in the 90-day range finding study. No treatment-related tumors were seen in female mice in this mouse chronic feeding study. No tumors were noted in a chronic rat study. Therefore, the Reference Dose (RfD) approach is considered to be protective of any carcinogenic effects and is recommended for use in cancer risk assessment for propiconazole. This approach is also consistent with results of voluntary nonguideline mechanism of action studies conducted by the propiconazole technical registrant.

*Mode of Action for Triazole Compounds.* Research by the U.S. Triazole Task Force and by EPA’s National Health and Environmental Effects Research Laboratory (NHEERL) indicates that the hepatic tumors associated with parent triazole compounds occur as a result in changes in liver metabolism rather than by a genetic response to the compound. The triazole compounds do not appear to be carcinogenic by a genotoxic mode of action, but rather by a threshold mechanism. Therefore, a Reference Dose (RfD) approach is considered appropriate for evaluating the hepatic cancer risk associated with these compounds.

*Free Triazoles.* No chronic toxicity or cancer studies are available for 1,2,4-triazole, triazole alanine, or triazole acetic acid. However, 1,2,4-triazole and triazole alanine are not mutagenic. Because a chronic cancer study is not available, the Agency used an RfD approach to assess cancer risks, using the most sensitive toxicity endpoint and an additional 10X uncertainty factor to account

for the absence of chronic toxicity studies. The Agency believes that this approach and the current chronic dietary exposure assessment are sufficiently protective of any cancer-related effects and is consistent with the approach for propiconazole.

### **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). When additional appropriate screening and/or testing protocols being considered under the Agency’s EDSP have been developed, propiconazole and the free triazole metabolites may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

Propiconazole. The toxicology database for propiconazole did not show any estrogen, androgen, or thyroid mediated toxicity.

Free Triazoles. The toxicology database for 1,2,4-triazole showed potential estrogen, androgen, and/or thyroid mediated toxicity, including testicular changes and sperm abnormalities, ovarian changes, delays in sexual maturation, and dose-related decreases in thyroid stimulating hormone. The Agency’s risk assessment for 1,2,4-triazole is protective of these effects. However, none of the available toxicity studies for triazole alanine and triazole acetic acid showed any estrogen, androgen, or thyroid toxicity.

### **4. Factors Considered in EPA’s Aggregate Assessment**

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (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. Because propiconazole and the other triazole fungicides, and other compounds may metabolize to the free triazoles in animals and plants, EPA has considered exposure both to propiconazole and to all sources of the free triazoles in the aggregate risk assessment. The components and basic assumptions of EPA’s exposure and risk assessments for food, drinking water, and residential exposure to propiconazole and the free triazoles are explained below.

**a. Dietary Exposure and Risk**

Dietary risk assessments consider exposure to pesticide residues from both food and drinking water. To estimate dietary risks from food and drinking water, EPA compares the estimated amount of potential exposure to pesticide residues in food and drinking water to the acute or chronic population adjusted dose, or PAD. The PAD is the dose at which an individual could be exposed without adverse health effects. The PAD is derived from the reference dose (RfD), which is adjusted for the FQPA SF. Both acute and chronic dietary risk assessments were conducted for propiconazole. For risks resulting from exposure in food and drinking water, a risk estimate that is less than 100% of the acute or chronic PAD (aPAD or cPAD) does not exceed EPA's level of concern. For propiconazole, the aPAD is 0.3 mg/kg/day for all population subgroups, and the cPAD is 0.1 mg/kg/day.

Although propiconazole is classified as a group C, possible human carcinogen, the Agency believes that the chronic dietary risk assessment will be protective of any potential cancer effects. Therefore an RfD approach was utilized for cancer risk assessment. Acute and chronic dietary risk assessments were conducted for the general US population and several population subgroups, including females age 13-49 and infants <1 year old. Additional details about the dietary risk assessment for propiconazole are described in the August 18, 2005, document, *Propiconazole Acute and Chronic Dietary Exposure Assessment for Reregistration Eligibility Decision (RED)* and in the June 15, 2006 document, *Propiconazole Revised Acute and Chronic Dietary Exposure Assessments for Reregistration Evaluation Decision (RED)- Phase 4*.

Food. For propiconazole, EPA assumes that residues are present, at the tolerance level, in all commodities with existing and proposed tolerances. To evaluate dietary exposure to the free triazoles in food, EPA considered all commodities with existing tolerances for parent triazole fungicides as of September 1, 2005. EPA assumed that 100% of the food or feed crops with tolerances for propiconazole or other triazole fungicides are treated. For a comprehensive list of the parent triazole fungicides and their existing tolerances, please see 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*.

Residue monitoring data for 1,2,4-triazole, triazole alanine, and triazole acetic acid are available for several commodities; these monitoring data were used to estimate anticipated residues for 1,2,4-triazole in food. For all other commodities, EPA estimated indirect residues of the free triazoles by multiplying the tolerance of the parent triazole compound by a metabolic conversion factor and a molecular weight conversion factor.

Dietary exposure was estimated using food consumption data from USDA's Continuing Surveys of food Intake by Individuals (CSFII) from 1994 to 1996 and 1998 and the Dietary Exposure Evaluation Model (DEEM-FCID™). For processed commodities without individual tolerances, EPA used default processing factors from DEEM.

Drinking Water. EPA has evaluated potential drinking water exposure to propiconazole because environmental fate data for propiconazole indicate it is persistent and moderately mobile in soil, with mobility depending on soil organic content. This evaluation includes a review of the

existing water monitoring and environmental fate data for propiconazole. To date, EPA has not established health advisory or maximum contaminant levels (MCLs) for residues of propiconazole in drinking water.

Because water monitoring data for propiconazole are limited, the Agency used screening-level models to estimate drinking water concentrations of propiconazole from surface and groundwater. To estimate propiconazole concentrations in surface water, EPA used the PRZM-EXAMS screening models, with an adjustment for the percent crop area treated in an index reservoir, for all crops except rice. The Agency modeled representative scenarios to estimate levels of propiconazole in surface water from runoff after application to agricultural crops, fruit and nut trees, and turf. To estimate drinking water concentrations of propiconazole following application to rice, the Agency used a modification of the conservative rice paddy model, which estimates concentrations of a chemical in the water column and in the undiluted water released from the rice paddy, accounting for some pesticide degradation, but does not consider movement of pesticide on suspended sediment. EPA's rice paddy scenario is based on high clay soils in the Mississippi Valley or Gulf Coast regions. To estimate propiconazole concentrations in groundwater sources of drinking water, EPA used the Tier I SCI-GROW model, which is based on the results of several prospective groundwater monitoring studies. Estimated Drinking Water Concentrations of Propiconazole (EDWCs) are presented in Table 6. Additional details regarding the drinking water exposure assessment for propiconazole may be found in the June 29, 2005, document, *Drinking Water Assessment of Propiconazole* and the June 7, 2006 document, *Revised Drinking Water Assessment of Propiconazole*.

<b>Table 6. Estimated Drinking Water Concentrations of Propiconazole</b>					
<b>Crop Scenario</b>	<b>Region Modeled</b>	<b>PCA</b>	<b>Estimated Drinking Water Concentration (EDWC), ppm</b>		<b>Screening-Level Model Used in Assessment</b>
			<b>Acute</b>	<b>Chronic</b>	
<b>Surface Water</b>					
Turf	York County PA	0.87	76.46	37.53	PRZM-EXAMS
	Osceola County, FL		65.28	26.54	
Rice	Mississippi Valley Gulf Coast	N/A	86.4	2.92	2002 Rice Paddy Model
<b>Groundwater</b>					
Turf & Ornamentals	Not applicable	N/A	0.72	0.72	SCI-GROW

Because very limited water monitoring data are available for 1,2,4-triazole, triazole alanine, and triazole acetic acid, the Agency used screening-level models to estimate drinking water concentrations of the triazole metabolites in surface and groundwater. As for propiconazole, EPA used the PRZM-EXAMS and SCI-GROW screening-level models to derive EDWCs for surface and groundwater, respectively. These values are presented in Table 7. The Agency does not have sufficient information to model potential residues of the triazole conjugates in drinking water; therefore, EPA has used the modeled estimates for 1,2,4-triazole, multiplied by a factor to correct for differences in molecular weight, in the dietary assessment for the conjugates. The use of modeled residue values for 1,2,4-triazole as a surrogate for residues of the triazole conjugates in drinking water is highly conservative. Additional details regarding the drinking water assessment for the free

triazoles may be found in the February 28, 2006 document, *1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid: Drinking Water Assessment in Support of Reregistration and Registration Actions for Triazole-derivative Fungicide Compounds*, which is in docket EPA-HQ-OPP-2005-0497.

<b>Table 7. Estimated Drinking Water Concentrations of Free Triazoles</b>					
<b>Crop Scenario</b>	<b>Region Modeled</b>	<b>PCA</b>	<b>Estimated Drinking Water Concentration (EDWC), ppm</b>		<b>Screening-Level Model Used in Assessment</b>
			<b>Acute</b>	<b>Chronic</b>	
<b>Surface Water</b>					
Turf	Pennsylvania golf course	N/A	0.041	0.011	PRZM-EXAMS
<b>Groundwater</b>					
Turf	Pennsylvania golf course	N/A	0.001	0.001	SCI-GROW

**b. Residential Exposure and Risk**

Residential risk assessments consider all potential nonoccupational exposures other than exposures from residues in food or drinking water. For propiconazole, EPA evaluated potential exposure and risk to residential handlers who are mixing, loading, or applying lawn and garden products or applying paint containing propiconazole with a paint brush, paint roller, or airless sprayer in and around the home. The Agency also evaluated potential post-application exposure and risk from adults re-entering treated areas, such as lawns or home gardens to do yard work and from children who may be either touching treated wood in decks or playsets, mouthing their hands or various objects that have contacted treated turf or wood, or eating soil containing pesticide residues. Most residential exposures, including toddler dermal and incidental oral exposure, are considered to be short-term in duration because of the infrequent, episodic use associated with homeowner products. However, for propiconazole, post-application exposure to treated decks and playsets is considered to be both short- and intermediate-term in duration because wood preservatives must remain on treated wood for efficacy. In addition, for 1,2,4-triazole, post-application exposure to toddlers ingesting soil containing pesticide residues is considered to be intermediate-term exposure because of this degradate’s long half-life in soil (~500 days).

To estimate risk from residential use of a pesticide, the Agency calculates a margin of exposure (MOE), which is the ratio of the NOAEL selected for risk assessment to the exposure. This MOE is compared to a level of concern, which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. The standard UF is 100X (10X for interspecies extrapolation and 10X intraspecies variation), plus any additional safety factors, such as an FQPA SF. An MOE less than the target MOE, or level of concern, is generally a risk concern to the Agency. As previously mentioned in this document, the FQPA SF for propiconazole has been reduced to 1X; therefore, the Agency’s level of concern is an MOE of 100 for propiconazole. The FQPA SF for the free triazoles, however, is 10X; therefore, the Agency’s level of concern is an MOE of 1000 for the free triazoles. Further, for the free triazoles, some exposure scenarios bear an additional 3X uncertainty factor for the lack of a NOAEL; in these cases, the Agency’s level of concern is an MOE of 3000.

Although propiconazole is registered as a wood preservative for dimensional lumber, it is not currently marketed for use. To complete reregistration, EPA must evaluate potential exposure and risk from all registered uses, including short- and intermediate-term post-application exposure to children playing on decks and play sets built from dimensional lumber treated with propiconazole. However, the Agency does not have adequate wood surface residue (i.e., wood wipe) data necessary to conduct a chemical-specific post-application exposure assessment. Therefore, EPA conducted a high-end deterministic screening-level assessment to estimate potential post-application exposure to children. The Agency is also requiring a confirmatory wood surface wipe study as part of this RED.

No other residential post-application exposure scenarios were evaluated because use of propiconazole in paint or caulk is not expected to result in exposure after the caulk and paint have dried. Although additional homeowner exposure could occur from use of propiconazole as a material preservative in a variety of consumer products, the technical registrants Syngenta and Janssen, have requested that propiconazole use on carpet fibers, apparel, and furnishings be deleted from product labels. The Agency published a *Federal Register Notice* on March 8, 2006, announcing receipt of this request. Because no comments were received in response to this *Notice*, EPA issued cancellation orders for these uses on May 26, 2006. Therefore, these uses have not been included in the risk assessment for this RED.

The Agency has evaluated residential exposure and risk associated with the free triazoles because other triazole fungicides, in addition to propiconazole, are used on residential lawns. EPA has based the exposure assessment for the free triazoles on the use of triademifon on residential turf because triademifon is the greatest source of residential exposure of any of the triazole fungicides. The Agency has evaluated dermal and inhalation exposure to residential handlers, dermal post-application exposure to adults doing yardwork and to children who may be mouthing their hands or various objects that have contacted treated or who may be eating soil containing pesticide residues. As a result of its review, the Agency has determined that there is potential residential exposure to 1,2,4-triazole, but no potential exposure to the triazole conjugates (TA and TAA), because these compounds are formed within the plant and residues are not available on the leaf surface. As previously mentioned, residential exposure to toddlers from soil ingestion is considered to be intermediate-term in duration because 1,2,4-triazole has a long half-life in soil.

Additional details regarding the residential exposure and risk assessments for propiconazole may be found in the following documents: *Propiconazole Occupational and Residential Exposure Assessment*, dated January 31, 2006; *Propiconazole Occupational and Residential Exposure Assessment of Antimicrobial Uses*, dated February 1, 2006; *Amendment to the Propiconazole Reregistration Eligibility Decision (RED) Document for Children's Postapplication Exposure to Treated Structures*, dated June 20, 2006; and *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*, dated February 7, 2006.

## **5. Aggregate Risk Assessment for Propiconazole and Free Triazoles**

Propiconazole, the other triazole fungicides, and other compounds may be metabolized to the free triazoles in animals and plants. Therefore, EPA has conducted aggregate risk assessments for potential food, drinking water, and residential exposure resulting from exposure to propiconazole

parent and from exposure to all sources of the free triazoles. Table 8 lists the aggregate risk assessments that the Agency has conducted for propiconazole and for the free triazoles (1,2,4-triazole, triazole alanine, and triazole acetic acid). As previously mentioned, EPA only evaluated two intermediate-term exposure scenarios for residential use: toddlers ingesting soil containing residues of 1,2,4-triazole and toddlers playing on decks or play sets made from wood treated with propiconazole.

Exposure Duration	Residues Considered		
	Propiconazole	1,2,4-Triazole	Triazole Alanine & Triazole Acetic Acid
Acute	food + drinking water	food + drinking water	food + drinking water
Short-Term	food + drinking water + residential*, †	food + drinking water + residential †	Not assessed, 1,2,4-triazole assessment is protective ‡
Intermediate-Term	food + drinking water + residential*	food + drinking water + residential**	
Chronic	food + drinking water	food + drinking water	food + drinking water

\* Residential exposure to children playing on decks and play sets constructed of propiconazole treated wood.  
 † Residential exposure to adults from yard work and to children from dermal exposure or from hand-to-mouth or object-to-mouth incidental oral exposure.  
 \*\* Residential exposure to toddlers via soil ingestion.  
 ‡ Residues of the conjugates are not found on the leaf surface and are therefore not available for dermal exposure or hand-to-mouth or object-to-mouth incidental oral exposure. Because 1,2,4-triazole is more toxic than the conjugates the risk assessment for 1,2,4-triazole is protective of the conjugates.

**a. Aggregate Risk from Propiconazole**

Acute Aggregate Risk. The acute aggregate risk assessment for propiconazole considers exposure from food and drinking water only because there are no other pathways of acute exposure. The Agency incorporated the peak estimated drinking water concentrations (EDWCs) for propiconazole into the dietary exposure, using the DEEM software. Total dietary exposure from food and water was then compared to the aPAD for propiconazole. At the 95<sup>th</sup> percentile, dietary exposure to the US population comprised 3% of the aPAD; exposure to infants < 1 year old (the most highly exposed subgroup) comprised 8% of the aPAD, and exposure to females age 13-49 comprised 2% of the aPAD. Because total dietary exposure from propiconazole is less than 100% aPAD, acute aggregate exposure from propiconazole is below the Agency’s level of concern.

Short-Term Aggregate Risk. Short-term aggregate exposure takes into account residential exposure plus average exposure levels to food and drinking water (considered to be a background exposure level). The highest residential handler exposure scenarios for agricultural (hose-end sprayer) and antimicrobial use (paint brush/roller) are used for the aggregate exposure assessment. Based on the residential use pattern, post-application exposure to propiconazole for adults are from dermal exposure only. Infants and children are expected to be exposed by both the dermal and oral routes (incidental exposure). This aggregate exposure assessment is considered highly conservative. As shown in Table 9, MOEs for aggregate short-term risk from food, drinking water, and residential use range from 120 to 500, and are all below the Agency’s level of concern.

The Agency considered short-term risk for residential handlers using propiconazole in home gardens and for residential handlers using paint containing propiconazole, as well as risk for adults and children receiving post-application exposure. Short-term MOEs for residential handlers and post-application exposure to adults and children (toddlers) are all greater than 100 and below EPA’s level of concern and are therefore not presented in Table 9. Combined short-term inhalation and dermal MOEs for residential handlers range from 120 to 40,000. Short-term post-application dermal MOEs range from 210 to 410 for toddlers and 350 to 50,000 for adults; post-application incidental oral MOEs range from 1,100 to 330,000 (children only). The combined short-term dermal and incidental oral MOE is 170 for children playing on treated lawns and 410 for children playing on decks or play sets built with lumber treated with propiconazole

*Intermediate-Term Aggregate Risk.* EPA considered intermediate-term aggregate risk for propiconazole for toddlers playing on decks or play sets built with lumber treated with propiconazole who are also receiving background exposure to residues in food and drinking water. The intermediate-term aggregate risk, which includes post-application exposure children and background exposure from food and drinking water, is an MOE of 130, as shown in Table 9 below.

<b>Table 9. Short- and Intermediate-Term Aggregate Risk Estimates for Residential Exposure to Propiconazole</b>					
Exposure Scenario	Level of Concern	MOE Food + Drinking Water	Combined Dermal and Inhalation MOE	Oral MOE (Incidental Ingestion)	Aggregate MOE
Residential Handler (Use on Turf and in Paint)					
Hose-end sprayer	100	9700	530	N/A	500
Paint Airless Sprayer	100	9700	120	N/A	120
Residential Post-Application (Residential Turf)					
Adult - General high contact activities	100	9700	350	N/A	340
Toddler – General high contact activities*	100	3800	450	4,500	160
Residential Post-Application (Treated Decks and Play sets)					
Toddler - General high contact activities**	100	3800	450 (short-term)	5,300 (short-term)	288
			150 (int.-term)	1,800 (int.-term)	130
* Toddler general high-contact activities include dermal exposure from playing on treated turf as well as incidental oral exposure from toddlers mouthing their hands, objects that have come in contact with turf, or ingesting soil containing residues.					
** Post application exposure to toddlers playing on decks & play sets is considered to be both short- and intermediate-term in duration.					

*Chronic Aggregate Risk.* Because the existing residential uses of propiconazole are not likely to result in chronic exposure to propiconazole, chronic aggregate includes food and drinking water only. The dietary exposure from drinking water (derived from screening-level models) has been included in the DEEM analysis. Because the RfD approach used to evaluate chronic dietary risk is considered protective of any cancer risk concern, only the results of the chronic analysis is given. Chronic dietary exposure to the US population comprised 3% of the cPAD, and exposure to infants < 1 year old (the most highly exposed subgroup) comprised 8% of the cPAD, which is below the



Agency's level of concern.

**b. Aggregate Risk from Free Triazoles**

*Acute Aggregate Risk.* The acute aggregate risk assessments for 1,2,4-triazole and for the triazole conjugates triazole alanine and triazole acetic acid only consider exposure from food and drinking water because there are no other pathways of acute exposure. The Agency incorporated the peak EDWCs for 1,2,4-triazole and for the triazole conjugates into the dietary exposure, using the DEEM software. Total dietary exposure from food and drinking water was then compared to the appropriate aPAD. At the 95<sup>th</sup> percentile of exposure, acute dietary exposure for children age 1-2 years (the most highly exposed population) comprised 32% of the aPAD for 1,2,4-triazole. For the triazole conjugates, the toxicological endpoint is only relevant to females of childbearing age. The DEEM results for the triazole conjugates showed that females age 13-49 years had dietary exposure at the 95<sup>th</sup> percentile comprising 27% of the aPAD. Therefore, acute aggregate risk for the free triazoles is below EPA's level of concern.

*Short-Term Aggregate Risk.* For 1,2,4-triazole, the short-term aggregate risk assessment considers worst-case residential exposure from triademifon, the triazole fungicide with the highest application rate on residential lawns, combined with background exposure from food and drinking water. The residential risk assessment for the triazoles includes the following exposure scenarios: adult handlers applying pesticide with a hose end sprayer or low-pressure hand wand, post-application exposure to adults and toddlers from dermal contact or incidental oral exposure from soil ingestion or from mouthing hands or objects that have contacted treated turf. Short-term dermal MOEs for residential handlers exposed to 1,2,4-triazole (from use of triademifon) range from 3,500 for children to 3,900 for adults. Short-term incidental oral MOEs for children are 7,300 for hand-to-mouth exposure and 30,000 for object-to-mouth exposure. Because all of these MOE values are above 1000, residential risks for 1,2,4-triazole are below the Agency's level of concern.

Short-term aggregate MOEs for 1,2,4-triazole range from 1,900 to 4,000 for all population subgroups. These MOEs, which consider potential residential exposure with background exposure from food and drinking water, are all greater than the target MOE of 1,000, and below the Agency's level of concern. The Agency believes that there is no potential residential exposure to the triazole conjugates (TA and TAA) because these compounds are formed within the plant and residues are not available on the leaf surface. Although residues of the triazole conjugates may also be available in soil, the risk assessment for soil ingestion of 1,2,4-triazole is believed to be protective because 1,2,4-triazole is more toxic than the triazole conjugates. Therefore, short-term aggregate risks for the free triazoles are below EPA's level of concern.

*Intermediate-Term Aggregate Risk.* For 1,2,4-triazole, the intermediate-term aggregate risk assessment considers potential exposure to children via soil ingestion combined with background exposure from food and drinking water. The intermediate-term MOE for children receiving incidental oral exposure via soil ingestion is 1,600,000, which is below the Agency's level of concern. Intermediate-term aggregate MOEs range from 7,600 to 28,000 for all population subgroups, and are all greater than 3000, the Agency's level of concern for intermediate-term MOEs. Because the risk assessment for soil ingestion of 1,2,4-triazole is believed to be protective of the triazole conjugates, the intermediate-term aggregate risks for the free triazoles are all below the Agency's level of concern.

*Chronic Aggregate Risk.* As with the acute aggregate risk assessments, the chronic aggregate risk assessments for 1,2,4-triazole and for the triazole conjugates only consider exposure from food and drinking water because there are no other pathways of chronic exposure. Chronic dietary exposure from food and drinking water for the most highly exposed subpopulation, children age 1-2 years comprised 39% of the cPAD for 1,2,4-triazole and 27% of the cPAD for the triazole conjugates. Therefore, chronic aggregate risks for the free triazoles are below EPA's level of concern.

**c. Pesticide and Pharmaceutical Assessment for Free 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 Food and Drug Administration (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, propiconazole shares a common metabolite, 1,2,4-triazole, with several 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 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 propiconazole, EPA-HQ-OPP-2005-0497) for additional information.

## **6. Occupational Exposure and Risk**

Workers can be exposed to a pesticide through mixing, loading, and/or applying the pesticide; these workers are called pesticide “handlers.” Workers can also be exposed to residues of a pesticide when re-entering treated areas. For dermal and inhalation exposures, worker risk is estimated by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the No Observed Adverse Effect Level (NOAEL) selected from animal studies. Based on the use pattern for propiconazole and the toxicological database for propiconazole, the Agency has determined that short- and intermediate-term (but not lifetime) exposures should be included in the risk assessment. The toxicological endpoints used in the occupational risk assessment are presented in Table 3 of this document, and EPA assumed 40% dermal absorption based on an animal study.

The Agency typically evaluates exposure to pesticide handlers using different levels of personal protective equipment (PPE). EPA typically conducts an initial exposure assessment assuming baseline clothing, and then adds PPE in a tiered approach to determine the level of additional PPE necessary to obtain appropriate MOEs. This approach allows the Agency to determine the appropriate PPE and other label language using a risk-based approach.

In the handler exposure assessments for propiconazole, EPA evaluated the following clothing scenarios:

- baseline, which consists of long-sleeve shirt, and long pants but no gloves or respirator,
- baseline plus chemical-resistant gloves, and
- engineering controls (for antimicrobial uses only).

All current propiconazole labels for agricultural use require baseline PPE plus chemical-resistant gloves; labels registered for antimicrobial use products also require baseline PPE, chemical-resistant gloves, and protective eyewear.

Because propiconazole is used both in agricultural and antimicrobial sites, the Agency conducted separate assessments for these sites. Additional details regarding the occupational exposure and risk assessments for propiconazole may be found in the following documents: *Propiconazole Occupational and Residential Exposure Assessment*, dated January 31, 2006 and *Propiconazole Occupational and Residential Exposure Assessment of Antimicrobial Uses*, dated February 1, 2006.

### **a. Handler Exposure and Risk**

*Agricultural Uses of Propiconazole.* The exposure and risk assessment for occupational handlers addressed the following scenarios: mixer/loader, applicator, and flagger. These scenarios were used to estimate exposures based on application of the formulations of propiconazole currently registered for use in agriculture (i.e., wettable powder (water soluble packs) and liquid). As previously mentioned, EPA evaluated both short- and intermediate-term occupational exposures and risks.

For agricultural scenarios, no chemical-specific handler data were available for propiconazole, so EPA used unit exposure values from the Pesticide Handlers Exposure Database (PHED) to estimate handler exposures. The Agency used standard default assumptions for the number of acres treated per day, worker body weight, hours worked, etc., for most handler scenarios.

For liquid formulations, handler risks for most scenarios were above EPA's level of concern (i.e., MOEs < 100) for mixer/loaders, both short- and intermediate-term exposure, with baseline clothing (long sleeve shirt, long pants, shoes and socks, but no gloves). However, these same handler risks were below the Agency's level of concern (MOEs > 100) with the addition of chemical-resistant gloves.

For wettable powders formulated in water-soluble packs (an engineering control), handler risks were below the Agency's level of concern (i.e., MOEs > 100) for all scenarios with baseline clothing. Also, handler risks for mixer/loader/applicators using liquid formulations and high- or low-pressure handwand, handgun sprayer, or seed piece dip were below the Agency's level of concern both at baseline and with gloves. Applicator and flagger risks were below EPA's level of concern (i.e., MOEs > 100) for all formulations with baseline clothing. Handler risk estimates for the agricultural uses of propiconazole are presented in Table 10.

Table 10. Short- and Intermediate-Term Handler Risk Estimates for Agricultural Uses of Propiconazole							
Exposure Scenario	Crops	Appl. Rate (lb ai/acre or lb ai/gallon)	Area Treated (acre/day)	Margin of Exposure (MOE)			
				Short-Term Exposure		Intermediate-Term Exposure	
				Baseline*	Baseline + Gloves	Baseline* + Gloves	
<i>Mixer/Loader – Liquid</i>							
Aerial	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	1200	13	1500	4.5	500
	Celery, Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum), Mint, Triticale	0.1125	350	46	5100	15	1700
	Non-bearing Citrus, Pecans, Non-bearing Hazelnuts, Peanuts	0.225	350	23	2600	7.7	850
	Grasses grown for seed (forage and fodder grasses), Wild Rice	0.225	350	23	2600	7.7	850
	Sod-farm turf	1.8	350	2.9	320	1.0	110
	Wheat	0.08	1200	19	2100	6.3	700
	Rice	0.28	1200	5.4	600	1.8	200
	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	200	80	9000	27	3000
	Celery, Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum), Mint, Triticale	0.1125	80	200	22000	67	7500
	Non-bearing Citrus, Non-bearing Hazelnuts, Pecans, Peanuts	0.225	80	100	11000	33	3700
	Grasses grown for seed (forage and fodder grasses)	0.225	80	100	11000	33	3700
	Sod farm turf	1.8	80	13	1400	4.2	470
	Golf Course turf	0.08	40	25	2800	8.4	930
Wheat	0.08	200	110	13000	38	4200	
Airblast	Pecans, Non-bearing Citrus	0.225	40	200	22000	67	7500
	Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum)	0.1125	40	400	45000	130	15000
	Ornamental (Flowering and Woody plants)	0.37	40	120	14000	41	4500
	Bananas and Plantains	0.084	40	540	60000	180	20000
	Barley, Rye, Oats, Wheat, Corn, Sunflower, Celery	0.1125	350	46	5100	15	1700
Chemigation	Grasses grown for seed (forage and fodder grasses), Non-bearing citrus, Peanut	0.225	350	23	2600	7.7	850
	Wheat	0.08	350	65	7200	22	2400
	Rice	0.28	350	18	2100	6.2	690
	Turf	1.8	100	10	1100	3.3	370
Handgun Sprayer							

Table 10. Short- and Intermediate-Term Handler Risk Estimates for Agricultural Uses of Propiconazole							
Exposure Scenario	Crops	Appl. Rate (lb ai/acre or lb ai/gallon)	Area Treated (acre/day)	Margin of Exposure (MOE)			
				Short-Term Exposure		Intermediate-Term Exposure	
				Baseline*	Baseline + Gloves	Baseline* + Gloves	
<i>Mixer/Loader - Wettable Powder in Water Soluble Packets</i>							
Aerial	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	1200	1800	N/A**	600	N/A
	Celery, Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum), Mint, Triticale	0.1125	350	6200	N/A	2100	N/A
Aerial	Non-bearing Citrus, Pecans, Non-bearing Hazelnuts, Peanuts	0.225	350	3100	N/A	100	N/A
	Grasses grown for seed (forage and fodder grasses), Wild rice	0.225	350	3100	N/A	100	N/A
	Sod-farm turf	1.8	350	390	N/A	130	N/A
	Wheat	0.08	1200	2500	N/A	840	N/A
	Rice	0.28	1200	720	N/A	240	N/A
	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	200	11000	N/A	3600	N/A
Groundboom	Celery, Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum), Mint, Triticale	0.1125	80	27000	N/A	9000	N/A
	Non-bearing Citrus, Non-bearing Hazelnuts, Pecans, Peanuts	0.225	80	14000	N/A	4500	N/A
	Grasses grown for seed (forage and fodder grasses)	0.225	80	14000	N/A	4500	N/A
	Sod Farm turf	1.8	80	1700	N/A	560	N/A
	Golf Course turf		40	3400	N/A	110	N/A
	Wheat	0.08	200	15000	N/A	5100	N/A
Airblast	Pecans, Non-bearing Citrus	0.225	40	27000	N/A	9000	N/A
	Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum)	0.1125	40	54000	N/A	18000	N/A
	Ornamental (Flowering and Woody plants)	0.37	40	16000	N/A	5500	N/A
	Bananas and Plantains	0.084	40	72000	N/A	24000	N/A
Chemigation	Barley, Rye, Oats, Wheat, Corn, Sunflower, Celery	0.1125	350	6200	N/A	2100	N/A
	Grasses grown for seed (forage and fodder grasses), Non-bearing citrus, Peanut	0.225	350	3100	N/A	1000	N/A
	Wheat	0.08	200	8700	N/A	2900	N/A
	Rice	0.28	350	2500	N/A	830	N/A
Handgun Sprayers	Turf	1.8	100	1400	N/A	450	N/A

Table 10. Short- and Intermediate-Term Handler Risk Estimates for Agricultural Uses of Propiconazole							
Exposure Scenario	Crops	Appl. Rate (lb ai/acre or lb ai/gallon)	Area Treated (acre/day)	Margin of Exposure (MOE)			
				Short-Term Exposure		Intermediate-Term Exposure	
				Baseline*	Baseline + Gloves	Baseline* + Gloves	
<i>Applicator</i>							
Aerial	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	1200	7500	16000	2500	5500
	Celery, Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum), Mint, Triticale	0.1125	350	26000	56000	8600	19000
	Non-bearing Citrus, Pecans, Non-bearing Hazelnuts, Peanuts	0.225	350	31000	28000	4300	9400
	Grasses grown for seed (forage and fodder grasses), Wild rice	0.225	350	31000	28000	4300	9400
	Sod-farm turf	1.8	350	1600	3500	540	1200
	Wheat	0.08	1200	11000	23000	3500	7700
	Rice	0.28	1200	3000	6600	1000	2200
	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	200	15000	15000	4900	4900
	Celery, Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum), Mint, Triticale	0.1125	80	37000	37000	12000	12000
	Non-bearing Citrus, Non-bearing Hazelnuts, Pecans, Peanuts	0.225	80	18000	18000	6100	6100
	Grasses grown for seed (forage and fodder grasses)	0.225	80	18000	18000	6100	6100
	Sod Farm turf	1.8	80	2300	2300	770	770
	Wheat	0.08	200	21000	21000	6900	6900
Airblast	Pecans, Non-bearing Citrus	0.225	40	1600	2300	520	770
	Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum)	0.1125	40	3100	4600	1000	1500
	Ornamental (Flowering and Woody plants)	0.37	40	960	1400	320	470
	Bananas and Plantains	0.084	40	4200	6200	1400	2100

Table 10. Short- and Intermediate-Term Handler Risk Estimates for Agricultural Uses of Propiconazole							
Exposure Scenario	Crops	Appl. Rate (lb ai/acre or lb ai/gallon)	Area Treated (acre/day)	Margin of Exposure (MOE)			
				Short-Term Exposure		Intermediate-Term Exposure	
				Baseline* + Gloves	Baseline* + Gloves	Baseline + Gloves	
<b>Flagger</b>							
Aerial applications	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	350	11000	N/A	3700	N/A
	Celery, Stone Fruits (Apricots, Cherry, Nectarine, Peach, Plum), Mint, Triticale	0.225	350	5600	N/A	1900	N/A
	Non-bearing Citrus, Pecans, Non-bearing Hazelnuts, Peanuts	1.8	350	700	N/A	230	N/A
	Grasses grown for seed (forage and fodder grasses), Wild rice	0.08	350	16000	N/A	5300	N/A
	Sod-farm turf	0.28	350	4500	N/A	1500	N/A
	Wheat						
	Rice						
<b>Mixer/Loader/Applicator (Liquid formulations)</b>							
High Pressure Handwand	Non-bearing Fruits and Nuts, Ornamental Woody and Flowering plants	0.0024	1000 gal handled/day †	N/A	780	N/A	260
Low Pressure Handwand	Non-bearing Fruits and Nuts, Ornamental Woody and Flowering plants		40 gal handled/day	550	110000	180	36000
Handgun Sprayer	Turf	1.8	5	N/A	12000	N/A	390
Seed Piece Dip	Sugarcane (HI only)	0.00021	1000 gal handled/day	8600	960000	2900	320000
MOE = NOAEL/Daily Dose where the NOAEL for both dermal and inhalation is 30.0 mg/kg/day for Short-term and 10.0 mg/kg/day for Intermediate-term exposures. The target MOE is 100 for both short- and intermediate-term occupational exposures. * Baseline clothing consists of long sleeve shirt, long pants, shoes and socks but no gloves or respirator. N/A – not applicable. **Gloves are not considered for scenarios with engineering controls, such as wettable powders with water soluble bags or aerial application with closed cockpit. † Amount handled is described as gal/day rather than area treated for high and low pressure handwand and seed piece treatment. <b>MOEs in bold</b> are above EPA's level of concern.							



*Antimicrobial Uses of Propiconazole.* As previously mentioned, propiconazole is registered for use as both a material preservative (in adhesives, caulk, paints, textiles, and metalworking fluid), and as a wood preservative. Occupational handler exposure can occur when a worker is adding preservative to treated materials. The exposure and risk assessment for occupational handlers addressed the following scenarios:

(1) Material Preservative

- Liquid pour (transfer of antimicrobial from a small container to an open vat),
- Liquid pump (transfer of antimicrobial to a closed tote via a chemical metering pump or gravity flow),
- Paint application by brush, roller, or airless sprayer; and

(2) Wood Preservative

- Blender spray operators
- Chemical operators
- Driptank operators
- High pressure/high volume spray
  - Wood treatment
  - Mushroom houses
  - Cooling towers
- Pressure treatment of wood

These scenarios were used to estimate exposures based on application of the formulations of propiconazole currently registered for antimicrobial use. The Agency evaluated both short- and intermediate-term occupational exposures and risks for these use scenarios. Table 11 provides a summary of short- and intermediate-term handler MOEs for antimicrobial uses.

*Material Preservative.* For use of propiconazole as a material preservative, combined inhalation and dermal total short-term handler MOEs range from < 1 to 6,500 at baseline (long-sleeved shirt, long pants, shoes and socks) and from 300 to 26,000 with the addition of chemical-resistant gloves. Likewise, intermediate-term handler MOEs range from < 1 to 2,200 at baseline and 100 to 8,600 with chemical-resistant gloves. Worker risks are of concern for workers applying paint containing propiconazole as an in-can preservative under the following scenarios:

- Painting with brush/roller or airless sprayer – combined intermediate-term MOE of 55, at baseline, and
- Painting with airless sprayer - combined short-term MOE of 75 and intermediate-term MOE of 25, at baseline.

*Wood Preservative.* For blender/spray operators, chemical operators, and driptank operators wearing gloves, short-term combined MOEs range from 400 to 850 and intermediate-term MOEs range from 130 to 280. Handler MOEs for high-pressure/high volume spray treatment range from 150 to 1,500 for short-term exposure and from 50 to 500 for intermediate-term exposure; again, these MOEs assume that chemical-resistant gloves are worn. The MOE of 50 is for application of propiconazole to mushroom houses in a high volume spray of 1000 gallons per day. For workers pressure treating wood, the combined short-term MOE ranges from 260 to 2,200 and the intermediate-term MOE ranges from 86 to 730 with gloves.

**Table 11. Short- and Intermediate-Term Handler Risk Estimates for Antimicrobial Uses of Propiconazole**

Use Site	Application Method	Appl. Rate (% ai by wt)	Amount Handled or Treated per Day	MOEs for Short-Term Exposure				MOEs for Intermediate-Term Exposure					
				Dermal		Inhal.		Dermal		Inhal.			
				Baseline	Gloves	Baseline	Gloves	Baseline	Gloves	Baseline	Gloves		
<b>MATERIAL PRESERVATIVE</b>													
Adhesives	Liquid Pour Liquid Pump	1.21	10,000 lbs	<1	320	4,300	<1	300	<1	110	1,700	<1	100
				95	6,900	37,000	95	5,900	2,200	14,000	32	2,000	
Metal Working Fluids	Liquid Pour Liquid Pump	0.07	2,500 lbs	60	16,000	120,000	60	15,000	20	5,400	47,000	20	4,900
				6,600	9,600	300,000	6,500	9,300	2,200	110,000	2,200	3,100	
Paint	Liquid Pour Liquid Pump	0.35	2,000 lbs	15	5,600	74,000	15	5,200	5	1,900	29,000	5	1,700
				330	24,000	130,000	330	21,000	110	50,000	110	6,900	
Textiles	Liquid Pour Liquid Pump	0.28	10,000 lbs	4	1,400	19,000	4	1,300	1	460	7,200	1	440
				410	30,000	160,000	410	26,000	140	62,000	140	8,600	
<b>Professional Application of Paint</b>													
Paint	Brush/ Roller Airless Sprayer	0.35	50 lbs	170	N/A*	37,000	170	N/A*	56	N/A*	14,000	55	N/A*
				79	N/A*	1,200	75	N/A*	26	N/A*	480	25	N/A*
<b>WOOD PRESERVATIVE</b>													
Blender/ Spray Operator		0.5	178,000	N/A	940	5,900	N/A	810	N/A	310	2,000	N/A	270
				N/A	470	2,900	N/A	400	N/A	980	N/A	160	N/A
Chemical Operator			N/A	N/A	860	120,000	N/A	850	N/A	290	40,000	N/A	280
				N/A	N/A	91,000	3,400	N/A	1,200	30,000	N/A	N/A	1,100
Diptank Operator		1.0	N/A	1,800	N/A	46,000	1,700	N/A	580	N/A	15,000	560	N/A
				N/A	N/A	1,400	N/A	150	N/A	470	N/A	56	N/A
<b>High Pressure/High Volume Spray Treatment</b>													
Wood Treatment		25 gal/day	N/A	N/A	4,800	N/A	N/A	510	N/A	190	1,600	N/A	170
				N/A	290	2,400	N/A	260	N/A	800	N/A	96	N/A
Mushroom House		100 gal/day	N/A	N/A	1,700	14,000	N/A	1,500	N/A	560	4,700	N/A	500
				N/A	170	1,400	N/A	150	N/A	470	N/A	56	N/A

Table 11. Short- and Intermediate-Term Handler Risk Estimates for Antimicrobial Uses of Propiconazole													
Use Site	Application Method	Appl. Rate (% ai by wt)	Amount Handled or Treated per Day	MOEs for Short-Term Exposure				MOEs for Intermediate-Term Exposure					
				Dermal		Inhal.	Total		Dermal		Inhal.	Total	
				Baseline	Gloves		Baseline	Gloves	Baseline	Gloves		Baseline	Gloves
Cooling Tower		100 gal/day	N/A	970	8,100	N/A	870	N/A	520	2,700	N/A	290	
		200 gal/day	N/A	490	4,100	N/A	430	N/A	160	1,400	N/A	140	
<b>Pressure Treatment</b>													
Treatment Operator		1	N/A	260	82,000	N/A	260	N/A	86	27,000	N/A	<b>86</b>	
Treatment Assistant		1	N/A	2,200	260,000	N/A	2,200	N/A	730	87,000	N/A	730	

N/A- not applicable. \* Gloves are not applicable to painters because paint products containing propiconazole are not labeled as pesticides (i.e., propiconazole is used as an in-can preservative). **MOEs in bold** are above EPA's level of concern.

**b. Post-Application Exposure and Risk**

The post-application occupational risk assessment for propiconazole considers exposure to agricultural workers re-entering areas previously treated with propiconazole as well as post-application exposure from use of propiconazole as a wood preservative. EPA identified a variety of post-application exposure scenarios by the type of activity (i.e., weeding, scouting, or hand harvesting crops; grading or stacking treated lumber; operating chemical equipment, trim saws, etc.) and the expected level of contact. Post-application exposure levels can vary over time according to the type of worker activity, the dissipation of chemical residues over time, and the nature of the crop or item that was treated. The Agency estimated post-application exposure and risk using dislodgeable foliar residue (DFR), turf transferable residue (TTR), and/or other dissipation or post-application monitoring data, as appropriate.

*Agricultural Uses.* Post-application exposure for agricultural uses of propiconazole was evaluated using chemical-specific DFR/TTR data. A total of six residue dissipation studies are available for corn, peaches, rice, pecans, ornamentals and turf. The DFR data have been extrapolated to similar crops. The turf TTR data have been used to complete all assessments for turf: sod-farm, recreational areas and golf courses. EPA used interim transfer coefficients derived from Agricultural Re-entry Task Force (ARTF) data according to current Agency policy.

Worker post-application risks for agricultural uses are summarized in Table 12. All occupational post-application short- and intermediate-term risks are below the Agency’s level of concern on the day of pesticide application (i.e., MOEs > 100 on *day 0*) except for hand-harvesting cut flowers on *day 0*. The MOE for hand-harvesting cut flowers is 97 on *day 0* but is 104 one day after treatment. Although the MOE on is slightly less than 100 on *day 0*, the MOE of 97 is within the negligible risk range, and thus below EPA’s level of concern. The current restricted-entry interval (REI) for propiconazole is 12 hours on some labels; which is consistent with the Worker Protection Standard (WPS) requirement based on the acute toxicity of technical propiconazole (Toxicity Category III). The propiconazole REI will remain 12 hours unless otherwise indicated by product-specific toxicity data.

**Table 12. Summary of Post-application Worker Risk Estimates for Agricultural Uses of Propiconazole**

Crop	Activity	Transfer Coefficient (cm <sup>2</sup> /hr)	Maximum Application Rate (lb ai/A)	MOE on Day of Application ( <i>Day 0</i> )	
				Short-Term Exposure	Intermediate – Term Exposure
Celery, Mint, Wild rice, (MN only), Barley, Oats, Rye, Wheat, Rice, Peanuts	irrigating, scouting, hand-weeding	100	0.28	36000	12000
	irrigating, scouting	1500		2400	800
	hand-harvesting	2500		1400	500

<b>Table 12. Summary of Post-application Worker Risk Estimates for Agricultural Uses of Propiconazole</b>					
<b>Crop</b>	<b>Activity</b>	<b>Transfer Coefficient (cm<sup>2</sup>/hr)</b>	<b>Maximum Application Rate (lb ai/A)</b>	<b>MOE on Day of Application (Day 0)</b>	
				<b>Short-Term Exposure</b>	<b>Intermediate – Term Exposure</b>
Corn (field, pop, sweet), Sunflower	hand-weeding	100	0.1125	110000	37000
	irrigating, scouting	1000		1100	3700
	De-tasseling, hand-harvesting	17000		700	220
Stone Fruits, Peaches, Non-bearing Apples,	irrigating, scouting	1000	0.1125	2600	860
	hand-weeding, hand harvesting, hand-pruning,	1500		1700	570
	Thinning	3000		860	290
Non-bearing Citrus	irrigation, scouting, hand-weeding	1000	0.225	1300	430
	hand-pruning, thinning	3000		430	140
Bananas, Plantains	irrigation, hand-weeding	100	0.084	35000	12000
	scouting, irrigation	1300		2700	900
	hand-harvesting,, thinning, hand-weeding/ pruning	2000		1700	600
Non-bearing Blueberries	scouting, hand-weeding/ pruning, irrigation, thinning	400	0.169	4300	1400
	hand-pruning	1500		1200	380
Ornamentals (Woody and Herbaceous) plants	pruning, tying	110	0.37	7100	2040
	transporting, moving potted plants	400		2000	560
	hand-harvesting (cut flowers)	Short-term 5100 Intermediate-term 2700		150	97
Pecans, Non-bearing Hazelnuts	hand-weeding, thinning, irrigating, scouting	500	0.225	5200	1700
	Hand-pruning, thinning	2500		1000	340
Turf (grasses grown for seed, golf courses, sod farms)	Turf maintenance	3400	1.8	1800	600
	hand-weeding/harvesting transplanting, hand-harvest mechanical harvesting	6800	1.8	900	300

*Antimicrobial Uses.* EPA evaluated post-application to machinists using metalworking fluids containing propiconazole and to sawmill workers handling lumber treated with propiconazole. Exposure to machinists was estimated using the best available information. Dermal exposure was simulated using the hand-immersion model ChemSTEER, which considers percent active ingredient and film thickness. Inhalation exposure was estimated using the Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) for oil mist. Post-application worker exposure for antimicrobial use of propiconazole as a wood preservative was evaluated using surrogate data from a study based on another wood preservative, DDAC, which measured worker exposure performing routine tasks at several sawmills/planar mills in Canada. The DDAC study monitored both inhalation and dermal exposure. EPA also used surrogate data from a study on chromated copper arsenic (CCA) conducted by the American Chemistry Council. This study monitored both inhalation and dermal exposure during post-application activities such as stacker operator and loader operator. MOEs for post-application worker exposure to metalworking fluids and wood preservatives are summarized in Table 13.

<b>Table 13. Summary of Post-application Worker Risk Estimates for Propiconazole Used in Metalworking Fluids and Wood Preservative</b>						
<b>Worker Activity</b>	<b>MOE for Short-Term Exposure on Day of Application (Day 0)</b>			<b>MOE for Intermediate-/Long-Term Exposure on Day of Application (Day 0)</b>		
	<b>Dermal</b>	<b>Inhalation</b>	<b>Total</b>	<b>Dermal</b>	<b>Inhalation</b>	<b>Total</b>
<b>Metalworking Fluid</b>						
Machinist	5,100	75,000	4,800	1,700	25,000	1,600
<b>Wood Preservative</b>						
Grader	2,700	110,000	2,600	890	38,000	870
Trim Saw Operator	6,100	56,000	5,500	2,000	19,000	1,800
Millwright	660	59,000	650	220	20,000	220
Clean Up Crew	150	5,600	150	51	1,900	<b>49</b>
Pressure Treatment – all scenarios	710	130,000	710	240	44,000	240
<b>MOEs in bold</b> are above EPA's level of concern.						

### c. Incident Reports

The Agency reviewed available sources of human incident data for incidents relevant to propiconazole. The following sources were used: 1) The Office of Pesticide Programs' (OPP) Incident Data System (IDS) consisting of reports submitted to EPA by registrants, other federal and state health and environmental agencies and the public since 1992; 2) Poison Control Center Data covering the years 1993 through 2003 for all pesticides; 3) California Department of Pesticide Regulation's pesticide poisoning surveillance program consisting of reports from physicians of

illness suspected of being related to pesticide exposure since 1982; 4) National Pesticide Information Center (NPIC) data that provides a ranking of the top 200 active ingredients for which telephone calls were received between 1984 and 1991; and 5) National Institutes of Occupational Safety and Health (NIOSH) Sentinel Event Notification System for Occupational Risks (SENSOR) that provides surveillance in seven states from 1998 through 2002. EPA's review of the human incident data for propiconazole can be found in the July 26, 2005 document, *Review of Propiconazole Incident Reports*.

All of the sources listed above, except for NPIC, contained information relevant to propiconazole. The IDS contained numerous incidents, most of which involved symptoms such as skin rash, itching, and irritation and respiratory effects such as difficulty breathing. However, this database contained little information about the disposition of the reported cases. Reports submitted to the IDS represent anecdotal reports or allegations. Poison Control Center Data listed 13 occupational exposure incidents among adults and older children, 63 nonoccupational exposure incidents among adults and older children, and 13 exposures to children under 6 years old. Only a small number of these incidents required treatment in a health care facility, and none were considered life threatening or required hospitalization. The most common symptoms reported were headache, skin irritation, erythema, vomiting, ataxia, dizziness, coughing, and difficulty breathing. In general, in comparison to other pesticides for which Poison Control Center Data are available, propiconazole appears to be less hazardous with less than one percent of reported propiconazole cases being symptomatic, compared to approximately 70% of all pesticide cases. The Agency also reviewed detailed descriptions of 13 cases submitted to the California Pesticide Illness Surveillance Program, and propiconazole was deemed to be the responsible for health effects in 8 of these cases. Reported symptoms included difficulty breathing, eye and skin irritation, headache and vomiting. Propiconazole was not reported on the list of the top 200 chemicals with incidents reported to NPIC. Propiconazole was associated with two cases out of a total of 4,221 cases reported to NIOSH SENSOR between 1998 and 2002. Both cases were as a result of drift; symptoms included nausea, vomiting, gastrointestinal pain, difficulty breathing, and throat irritation.

In general, in conclusion from the review of the IDS, it appears that a majority of cases involved skin symptoms such as rash, itching, skin irritation and respiratory effects. Poison Control Center Data tends to support the IDS results with dermal irritation, erythema, and difficulty breathing being among the most common effects reported.

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

A summary of the Agency's environmental fate and effects risk assessment is presented below. For detailed discussion of all aspects of the environmental risk assessment, please see the documents, *Environmental Fate and Effects Division Risk Assessment for the Reregistration of Propiconazole*, dated November 29, 2005, *Environmental Fate and Effects Division Revised RED for the Reregistration of Propiconazole*, dated June 30, 2006, and *Terrestrial Plant Runoff Risk Assessment for Propiconazole on Turf Using PRZM*, dated July 14, 2006. These documents are available on the internet ([www.regulations.gov](http://www.regulations.gov)) and in the public docket under docket number EPA-HQ-OPP-2005-0497. This risk assessment was refined and updated to incorporate public comments submitted during Phase 3 of the public participation process and additional studies submitted by the registrant. Major changes to the risk assessment include the following:

- Incorporation of information on dissipation and degradation of propiconazole in the environment,
- Revision of estimated environmental concentrations (EECs) for propiconazole in water for wheat and rice and in various food items for turf and rice,
- Use of EPA's T-REX Model to estimate risk quotients (RQs) for birds and mammals; and
- Revision of Risk Quotients (RQs) for aquatic and terrestrial organisms.

## **1. Environmental Fate and Transport**

Propiconazole appears to be persistent and moderately mobile to relatively immobile in most soil and aqueous environments. Propiconazole degradation in the aquatic environment appears to be dependent solely on aqueous photolysis in the presence of photo sensitizers that are quite common in photolysis studies. In soil environments, propiconazole dissipation appears to be dependent on incorporation or binding to soil organic matter content.

Laboratory and terrestrial field dissipation data indicate that propiconazole is stable in soil and aqueous environments. Propiconazole was stable to hydrolysis; aqueous photolysis; soil photolysis; aerobic aquatic metabolism, aerobic soil metabolism, and anaerobic aquatic metabolism. The terrestrial field dissipation data were consistent with laboratory data with reported half-lives of greater than 100 days for four soil textures. However, in supplemental aquatic dissipation studies using basin irrigation and flow-through irrigation systems in rice fields, propiconazole was found to dissipate rapidly with a half-life of less than 5 days. Aqueous photolysis studies using sensitizers indicated rapid degradation with a half-life of less than 1 day for propiconazole, which appears to also be the case in rice fields. Furthermore, aquatic metabolism and dissipation studies indicate propiconazole dissipates by incorporation of binding to the organic matter content of soil/sediment.

Propiconazole mobility in soil appears to be dependent on the soil's organic matter content. In general, propiconazole appears to be moderately mobile in soils with low organic matter content and relatively immobile in soils with high organic matter content. Therefore, propiconazole may reach groundwater in soils with low organic content. More importantly, propiconazole may contaminate surface water through off-site runoff and spray drift.

## **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 acute and chronic 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 14 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. For a more detailed explanation of the ecological risks posed by the use of propiconazole, refer to the document, *Environmental Fate and Effects Division Revised RED for the Reregistration of Propiconazole*, dated June 30, 2006.

<b>Table 14. EPA's Levels of Concern (LOCs) and Risk Presumptions</b>			
<b>If a calculated RQ is greater than the LOC presented, then the Agency presumes that...</b>	<b>LOC terrestrial animals</b>	<b>LOC aquatic animals</b>	<b>LOC Plants</b>
<b>Acute Risk</b> ...there is potential for acute risk; regulatory action may be warranted	0.5	0.5	1.0
<b>Acute Listed (Endangered and Threatened) Species</b> ...listed species may be adversely affected	0.1	0.05	1.0
<b>Chronic Risk</b> ...there is potential for chronic risk	1	1	NA

**a. Terrestrial Organisms**

Exposure to Birds and Mammals. The Agency assessed exposure to terrestrial organisms by first predicting the amount of propiconazole residues found on animal food items and then by estimating the amount of pesticide consumed by using information on typical food consumption by various species of birds and mammals. The amount of residues on animal feed items are based on the Fletcher nomogram (a model developed by Fletcher, Hoerger, Kenaga, et al.), a default half-life of 35 days and/or a chemical-specific foliar dissipation half-life, the current maximum application rate for propiconazole, the maximum number of applications per year (when specified), and the minimum interval between applications. For crops with more than one application, EPA used the T-REX computer model to account for residue dissipation between pesticide applications. EPA modeled the mean and maximum residues of propiconazole in various food items immediately after application of propiconazole to representative crops. EPA used the maximum EECs and standard food consumption values to estimate dietary exposure levels for birds and mammals. EECs were determined for the following food categories: *short grass, tall grass, broadleaf forage/small insects, and fruit, pods, seeds/large insects*. The EEC values on these food items may be found in the June 30, 2006 document, *Environmental Fate and Effects Division Revised RED for the Reregistration of Propiconazole*.

As mentioned above, EPA used a default 35-day foliar dissipation half-life to derive EECs. EPA has limited chemical-specific data for foliar dissipation in wheat, from field trials for propiconazole. These data were used as a surrogate for all potential vegetative feed forms for birds and mammals. However, there are key uncertainties in these data. In the propiconazole field trials for wheat, only a few samples were taken at the time of propiconazole application allowing residue dissipation could be determined over time. Further, these field trials did not record local weather data, which can affect dissipation. EPA took the 95<sup>th</sup> percentile upper confidence limit on the mean foliar dissipation half-life to derive a 14.4 day foliar dissipation half-life. This value was used to give a lower range for EECs for certain crops. The Agency is requiring a confirmatory foliar dissipation study as part of this RED. This study would measure dissipation of propiconazole over time from foliage of several representative crop groups.

Toxicity to Birds and Mammals. EPA determines the potential effects a pesticide can

produce in a terrestrial organism by reviewing guideline toxicity studies that describe acute and chronic effects of the chemical on birds and mammals. Table 15 summarizes the toxicity effects and reference values used to assess potential risks to mammals and birds from unintentional exposure to propiconazole. These toxicity values were used to calculate RQs based both on the dose (in terms of mg/kg/body weight given in a gavage study) and diet (in terms of mg/kg of food consumed). Dose-based RQs assumes that the uptake and absorption of a compound from a dose given by oral gavage is similar to the dose the organism receives in the field from eating food items containing residues of the compound. However, a gavage dose represents a short-term high-intensity exposure, which is likely to be different from a typical dose level and duration in the field. Dietary-based RQs assume that the dose of a compound administered in a laboratory feeding study is similar to the level of residues the organism consumes in the field. However, the diet in a laboratory feeding study differs significantly from the diet of an animal foraging in for food the field.

<b>Table 15. Toxicity Reference Values for Mammals and Birds for Propiconazole.</b>			
<b>Exposure Scenario</b>	<b>Species</b>	<b>Toxicity Reference Value</b>	<b>Toxicity Category or Effect</b>
<b>Mammals</b>			
Acute	Mouse	LD <sub>50</sub> = 729 mg ai/kg bwt	Category III
Chronic	Rat	NOAEL = 43 mg/kg bwt	Reduced body weight gain, liver changes in F0 generation, decreased offspring survival & body weight, hepatic lesions
<b>Birds</b>			
Acute	Bobwhite quail	LD <sub>50</sub> = 2825 mg ai/kg bwt	Practically non-toxic
Chronic		NOAEC = 1000 mg/kg diet	No treatment-related effects
LD <sub>50</sub> - Median Lethal Dose or Concentration, statistically derived single dose or concentration that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). NOAEL – no observed adverse effect level, dose of compound in mg ai/kg body weight/day; NOAEC – lowest observed adverse effect concentration or concentration of compound in food associated with adverse effects, dose in mg ai/kg food consumed.			

Acute mammalian RQs for herbivores/insectivores were calculated on the basis of dose (mg/kg body weight/day by gavage). Acute dose-based RQs assuming a default 35 day half-life are below the LOC for all propiconazole uses except RQs for turf (Table 16a). The RQs for turf exceeded the listed species LOC for mammals in all food categories except for *fruits/pods/large insects* and *grain* (represented by the lower end of range of RQs presented). However, RQs based on multiple applications of propiconazole to turf exceeded the acute LOC of 0.5 only for 15 g and 35 g smaller mammals in the *short grass* food category. Remaining RQs did not exceed any levels of concern.

Table 16a. Acute RQs for Terrestrial Mammals Exposed to Propiconazole (35 day half-life).*			
Exposure Scenario (Crop)	Ranges of Acute RQs** by Body Weight		
	15 g	35 g	1000 g
Barley, Rye, Triticale	0.0003 – 0.02	0.00017 – 0.01	0.000036 – 0.003
Wheat	0.00 – 0.024	0.00 – 0.017	0.00 – 0.0038
Pecan, Grasses grown for seed	0.00 – 0.09	0.00 – 0.08	0.00 – 0.04
Corn, Celery	0.00 – 0.08	0.00 – 0.053	0.00 – 0.012
Peanut	0.00 – 0.06	0.00 – 0.05	0.00 – 0.03
Rice, Wild Rice	0.00 – 0.04	0.00 – 0.04	0.00 – 0.02
Stone Fruits	0.00 – 0.07	0.00 – 0.06	0.00 – 0.03
Turf and Ornamentals, ground cover	0.01 – <b>0.77</b>	0.01 – <b>0.66</b>	0.00 – 0.35
Turf and Ornamentals, lawns, turf, golf courses	0.01 – <b>0.7</b>	0.01 – <b>0.6</b>	0.00 – 0.32
Turf and Ornamentals, sod farm	0.01 – <b>0.61</b>	0.01 – <b>0.52</b>	0.00 – 0.28

\*Acute RQs are based on an EPA default 35 foliar dissipation half-life. \*\*Ranges of acute RQs are based on a variety of food items, including *short grass*; *tall grass*; *broadleaf plants and small insects*; and *fruits, pods, seeds, and large insects*. **RQs in bold** are above EPA's level of concern (LOC).

For crops where RQs exceeded the Agency's LOC (Table 16a), EPA revised the dose-based RQs by using the limited chemical-specific data on foliar dissipation half-life previously described. EPA ran the T-REX model using a 14.4 day foliar dissipation half-life derived from propiconazole specific data, rather than the default foliar dissipation half-life of 35 days used in the original screening-level assessment. Revised RQs are presented in Table 16b below and show no acute risks of concern for mammals except for the smallest mammals feeding on *short grass*. In addition, there are no listed species risks of concern for all weight classes of mammals feeding on *fruits, pods, seeds/large insects*. However, the listed species LOC of 0.1 is exceeded for all weight classes of mammals feeding on *short grass, tall grass, and broadleaf plants and small insects*.

Table 16b. Revised Acute RQs for Terrestrial Mammals Exposed to Propiconazole (14.4 day half-life).*			
Exposure Scenario (Crop)	Ranges of Acute RQs** by Body Weight		
	15 g	35 g	1000 g
Turf and Ornamentals, ground cover	0.01 – <b>0.57</b>	0.01 – 0.49	0.00 – 0.26
Turf and Ornamentals, lawns, turf, golf courses	0.01 – 0.48	0.01 – 0.41	0.00 – 0.22
Turf and Ornamentals, sod farm	0.01 – 0.39	0.00 – 0.34	0.00 – 0.18

\*Based on chemical-specific 14.4 day foliar dissipation half-life. \*\*Represent variety of food items, including *short grass*; *tall grass*; *broadleaf plants and small insects*; and *fruits, pods, seeds, and large insects*. **RQs in bold** > LOC.

Chronic risks to mammals based on the default 35-day half-life were calculated using both the dietary- and dose-based RQs. Dietary-based RQs, not presented in the table below, only exceeded the chronic LOCs for multiple applications to turf and ranged from 1.1 to 2.6. However, dose-based chronic RQs (Table 17a) were as high as 13 for mammals foraging in *short grass* when EPA assumed multiple applications of propiconazole to the crops listed below. Chronic RQs only begin to exceed LOCs after the 3<sup>rd</sup> application and no chronic LOCs are exceeded after 2 applications. Acute risks would also be lower based on fewer applications. All other exposure scenarios resulted in RQs below the Agency’s LOC and are therefore not presented in Table 17a.

Exposure Scenario (Crop)	Ranges of Chronic RQs ** by Body Weight		
	15 g	35 g	1000 g
Pecan, Grasses grown for seed	0.02 - <b>1.51</b>	0.02 - <b>1.29</b>	0.0 - 0.69
Stone Fruits	0.02 - <b>1.13</b>	0.01 - 0.96	0.01 - 0.52
Turf and Ornamentals, ground cover	0.18 - <b>13</b>	0.16 - <b>11</b>	0.08 - <b>6</b>

\*Based on an EPA default 35 foliar dissipation half-life. \*\*Represent a variety of food items, including *short grass*; *tall grass*; *broadleaf plants and small insects*; and *fruits, pods, seeds, and large insects*. **RQs in bold** are above EPA’s level of concern (LOC).

When the Agency revised the chronic dose-based RQs using chemical-specific foliar dissipation half-life data, almost all pecan, stone fruit, and grasses grown for seed chronic RQs do not exceed the Agency’s chronic LOC of 1 except for the smallest weight class of mammal feeding on *short grass* in pecans (the RQ only barely exceeds at 1.04). For turf, chronic RQs do not exceed the Agency’s chronic LOC for all weight classes of mammals feeding on *fruits, pods, large insects/seeds*; however, turf RQs exceed the Agency’s chronic LOC for mammals feeding on *short and tall grass*, and *broadleaf plants and small insects*.

Exposure Scenario (Crop)	Ranges of Chronic RQs** by Body Weight		
	15 g	35 g	1000 g
Pecan, Grasses grown for seed	0.01 - <b>1.04</b>	0.01 - 0.89	0.01 - 0.47
Stone Fruits	0.00 - 0.89	0.01 - 0.76	0.01 - 0.41
Turf and Ornamentals, ground cover	0.13 - <b>9.64</b>	0.11 - <b>8.23</b>	0.06 - <b>4.41</b>

\*Based on a chemical-specific 14.4 day foliar dissipation half-life. \*\*Represent a variety of food items, including *short grass*; *tall grass*; *broadleaf plants and small insects*; and *fruits, pods, seeds, and large insects*. **RQs in bold** are above EPA’s level of concern (LOC).

Avian acute RQs based on the default 35-day foliar dissipation half-life do not exceed the Agency’s LOC of 0.5 except RQs for the smallest weight class of birds feeding on short grass

derived from maximum residues from multiple applications to turf and ornamental uses (see bolded numbers in Table 18a). When these RQs were revised using chemical-specific foliar dissipation half-life data, only the RQ of 0.53 for smallest weight class of bird feeding on short grass exceeds the LOC of 0.5 (Table 18b). However, RQs based on predicted maximum residues and multiple applications to turf and ornamentals exceed the listed species LOC of 0.1 for all weight classes of birds feeding on short grass and tall grass and for smaller birds feeding on broadleaf forage and small insects based. For RQs based on predicted, mean residues resulting from multiple applications to turf and ornamentals, only birds feeding on short grass exceed the endangered species LOC. No other exposure scenarios result in RQs that exceed the Agency's LOCs. Acute RQs are summarized in Tables 18a and b below; ranges are based on a variety of food items, weight classes of birds, and number of applications.

Dietary-based avian chronic RQs presented in Table 18a show that the chronic LOC is slightly exceeded for use of propiconazole on turf. However, chronic data for birds showed no treatment-related effects at any of the test levels up to 1000 mg/kg diet and, as such, a LOAEC could not be determined. Consequently, the actual NOAEC could be much greater than that observed in the study used to assess chronic avian risk and the RQs could be lower. Dietary-based chronic avian RQs only exceeded the LOC for multiple applications to turf and the highest RQ was 1.3 (Chronic LOC is 1). In addition, these RQs have been further refined by using chemical-specific foliar dissipation half-life data resulting in a maximum RQ of only 1.02 (Table 18a). Based on the lack of observed effects in the chronic study, and the fact that RQs based on this study only slightly exceed the LOC, the Agency does not consider there to be chronic avian risks of concern for propiconazole.

<b>Table 18a. Acute and Chronic RQs for Birds Exposed to Propiconazole (35 day half-life).*</b>				
<b>Exposure Scenario (Crop)</b>	<b>Ranges of Acute RQs**</b>		<b>Ranges of Chronic RQs**</b>	
	<b>Based on Maximum Residues</b>	<b>Based on Mean Residues</b>	<b>Based on Single Application</b>	<b>Based on Multiple Applications</b>
Barley, Rye, Triticale	0.00 – 0.02	0.00 – 0.01	0.0016 – 0.027	NA
Wheat	0.00 – 0.02	0.00 – 0.00	0.0021 – 0.034	0.0011 – 0.02
Pecan, Grasses grown for seed	0.00 – 0.08	0.00 – 0.03	0.0034 – 0.054	0.009 – 0.149
Corn, Celery	0.00 – 0.03	0.00 – 0.01	0.0 – 0.03	0.0 – 0.05
Peanut	0.00 – 0.06	0.00 – 0.02	0.00 – 0.05	0.01 – 0.1
Rice, Wild Rice	0.00 – 0.1	0.00 – 0.03	0.0034 – 0.054	0.004 – 0.08
Stone Fruits	0.00 – 0.061	0.00 – 0.02	0.0017 – 0.027	0.007 – 0.112
Turf and Ornamentals, ground cover	0.00 – <b>0.70</b>	0.00 – 0.25	0.027 – 0.427	0.08 – <b>1.3</b>
Turf and Ornamentals, lawns, turf, golf courses	0.00 – <b>0.63</b>	0.00 – 0.22	0.027 – 0.427	0.074 – <b>1.18</b>

Table 18a. Acute and Chronic RQs for Birds Exposed to Propiconazole (35 day half-life).*				
Exposure Scenario (Crop)	Ranges of Acute RQs**		Ranges of Chronic RQs**	
	Based on Maximum Residues	Based on Mean Residues	Based on Single Application	Based on Multiple Applications
Turf and Ornamentals, sod farm	0.00 – <b>0.54</b>	0.00 – 0.19	0.027 – 0.427	0.06 – <b>1.02</b>

\* Based on an EPA default 35 foliar dissipation half-life. \*\*Represent a variety of food items, including short grass; tall grass; broadleaf plants and small insects; and fruits, pods, seeds, and large insects. RQs are also based on different weight classes of birds and single and multiple applications. **RQs in bold** are above EPA's level of concern (LOC).

Table 18b. Revised Acute and Chronic RQs for Birds Exposed to Propiconazole (14.4 day half-life).*		
Exposure Scenario (Crop)	Ranges of Acute RQs (based on multiple applications)	Ranges of Chronic RQs (based on multiple applications)
Turf and Ornamentals, ground cover	0.00 – <b>0.53</b>	0.06 – 0.96
Turf and Ornamentals, lawns, turf, golf courses	0.00 – 0.45	0.05 – 0.81
Turf and Ornamentals, sod farm	0.00 – 0.37	0.04 – 0.66

\*Based on a chemical-specific 14.4 day foliar dissipation half-life. \*\* Represent a variety of food items, including short grass; tall grass; broadleaf plants and small insects; and fruits, pods, seeds, and large insects. RQs are also based on different weight classess of birds and single and multiple applications. **RQs in bold** are above EPA's level of concern (LOC).

Non-Target Insects & Other Terrestrial Organisms. EPA currently does not estimate RQs for terrestrial non-target insects. In addition, there were no data on non-target terrestrial insects, such as honeybees. Propiconazole does not appear to have any adverse effects on soil microbes as evidenced by soil biochemical analysis. Also, propiconazole showed no toxicity to earthworms.

Non-Target Terrestrial Plants. Terrestrial plants inhabiting dry and semi-aquatic (wetland) areas may be exposed to pesticides from runoff and/or spray drift. Therefore, EPA estimated exposure to terrestrial plants using the Terr-PLANT model based on the maximum label application rate, a default amount of runoff based on solubility, and default assumptions regarding drift. EECs for non-target plants resulting from a single application of propiconazole are presented in Table 19.

<b>Crop</b>	<b>Application Rate (lbs ai/A)</b>	<b>Application Method</b>	<b>Total loading to adjacent areas (lb ai/A)</b>	<b>Total loading to semi-aquatic areas (lb ai/A)</b>	<b>Drift EEC (lb ai/A)</b>
Stone fruit	0.1125	Ground spray	0.0034	0.0236	0.0011
		Aerial spray	0.0079	0.0281	0.0056
Wheat	0.08	Ground spray	0.0024	0.0168	0.008
		Aerial spray	0.0056	0.020	0.004
Grasses grown for seed, forage, fodder grasses	0.225	Ground spray	0.0068	0.0473	0.0023
		Aerial spray	0.0158	0.0563	0.0113
Turf and ornamentals – ground cover	1.78	Ground spray	0.0534	0.3738	0.178
		Chemigation	0.12446	0.4450	0.089

EPA determines the potential effects a pesticide can produce in nontarget plants by reviewing guideline toxicity studies that describe acute effects toxicity information for various terrestrial plants. Tier 2 terrestrial plant data are available to show effect of technical propiconazole on both seedling emergence and vegetative vigor. The seedling emergence study considered percent emergence, plant height, and plant dry weight to determine the EC<sub>25</sub> and NOAEC for each of the species tested at use rates of 0.0185, 0.056, 0.167, 0.5, and 1.5 lb ai/A. The monocots tested included onion, corn, oats, and ryegrass. Although the dicot species included carrot, soybean, lettuce, cucumber, tomato, and cabbage, only cabbage showed a dose response sufficient to derive an EC<sub>25</sub>. The other dicot species appeared to be unaffected by the treatments. Therefore, for the purposes of risk assessment, the EC<sub>25</sub> is assumed to be >1.5 lb ai/A for all of these species except cabbage. The EC<sub>25</sub> for cabbage is 0.18 lb ai/A, and the NOAEC is 0.056 lb ai/A based on plant dry weight. The vegetative vigor study was performed using the same species and application rates as the seedling emergence studies. Plant height and plant dry weight were the parameters measured to determine a dose-response. Ryegrass was determined to be the most sensitive monocot based on plant height, with an EC<sub>25</sub> of 0.315 lb ai/A and a NOAEC of 0.0185 lb ai/A. As with the seedling emergence study, cabbage was the most sensitive dicot based on plant dry weight, with an EC<sub>25</sub> of 0.039 lb ai/A and a NOAEC of 0.056 lb ai/A. These data are summarized in Table 20 below.

<b>Species</b>	<b>EC<sub>25</sub> (lb ai/A)</b>	<b>NOAEC/EC<sub>05</sub> (lb ai/A)</b>	<b>Effect</b>
<b>Monocot</b>			
Onion, corn, oat, ryegrass	>1.5	1.5	Seedling emergence: emergence, shoot length, dry weight
Ryegrass	0.315	0.0185	Vegetative vigor: plant height

Species	EC <sub>25</sub> (lb ai/A)	NOAEC/EC <sub>05</sub> (lb ai/A)	Effect
<b>Dicot</b>			
Cabbage	0.18	0.056	Seedling emergence: plant dry weight
	0.039	0.056	Vegetative vigor: plant dry weight

EC<sub>25</sub> – 25% Effect Concentration, statistically derived single dose or concentration that can be expected to cause effects in 25% of the test organisms; EC<sub>05</sub> – 5% Effect Concentration, statistically derived single dose or concentration that can be expected to cause effects in 5% of the test organisms; NOAEC – No adverse effects concentration.

Although propiconazole is a fungicide, it poses a potential risk to terrestrial plants for some uses. The Agency calculated RQs for seedling emergence effects (using total exposure from drift and runoff) and RQs for vegetative vigor for exposure via spray drift. RQs for nonlisted and listed plant species are presented in Table 21 below. This screening-level risk assessment for nontarget terrestrial plants suggests potential adverse effects on seedling emergence from runoff and spray drift to adjacent fields and potential risk of adverse effects on vegetative vigor from spray drift alone. RQs are below the LOC except for nonlisted dicots based on use on turf and listed dicots based on use in grasses grown for seed, rice, wild rice, peanut, and turf use. The RQs for terrestrial dicots (2.1-2.5) exceed the acute LOC of 1.0 for terrestrial plants in semi-aquatic areas at the maximum application rate for turf. The RQs for listed terrestrial dicots in semi-aquatic areas is greater than the LOC for use on turf and ornamentals and equal to the LOC for use on grass grown for seed, rice, wild rice, peanut, and turf use. For monocots, RQs for listed species exceed the LOC for spray drift from propiconazole use on turf and ornamentals.

Scenario		RQs for Nonlisted Species*				RQs for Listed Species**			
Use Sites	Application Method	adjacent to treated sites		in semi-aquatic areas		adjacent to treated sites		in semi-aquatic areas	
		Total Exposure	Drift	Total	Drift	Total	Drift	Total	Drift
<i>Nontarget Dicots</i>									
Grasses grown for seed, Rice, Wild rice, Peanut	Aerial	0.09	0.30	<0/31	0.30	0.04	0.20	<b>1.01</b>	0.20
	Ground	0.04	0.06	0.26	0.06	0.12	0.04	0.84	0.04
Turf and ornamentals – ground cover	Ground	0.03	0.46	<b>2.1</b>	0.46	0.95	0.32	<b>6.68</b>	0.32
	Chemigation	0.7	<b>2.28</b>	<b>2.47</b>	<b>2.28</b>	<b>2.23</b>	<b>1.59</b>	<b>7.95</b>	<b>1.59</b>
<i>Nontarget Monocots</i>									
Grasses grown for seed, Rice, Wild rice, Peanut	Aerial	<0.01	0.036	<0.06	<0.04	0.01	0.61	0.04	0.61
	Ground	<0.005	0.007	<0.03	0.007	0.005	0.12	0.03	0.12
Turf and ornamentals – ground cover	Ground	<0.04	0.06	<0.25	0.06	0.036	0.96	0.25	0.96
	Chemigation	<0.08	0.28	<0.3	0.28	0.083	<b>4.81</b>	0.30	<b>4.81</b>

\* RQs for nonlisted species are based on EC<sub>25</sub> ; \*\* RQs for listed species based on NOAEC or EC<sub>05</sub>. Total exposure includes runoff and drift ; drift is from spray drift alone. RQs for total exposure based on seedling emergence endpoint; RQs for spray drift are based on vegetative vigor endpoint.



EPA's screening-level model Terr-PLANT assumes that a certain default fraction of total pesticide applied will be transported to adjacent fields via surface runoff and spray drift. For propiconazole, Terr-PLANT assumes that a default value of 2% propiconazole applied is available to nontarget plants in adjacent fields. Terr-PLANT calculates exposure based only on a single application, whereas propiconazole labels allow for multiple applications of propiconazole (i.e., as many as 5 applications to stone fruit). Therefore, Terr-PLANT may potentially underestimate exposure and risk to plants. However, the effects of multiple applications would only be additive if the affected plants could not recover from the effects of successive applications. Furthermore, there is uncertainty in the likelihood of co-exposure of spray drift and runoff, particularly after subsequent applications.

To address uncertainties in the Terr-PLANT model and further characterize the risk to nontarget terrestrial plants from runoff, EPA compared the EEC of 0.37 lb ai/A from a single application of 1.78 lb ai/A of propiconazole to turf, with peak runoff EECs simulated by PRIZM over 30 years. The transport of propiconazole from the peak runoff event for each of 30 years simulated by PRZM ranged from 0.009 lb ai/A to 0.245 lb ai/A. These EECs, which reflect 4 applications of propiconazole at 1.78 lb ai/A, would result in acute RQs ranging from 0.05 to 1.4 if used in the risk assessment. Peak storm events simulated by PRZM would result in RQs at or above the LOC of 1.0 in 6 of the 30 years simulated, indicating a potential risk to plants adjacent to treated fields under certain conditions if the maximum rate and number of applications are applied. Additional details of this assessment may be found in the July 18, 2006 document, *Terrestrial Plant Runoff Risk Assessment for Propiconazole on Turf Using PRZM*. Use data indicate that typical rates in the states with the greatest use range from 0.7 to 1.2 lbs ai/A. Since these typical rates are at least 1/3 less than the maximum rate, the 25% effect on seedling emergence represented by the toxicity endpoint might occur even less frequently than suggested by the PRZM model output.

EPA also used the AG-DRIFT model, which simulates spray drift at various distances from the site of application, to further characterize exposure and risk to nontarget terrestrial plants. Pesticide application was simulated using low-boom ground spray equipment to turf, using nozzles which produce a very fine to fine droplet size spectrum. Using the 90<sup>th</sup> percentile drift data generated by the Spray Drift Task Force on which AgDrift is based, the model predicted the distances to which point exposure would be equivalent to the EC25 values for various crops tested in the propiconazole vegetative vigor studies. As shown in Table 22 below, an AgDRIFT simulation for the four most sensitive plants in a vegetative vigor study showed that spray drift RQs from ground application of propiconazole to turf would exceed the LOC to distances of 3 ft, 7 ft, 13 ft and 43 ft, assuming 10 mph wind perpendicular to the spray path.

<b>Distance of Spray Drift Deposition with Ag-DRIFT following application of 1.78 lb ai/A to Turf</b>	<b>Vegetative Vigor EC<sub>25</sub> for Sensitive Test Crops</b>			
	<b>Corn 0.968 lb ai/A</b>	<b>Onion 0.334 lb ai/A</b>	<b>Soybean 0.16 lb ai/A</b>	<b>Cabbage 0.039 lb ai/A</b>
	3.3 ft	6.6 ft	13.1 ft	42.7 ft

The results indicate that exposure that would result in risk quotients at the acute LOC would be expected to occur within 50 feet of turf treated with propiconazole. An additional calculation was

done to determine the distance at which point deposition would be equivalent to the lowest NOAEC in the vegetative vigor test (0.0185 lb ai/A for ryegrass). The calculated distance of 91.86 feet suggests that listed plants more than 100 feet of a treated field may be at less risk.

The next highest application rate for propiconazole after turf is 0.225 lb ai/acre for grasses grown for seed, pecan, and rice, which is lower than the EC<sub>25</sub> for all but soybeans and cabbage in the vegetative vigor test. However, drift from aerial application of 0.225 lb ai/acre could result in point deposition equal to the cabbage vegetative vigor EC<sub>25</sub> of 0.039 lb ai/A up to a distance of 49 feet, assuming a default fine to medium droplet size spectrum. Drift from aerial application of 0.225 lb ai/acre could result in point deposition equal to the ryegrass vegetative vigor NOAEC of 0.0185 lb ai/A up to a distance of 118 feet, assuming the same fine to medium droplet size spectrum.

### b. Aquatic Organisms

*Freshwater and Estuarine/Marine Fish and Invertebrates.* To assess potential risks to aquatic animals, the Agency considers predicted estimated environmental concentrations (EECs) in surface water using the Tier II model PRZM/EXAMS. Unlike the drinking water assessment described in the human health risk assessment section of this document, the exposure values used in the ecological risk assessment consider pesticide transport as a result of runoff, erosion, off-target spray drift, and environmental fate of pesticides in surface water but do not include the Index Reservoir (IR) and Percent Cropped Area (PCA) factor refinements. These factors represent a drinking water reservoir, not the variety of aquatic habitats relevant to a risk assessment for aquatic animals, such as ponds adjacent to treated fields. Therefore, the EEC values used to assess exposure and risk to aquatic animals are not the same as those used to assess exposure and risk to humans from pesticides in drinking water.

The EECs of propiconazole used in the ecological risk assessment are summarized in Table 23 below. The highest EEC is 86.5 and is associated with the use of propiconazole on rice. The rice scenario represents the most conservative aquatic exposure estimate of the potential exposure scenarios for propiconazole; the rice EEC value of 86.5 ppb represents paddy discharge water with consideration of adsorption, degradation, and dilution but does not account for degradation after discharge. The turf scenario represents the next highest EECs; this scenario assumes use at the maximum rate, maximum number of applications, and minimum time interval between applications.

Use Scenario and State	Peak (µg/L)	96-hour average (µg/L)	21-day average (µg/L)	60-day average (µg/L)	90-day average (µg/L)
Wheat ND	3.70	3.64	3.41	3.12	3.08
Grass Seed OR	5.69	5.63	5.41	5.06	4.95
Rice	86.5	71.1	34.2	17.8	11.9
Pecans GA	12.15	11.93	11.21	10.15	9.49

**Table 23. Estimated Environmental Concentrations of Propiconazole in Surface Water**

Use Scenario and State	Peak (µg/L)	96-hour average (µg/L)	21-day average (µg/L)	60-day average (µg/L)	90-day average (µg/L)
Peaches GA	3.35	3.28	3.01	2.55	2.35
Sweet Corn FL	13.28	13.00	12.32	10.70	9.77
Sweet Corn OR	4.49	4.46	4.30	4.09	4.06
Dry Beans MI	6.49	6.41	6.17	5.83	5.64
Peanuts NC	7.00	6.89	6.49	6.16	5.75
Barley (based on ND Wheat)	1.92	1.89	1.79	1.66	1.61
Celery (based on FL Carrots)	9.83	9.68	9.12	7.07	5.97
Turf PA	40.35	39.59	37.28	34.83	33.98
Turf FL	34.77	34.09	31.14	27.93	27.04

EPA determines the potential effects a pesticide can produce in an aquatic organism by reviewing guideline toxicity studies that describe acute and chronic effects for various aquatic animals. Table 24 below summarizes the toxicity effects and reference values used to assess risk of propiconazole to aquatic organisms. No acceptable guideline chronic toxicity studies were available for propiconazole in estuarine/marine fish; however, the LC<sub>50</sub> for spot was 2244 ug/L, compared with an LC<sub>50</sub> of 850 ug/L for rainbow trout.

**Table 24. Propiconazole Toxicity Reference Values for Aquatic Organisms.**

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value (ppb)	Toxicity Category or Effect	
Freshwater Fish	Acute	rainbow trout	96 hours	LC <sub>50</sub> = 850	Highly toxic
	Chronic	Fathead minnow	Early life stage	NOAEC = 95	Mortality, length, weight
Freshwater Invertebrate	Acute	<i>Daphnia magna</i>	96 hours	LC <sub>50</sub> = 4800	Slightly toxic
	Chronic	<i>Daphnia magna</i>	Study not suitable for use in risk assessment		
Estuarine/Marine Fish	Acute	Spot	96 hours	LC <sub>50</sub> = 2244	Moderately toxic
	Chronic	No acceptable guideline studies were available			
Estuarine/Marine Invertebrates	Acute	Mysid shrimp	96 hours	LC <sub>50</sub> = 510	Highly toxic
	Chronic	Mysid shrimp	Life cycle	NOAEC = 205	Mortality and number of offspring

Table 25 presents acute and chronic RQs for both estuarine/marine and freshwater fish and invertebrates. Based on the maximum 1-in-10 year peak surface water concentrations and the most sensitive 96-hour LC<sub>50</sub> values for fish and aquatic invertebrates, all propiconazole RQs are less than the Agency’s LOC for acute risk (0.5). However, the freshwater fish RQ is equal to the acute listed species LOC of 0.05 based on EECs in surface water from turf use in Pennsylvania, but does not exceed based on EECs in surface water from turf use in Florida. In addition, the estuarine/marine fish acute RQ exceeds the listed species LOC based on rice use. And finally, the estuarine/marine invertebrate acute RQs exceed the acute listed species LOC (0.05) for both the turf and rice uses. No LOCs were exceeded for any other crop to which propiconazole is applied; RQs for the other crops are significantly less than the turf RQ and the LOC and therefore were not included in Table 25.

Chronic RQs that for freshwater fish and for estuarine/marine invertebrates do not exceed the Agency’s chronic LOC of 1 based on average surface water concentrations of propiconazole resulting from both the turf and rice scenarios and available toxicity data. These RQs are presented in Table 25 below. As previously mentioned, the Agency does not have adequate chronic toxicity data to assess chronic risks from propiconazole uses to estuarine/marine fish or freshwater invertebrates. There is a data gap for these studies; however, the existing data may be upgraded.

<b>Table 25. Summary of Acute and Chronic Risk Quotients for Aquatic Organisms Exposed to Propiconazole.</b>					
<b>Crop Scenario</b>	<b>EECs (ppb)</b>	<b>Freshwater RQs</b>		<b>Estuarine/Marine RQs</b>	
		<b>Fish</b>	<b>Invertebrates</b>	<b>Fish</b>	<b>Invertebrates</b>
<i>Acute Risks</i>					
Turf	40.35 (peak)	0.05	0.008	0.02	0.08
Rice	86.5	0.1	0.02	0.04	0.17
<i>Chronic Risks</i>					
Turf	34.8 (fish – 60 day average) 37.3 (invertebrate – 21 day average)	0.36	No data	No data	0.18
Rice	17.81 (fish – 60 day average) 34.24 (invertebrates – 60 day average)	0.19	No data	No data	0.17

*Aquatic Plants.* EPA determines the potential effects a pesticide can produce in aquatic plants by reviewing guideline toxicity studies that describe acute and chronic effects for various aquatic plants. Table 25 summarizes the toxicity data used to assess risk of propiconazole to aquatic plants. These studies showed that the marine diatom, *Skeletonema costatum*, is the most sensitive aquatic plants species of those tested with a NOAEC of 18 ug/L. The NOAEC is used to calculate acute listed species RQs and the EC<sub>50</sub> is used to calculate acute RQs for aquatic plants.

Table 26. Acute Toxicity of Propiconazole to Aquatic Plants			
Species	EC <sub>50</sub> (ug ai/L)	NOAEC/EC <sub>05</sub> (ug ai/L)	Effect
<i>Vascular Plants</i>			
Duckweed ( <i>Lemna gibba</i> )	4828	<2540	Fronnd count
<i>Non-Vascular Plants</i>			
Freshwater diatom ( <i>Navicula pelliculosa</i> )	93	51	Dry cell weight
Blue green algae ( <i>Skeletonema costatum</i> )	21	<18	Dry cell weight

As shown in Table 27 below, the use of propiconazole on rice and turf may present risk to non-vascular estuarine/marine plants; both the acute and listed species RQs exceed the LOC of 1. In addition, the use of propiconazole on rice may present an acute risk to listed freshwater non-vascular plants; the listed species RQs exceed the LOC of 1.

The RQs for freshwater vascular plants based on both turf and rice use and the RQs for freshwater non-vascular plants based on turf use do not exceed the LOC. In addition, RQs based on EECs for other crops do not exceed the Agency's LOC and are therefore not presented in Table 27 below. As previously mentioned, the highest modeled EECs are for the use of propiconazole on rice.

Table 27. Risk Quotients for Aquatic Plants Exposed to Propiconazole.							
Crop	EECs (ppb)	Freshwater Vascular Plants		Freshwater Non-Vascular Plants		Estuarine/Marine Non-Vascular Plants	
		Listed	Acute	Listed	Acute	Listed	Acute
Turf – Florida	34.88	Not calculated, less than PA turf and not of concern				>1.93	1.66
Turf – Pennsylvania	40.35	>0.016	0.008	0.79	0.43	>2.24	1.92
Rice	86.5	> 0.03	0.02	1.7	0.93	>4.81	4.12

**RQs in bold** are above EPA's level of concern (LOC).

### 3. Endangered Species

The screening-level risk assessment for propiconazole indicates a potential for adverse effects on listed species as noted below, should exposure actually occur at modeled levels:

#### Terrestrial organisms

- Mammals
  - Acute RQs for turf and ornamentals exceed LOCs for small mammals feeding on *short grass, tall grass, broadleaf forage and small insects*;

- Chronic RQs for turf and ornamentals exceed LOC for all mammals feeding on *short grass, tall grass, broadleaf forage and small insects*;
- Birds
  - Acute RQs for turf and ornamentals exceed LOCs for all birds feeding on *short grass and tall grass* and for smaller birds feeding on *broadleaf forage and small insects*;
  - Chronic RQs for turf and ornamentals barely exceed the LOC. Although these RQs were based on a study that showed no effects at the highest dose tested; EPA cannot preclude potential adverse effects to listed species;
- Plants
  - Acute RQs for turf and ornamentals exceed LOCs for listed terrestrial plants (monocots and dicots) adjacent to treated sites and in semi-aquatic areas;
  - Acute RQs for grasses grown for seed, rice, and peanuts are equal to the LOC for dicots in semi-aquatic areas.

#### Aquatic Organisms

- Freshwater
  - Acute fish RQ for Pennsylvania turf is equal to LOC for listed species; Florida turf scenario does not exceed LOC;
  - Acute fish RQ for rice exceeds LOC for listed species;
  - Because no data are available to evaluate chronic risks to freshwater invertebrates, EPA has a potential concern for listed species;
- Estuarine/Marine
  - Acute invertebrate RQs for turf and rice exceed LOC for listed species;
  - Because no data are available to evaluate chronic risks to estuarine/marine fish, EPA has a potential concern for listed species;
- Plants
  - Acute RQs for turf exceed LOCs for listed estuarine/marine nonvascular plants; and
  - Acute RQs for rice exceed LOCs for listed freshwater and estuarine/marine nonvascular plants.

These conclusions are based solely on EPA's screening-level assessment and do not constitute "may effect" findings under the Endangered Species Act for any listed species.

#### 4. Ecological Incidents

EPA completed a review of the Ecological Incident Information System (EIIS) database for ecological incidents involving propiconazole in November 2005. This database reported a total of six incidents associated with the use of propiconazole: four involving damage to terrestrial plants, and the remaining two involving damage to fish and shrimp. However, because no environmental sampling was conducted to evaluate pesticide residues, there is considerable uncertainty about the credibility of these incidents. Therefore, all of the propiconazole incidents were classified as having a "possible" rather than a "probable" or