



United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

EPA 738R-06-027
July 2006

Reregistration Eligibility Decision (RED) for Propiconazole

REREGISTRATION ELIGIBILITY

DECISION

for

Propiconazole

Case No. 3125

List C

Approved by:

/S/

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July 18, 2006

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC ₅₀	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD ₅₀	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRs	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

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

alanine, and triazole acetic acid, which are considered in this RED. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs (OPP) concerning common mechanism determinations and procedures for evaluating cumulative effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

Propiconazole also shares a common metabolite, 1,2,4-triazole, with several triazole-derivative pharmaceutical compounds. Thus, EPA must consider the incremental impact of exposure to 1,2,4-triazole pesticide residues to individuals using triazole-derivative pharmaceutical products. To this end, EPA is working with the U.S. Food and Drug Administration (FDA), which has regulatory authority for drug products, to assess the risks posed by 1,2,4-triazole residues that could result from concurrent exposure to triazole-derivative pharmaceutical and pesticide products. This assessment will provide the basis of safety findings reflecting the joint perspectives of FDA and EPA, and will inform a decision by both Agencies about whether appropriate measures are needed to reduce exposures from one or both sources of 1,2,4-triazole residues.

This document presents EPA's revised human health and ecological risk assessments, its progress toward tolerance reassessment, and the reregistration eligibility decision for propiconazole. The document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment; Section II provides a profile of the use and usage of the chemical; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The revised risk assessments for propiconazole are available in the OPP docket and in the Agency's electronic docket on the internet at <http://www.regulations.gov> under docket number EPA-HQ-OPP-2005-0497.

II. Chemical Overview

A. Regulatory History

Propiconazole was first registered in 1981 by Ciba Geigy for use on grass grown for seed. The Agency approved additional uses on sugarcane, pecan, cereal grains, rice, and bananas (import only) in 1987 and tolerances were established for these commodities. Additional food uses on celery, stone fruit, and wild rice were approved by EPA in 1993, and uses on corn, pineapple and peanuts were approved in 1994. Novartis became the technical registrant for propiconazole in 1996, after the merger of Ciba Geigy and Sandoz. Syngenta, one of the current technical registrants, acquired propiconazole in 2000 as the result of a merger of Novartis and Zeneca.

Today, propiconazole is registered for use on numerous food and feed crops; 55 permanent and 15 temporary tolerances have been established. Propiconazole is also registered for use on turf and ornamentals and for use as a wood preservative. The Agency has approved FIFRA Section 24c Special Local Need registrations for propiconazole on mint, sunflower grown for seed, nonbearing blueberries, sugarcane seed pieces, wheat, corn, bananas, and nonbearing hazelnuts. EPA has also approved FIFRA Section 18 Emergency Exemptions for propiconazole on dry bean, sorghum,

blueberries, cranberries, and raspberries. Although the registrant has submitted petitions to the Agency for additional food uses, these have not been considered as part of this reregistration eligibility decision (RED) and will be addressed by the Agency at a later time as a separate decision.

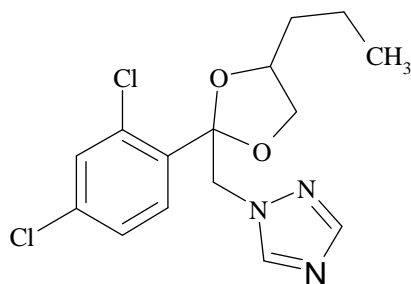
Propiconazole is also registered for use as an antimicrobial pesticide by Janssen Pharmaceutica; the first antimicrobial product was registered in 1996. Today propiconazole is used in material preservation and wood preservation products. As a materials preservative, propiconazole is used in items such as metalworking fluids, adhesives, caulks, coatings, stains, paints, inks, paper, textiles, canvas, cordage, leather, and leather finishing pastes, fat liquors, or finishes. The two major registrants, Syngenta and Janssen, have requested amendments to their propiconazole registrations deleting use for treatment of carpet fibers, apparel, and furnishings¹. The primary textile use includes “canvas” (i.e., awnings, boat covers, carpet backing, cordage, tents, tarpaulins, and wall coverings). As a wood preservative, the products can be used on green or fresh cut lumber, poles, posts, and timbers; manufactured wood products such as logs (such as those used in the construction of log homes), wood chips/sawdust, plywood veneer, and particle board; dry lumber; and finished wood products such as millwork, shingles, shakes, siding, plywood, and structural lumber and composites. The majority of the products are intended for use at wood treatment facilities; however, propiconazole is also formulated for use in mushroom houses, to protect timber trays and benches, and for use on wood in cooling towers.

Because propiconazole is on List C of Reregistration Priorities, EPA did not complete a Registration Standard. However, two Data Call-Ins (DCIs) were issued for propiconazole on September 30, 1993 and January 4, 1994. Generic data requirements necessary to complete reregistration included environmental fate and effects studies, product and residue chemistry studies, and avian, fish, invertebrate, and mammalian toxicity studies. Propiconazole was also included in the Agricultural Re-entry DCI issued on October 6, 1995 for worker dermal and inhalation exposure monitoring and foliar residue dissipation studies.

B. Chemical Identification

1. Propiconazole

Chemical Structure:



Common Name: Propiconazole

Chemical Name: 1-((2-(2,4-Dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl)methyl)-1H-1,2,4-

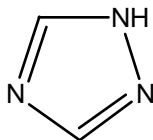
¹ EPA published a Notice of this request in the *Federal Register* on March 8, 2006 (71FR11622) and issued an order amending propiconazole registrations on May 26, 2006.

Trade Name:	triazole Tilt, Alamo®, Banner®, Orbit®, and Quilt™
Chemical Family:	Triazole, Conazole
Case Number:	3125
CAS Number:	60207-90-1
PC Code:	122101
Molecular Weight:	342.23
Empirical Formula:	C ₁₅ H ₁₇ Cl ₂ N ₃ O ₂
Basic Manufacturer:	Janssen Pharmaceutica, Inc.; Syngenta Crop Protection
Other Technical Registrants:	Dow AgroSciences; Irvita Plant Protection; Makteshim-Agan

2. Free Triazole Metabolites

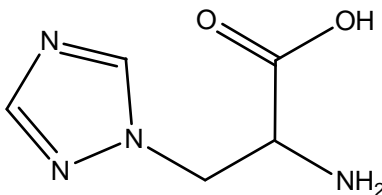
Propiconazole and other triazole fungicides are metabolized in animals and plants to form compounds containing the triazole moiety (free triazole metabolites), including 1,2,4-triazole, triazole alanine, and triazole acetic acid, which are also considered in this decision. Because triazole alanine and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

a. 1,2,4-Triazole



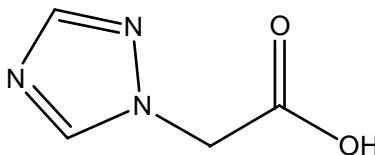
Chemical Name: 1,2,4-Triazole
 Common Names: 1,2,4-T; free triazole
 CAS Number: 288-88-0
 PC Code: 600074
 Molecular weight: 69.07

b. Triazole Alanine



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

c. Triazole Acetic Acid



Chemical Name: Triazole Acetic Acid (TAA)

CAS No. 28711-29-7

PC Code: 600082

Molecular weight: 127.10

C. Use Profile

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

Type of Pesticide:	Fungicide, Antimicrobial
Target Pest:	Bacteria, fungi, viruses (plant pathogens and spoilage agents)
Mode of Action:	Inhibits an enzyme involved in ergosterol biosynthesis, which is critical to the formation of the cell walls in fungi, thereby slowing or stopping fungal growth.
Use Sites:	Propiconazole is used on a number of agricultural crops, fruit and nut trees, ornamentals, and turf. Propiconazole is also used as a wood preservative and as an antimicrobial/material preservative in adhesives, paints, coatings, leather, paper; textiles, and specialty industrial products.
Terrestrial Food and Feed Uses:	Banana; Barley; Celery; Dry beans and peas; Field corn, Sweet corn, and Popcorn; Filbert; Pecan; Plantain; Stone fruits; Sunflower; Wheat; Barley; Cereal grains; Citrus; Kumquat; Lemon; Lime; Mint; Oats; Orange; Peanuts, Pineapple (seed piece treatment); Rice and Wild rice; Rye; Sugarcane; Tangerine; Tree nuts; Triticale; Wheat
Terrestrial NonFood Uses:	Turf, including golf courses and sod farms; Ornamentals; Nonbearing citrus, fruit, and nut trees
Antimicrobial Uses:	Adhesives, Coatings, Paints, Wood preservative
Use Classification:	General Use

Formulation Types: Emulsifiable concentrate, Flowable concentrate, Liquid ready-to-use, Liquid soluble concentrate, Wettable powder, Dust

Application Methods: Band treatment; Chemigation; Dip treatment; Directed spray; Ground spray; Hides and skins treatment; High volume spray (dilute); Industrial preservative treatment; Injection treatment; Low volume spray (concentrate); Soak; Spray; Tree injection treatment; Wood protection treatment by pressure; Wood surface treatment

Application Rates: Propiconazole application rates vary by use. For most agricultural uses, propiconazole is applied at less than 1 pound active ingredient per acre (lb ai/A) for crops, but it may be applied at up to 1.8 lb ai/A for turf and ornamentals. Antimicrobial end-use products contain propiconazole at concentrations ranging from 0.1 to 50% ai. Maximum concentrations for various antimicrobial uses are 0.65% ai solution for an open dip tank, 0.8% ai solution for conventional spray, and 50% ai solution for electrostatic spray.

Application Timing: At bud break; At emergence; At pegging; Bloom; Boot; Crown; Delayed dormant; Dormant; Early bloom; Early fall; Early spring; Early summer; Fall; Foliar; Internode elongation; Late fall; Late spring; Late winter; May; Nonbearing; Nonbearing nurserystock; Not on label; Nurserystock; Petal fall; Petal fall through foliar; Pink; Popcorn; Postplant; Prebloom; Precutting; Preharvest; Preplant; Seed piece; Seedling stage; Shock/slug; Spring; Summer; Tillering; When needed; Winter

D. Estimated Usage of Propiconazole

A screening-level estimate of the usage of propiconazole indicates that approximately 345,000 pounds of propiconazole active ingredient (ai) were used annually from 1999 to 2004. A five year average was calculated using EPA source data and data from the US Department of Agriculture’s (USDA) National Agricultural Statistics Service (NASS) for the years 2000 to 2004. These data are presented in Table 1 below.

Table 1. National Agricultural Usage of Propiconazole – Highest Use Sites			
Crop	Average Annual Amount Used (lbs. a.i.)	Average Annual Total Area Treated (A)	Average Annual Percent Crop Treated
Almonds	830	8,000	>5
Apples	33	300	>1
Apricots	840	8,100	29
Barley	11,000	150,000	3
Celery	2,500	23,000	49
Cherries	3,900	36,000	18

Table 1. National Agricultural Usage of Propiconazole – Highest Use Sites

Crop	Average Annual Amount Used (lbs. a.i.)	Average Annual Total Area Treated (A)	Average Annual Percent Crop Treated
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. 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. 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 – 2nd 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.

Table 2. Acute Toxicity Profile for Propiconazole				
Guideline	Study Type	MRID	Results	Toxicity Category
870.1100	Acute Oral – Rat	00058591	LD ₅₀ = 1517 mg/kg	III
870.1200	Acute Dermal - Rabbit	0058596	LD ₅₀ ≥ 4000 mg/kg	III
870.1300	Acute Inhalation	41594801	LC ₅₀ ≥ 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 ₅₀ or LC ₅₀ - 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.

Table 3. Toxicological Doses and Endpoints for Propiconazole for Use in Human Health Risk Assessments			
Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Endpoint for Risk Assessment
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.

Table 3. Toxicological Doses and Endpoints for Propiconazole for Use in Human Health Risk Assessments

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Endpoint for Risk Assessment
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; increased liver weight in males and increase in liver lesions (masses/raised areas/swellings/nodular areas).

Table 3. Toxicological Doses and Endpoints for Propiconazole for Use in Human Health Risk Assessments

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Endpoint for Risk Assessment
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.

Table 4. Toxicological Doses and Endpoints for 1,2,4-Triazole for Use in Human Health Risk Assessments

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Endpoint for Risk Assessment
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).

Table 4. Toxicological Doses and Endpoints for 1,2,4-Triazole for Use in Human Health Risk Assessments

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Endpoint for Risk Assessment
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.			

Table 5. Toxicological Doses and Endpoints for the Triazole Conjugates for Use in Human Health Risk Assessments

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Endpoint for Risk Assessment
Acute Dietary (females 13-49)	NOAEL = 100 mg/kg/day UF = 100 Acute RfD = 1 mg/kg/day	FQPA SF = 10 $aPAD = \frac{\text{acute RfD}}{FQPA SF}$ = 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 $cPAD = \frac{\text{chronic RfD}}{FQPA SF}$ = 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.

Table 5. Toxicological Doses and Endpoints for the Triazole Conjugates for Use in Human Health Risk Assessments

Exposure Scenario	Dose, Uncertainty Factors (UF)	FQPA Safety Factor (SF) and Level of Concern	Study and Toxicological Endpoint for Risk Assessment
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 tirazole 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 FFDCA, 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, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). 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 (FFDCA, 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*.

Table 6. Estimated Drinking Water Concentrations of Propiconazole					
Crop Scenario	Region Modeled	PCA	Estimated Drinking Water Concentration (EDWC), ppm		Screening-Level Model Used in Assessment
			Acute	Chronic	
Surface Water					
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
Groundwater					
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.

Table 7. Estimated Drinking Water Concentrations of Free Triazoles					
Crop Scenario	Region Modeled	PCA	Estimated Drinking Water Concentration (EDWC), ppm		Screening-Level Model Used in Assessment
			Acute	Chronic	
Surface Water					
Turf	Pennsylvania golf course	N/A	0.041	0.011	PRZM-EXAMS
Groundwater					
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 95th 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.

Table 9. Short- and Intermediate-Term Aggregate Risk Estimates for Residential Exposure to Propiconazole					
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) 150 (int.-term)	5,300 (short-term) 1,800 (int.-term)	288 130
* 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 95th 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 95th 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*	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
Groundboom	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		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
Chemigation	Barley, Rye, Oats, Wheat, Corn, Sunflower, Celery	0.1125	350	46	5100	15	1700
	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
Handgun Sprayer	Turf	1.8	100	10	1100	3.3	370

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*	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
	Non-bearing Citrus, Pecans, Non-bearing Hazelnuts, Peanuts	0.225	350	3100	N/A	100	N/A
Aerial	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
Groundboom	Barley, Rye, Oats, Wheat, Corn, Sunflower	0.1125	200	11000	N/A	3600	N/A
	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*	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
Groundboom (Open Cab)	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*	Baseline + Gloves	Baseline*	Baseline + Gloves
<i>Flagger</i>							
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						
	Non-bearing Citrus, Pecans, Non-bearing Hazelnuts, Peanuts	0.225	350	5600	N/A	1900	N/A
	Grasses grown for seed (forage and fodder grasses), Wild rice						
	Sod-farm turf	1.8	350	700	N/A	230	N/A
	Wheat	0.08	350	16000	N/A	5300	N/A
	Rice	0.28	350	4500	N/A	1500	N/A
<i>Mixer/Loader/Applicator (Liquid formulations)</i>							
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
<p>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 MOEs in bold are above EPA's level of concern.</p>							

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
- Diptank 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 diptank 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.	Total		Dermal		Inhal.	Total	
				Baseline	Gloves		Baseline	Gloves	Baseline	Gloves		Baseline	Gloves
MATERIAL PRESERVATIVE													
Adhesives	Liquid Pour	1.21	10,000 lbs	<1	320	4,300	<1	300	<1	110	1,700	<1	100
	Liquid Pump			95	6,900	37,000	95	5,900	32	2,200	14,000	32	2,000
Metal Working Fluids	Liquid Pour	0.07	2,500 lbs	60	16,000	120,000	60	15,000	20	5,400	47,000	20	4,900
	Liquid Pump			6,600	9,600	300,000	6,500	9,300	2,200	3,200	110,000	2,200	3,100
Paint	Liquid Pour	0.35	2,000 lbs	15	5,600	74,000	15	5,200	5	1,900	29,000	5	1,700
	Liquid Pump	0.35	10,000 lbs	330	24,000	130,000	330	21,000	110	7,900	50,000	110	6,900
Textiles	Liquid Pour	0.28	10,000 lbs	4	1,400	19,000	4	1,300	1	460	7,200	1	440
	Liquid Pump			410	30,000	160,000	410	26,000	140	9,900	62,000	140	8,600
Professional Application of Paint													
Paint	Brush/Roller	0.35	50 lbs	170	N/A*	37,000	170	N/A*	56	N/A*	14,000	55	N/A*
	Airless Sprayer	0.35	500 lbs	79	N/A*	1,200	75	N/A*	26	N/A*	480	25	N/A*
WOOD PRESERVATIVE													
Blender/Spray Operator		0.5	178,000	N/A	940	5,900	N/A	810	N/A	310	2,000	N/A	270
		1.0	178,000	N/A	470	2,900	N/A	400	N/A	160	980	N/A	130
Chemical Operator			N/A	N/A	860	120,000	N/A	850	N/A	290	40,000	N/A	280
Diptank Operator		0.5	N/A	3,500	N/A	91,000	3,400	N/A	1,200	N/A	30,000	1,100	N/A
		1.0	N/A	1,800	N/A	46,000	1,700	N/A	580	N/A	15,000	560	N/A
High Pressure/High Volume Spray Treatment													
Wood Treatment		25 gal/day		N/A	580	4,800	N/A	510	N/A	190	1,600	N/A	170
		50 gal/day		N/A	290	2,400	N/A	260	N/A	96	800	N/A	86
Mushroom House		100 gal/day		N/A	1,700	14,000	N/A	1,500	N/A	560	4,700	N/A	500
		1000 gal/day		N/A	170	1,400	N/A	150	N/A	56	470	N/A	50

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	
Pressure Treatment													
Treatment Operator		1	N/A	N/A	260	82,000	N/A	260	N/A	86	27,000	N/A	86
Treatment Assistant		1	N/A	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.

Crop	Activity	Transfer Coefficient (cm ² /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

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

Crop	Activity	Transfer Coefficient (cm ² /hr)	Maximum Application Rate (lb ai/A)	MOE on Day of Application (Day 0)	
				Short-Term Exposure	Intermediate – Term Exposure
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
				170	104
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.

Table 13. Summary of Post-application Worker Risk Estimates for Propiconazole Used in Metalworking Fluids and Wood Preservative						
Worker Activity	MOE for Short-Term Exposure on Day of Application (Day 0)			MOE for Intermediate-/Long-Term Exposure on Day of Application (Day 0)		
	Dermal	Inhalation	Total	Dermal	Inhalation	Total
Metalworking Fluid						
Machinist	5,100	75,000	4,800	1,700	25,000	1,600
Wood Preservative						
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	49
Pressure Treatment – all scenarios	710	130,000	710	240	44,000	240
MOEs in bold 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) 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.

Table 14. EPA's Levels of Concern (LOCs) and Risk Presumptions			
If a calculated RQ is greater than the LOC presented, then the Agency presumes that...	LOC terrestrial animals	LOC aquatic animals	LOC Plants
Acute Risk ...there is potential for acute risk; regulatory action may be warranted	0.5	0.5	1.0
Acute Listed (Endangered and Threatened) Species ...listed species may be adversely affected	0.1	0.05	1.0
Chronic Risk ...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 95th 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.

Table 15. Toxicity Reference Values for Mammals and Birds for Propiconazole.			
Exposure Scenario	Species	Toxicity Reference Value	Toxicity Category or Effect
Mammals			
Acute	Mouse	LD ₅₀ = 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
Birds			
Acute	Bobwhite quail	LD ₅₀ = 2825 mg ai/kg bwt	Practically non-toxic
Chronic		NOAEC = 1000 mg/kg diet	No treatment-related effects
LD ₅₀ - 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.

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 – 0.77	0.01 – 0.66	0.00 – 0.35
Turf and Ornamentals, lawns, turf, golf courses	0.01 – 0.7	0.01 – 0.6	0.00 – 0.32
Turf and Ornamentals, sod farm	0.01 – 0.61	0.01 – 0.52	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*.

Exposure Scenario (Crop)	Ranges of Acute RQs** by Body Weight		
	15 g	35 g	1000 g
Turf and Ornamentals, ground cover	0.01 – 0.57	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 3rd 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 - 1.51	0.02 – 1.29	0.0 – 0.69
Stone Fruits	0.02 – 1.13	0.01 – 0.96	0.01 – 0.52
Turf and Ornamentals, ground cover	0.18 – 13	0.16 – 11	0.08 – 6

*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 – 1.04	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 – 9.64	0.11 – 8.23	0.06 – 4.41

*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.

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
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 – 0.70	0.00 – 0.25	0.027 – 0.427	0.08 – 1.3
Turf and Ornamentals, lawns, turf, golf courses	0.00 – 0.63	0.00 – 0.22	0.027 – 0.427	0.074 – 1.18

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 – 0.54	0.00 – 0.19	0.027 – 0.427	0.06 – 1.02

* 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 – 0.53	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 classes 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.

Table 19. Propiconazole EECs derived from the Terr-PLANT screening model (and based on a single application)					
Crop	Application Rate (lbs ai/A)	Application Method	Total loading to adjacent areas (lb ai/A)	Total loading to semi-aquatic areas (lb ai/A)	Drift EEC (lb ai/A)
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 EC₂₅ 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 EC₂₅. The other dicot species appeared to be unaffected by the treatments. Therefore, for the purposes of risk assessment, the EC₂₅ is assumed to be >1.5 lb ai/A for all of these species except cabbage. The EC₂₅ 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 EC₂₅ 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 EC₂₅ of 0.039 lb ai/A and a NOAEC of 0.056 lb ai/A. These data are summarized in Table 20 below.

Table 20. Acute Toxicity of Propiconazole to Terrestrial Plants			
Species	EC₂₅ (lb ai/A)	NOAEC/EC₀₅ (lb ai/A)	Effect
Monocot			
Onion, corn, oat, rygrass	>1.5	1.5	Seedling emergence: emergence, shoot length, dry weight
Ryegrass	0.315	0.0185	Vegetative vigor: plant height

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

EC₂₅ – 25% Effect Concentration, statistically derived single dose or concentration that can be expected to cause effects in 25% of the test organisms; EC₀₅ – 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	1.01	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	2.1	0.46	0.95	0.32	6.68	0.32
	Chemigation	0.7	2.28	2.47	2.28	2.23	1.59	7.95	1.59
<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	4.81	0.30	4.81

* RQs for nonlisted species are based on EC₂₅ ; ** RQs for listed species based on NOAEC or EC₀₅. 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 90th 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.

Distance of Spray Drift Deposition with Ag-DRIFT following application of 1.78 lb ai/A to Turf	Vegetative Vigor EC ₂₅ for Sensitive Test Crops			
	Corn 0.968 lb ai/A	Onion 0.334 lb ai/A	Soybean 0.16 lb ai/A	Cabbage 0.039 lb ai/A
	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 EC₂₅ 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 EC₂₅ 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

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 LC₅₀ for spot was 2244 µg/L, compared with an LC₅₀ of 850 µg/L for rainbow trout.

Exposure Scenario	Species	Exposure Duration	Toxicity Reference Value (ppb)	Toxicity Category or Effect	
Freshwater Fish	Acute	rainbow trout	96 hours	LC ₅₀ = 850	Highly toxic
	Chronic	Fathead minnow	Early life stage	NOAEC = 95	Mortality, length, weight
Freshwater Invertebrate	Acute	<i>Daphnia magna</i>	96 hours	LC ₅₀ = 4800	Slightly toxic
	Chronic	<i>Daphnia magna</i>	Study not suitable for use in risk assessment		
Estuarine/Marine Fish	Acute	Spot	96 hours	LC ₅₀ = 2244	Moderately toxic
	Chronic	No acceptable guideline studies were available			
Estuarine/Marine Invertebrates	Acute	Mysid shrimp	96 hours	LC ₅₀ = 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 LC₅₀ 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.

Crop Scenario	EECs (ppb)	Freshwater RQs		Estuarine/Marine RQs	
		Fish	Invertebrates	Fish	Invertebrates
<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 EC₅₀ is used to calculate acute RQs for aquatic plants.

Species	EC ₅₀ (ug ai/L)	NOAEC/EC ₀₅ (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.

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

“highly probable: association with propiconazole. No detailed information was available for the terrestrial plant incidents; therefore, the extent of damage and recovery is not known.

IV. Risk Management, Reregistration, and Tolerance Reassessment

A. Determination of Reregistration Eligibility

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

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient propiconazole. Based on a review of these data and on public comments on the Agency’s assessments for the active ingredient propiconazole, the Agency has sufficient information on the human health and ecological effects to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing the active ingredient propiconazole are eligible for reregistration provided that: (i) required product-specific data are submitted, (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. Necessary label changes are described in Section V. Appendix A summarizes the uses of propiconazole that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of propiconazole, and lists the submitted guideline studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of propiconazole, the Agency has determined that propiconazole products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of propiconazole. If all changes outlined in this document are incorporated into the product labels, then all current risks for propiconazole will be adequately mitigated for the purposes of this determination under FIFRA. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in *Section III.B.3.* of this document.

B. Public Comments and Responses

Through the Agency’s public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for propiconazole. EPA released its preliminary risk assessments for propiconazole for public comment on February 15, 2006, for a 60-day public comment period (Phase 3 of the public participation process). During the public

comment period on the risk assessments, which closed on April 17, 2006, the Agency received comments from the American Mushroom Institute, the University of Georgia, the University of Hawaii, the US Triazole Task Force, and the major technical registrants, Janssen Pharmaceutica Inc. and Syngenta Crop Protection. These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket (EPA-HQ-OPP-2005-0497) at the address given above and in the EPA's electronic docket at <http://www.regulations.gov>.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to propiconazole are within acceptable levels. In other words, EPA has concluded that the tolerances for propiconazole meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to propiconazole from all possible sources.

b. Determination of Safety to U.S. Population

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

As discussed in Section III, the aggregate risks from propiconazole from food, drinking water, and residential exposure are not of concern. Furthermore, aggregate risks from the free triazoles (1,2,4-triazole, triazole acetic acid, and triazole alanine) are not of concern. The aggregate risk assessment for the free triazoles considers all currently registered uses of all triazole fungicides.

c. Determination of Safety to Infants and Children

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

due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of propiconazole residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of propiconazole, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the FQPA SF has been removed (i.e., reduced to 1X) for propiconazole. In addition, the Agency determined whether infants and children show potential susceptibility from exposure to residues of the free triazole degradates 1,2,4-triazole, triazole acetic acid, and triazole alanine. EPA retained a 10X FQPA SF for 1,2,4-triazole based on nervous system effects and database uncertainties, including a data gap for acute and developmental neurotoxicity studies. (A developmental neurotoxicity study is required for 1,2,4-triazole.) The Agency also retained a 10X FQPA SF for the triazole conjugates to address concerns for increased susceptibility seen in the available rat developmental toxicity and two-generation reproduction and to address uncertainties associated with an incomplete database. There are 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. The rationale for the decisions on the FQPA SF for both propiconazole and the free triazoles can be found in Section III and in the documents, *Propiconazole – 3X database uncertainty factor used in risk assessment*, dated December 29, 2005 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, both of which may be found in the docket EPA-HQ-OPP-2005-0497.

2. Endocrine Disruptor Effects

EPA is required under the FFDCFA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate.” Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, 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). In the available toxicity studies on propiconazole, there was no evidence of estrogen, androgen, and/or thyroid-mediated toxicity. Although the available toxicity data for 1,2,4-triazole indicate potential estrogen, androgen, and thyroid effects, the Agency believes that the current risk assessment is protective of these effects. When additional appropriate screening and/or testing protocols being considered by the Agency’s EDSP have been developed, propiconazole may be subjected to further screening and/or testing to better

characterize effects related to endocrine disruption.

3. Cumulative Risks

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

D. Tolerance Reassessment Summary

1. Tolerance Definition

EPA has established tolerances for propiconazole in/on animal and plant commodities under 40 CFR §180.434. These tolerances are currently expressed in terms of the combined residues of propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole) and its metabolites determined as residues converted to 2,4-dichlorobenzoic acid (DCBA) and expressed as parent compound. As part of the tolerance reassessment for propiconazole, the tolerance expression should be revised to parent propiconazole *per se*, (1-[[2-(2,4-dichlorophenyl)-4propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole). Because the analytical method is a common moiety method detecting all residues (parent and metabolites) that are converted to DCBA, the field trial studies reported total residues, and tolerance levels based on these data may be overestimated. (Future field trial studies should use a method that analyzes for both parent and metabolites.) Although the free triazoles are not included in tolerance expression; they are considered in the risk assessment supporting tolerance reassessment. A summary of the residues considered in the risk assessment and in the tolerance expression for propiconazole is given in Table 28.

Matrix	For Risk Assessment ¹		For Tolerance Expression
	Propiconazole	Free Triazoles	
Plants, rotational crops, livestock	Parent plus all metabolites convertible to 2,4-DCBA	1,2,4-triazole, triazole alanine, triazole acetic acid	Parent only
Water	Parent only	1,2,4-triazole	Not applicable

Table 28. Summary of Propiconazole Residues of Concern for Tolerance Expression and Risk Assessment			
Matrix	For Risk Assessment¹		For Tolerance Expression
	Propiconazole	Free Triazoles	
¹ Three risk assessments were conducted, one for propiconazole parent, one for 1,24,-triazole, and a combined assessment for the triazole conjugates, triazole alanine and triazole acetic acid.			

2. Tolerance Reassessment Summary

The reassessments of tolerances for some commodities are contingent upon the implementation of requested label revision(s). The propiconazole tolerance reassessment is summarized in Table 29.

Table 29. Tolerance Reassessment Summary for Propiconazole			
Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
Tolerances Established Under 40 CFR §180.434(a) for Raw Agricultural Commodities (RACs)			
Banana	0.2	0.2	[Banana]
Barley, grain	0.1	0.3	Available residue data for wheat support raising barley tolerance.
Barley, straw	1.5	15.0	Available residue data for wheat support raising the barley tolerance.
Cattle, fat	0.1	0.1	Maximum theoretical dietary burden (MTDB) of 0.08 ppm supports maintaining tolerance at current level.
Cattle, kidney	2.0	2.0	MTDB of 1.01 ppm supports maintaining tolerance at current level.
Cattle, liver	2.0	2.0	MTDB of 1.33 ppm supports maintaining tolerance at current level.
Cattle, meat byproducts, except kidney and liver	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Cattle, meat	0.1	0.1	MTDB of 0.04 ppm supports maintaining tolerance at current level.
Celery	5.0	5.0	Available residue data support maintaining tolerance at current level.
Corn, field, grain	0.1	0.1	Tolerance expires on November 30, 2008.
Corn, field, stover	12	12	Tolerance expires on November 30, 2008.
Corn, field, forage	12	12	Tolerance expires on November 30, 2008.

Table 29. Tolerance Reassessment Summary for Propiconazole

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
Corn, sweet, kernel plus cob with husks removed	0.1	0.1	Tolerance expires on November 30, 2008.
Fruit, stone, group 12	1.0	1.0	Available residue data support maintaining tolerance at current level.
Goat, fat	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Goat, kidney	2.0	2.0	MTDB of 1.01 ppm supports maintaining tolerance at current level.
Goat, liver	2.0	2.0	MTDB of 1.33 ppm supports maintaining tolerance at current level.
Goat, meat byproducts, except kidney and liver	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Goat, meat	0.1	0.1	MTDB of 0.04 ppm supports maintaining tolerance at current level.
Grass, forage	0.5	0.5	Available residue data support maintaining tolerance at current level.
Grass, hay	40	40	Available residue data support maintaining tolerance at current level.
Grass, straw	40	40	Available residue data support maintaining tolerance at current level.
Hog, fat	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Hog, kidney	2.0	2.0	MTDB of 1.01 ppm supports maintaining tolerance at current level.
Hog, liver	2.0	2.0	MTDB of 1.33 ppm supports maintaining tolerance at current level.
Hog, meat byproducts, except kidney and liver	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Hog, meat	0.1	0.1	MTDB of 0.04 ppm supports maintaining tolerance at current level.
Horse, fat	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Horse, kidney	2.0	2.0	MTDB of 1.01 ppm supports maintaining tolerance at current level.
Horse, liver	2.0	2.0	MTDB of 1.33 ppm supports maintaining tolerance at current level.
Horse, meat byproducts, except kidney and liver	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Horse, meat	0.1	0.1	MTDB of 0.04 ppm supports maintaining tolerance at current level.

Table 29. Tolerance Reassessment Summary for Propiconazole

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
Milk	0.05	0.05	MTDB of 0.03 ppm supports maintaining tolerance at current level.
Mushroom	0.1	0.1	Pending approval of a label use on mushrooms and submission of directions for use (OPPTS 860.1200). Use supported by IR-4.
Oat, forage	10.0	10.0	[Oat, forage]
Oat, grain	0.1	0.1	[Oat, grain]
Oat, hay	30.0	2.0	Available data for wheat support lowering tolerance for oat hay.
Oat, straw	1.0	1.0	Available residue data support maintaining tolerance at current level.
Peanut	0.2	0.2	Tolerance expires November 30, 2008.
Peanut, hay	20.0	20.0	Tolerance expires November 30, 2008.
Pecans	0.1	Reassign	Tolerance should be reassigned concomitant with establishing a tolerance of 0.1 ppm for <i>Nut, tree, Group 14</i>
Pineapple	0.1	0.1	Tolerance expires November 30, 2008. Pineapple processing study required.
Pineapple, fodder	0.1	Revoke	No longer considered a significant livestock feed item, revoke. Tolerance expires November 30, 2008.
Plum, prune, fresh	1.0	Revoke	Tolerance should be revoked because a crop group tolerance has been established for <i>Fruit, stone, Group 12</i> .
Rice, grain	0.1	0.3	Available residue data support raising tolerance.
Rice, straw	3.0	3.0	Available residue data support maintaining tolerance at current level.
Rye, grain	0.1	0.3	Available residue data support raising tolerance.
Rye, straw	1.5	15.0	Available residue data for wheat straw support raising the tolerance.
Sheep, fat	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level.
Sheep, kidney	2.0	2.0	MTDB of 1.01 ppm supports maintaining tolerance at current level.

Table 29. Tolerance Reassessment Summary for Propiconazole			
Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
Sheep, liver	2.0	2.0	MTDB of 1.33 ppm supports maintaining tolerance at current level.
Sheep, meat byproducts, except kidney and liver	0.1	0.1	MTDB of 0.08 ppm supports maintaining tolerance at current level
Sheep, meat	0.1	0.1	MTDB of 0.04 ppm supports maintaining tolerance at current level.
Wheat, grain	0.1	0.30	Available residue data support raising tolerance.
Wheat, straw	1.5	15.0	Available residue data support raising tolerance.
Tolerances To Be Proposed Under 40 CFR §180.434(a) for Raw Agricultural Commodities			
Grain, aspirated grain fractions	20 (sorghum)	5.0	Available residue data support lowering tolerance. Time-limited tolerance for sorghum Section 18 registration expires June 30, 2008.
Barley, hay	None established	2.0	Translate from wheat hay
Corn, pop, grain	None established	0.1	Translate from field corn
Corn, pop, stover	None established	12	Translate from field corn
Corn, sweet, forage	None established	12	Translate from field corn
Corn, sweet, stover	None established	12	Translate from field corn
Nut, tree, group 14	None established	0.1	[Nut, tree. Group 14]
Rice, bran	None established	1.0	Rice processing study shows 2.9x concentration factor for rice bran.
Rice, hulls	None established	1.2	Rice processing study shows 3.8x processing factor for rice hulls.
Rye, forage	None established	2.0	Available residue data support tolerance.
Wheat, forage	None established	2.0	Available residue data support tolerance.
Wheat, hay	None established	2.0	Available residue data support tolerance.
Wheat, bran	None established	1.0	Available residue data support tolerance.
Time-limited Tolerances Established Under 40 CFR §180.434(b) for FIFRA §18 Emergency Exemptions			
Blueberry	1.0	N/A	Tolerance expires December 31, 2007.
Cranberry	1.0	N/A	Tolerance expires December 31, 2007.

Table 29. Tolerance Reassessment Summary for Propiconazole			
Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
Dry bean	0.5	N/A	Tolerance expired December 31, 2005. [Bean, dry]
Dry bean forage	8.0	N/A	Tolerance expired December 31, 2005. [Bean, dry, forage]
Dry bean hay	8.0	N/A	Tolerance expired December 31, 2005. [Bean, dry, hay]
Grain, aspirated grain fractions	20 (sorghum)	5.0	Available residue data support lowering tolerance. Tolerance expires June 30, 2008.
Sorghum, grain, grain	0.2	N/A	Tolerance expires June 30, 2008.
Sorghum, grain, stover	1.5	N/A	Tolerance expires June 30, 2008.
Soybean	2.0	N/A	Tolerance expires December 31, 2009.
Soybean, forage	10.0	27N/A	Tolerance expires December 31, 2009.
Soybean, hay	25.0	N/A	Tolerance expires December 31, 2009.
Tolerances Established Under 40 CFR §180.434(c) for Regional Registrations			
Sunflower	None established	TBD	To be determined pending submission of field trial data.
Mint, tops (leaves and stems)	0.3	0.3	Regional registration for use west of the Cascade Mountains only. [Peppermint, tops] [Spearmint, tops]
Wild rice	0.5	0.5	Regional registration for use only in Minnesota. [Rice, wild]

a. Tolerances for Raw Agricultural Commodities (RACs) Established Under 40 CFR §180.434(a)

The Agency has recently updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of these changes, tolerances must be established for raw agricultural commodities recently added to the list in Table 1, OPPTS GLN 860.1000 and certain tolerances for crops in a crop group should be reassigned. The established tolerance for plums should be revoked because a stone fruit group tolerance has been established. The established tolerance for pineapple fodder should be revoked because this commodity is no longer considered a significant livestock feed item. The established tolerances for RACs listed under 40 CFR §180.434(a) are reassessed at the same levels except those listed for barley, rice, rye, and wheat; higher tolerances are required for these crops to reflect the results of recent field trials. The established tolerances for cattle, goat, hog, horse, and sheep commodities listed under 40 CFR §180.434(a) are reassessed at the same levels as well, because EPA is unable to separate the parent residues from the metabolites, and because the pending petitions for new uses are likely to result in an increased dietary burden.

b. Tolerances for RACs to be Proposed under 40 CFR §180.434(a)

Because of changes to Table 1 in OPPTS GDLN 860.1000, new tolerances must be proposed for barley hay, rye forage, and wheat forage and hay. The required data for wheat hay and forage will be translated to barley hay and rye forage. Because the tolerance level for oat hay was not determined from residue data but was calculated from the oat forage level using a 3x dry-down factor, the required data for wheat hay should be translated to oat hay to provide a more realistic level for this tolerance. Based on the cited field trials with Stratego™ Twin-Pak™ and Stratego™, the Agency proposes new tolerances on wheat hay and forage at 2.0 ppm. The Agency now recommends that wheat hay data be translated to oats to establish a more appropriate level for the oat hay tolerance at 2.0 ppm.

The Agency is translating the wheat grain, wheat straw, wheat hay, and wheat forage data to barley and rye grain, straw, hay and forage. Therefore, the reassessed tolerances for barley grain and rye grain should be 0.3 ppm, for barley and rye straw should be 15.0 ppm. New tolerances for barley hay and rye forage should be established at 2.0 ppm. Data from a wheat processing study indicate the need for 1.0 ppm tolerance for wheat bran and a 5.0 ppm tolerance for aspirated grain fractions. The available rice processing data indicate that residues of propiconazole may concentrate in rice bran at 2.9x, in rice hulls at 3.8x, and in polished rice at 0.12x. Based on a highest average field trial (HAFT) residue value of 0.28 ppm, new tolerances of 1.0 and 1.2 ppm must be proposed for rice bran and hull, respectively.

The commodity definitions for the corn RAC tolerances are currently expressed as corn *per se*. When the definition is revised to "*corn, field*," tolerances for popcorn grain and stover, expressed in terms of "*corn, pop*," will need to be established at levels of 0.1 ppm and 12 ppm, respectively. In addition, tolerances for "*corn, sweet, forage*" and "*corn, sweet, stover*" will need to be established at 12 ppm. Processing data are required for pineapple juice.

c. Time-Limited Tolerances Established Under 40 CFR §180.434(b)

Time-limited tolerances have been established for blueberry; cranberry; grain, aspirated fractions; sorghum grain, grain; sorghum grain, stover; soybean; soybean forage; and soybean hay to support FIFRA Section 18 registrations for these commodities. These time-limited tolerances have expiration dates ranging from December 31, 2007 to December 31, 2009. Where appropriate, FIFRA Section 3 tolerances will be established for these crops; e.g., permanent tolerance for aspirated grain fractions. Although time-limited tolerances were established in the past for dry bean, dry bean forage, and dry bean hay, these tolerances expired on December 31, 2005.

d. Tolerances with Regional Registrations Established Under 40 CFR §180.434(c)

Tolerances with regional registrations have been established for the following RACs as defined: mint, tops (leaves and stems) and wild rice. The tolerance for mint is restricted to use

west of the Cascade Mountains only, and the tolerance for wild rice is restricted to Minnesota. Sufficient field trial data are available to reassess the established tolerances with regional registrations for mint and wild rice at the same levels.

3. Codex Harmonization

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for propiconazole in/on various raw agricultural commodities. The Codex MRLs are expressed in terms of propiconazole *per se*, which is harmonized with the US tolerance expression. EPA has harmonized tolerance levels on most commodities with Codex MRLs to the extent possible. A comparison of the Codex MRLs and corresponding reassessed U.S. tolerances is presented in Table 30.

Current Codex MRLs			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined by Codex)	MRL (mg/kg)	Step		
Almonds	0.05	CXL	N/A	No current U.S. registration.
Banana	0.1	CXL	0.2*	Unable to harmonize due to higher U.S. use rate.
Barley (grain)	0.05	CXL	0.3*	Unable to harmonize due to higher U.S. use rate.
Coffee beans	0.1	CXL	N/A	No current U.S. registration.
Edible offal (mammalian)	0.05	CXL	N/A	No current U.S. registration.
Eggs	0.05	CXL	N/A	MRL set at limit of quantification (LOQ). Current U.S. tolerance of 0.1 will be revoked because poultry metabolism data show no finite residues in eggs.
Grapes	0.5	CXL	N/A	No current U.S. registration
Mango	0.05	CXL	N/A	No current U.S. registration.
Meat (from mammals other than marine)	0.05	CXL	0.1*	MRL set at LOQ. Unable to harmonize due to higher U.S. use rate.
Milks	0.01	CXL	0.05*	Unable to harmonize due to higher U.S. use rate. MRL set at LOQ.
Oat (grain)	0.05	CXL	0.1	MRL set at LOQ.
Peanut	0.05	CXL	0.1*	Unable to harmonize due to higher U.S. use rate.
Peanut, whole	0.1	CXL	N/A	Not currently regulated by U.S. EPA.
Pecan	0.05	CXL	0.1*	Unable to harmonize due to higher U.S. use rate.
Poultry meat	0.05	CXL	N/A	No current U.S. registration. MRL set at LOQ.
Rape seed	0.05	CXL	N/A	No current U.S. registration.
Rye	0.05	CXL	0.3*	MRL set at LOQ. Unable to harmonize due to higher U.S. use rate.
Stone fruits	1.0	CXL	1.0	U.S. established crop group tolerance for stone fruits.
Sugar beet	0.05	CXL	N/A	No current U.S. registration.
Sugar beet leaves or tops	0.5	CXL	N/A	No current U.S. registration.

Current Codex MRLs			Reassessed U.S. Tolerance (ppm)	Recommendation and Comments
Commodity (As Defined by Codex)	MRL (mg/kg)	Step		
Sugar cane	0.05	CXL	N/A	Registered in U.S. for use as seed piece treatment, which is considered a non food use.
Wheat	0.05	CXL	0.30*	Unable to harmonize due to higher U.S. use rate. MRL set at LOQ.

* US Tolerance cannot be harmonized with Codex MRLs because US GAP requires higher tolerances than Codex MRL.

4. Residue Analytical Method

Plant commodities. Residue methods AG-454, AG-454B and AG-626 (both are modification of method AG-454) were used to determine residues of propiconazole and its metabolites on samples of raw agricultural and processed commodities from field trials and processing studies. The methods use a single moiety detection in which residues are converted to 2,4-DCBA, determined as the 2,4-DCBA methyl ester, and reported as propiconazole equivalents using a conversion factor of 1.79. The reported level of quantification (LOQ) for this method is 0.05 ppm. Concurrent method recoveries were acceptable. Previously, EPA required enforcement method validation for Method AG-454A using bananas. These data are no longer needed.

For enforcement purposes, residue method AG-354 is available for the determination of propiconazole *per se* in/on plant commodities using gas chromatography and flame ionization detection, and the reported LOQ is 0.05 ppm. The Multiresidue Methods Section 302 (Luke Method; Protocol D) also picks up parent propiconazole.

Animal commodities. Residue methods AG-517 and AG-629 (a modification of method AG-517) were used for determination of propiconazole and its metabolites in animal commodities. The methods use a single moiety detection in which residues are converted to 2,4-DCBA, determined as the 2,4-DCBA methyl ester, and reported as propiconazole equivalents using a conversion factor of 1.79. The method LOQ is 0.05 ppm for residues in meat, poultry, and eggs and 0.02 ppm for residues in milk. Samples from the ruminant and poultry feeding studies were analyzed using method AG-359 (an early version of method AG-517) and method AG-517. For enforcement purpose, the Multiresidue Methods Section 302 (Luke Method; Protocol D) picks up parent propiconazole.

Multiresidue methods. The October 1999 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that propiconazole is completely recovered (>80%) using Multiresidue Methods Section 302 (Luke Method; Protocol D). The recovery of propiconazole metabolites CGA-91305, CGA-118244, and 1,2,4-triazole is variable using Section 302. Propiconazole and metabolites CGA-91305, CGA-118244, and 1,2,4-triazole are not recovered using Multiresidue Methods Sections 303 (Mills, Onley, and Gaither; Protocol E, nonfatty) and 304 (Mills, fatty food).

E. Regulatory Rationale

The following is a summary of the rationale for mitigation measures necessary for managing risks associated with the use of propiconazole and for products containing propiconazole to be eligible for reregistration. Where labelling revisions are warranted, specific language is set forth in Table 31 of this document.

1. Human Health Risk Management

a. Aggregate Risk Mitigation for Propiconazole

Acute, short-term, and chronic aggregate risks for propiconazole are below the Agency's level of concern. EPA has considered the contribution of acute and chronic dietary exposure from food and drinking water as well as exposures to residential handlers and post-application residential exposures in the aggregate risk assessment for propiconazole. Therefore, no mitigation is necessary at this time. However, a wood wipe study is required for propiconazole to confirm EPA's conclusions on post-application residential exposure to treated wood.

b. Aggregate Risk Mitigation for Free Triazoles

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

c. Occupational Risk Mitigation

A wide range of factors is considered in making risk management decisions for worker risks. These factors include, in addition to the estimated MOEs, incident data, the nature and severity of adverse effects observed in the animal studies, uncertainties in the risk assessment, alternative registered pesticides, the importance of the chemical in integrated pest management (IPM) programs, and other factors. Mitigation measures may include reducing application rates, adding personal protective equipment (PPE) to end-product labels, requiring the use of engineering controls, and other measures.

Occupational exposure assessments are completed by the Agency considering the use of baseline PPE and, if warranted, for handlers, increasing levels of PPE and engineering controls in order to estimate the potential impact on exposure and risk. The target MOE for propiconazole is 100, based on information provided in Section III of this document. When MOEs for occupational risk are less than 100, EPA strives to reduce worker risks through the use of PPE and engineering controls or other mitigation measures. In some cases, the Agency may accept MOEs less than 100 when all mitigation measures that are feasible and practical have been applied, particularly when there are critical pest management needs associated with the use of the pesticide.

Handler Risk Mitigation

Agricultural Uses. The Agency evaluated handler risks for both liquid and wettable powder formulations of propiconazole. For liquid formulations, handler risks for most scenarios were of concern for mixer/loaders wearing baseline clothing (long sleeve shirt, long pants, shoes, and socks), but these risks can be mitigated with the addition of chemical-resistant gloves (i.e., MOEs with gloves are >100). Therefore all handlers using liquid formulations of propiconazole must wear chemical-resistant gloves and all labels must reflect this requirement. For wettable powders, which are all formulated in water-soluble packs, handler risks were below the Agency's level of concern (MOEs are >100) with baseline clothing. Provided that all wettable powder formulations are in water-soluble packs, no additional mitigation is necessary. In addition, gloves are required for all handlers involved in seed piece treatments or dips because seed piece treatment is a potentially messy operation. All current propiconazole labels require gloves for this use.

Antimicrobial Uses. Material Preservative. The Agency evaluated handler risks associated with use of propiconazole as a material preservative in paints, caulks, textiles, and as a wood preservative. When propiconazole is used as a material preservative, 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. Workers applying paint containing propiconazole as an in-can preservative have a combined short-term MOE of 75 for airless sprayer and intermediate-term MOEs of 55 and 25, for brush/roller or airless sprayer, respectively, at baseline. Although the use of chemical-resistant gloves improves the MOEs for painting, EPA cannot require workers using paint containing propiconazole to wear gloves because paint is considered a treated article when it contains propiconazole as an in-can preservative. Treated articles are exempt from FIFRA labeling requirements.

To mitigate risk to painters, the registrant has agreed to decrease the amount of propiconazole that may be used as a preservative in paint from 0.35% to 0.125% a.i. When paint contains 0.125% propiconazole, MOEs are expected to increase about threefold, resulting in short- and intermediate-term MOEs for painters using brush/roller >100; and MOEs for painters using an airless sprayer > 100 for short-term exposure and ~75 for intermediate-term exposure. However, there is some uncertainty in the dermal component of these MOEs because the underlying exposure monitoring data is from cooling tower workers (no gloves) rather than from painters, and only two replicates are available for cooling tower exposure. Because of these uncertainties, the Agency is requiring additional worker exposure monitoring studies for painters using brush rollers and airless sprayers as confirmatory data. The propiconazole registrants are members of the Antimicrobial Exposure Assessment Task Force II (AEATF II), which will be conducting these studies. In addition, EPA is assuming that 40% of propiconazole in paint is biologically available and absorbed through the skin, based on a rat dermal penetration study with technical grade propiconazole. However, this may differ from the absorption of propiconazole in paint because the paint matrix may limit dermal absorption. Registrants have agreed to conduct a dermal absorption study to determine how much propiconazole is absorbed through the skin when this chemical is suspended in a

paint matrix. EPA is requiring a dermal absorption study for a paint product containing propiconazole as part of this RED. At this time, the Agency believes that reducing the percent active ingredient in paint is sufficient to mitigate risk concerns for painters, given the uncertainties in underlying exposure monitoring data and dermal absorption of propiconazole in paint.

Wood Preservative. For blender/spray operators, chemical operators, and diptank operators, short-term combined MOEs range from 400 to 850 with gloves, and intermediate-term MOEs range from 130 to 280 with gloves. 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; these MOEs assume the use of chemical-resistant gloves. The MOE of 50 is for application of propiconazole to mushroom houses in a high volume spray of 1000 gallons per day. However, according to Phase 3 comments from the American Mushroom Institute, no more than 100 gallons are applied in a mushroom house in a given day (MOE is 500), thus addressing the risk concern. 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. For workers pressure treating wood, the combined intermediate-term dermal and inhalation MOE is 86 with gloves, which falls within the negligible risk range. Also, EPA used monitoring data for other wood preservatives to estimate handler exposure to propiconazole used as a wood preservative. This assumes that the exposure patterns at treatment facilities using other wood preservatives would be the same as for propiconazole. Given this uncertainty, no mitigation is warranted at this time, but a confirmatory worker monitoring study for pressure treatment of wood will be required as part of this RED. Registrants have agreed to conduct this additional worker exposure monitoring study.

Post-Application Worker Risk Mitigation

Agricultural Uses. Agricultural workers re-entering sites previously treated with propiconazole have short-term MOEs ranging from 150 to 36,000 on the day of pesticide application. Because these MOEs are all below the Agency's level of risk concern, no mitigation is necessary. Intermediate-term MOEs for re-entry workers range from 97 (for cut flowers) to 37,000. However, all MOEs are > 100 on the day after pesticide application; including the MOE for cut flowers, which is 104. Although the MOE on is slightly less than 100 on *day 0*, EPA considers this MOE of 97 to be within the same negligible risk range as the MOE of 104 on *day 1*. Therefore, the Agency does not believe that the risk reduction justifies a 24 hour REI for propiconazole. 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 REI may increase depending on the toxicity of propiconazole end-use products; this will be determined during product reregistration.

Antimicrobial Uses. Machinists who are exposed to propiconazole in metal working fluids have a combined short-term inhalation and dermal MOE of 4,800 and a combined intermediate-term MOE of 1,600. Because these MOEs are > 100, and below the Agency's level of concern, no mitigation is needed for post-application risk from metalworking fluids. Saw mill workers who are exposed to wood after it is treated have short-term dermal MOEs

ranging from 150 to 2,700 and inhalation MOEs ranging from 150 to 5,500. Intermediate-term MOEs (for workers exposed for a longer duration) range from 51 to 2000 for dermal exposure and 1,900 to 44,000 for inhalation exposure. Intermediate-term dermal MOEs are of concern only for one scenario: workers performing clean up activities. However, these MOEs are based on data for a surrogate chemical, which is also used as a wood preservative in saw mills, but with a different percent active ingredient, application rates, etc. As previously mentioned, there are no adequate data showing how much propiconazole residue is dislodged from treated wood. As a result, EPA believes that the risk to clean up crew workers is an overestimate and risks are not of concern. Moreover, all other exposure scenarios for this industry are low and not of concern, and it is not practical to impose restrictions. To address these uncertainties EPA is requiring confirmatory exposure monitoring data for post-application workers handling wood treated with propiconazole as well as the confirmatory wood wipe study previously mentioned.

2. Non-Target Organism (Ecological) Risk Management

Ecological risk mitigation measures may include lowering application rates, reducing the number of applications allowed in a year, restricting the timing of applications, extending the time between applications, and changing pesticide use to minimize runoff or spray drift. In some situations, certain uses or application methods may need to be deleted to address ecological risk concerns.

The screening-level risk assessment for propiconazole suggests that exposure to propiconazole is likely to result in some exceedance of EPA's acute or endangered species LOC for birds, mammals, terrestrial and aquatic plants, and chronic LOC for mammals. However, for birds, the acute RQ of 0.53 is very close to the LOC of 0.5. The Agency has addressed these risk concerns to the extent feasible while considering some of the factors listed above. Specific risk mitigation measures are described in the following sections.

EPA does not currently have enough chronic toxicity data to quantify risks for propiconazole for freshwater invertebrates (*Daphnia*) and estuarine/marine fish, because of outstanding data requirements from a previous DCI. Chronic toxicity data must be submitted to support the continued registration of propiconazole.

a. Terrestrial Organisms

Birds and Mammals

Mammals. Acute mammalian RQs for propiconazole are below the LOC for all propiconazole uses except turf. The acute mammalian RQs for turf exceeded the listed species LOC for mammals feeding on *short grass, tall grass, or broadleaf forage and small insects*. Acute RQs for multiple applications of propiconazole to turf exceeded the acute LOC of 0.5 for 15 g and 35 g smaller mammals in the *short grass* food category only. When the Agency revised the RQs for turf using chemical-specific data on foliar dissipation half-life, rather than the 35 day default used in the original screening-level risk assessment, only acute RQs for small mammals feeding on *short grass* exceeded the LOC. However, with the revised RQs, 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*. In the screening-level risk assessment for propiconazole, EPA used the labeled turf application rate of 1.78 lbs ai/A with 2-4 applications per year. Actual use data show that much lower rates and fewer applications are used, even in the states with the greatest use.

Although the revised RQs were calculated with propiconazole-specific foliar dissipation data, the data set was small. The resulting RQs could overestimate or underestimate potential risk to mammals. Therefore, a confirmatory foliar dissipation study is required as part of this RED. This study would measure dissipation of propiconazole over time from foliage of several representative crop groups.

Chronic risks to mammals were calculated using both the dietary and dose-based RQs. Dietary based mammalian RQs based on maximum residues ranged from 1.1 to 2.6 and exceeded the chronic LOC for multiple applications to turf. However, dose-based chronic RQs were as high as 13 for mammals foraging in short grass following multiple applications of propiconazole to turf. For turf, chronic RQs only begin to exceed LOCs after the 3rd application and no chronic LOCs are exceeded after 2 applications. RQs based on mean residues would be lower. Acute risks would also be lower based on fewer applications. All other exposure scenarios resulted in RQs below the Agency's LOC. When EPA refined the chronic dose-based RQs as mentioned above, the only chronic RQs exceeding the LOC are for small mammal feeding on short grass following application of propiconazole to pecans (the RQ of 1.04 only barely exceeds the LOC of 1). For turf, chronic RQs exceed the Agency's chronic LOC for mammals feeding on grasses, broadleaf plants, and small insects.

The greatest use of propiconazole on turf occurs in the Midwestern United States, New York, and Pennsylvania. EPA proprietary data show that lawn care operators applied 15,000 lbs annually, and turf management and nursery and greenhouse operations applied 75,000 lbs annually from 1998 to 2001. Average annual application rates to golf course turf range from 0.2 to 1.3 lbs ai/A, with 17 states reporting annual use propiconazole at an average annual rate of 0.5 lb ai/A or less. In states with the greatest use, the average annual application rate ranged from 0.7 to 1.2 lbs ai/A. The mammalian RQs presented above are based on multiple applications at the labelled application rate of 1.78 lbs ai/A, and are therefore believed to overstate risk to mammals from typical use.

Birds. Avian acute RQs only exceed the Agency's LOC of 0.5 for turf and ornamental uses, when the smallest weight class of birds feeding on short grass following multiple propiconazole applications; for this scenario acute RQs range from 0 to 0.7. When these RQs were refined by using chemical-specific foliar dissipation half-life data, only the RQ of 0.53 for the smallest weight class of birds feeding on short grass exceeded the LOC of 0.5. Also, based on predicted maximum residues and multiple applications to turf and ornamentals, acute RQs 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 on predicted, mean residues resulting from multiple applications to turf and ornamentals, only birds feeding on *short grass* exceed the endangered species LOC. Avian RQs did not exceed LOCs for any other uses.

Dietary-based chronic avian RQs slightly exceed the LOC for the turf use. However, the

chronic toxicity study 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 slightly exceeded the LOC of 1 for multiple applications to turf; the highest RQ was 1.3. In addition, when these RQs were further refined by using chemical-specific foliar dissipation half-life data, the maximum RQ is 1.02 and equivalent to the chronic LOC of 1. Therefore, at this time, EPA does not have a concern for chronic risks to birds and no mitigation is necessary.

Non-Target Insects

EPA does not have sufficient data to determine whether propiconazole use poses potential risks to non-target insects. However, the Agency does not expect adverse effects to insects because propiconazole does not cause adverse effects to soil microbes or earthworms.

Plants

Propiconazole poses a potential risk to terrestrial plants for some uses. Non-listed and listed species RQs resulting from single applications of propiconazole range from <1 to 7.95. RQs exceed the LOC 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. Dicot RQs for a single application of propiconazole to turf and ornamentals range from 0.59 to 2.47 for non-listed species and 0.32 to 7.95 for listed species. Monocot RQs exceed only the LOC for listed species following a single application to turf and ornamentals; no other RQs exceed the LOC. As previously mentioned, the RQ for turf and ornamentals assumes application to turf at the maximum label rate 1.78 lb ai/A; which is greater than the actual rates used on turf (maximum of 0.7 to 1.2 lbs ai/A).

As previously mentioned, underlying assumptions used to derive plant RQs introduce some uncertainty into the conclusions of the screening-level risk assessment. For example, the Terr-PLANT model assumes that 2% for propiconazole is lost to runoff from each of ten acres of a treated field to non-target plants adjacent to the treated field. The Agency is currently developing a plant exposure model which, among other things, will use PRZM to estimate the amount of pesticide in runoff based on the persistence and mobility of the chemical, and soil and weather data in specific crop scenarios. Although this refined exposure model is not yet available, the transport of propiconazole in runoff from use on turf was estimated by PRZM as part of the aquatic risk assessment, and can be used to further characterize the potential for risk to terrestrial dicots.

The TERR-PLANT model assumed an EEC of 0.36 lb ai/A from a single application of 1.78 lb ai/A on turf. 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 7 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. Use data indicate that typical rates in the states with the greatest use range from 0.7 to 1.2 lbs ai/A

per year. Since these typical rates are at least one-third 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.

The Agency believes that the label changes to address spray drift will also reduce potential risks to terrestrial plants. The Ag-DRIFT model shows deposition of fine to medium size spray droplets at levels equal to the vegetative vigor EC₂₅ at distances ranging from 3 to 43 feet from the treated field. The spray drift mitigation will require use of medium coarse to coarse spray droplets to minimize drift. This larger droplet size is expected to reduce the distance from the treated field at which nontarget plants would be at risk for adverse effects (vegetative vigor). If one runs an Ag-DRIFT simulation using this larger droplet size spectrum, RQs for the three less sensitive plants would be below the the LOC at distances beyond 3 feet from the treated field; and the RQ for the most sensitive plant would be below the LOC at distances beyond 13 feet from the field. The distance to which deposition is at or above the LOC for the aerial application to grass grown for seed, pecans, rice, wild rice and peanuts is reduced from 49 feet to 26 feet, based on the most sensitive plant tested. As with seedling emergence, the vegetative vigor LOC represents an effect (mainly plant height here, or dry weight) to 25% of test plants. The distance to which the endangered species LOC (based on the no observed adverse effect level) is met is reduced by spray drift mitigation from 92 feet to 33 feet for the turf use, and from 118 feet to 75 feet for the aerial uses at 0.225 lb ai/A, based on the most sensitive plant tested.

b. Aquatic Organisms

Freshwater Fish and Invertebrates

All RQs for freshwater fish and invertebrates are less than the Agency's LOC of 0.5 for acute risk. These RQs are considered to be conservative because they are based on the maximum 1 in 10 year peak surface water concentrations and the most sensitive 96-hour LC₅₀ values for fish and aquatic invertebrates. For endangered species, 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.

Chronic RQs for freshwater fish do not exceed the Agency's chronic LOC of 1 based on average surface water concentrations of propiconazole resulting from the highest exposure scenarios, for use on turf and rice, and available toxicity data. As previously mentioned, the Agency does not have sufficient data to assess chronic risks from propiconazole uses to estuarine/marine fish or freshwater invertebrates.

Estuarine/Marine Fish and Invertebrates

The Agency's screening-level risk assessment shows that RQs for estuarine/marine fish do not exceed the acute LOC for any use, but exceed the listed species LOC for the rice use. The estuarine/marine invertebrate acute RQs exceed the acute listed species LOC (0.05) from the highest exposure scenarios, for use on turf and rice. The risk assessments must be further refined to determine whether propiconazole use on turf or rice is likely to occur in areas inhabited by

endangered species. As previously mentioned, the acute RQs are based on conservative inputs, including the maximum 1-in-10 year peak EEC and the most sensitive 90-hour LC₅₀ value. In addition, the modeled application rate for turf is higher than what is actually used, even in the areas of greatest use. Furthermore, only one application of propiconazole is made to rice in most states, but two applications were modeled. No levels of concern were exceeded for any other crops.

Chronic RQs 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. As previously mentioned, EPA does not have sufficient data to assess chronic risks from propiconazole uses to estuarine/marine fish.

Plants

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. 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 freshwater non-vascular plants; the listed species RQs exceed the LOC of 1. However, as previously stated, the RQs are based on higher than typical application rates for turf, and the RQs for rice are based on two applications, where one application is commonly used.

3. Summary of Mitigation Measures

The following mitigation measures are necessary for the active ingredient propiconazole and for end-use products containing propiconazole to be eligible for reregistration. These include use restrictions, voluntary cancellations and/or use deletions, and personal protective equipment.

- Handlers using liquid formulations of propiconazole for agricultural use must wear chemical-resistant gloves;
- Handlers using propiconazole for seed piece treatment or dips must wear chemical-resistant gloves;
- Wettable powder formulations of propiconazole must be packaged in water-soluble bags;
- Decrease the amount of propiconazole that may be used as a preservative in paint from 0.35% to 0.125% a.i.; and
- Label restrictions to minimize spray drift, including restrictions on droplet size and application height.

Because the technical registrants have requested that the following uses be deleted from all labels, they are not eligible for reregistration:

- Use of propiconazole on apparel, carpet fibers, and home furnishings
- Registrants have requested that their registration be amended to delete these uses; and EPA issued a formal order deleting these uses on May 26, 2006. Therefore, these uses are not being

considered for reregistration.

F. Other Labeling Requirements

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

1. Endangered Species Considerations

As stated in Chapter III of this document, the Agency's screening-level assessment preliminary 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.

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

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED being implemented at that time.

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

2. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, EPA will continue to work with all interested parties on this important issue.

From its assessment of propiconazole, as summarized in this document, the Agency concludes that certain drift mitigation measures are needed to address the risks from off-target drift for propiconazole, including a requirement for medium to coarse droplet size. Label

statements implementing these measures are listed in the "spray drift management" section of the label table (Table 31) in Section V of this RED document. In the future, propiconazole product labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

The Agency has determined that propiconazole is eligible for reregistration, provided that the risk mitigation measures outlined in this document are adopted and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Summary Table (Table 31). In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring label amendments, product specific data and additional generic (technical grade) data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Below are tables of additional generic data and label amendments that the Agency intends to require for propiconazole to be eligible for reregistration.

A. Manufacturing Use Products

1. Generic Data Requirements

The generic database supporting the reregistration of propiconazole for the above eligible uses has been reviewed and determined to be substantially complete. However, there are a few outstanding generic data requirements for residue chemistry, aquatic toxicity, and environmental fate remaining, which must be fulfilled to support the continued registration of propiconazole. (See Data Gaps listed in Appendix B.) These outstanding data requirements, were included in previous DCIs and therefore will not be included in the generic DCI for this RED.

In addition, the Agency has identified data necessary to confirm the registration eligibility decision for propiconazole. These studies are listed herein and will be included in the generic DCI for this RED, which the Agency intends to issue at a future date.

Human Health

OPPTS 860.1200	Directions for Use for Sunflower Breeder's Seed
OPPTS 860.1500	Crop Field Trials for Sunflower Breeder's Seed
OPPTS GDLN 870.7600	Dermal Penetration (for Paint Containing Propiconazole)
OPPTS GDLN 875.1200	Dermal Exposure – Indoor, for the following scenarios: <ul style="list-style-type: none">○ Painters using brush/roller○ Painters using airless sprayer○ Workers pressure treating wood○ Workers handling treated wood
OPPTS GDLN 875.1400	Inhalation Exposure – Indoor, for the following scenarios: <ul style="list-style-type: none">○ Painters using brush/roller○ Painters using airless sprayer○ Workers pressure treating wood○ Workers handling treated wood
OPPTS GDLN 875.1100	Dermal Exposure – Outdoor, for painters using brush roller and airless sprayer
OPPTS GDLN 875.1300	Inhalation Exposure – Outdoor, Outdoor, for painters using brush roller and airless sprayer

Ecological Effects

OPPTS GDLN 876.7200	Soil Residue Dissipation – modified for foliage dissipation
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<i>Special Studies</i>	Dislodgeable Residues of Propiconazole from treated Wood (wood wipe study for dimensional lumber)
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Data Requirements for Free Triazoles

The Agency is also requiring additional data for the free triazoles, 1,2,4-triazole, triazole alanine, and triazole acetic acid. However, any DCIs for the free triazoles will be issued separately from the DCI for propiconazole.

2. Labeling for Manufacturing Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 31.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Revised labels are due 8 months from the date of receipt of the PDCI mentioned above. Specific language to incorporate these changes is provided in Table 31. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

For propiconazole to be eligible for reregistration, all propiconazole labels must be amended to incorporate the risk mitigation measures outlined in Section IV. Table 31 describes how language on the labels should be amended.

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 18 months after the date of approval of revised labels implementing the changes described in this RED. Others, including end-use registrants, may generally sell, distribute, and use existing stocks bearing previously approved labeling until these existing stocks have been exhausted, provided such sale, distribution, and use are in accordance with previously approved labeling. Existing stocks are defined as stocks of registered pesticide products currently in the United States, which have been packaged, labeled, and released for shipment. EPA's existing stocks policy is described in the Federal Register of June 26, 1991 (56 FR 29362; FRL-3846-4).

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	<p>“Only for formulation into a <i>fungicide/material preservative/wood preservative</i> for the following uses: - [Registrant, please insert].”</p> <p>“Unless packaged in water-soluble packaging, this product may not be formulated into wettable powder end-use products.”</p> <p>“This product may not be formulated into end-use products for use in carpet fibers, apparel, and furnishings (except shower curtains).”</p> <p>“This product may not be formulated into paints and stains unless the maximum concentration of propiconazole is less than or equal to 0.125% by weight.”</p>	Directions for Use
Environmental Hazards Statements	<p>“ENVIRONMENTAL HAZARDS”</p> <p>“This product is toxic to fish and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.”</p>	Precautionary Statements: Environmental Hazards

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
End-Use Products Intended for Occupational Use (WPS and Non-WPS)		
<p>PPE Requirements* for Wettable Powder (WP) Formulations.</p> <p><i>Wettable Powder products labeled for use on agricultural or ornamental crops must be packaged in water soluble packaging to be eligible for reregistration.</i></p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are [Registrant, please insert correct material(s).] Follow the instructions for category [insert A, B, C, D, E, F, G, or H] on the chemical-resistance category selection chart in the EPA Label Review Manual, 3rd Edition (EPA-735-B-03-001, August 2003).</p> <p>“Mixers, loaders, applicators, and other handlers must wear:</p> <ul style="list-style-type: none"> - long-sleeved shirt and long pants, - shoes and socks.” <p>“In addition, mixers/loader must wear</p> <ul style="list-style-type: none"> - chemical-resistant gloves and - a chemical-resistant apron.“ <p>“All handlers using propiconazole as a seed piece treatment must wear</p> <ul style="list-style-type: none"> - chemical-resistant gloves and - a chemical-resistant apron.“ <p>“See Engineering Controls for additional requirements.”</p>	<p>Immediately following/below</p> <p>Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements* for Liquid Concentrate Formulations</p> <p><i>For all liquid formulations labeled for use on agricultural or ornamental crops,</i></p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)].”</p> <p>For more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on the chemical-resistance category selection chart in the EPA Label Review Manual, 3rd Edition (EPA-735-B-03-001, August 2003).</p> <p>“All handlers must wear:</p> <ul style="list-style-type: none"> - long-sleeved shirt and long pants, - shoes and socks, and - chemical-resistant gloves.” <p>“In addition, all handlers (mixers, loaders, and applicators, or individuals performing one or more of these tasks), who are applying this pesticide using hand-held equipment must wear</p> <ul style="list-style-type: none"> - long-sleeved shirt and long pants, - shoes and socks, and - chemical-resistant gloves.” <p>“All handlers using propiconazole as a seed piece treatment must wear</p> <ul style="list-style-type: none"> - chemical-resistant gloves and - a chemical-resistant apron. “ 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
<p>PPE Requirements* for Liquid Concentrate Formulations</p> <p><i>For all liquid formulations labeled for use as a material preservative or wood preservative.</i></p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are [registrant inserts correct material(s)].”</p> <p>For more options, follow the instructions for category [insert A, B, C, D, E, F, G or H] on the chemical-resistance category selection chart in the EPA Label Review Manual, 3rd Edition (EPA-735-B-03-001, August 2003).</p> <p>“Mixers and loaders using liquid formulations must wear:</p> <ul style="list-style-type: none"> - long-sleeved shirt and long pants, - shoes and socks, and - chemical-resistant gloves.” 	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>
<p>Engineering Controls</p> <p><i>For all formulations labeled for use on agricultural or ornamental crops, aerial applicators must use enclosed cockpits.</i></p>	<p>Enclosed Cockpits</p> <p>“Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)].”</p>	<p>Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals</p>

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
Engineering Controls: <i>Wettable Powder formulations must be packaged in water soluble packaging to be eligible for reregistration.</i>	<p>“Engineering Controls: Water-soluble packets, when used correctly, qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water-soluble packets must:</p> <ul style="list-style-type: none"> - wear the personal protective equipment required in the PPE section of this labeling for mixers and loaders - be provided, and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown, chemical-resistant gloves, chemical-resistant footwear, and a PF 5 dust-mist respirator.” 	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Requirements	<p>“Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>“Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	<p>“User Safety Recommendations”</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/ PPE immediately if pesticide gets inside, then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	Precautionary Statements under: Hazards to Humans and Domestic Animals (Must be placed in a box.)
Environmental Hazards Statements	<p>“ENVIRONMENTAL HAZARDS”</p> <p><i>For end use products containing directions for use on agricultural crops and ornamentals:</i> “This product is toxic to fish and shrimp. Do not apply directly to water, or to areas where surface water is present, or to inter-tidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwater or rinsate.”</p> <p><i>For end-use products intended for use as either a material preservative or wood preservative:</i> “This product is toxic to fish and shrimp. Do not apply directly to water. Do not contaminate water when</p>	Precautionary Statements: Hazards to Humans and Domestic Animals

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
	disposing of equipment wastewaters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Eliminations System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.”	
Restricted-Entry Interval <i>For products labeled for use on agricultural or ornamental crops.</i>	“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.”	Directions for Use, in Agricultural Use Requirements box
Early Reentry Personal Protective Equipment <i>For Products Subject to WPS as required by Supplement 3 of PR Notice 93-7</i>	“PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is <ul style="list-style-type: none"> - coveralls, - shoes and socks, and - chemical-resistant gloves made of any waterproof material.” 	Directions for Use, in Agricultural Use Requirements Box
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Directions for Use directly above the Agricultural Use Box
Application Restrictions <i>For products labeled for use as material preservatives</i>	“Do not apply more than [Registrant, insert amount equal to 0.125% by weight] per gallon as a preservative for paints and stains.”	Directions for Use
Use Restrictions <i>For products labeled for use on agricultural or ornamental crops</i>	Do not harvest rice until 45 days after last application of propiconazole. The preharvest interval (PHI) for rice is 45 days. Note: The maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated product per acre, not just as lbs ai/A.	Directions for Use

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
Spray Drift Label Language for Products Applied as a Spray	<p>"Spray Drift Management"</p> <p>"A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product."</p> <p><u>Wind Speed</u> "Do not apply at wind speeds greater than 15 mph."</p> <p><u>Droplet Size</u> "Apply as a medium or coarser spray (ASAE Standard 572)"</p> <p><u>Temperature Inversions</u> "If applying at wind speeds less than 3 mph, the applicator must determine if a) conditions of temperature inversion exist, or b) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions."</p> <p><u>Other State and Local Requirements</u> "Applicators must follow all state and local pesticide drift requirements regarding application of propiconazole. Where states have more stringent regulations, they must be observed."</p> <p><u>Equipment</u> "All application equipment must be properly maintained and calibrated using appropriate carriers or surrogates."</p> <p><i>Additional requirements for aerial applications:</i></p> <ol style="list-style-type: none"> 1. "The boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter." 2. "Release spray at the lowest height consistent with efficacy and flight safety. Do not release spray at a height greater than 10 feet above the crop canopy unless a greater height is required for aircraft safety." 3. "When applications are made with a crosswind, the swath must be displaced downwind. The applicator must compensate for this displacement at the up and downwind edge of the application area by adjusting the path of the aircraft upwind." 	Directions for Use under General Precautions or Restrictions and/or Application Instructions

Table 31. Summary of Labeling Changes for Propiconazole		
Description	Amended Labeling Language	Placement on Label
	<p><i>Additional requirement for groundboom application:</i></p> <p>1. “Do not apply with a nozzle height greater than 4 feet above the crop canopy.”</p>	
<i>End Use Products Primarily Used by Consumers/Homeowners</i>		
Environmental Hazards Statement	<p>“ENVIRONMENTAL HAZARDS”</p> <p>“This product is toxic to fish and shrimp. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment washwaters or rinsate.” “Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas.”</p>	Precautionary Statements under Environmental Hazards
Entry Restrictions	<p>Products applied as a spray:</p> <p>“Do not allow adults, children, or pets to enter the treated area until sprays have dried.”</p> <p>Products applied dry:</p> <p>“Do not allow adults, children, or pets to enter the treated area until dusts have settled.”</p>	Directions for use under General Precautions and Restrictions
General Application Restrictions	<p>“Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift.”</p>	Place in the Direction for Use

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

VI. APPENDICES

APPENDIX A1. Propiconazole Food/Feed Use Patterns Eligible for Reregistration (Case 3125)

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Bananas and Plantains							
Preharvest foliar Ground Airblast, high- pressure handwand, backpack sprayer	41.8% EC [PR-040005]	0.086	8 for mist sprayer 4 for all other application methods	0.675	21	N/A	Apply before disease symptoms appear at the onset of the rainy season. Applications should be made using orchard oil and an emulsifier. Do not apply within 100 yards of non-bagged bananas or directly to non- bagged bananas.
Celery							
Preharvest foliar Ground or aerial	41.8% EC [100-617] [100-737] 45% WP [100-780]	0.1125	4	0.45	7	14	
Foliar Aerial, ground, and sprinkler irrigation	Quilt® 11.7% ai [100-1178]	0.1138	4	0.45	7	7	

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Cereals (Including Wheat, Barley, Triticale, and Rye)							
Preharvest foliar Ground or aerial	41.8% EC [100-617] [100-737] 45% WP [100-780]	0.1125	2	0.167		NS	For barley, oats, ryle, and triticales, apply to the emerging flag leaf; but do not apply after the ligule of the flag leaf emerges (Feekes growth stage 9). For wheat only, apply until full head emergence (Feekes growth stage 10.5).
Corn (Including Field Corn, Field Corn Grown for Seed, Sweet Corn, and Popcorn)							
Preharvest foliar Ground or aerial	41.8% EC [100-617] [100-737] 45% WP [100-780]	0.1125	2	0.45	7	14 (sweet corn)	Start treatment when disease appears and repeated on a 7- to 14-day schedule. Do not apply to field corn or field corn grown for seed after silking. Do not harvest forage from field corn, field corn grown for seed, and popcorn within 30 days of application. Do not harvest sweet corn forage within 14 days of application.
Preharvest foliar Ground or aerial (post silk)	41.8% EC [LA-020003] [KS-030002] [MN-990014] [NE-990006] [IL-040004]	0.1125	2	0.45	7	14 (sweet corn) 30 (seed, field, and popcorn)	Treatment should be started when disease appears and repeated on a 7- to 14-day schedule. Do not feed livestock treated forage or fodder and harvest of sweet corn forage within 14 days of application are prohibited.

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Between V4 to after silking	Stratego® 11.4% ai [264-779]	0.1125	2	0.29	7	30 (forage) before silking	
Corn Grown for Seed (See Also “Corn”)							
Preharvest foliar Ground or aerial, and sprinkler irrigation	41.8% EC [100-617] [IN-990003]	0.1125	2	0.45	7	30	Treatment should be started when disease appears and repeated on a 7- to 14-day schedule. Making more than two applications after 50% silk and feeding livestock treated forage or fodder are prohibited. Applications should be made in a minimum of 10 (ground) or 5 (aerial) gal of water/A.
Preharvest Aerial, ground, and sprinkler irrigation	41.8% EC	0.1125	2	0.45	7	7	When disease first appears.

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Grasses Grown for Seed							
Preharvest foliar Ground or aerial	41.8% EC [100-617] [100-737] 45% WP [100-780]	0.225 (0.1125- bluegrass)	4	0.9	14	20	Use is limited to ID, MN, NE, OR, and WA. Apply multiple treatments on a 14- to 21-day schedule. The feeding of treated hay is prohibited within 20 days of the last application, and the grazing of treated areas is prohibited within 140 days. Applications should be made in a minimum of 20 (ground) or 10 (aerial) gal of water/A.
Preharvest foliar Ground or aerial	41.8% EC [ID-950012] [OR-050012] [WA-950033] [IN-990003] [NV-010004] [MT-030004]	0.225	2	0.45	14	20	Apply just prior to anthesis. Make second application 7-10 days later. Should be tank mixed with an appropriate surfactant. The feeding of treated hay is prohibited within 20 days of the last application, and the grazing of treated areas is prohibited within 140 days. Applications should be made in a minimum of 20 (ground) or 10 (aerial) gal of water/A.

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Mint							
Preharvest foliar Ground	41.8% EC [OR-050011]	0.1125	2	0.225	10	90	Apply when plants are 2-4" high. Make second application 10-14 days later. Applications should be made in a minimum of 20 gal of water/A.
Nectarines (See "Stone fruits")							
Oats							
Preharvest foliar Ground or aerial	41.8% EC [100-617]	0.1125	1	0.1125	N/A	40	Highest yields when applied to the emerging flag leaf; do not apply after the ligule of the flag leaf emerges (Feekes growth stage 8). Applications should be made in a minimum of 10 (ground) or 5 (aerial) gal of water/A.
Peaches (See "Stone fruits")							
Peanuts							
Preharvest foliar Chemigation or directed ground	41.8% EC [100-617] 45% WP [100-780]	0.225	2	0.45	14	21	Apply to crown and pegging zones. Begin applications 45 or 60 days after planting or at the first appearance of disease; make second application 14 days or 3-4 weeks later.
Preharvest foliar Ground or aerial	41.8% EC [100-617] 41.8% EC [100-737] 45% WP [100-780]	0.1125	4	0.45	10	14	Begin applications 35-40 days after planting and repeat on a 10- to 14-day schedule.

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Preharvest foliar Ground or aerial	11.4% ai Stratego® [264-779]	0.1134	6	0.68	14	14	
Pecans							
Preharvest foliar Ground or aerial	Stratego® 11.4% ai [264-779] Tilt® 41.8% EC [100-617] Tilt Bravo SE® 2.9 % ai [100-1192]	0.081	3	0.24	14	30	Apply on a 14-day schedule during bud break, prepollination sprays, or during nut formation and cover sprays. Use higher rates when disease pressure is heavier. Do not apply after shuck split.
Pineapple Seed Piece Treatment							
Postharvest Cold or hot water dip (Seed treatment)	45% WP [100-780]	0.1125 lb ai/500 gal water	1	0.1125 lb ai/500 gal water	N/A	N/A	Use is limited to Hawaii; immerse or soak crowns (seed pieces) for control of disease.
Plantains (See “Bananas and Plantains”)							
Plums (See “Stone fruits”)							

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Rice							
Preharvest foliar Aerial	41.8% EC [100-617] [100-737] Stratego® 11.4% ai [264-779]	0.2813 or 0.16	2@ 0.1688 lb ai/A or 1@ 0.2813 lb ai/A	0.34	10	35	If 5% of tillers are infected, 2 appls. should be made, one at 1st internode elongation (up to 2-inch panicle) and one at swollen boot (10-14 days after 1st appl. but before the boot splits and head emerges). If >10% of tillers are infected, the higher single application rate should be made at first internode elongation. Do not use in California. In Arkansas, do not use in areas of the following counties: Mississippi, Poinsett, Cross, St. Francis, and Lee. Do not use in rice fields where crayfish are commercially farmed. Do not drain water from treated rice fields into ponds used for commercial catfish farming. Do not apply to stubble or ratoon crop rice. Do not use water drained from treated fields to irrigate other crops.
Wild Rice							
Preharvest foliar Aerial	41.8% EC [100-617] [100-737] 45% WP [100-780]	0.225	2@ 0.1688 lb ai/A or 1@ 0.225 lb ai/A	0.34	10	NS	Use is limited to Minnesota. Apply at lower rate at both booting and heading, OR make one application at the higher rate at booting. Do not use water from treated fields to

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
							irrigate other crops.
Rye (See "Cereals")							
Stone Fruits (Sweet or tart Cherry, Apricots, Nectarines, Peaches, and Plums or Prune)							
Preharvest foliar Ground or aerial	41.8% EC [100-702] 45% WP [100-781]	0.1125	2	0.225		10	Two applications may be made during the period beginning 10-14 days before harvest through the day of harvest. Alternatively, the first application may be made at early bloom stage and the second application may be made as needed through petal fall.
Sugarcane Seed Piece Treatment							
Postharvest Cold or hot water dip	45% WP [100-780]	0.1125 lb ai/500 gal water	1	0.1125 lb ai/500 gal water	N/A	N/A	Use is limited to Hawaii. Immerse or soak cut seed pieces for control of disease.
Sunflower (Breeder's seed)							
Foliar spray	41.8% EC [IL-050002] [TX-000006]	0.1125	4	0.45	7	N/A	Apply foliar spray, when disease first appears.

Application Type Application Equipment	Formulation ¹ [EPA Reg. No.]	Maximum Single Application Rate (lb ai/A)	Maximum Number of Apps. per Season	Maximum Seasonal Rate (lb ai/A)	Minimum Application Interval (days)	Preharvest Interval (PHI) (days)	Use Directions and Limitations ²
Wheat (See also "Cereals")							
Preharvest foliar Ground or aerial	41.8% EC [GA-980003] [IN-980003] [MI-980001] [MN-980003] [MS-980004] [VA-980003] [WA-980018] [AR-030008] [MO-980003] [KS-030001] [TN-030002] [OH-040002] [KY-050002]	0.1125	1	0.1125	N/A	40	Apply to the emerging flag leaf. Do not apply after full head emergence (Feekes growth stage 10.5).

¹ The 41.8% EC formulations have been determined to contain 3.6 lb ai/gal of propiconazole based on historical data.

² Propiconazole may be tank mixed with other fungicides; however labels for EPA Reg. Nos. 100-702 and 100-781 state that tank mixing with Cyprex® may cause crop injury.

Note: The 41.8% EC [EPA Reg. Nos. 100-617 and 100-737] and the 45% WP [EPA Reg. No. 100-780] are the only products currently registered for use on rotatable crops. The labels for these formulations state that soybeans may be planted as a double crop following a cereal crop which has been treated with the product, but soybean hay, forage, and fodder may not be used as any component of animal feed or bedding. The labels specify that any food/feed crops not listed on the label should not be planted within 105 days of treatment.

APPENDIX A2: Maximum Rates and Applications for Nonfood Uses of Propiconazole Eligible for Reregistration

Application Type and/or Timing Application Equipment	Typical Formulation [EPA Reg. No.]	Maximum Application Rate	Maximum Number of Applications Per Crop Cycle	Maximum Annual Application Rate (lb ai/A/year)	Minimum Retreatment Interval
NONBEARING FRUIT AND NUT TREES					
Non-bearing Apple					
Foliar Hose-end and pump-up sprayer	Alamo [®] 14.3% ai [100-741] Tilt 41.8 % EC [100-617]	0.08 lb ai/A	Not Specified	7.2 lb ai/A/year	14 days
Non-bearing Nectarine, Peach Plum, Cherry					
Foliar Hose-end and pump-up sprayer	Tilt [®] 41.8% EC [100-617]	0.04 lb ai/100 gal	Not Specified	7.2 lb ai/A/year	14 days
Non-bearing Pecan					
Non-bearing Aerial, ground, hose-end and pump-up sprayer	Tilt [®] 41.8% EC [100-617]	0.12 lb ai/100 gal	3	7.2 lb ai/A/yr	14 days
Non-bearing Citrus					
June, July, August Aerial, ground, hose-end and pump-up sprayer	Orbit [®] 41.8% EC [100-702] Banner GL [®] 41.8% EC [100-736]	0.225 lb ai/A	Not Specified	7.2 lb ai/A/yr	14 days
Non-bearing Walnut					
Foliar Spray	Tilt [®] 41.8% EC [100-617]	0.08 lb ai/100 gal.	Not Specified	7.2 lb ai/A/yr	14 days

Application Type and/or Timing Application Equipment	Typical Formulation [EPA Reg. No.]	Maximum Application Rate	Maximum Number of Applications Per Crop Cycle	Maximum Annual Application Rate (lb ai/A/year)	Minimum Retreatment Interval
TURF AND ORNAMENTALS					
Ground Cover					
Foliar Hose-end and pump-up sprayer	Banner GL [®] 41.8% EC [100-736]	0.7524 lb ai/A	Not Specified	37 packets	14 days
Lawns, Turf, and Golf Courses					
Foliar Hose-end and pump-up sprayer Ground boom sprayer	Banner GL [®] 41.8% EC [100-736] Tilt [®] 41.8% EC [100-617]	1.79 lb ai/A	Not Specified	7.2 lb ai/A/yr	14 days
Industrial/Commercial Lawns and Turf					
When needed Ground spray	Banner GL [®] 41.8% ai [100-736] Tilt Bravo [®] SE 2.9% [100-1192]	0.02 lb/1K sq. ft.	2	Not Specified	14 days
Shade Trees (injection)					
Root Injection	Alamo [®] 14.3% liquid [100-741]	0.0069 lb ai/ DBH	1	Not Specified	Not Applicable
Shade Trees (outdoor spray), Herbaceous Plants, Ornamental Woody Shrubs and Vines					
Hose-end and pump-up sprayer	Banner GL [®] 41.8% ai [100-736] Tilt [®] 41.8% EC [100-617]	0.24 lb ai/100 gal	Not Specified	7.2 lb ai/A/yr	Not Specified
Sod Farm Turf					
Ground bloom Sprayer	Alamo [®]	1.79 lb ai/A	Not Specified	7.2 lb ai/A/yr	7

Application Type and/or Timing Application Equipment	Typical Formulation [EPA Reg. No.]	Maximum Application Rate	Maximum Number of Applications Per Crop Cycle	Maximum Annual Application Rate (lb ai/A/year)	Minimum Retreatment Interval
	14.3% ai liquid [100-741] Banner GL 41.8% ai [100-736] Tilt® 41.8% EC [100-617]				
Non-bearing Blueberries					
Non-bearing Spray	41.8% EC [FL-940005]	0.169 lb ai/A	5	0.85 lb ai/A/yr	28 days (June-October)
Non-bearing Hazelnuts					
At emergence Aerial and ground	41.8% EC [OR-040003]	0.225 lb ai/A	No more than 32 oz of Orbit®/A/season	0.90	14 days

Note:

PPZ 1.55% HG [EPA Reg. No. 100-773] and PPZ 1.55% Multi-purpose fungicide [Reg. No. 100-952] are also used in residential consumer market. These labels have lower application rates than Alamo/Banner MAXX [EPA Reg No. 100-741].

APPENDIX A3 Propiconazole Antimicrobial Uses Eligible for Reregistration

Use Site	Typical Formulation [EPA Reg. No.] % ai	Maximum Application Rate	Maximum Number of Applications/ Minimum Retreatment Interval	Use Directions and Limitations	Application Method from Labels
Antimicrobial Uses –Material Preservative					
Adhesives, coatings, caulks, sealants, and inks	50% SL [43813-37]	1.213% ai by weight of material	NS	For Commercial or Industrial Use Only	
	9.7% ai [43813-19]				
	7% Liquid Concentrate [5383-114]	0.125-5.0%	NS	For Commercial or Industrial Use Only	
	8% Liquid [1448-394]	0.6 -10 %	NS		
	23.6% EC [43813-16]	0.2 – 5% based on total weight of material	NS	For Commercial or Industrial Use Only Do not use on products that will contact food	
Industrial Coatings, Industrial Specialty Industrial Products	50% SL [43813-37]	0.1-2.4% based on total weight of material	NS	For Commercial or Industrial Use Only	
	7% Liquid Concentrate [5383-114]	0.125-5%		For Commercial or Industrial Use Only	
Material Preservative for Paints and Stains	10% Liquid Concentrate [5383-114]	0.125 % ai by weight of material to be preserved		For Commercial or Industrial Use Only	
Leather Processing, Material Preservative for Leather Finishing Pastes etc	4.5% ai [71406-1] [70227-6]	0.05 to 0.4% by weight of tanned leather ; 0.01 to 0.25% by weight of leather finishing pastes, fatliquors, or finishes	NS	For Commercial or Industrial Use Only	Add to tanning solution or finishing solution OR Add to leather finishing pastes, fatliquors, or finish
Metal working/Cutting Fluids	23.6% EC [43813-16]	50 -700 ppm ai in diluted fluid	NS	For Commercial or Industrial Use Only	Added to Metalworking Fluids using Liquid Pump or Liquid Pour
	50% SL [43813-37]	50-700 ppm ai in diluted fluid	Not Specified	For Commercial or Industrial Use Only	

Use Site	Typical Formulation [EPA Reg. No.] % ai	Maximum Application Rate	Maximum Number of Applications/ Minimum Retreatment Interval	Use Directions and Limitations	Application Method from Labels
Textiles/Canvas	7% ai [5383-114]	0.5-2.5	Not Specified	Not for use on carpet fibers, home furnishings (except shower curtains), or apparel	
	50% SL [43813-37]	0.28% ai by weight of material to be preserved	Not Specified		
	23.6% EC [43813-16]	2000 ppm ai in treatment solution	Not Specified		Dye Incorporation, Pad, Exhaust, or Spray Application
	50% SL [43813-37]	2000 ppm in treatment solution (0.4% product)	Not Specified		Dye Incorporation, Pad, Exhaust, or Spray Application
Antimicrobial Uses – Wood Preservative					
Wood in Commercial/Industrial Water Cooling Systems	23.6% EC [43813-16]	0.5 – 1.1% ai solution (0.23 – 0.46 lbs ai/1000 sq. ft wood	When Needed, Repeat Shock Treatment every 4-6 months	Not Specified	High volume spray
Mushroom Houses-Empty Premises/ Equipment	23.6% EC [43813-15] [43813-16]	0.31 lb/25 gal 0.06 lb/1000 sq. ft. 0.0125 lb ai/gal; 1 gal/200 sq ft wood	13 week application interval	For spray treatment, apply 25 gallons of treatment solution per 5000 square feet of surface For dip treatment, submerge trays or boards for no more than 30 seconds	Spray and dip tank
Wood Protection Treatment to Buildings (Indoor)	23.6% EC [43813-16]	30 l cu.m (L)	Typically 1	Not Specified	Conventional or electrostatic spray and dip tank
Wood Protection Treatment to Buildings (Outdoor)		0.3532 lb ai/iK sq. ft.	Typically 1	Not Specified	Conventional or electrostatic spray and dip tank
Wood Protection Treatment to Forest Products (Seasoned)		6.8 lb/90 gal	Typically 1	Not Specified	Pressure treatment (double vacuum, full-cell or modified full-cell) and brush applied
Wood Protection Treatment to Forest Products (Unseasoned)		20% ai [70227-4] 50% ai [43813-21] [43813-37]	41.7 lb/90 gal	Typically 1	Not Specified

Use Site	Typical Formulation [EPA Reg. No.] % ai	Maximum Application Rate	Maximum Number of Applications/ Minimum Retreatment Interval	Use Directions and Limitations	Application Method from Labels
Non-pressure Treatment of Wood & Wood Products					
Anti-Sapstain	1% Liquid Ready-to-Use [1448-414]	0.02% ai solution (0.5 to 2.0 gallons per 100 gallons of water)	Not Specified	Not Specified	Immersion, Dip treatment, Conventional Spray, Electrostatic Spray
	3% Liquid [1022-585]	0.06 % ai solution (1 gallon per 50 to 75 gallons of dip vat solution)	Not Specified	For Commercial or Industrial Use Only	Immersion, Dip Treatment
	3.5% Liquid [60061-112]	For high-pressure spray application, mix 1 gallon per 2 to 500 gallons water For dip application, mix 1 gallon per 20 to 1,000 gallons water	Not Specified	For Commercial or Industrial Use Only	Immersion, Dip Treatment, High-pressure Application
	4.5% Liquid [71406-1] [70227-6] [60061-114]	Deposit rate of 0-20 ug ai/cm ² wood surface	Not Specified	For Commercial or Industrial Use Only	Bulk Dip Tanks, Conventional Spray Systems, Low volume spray systems
	5% Liquid [72616-1] [60061-107]	0.1-0.2% ai solution (1 gallon with 25-300 gallons of water)	Not Specified	For Commercial or Industrial Use Only	Dip Tank, Immersion, Conventional Spray, High-Pressure Spray
	50% SL [43813-37]	0.5-1.0% ai solution	Not Specified	For Commercial or Industrial Use Only	Immersion, roller coater, flood, spray, brush treatment
Anti-Saptain	7% Liquid Concentrate [5383-114]	0.5 to 5% ai solution	Not Specified	For Comemrcial or Industrial Use Only	Dip Tank, Immersion, Conventional Spray, High-Pressure Spray
	8% Liquid Concentrate [1448-394]	0.5-5% ai solution	Not Specified	For Commercial or Industrial Use Only	Dip Tanks, Conventional Spray Systems
	9.7% Liquid Concentrate [43813-19]	0.5 - 1% ai solution	Not Specified	Not Specified	Immersion, Roller Coater, Flood Spray, Brush
	10% Liquid	0.04 to 1.7% ai solution	Not Specified	For Commercial or Industrial	Dip Tanks, Conventional

Use Site	Typical Formulation [EPA Reg. No.] % ai	Maximum Application Rate	Maximum Number of Applications/ Minimum Retreatment Interval	Use Directions and Limitations	Application Method from Labels
	Concentrate [60061-102]	(1 gallon with 50 to 2000 gallons water)		Use Only	Spray Systems
Anti-Sapstain for fresh sawn lumber	20% Liquid Concentrate [70227-4]	0.05 – 0.5% ai solution	Not Specified	Not Specified	Dip Tank, Spray Box
Wood preservative/Decay Control	9.7% Liquid Concentrate [43813-19] [62190-17]	0.5%- 5% ai solution	Not Specified	For Commercial or Industrial Use Only	Immersion, Roller Coater, Flood Spray, Brush onventional Spray, Electrostatic Spray
	0.1% Liquid Ready- to-Use [60061-109]	0.1% Ready-to Use, 5 to 10 gallons per 1000 board feet for diptank; 1 gallon per 200 square feet for brush application	Not Specified	For Commercial or Industrial Use Only	Diptank or Brush Application
	[60061-115] 0.997% ai	Dilute one part product with 4 parts petroleum solvent	Not Specified	Dilute one part product with 1.5 to 4 parts petroleum solvent	Immersion, pressure treatment
	23.6% EC [43813-16]	0.5 – 1 % ai solution	Not Specified	For Cmmercial or Industrial Use Only Do not use on wood that will contact food	Immersion, roller coating, or flood coating
Wood Preservative	50% SL [43813-37]	0.5-1.0% ai solution	Not Specified	For Commerical or Industrial Use Only	Immersion, roller coater, flood, spray, brush, or pressure treatment
Pressure Treatment of Wood					
Wood preservative	0.4% ai [62190-12]	0.5 to 7% aqueous solution by weight	Not Specified	For Commercial or Industrial Use Only	Use only in vacuum pressure impregnation systems
Wood Preservative – machined and manufactured wood products	0.5% Liquid Ready- to Use [75101-1]	30 L/meter ³	Not Specified	Wood must be clean and dry before treatment.	Pressure treatment (double vacuum process)
	0.997% ai Liquid [60061-115]	0.5 % ai solution	Not Specified	Dilute product with petroleum solvent	Immersion, pressure treatment

Use Site	Typical Formulation [EPA Reg. No.] % ai	Maximum Application Rate	Maximum Number of Applications/ Minimum Retreatment Interval	Use Directions and Limitations	Application Method from Labels
Wood preservative	50% SL [43813-37]	0.5-1.0% ai solution	Not Specified	For Commercial or Industrial Use Only	Double vacuum, full cell, or modified full cell pressure treatment

APPENDIX B: Data Supporting Guideline Requirements for the Reregistration of Propiconazole

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	40583701, 43764401
830.1600	61-2A	Start. Mat. & Mnfg. Process	All	40583701, 43420701
830.1670	61-2B	Formation of Impurities	All	40583701, 43764401
830.1700	62-1	Preliminary Analysis	All	40583702, 43764402
830.1750	62-2	Certification of limits	All	40583702, 43764401
830.1800	62-3	Analytical Method	All	40583702, 43764402
830.6302	63-2	Color	All	40583703, 42030201, 43698701
830.6303	63-3	Physical State	All	40583703, 42030201, 43698701
830.6304	63-4	Odor	All	40583703, 42030201, 43698701
830.7220	63-6	Boiling Point	All	40583703, 42030201, 43698701
830.7300	63-7	Density	All	40583703, 42030201, 43698701
830.7840 830.7860	63-8	Solubility	All	40583703, 42030201
830.7950	63-9	Vapor Pressure	All	40583703, 42030201
830.7370	63-10	Dissociation Constant	All	40583703, 42030201, 43698701
830.7550	63-11	Octanol/Water Partition Coefficient	All	42030201, 43698701
830.7000	63-12	pH	All	42030201, 43698701
830.6313	63-13	Stability	All	43698701, 00067961
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity		00079689, 00067926

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
850.2200	71-2A	Avian Dietary Toxicity - Quail		00072210, 00133366
850.2200	71-2B	Avian Dietary Toxicity - Duck		00067927, 00072210, 00133367
850.2300	71-4A	Avian Reproduction - Quail		00133369
850.1075	72-1A	Fish Toxicity Bluegill		0067922
850.1075	72-1B	Fish Toxicity Bluegill -TEP		00132922, 00072209
850.1075	72-1C	Fish Toxicity Rainbow Trout		00067921 (0072209), 0067923, 00132926
None	72-3D	Fish Toxicity Rainbow Trout TEP		00132927
850.1010	72-2A	Invertebrate Toxicity		00067925, 00244273
850.1010	72-2B	Invertebrate Toxicity - TEP		00132932, 00072209
850.1075	72-3A	Estuarine/Marine Toxicity - Fish		00132921
850.1025	72-3B	Estuarine/Marine Toxicity - Mollusk		00260201
850.1035 850.1045	72-3C	Estuarine/Marine Toxicity - Shrimp		00260201
None	72-3D	Estuarine/marine Fish Acute Toxicity Test (TEP)		
None	72-3E	Estuarine/marine Mollusk (Oyster) Acute Toxicity Test (Shell Deposition) (TEP)	00132924	00132933, 0072209
None	72-3F	Estuarine/marine Mysid (Shrimp) Acute Toxicity Test (TEP)		00132934, 0072209
850.1400	72-4A	Fish- Early Life Stage		00072210
850.1300 850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle		Data Gap
850.4225	123-1A	Seed Germ./ Seedling Emergence		41673203
850.4250	123-1B	Vegetative Vigor		41673201

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
850.4400	123-2	Aquatic Plant Growth		00132937, 00132938, 00132939, 00133362
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat		00058591
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat		00058596
870.1300	81-3	Acute Inhalation Toxicity-Rat		41594801
870.2400	81-4	Primary Eye Irritation-Rabbit		00058597
870.2500	81-5	Primary Skin Irritation		00058598
870.2600	81-6	Dermal Sensitization		00058600
870.6200	81-8	Acute Neurotoxicity Screen – Rats		46604601
870.3100	82-1A	90-Day Feeding - Rodent		00058606, 42050501, 42050502, 45215801
870.3150	82-1B	90-Day Feeding - Non-rodent		00058607
870.3200	82-2	21-Day Dermal - Rabbit/Rat		00116591
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent		00151515
870.4200	83-2A	Oncogenicity - Rat		00129918
870.4200	83-2B	Oncogenicity - Mouse		00129570, 44381401
870.3700	83-3A	Developmental Toxicity - Rat		40425001
870.3700	83-3B	Developmental Toxicity - Rabbit		40425004
870.3800	83-4	2-Generation Reproduction - Rat		00151514
870.4100	83-1A	Chronic Dietary - Rodent		00129918
870.4100	83-1B	Chronic Dietary – Non-rodent		00151515
870.5300	84-2	In Vitro Cell Transformation		00133349
870.5385	84-2B	Structural Chromosomal Aberration		00058603
870.5450	84-2	Rodent Dominant Lethal Assay		00058602

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells		00133347, 00133348
870.5575	84-2	Mitotic Gene Conversion in <i>Saccharomyces Cerevisiae</i>		00133343
870.7485	85-1	General Metabolism		42403901, 41326701, 00074506, 00074507, 00164795
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.1100	231	Estimation of Dermal Exposure, Outdoor Sites		45524304, 45469501, ORTF# OMA002, ORTF# OMA004, New Data Requirement (Paint Use)
875.1200	233	Estimation of Dermal Exposure, Indoor Sites		45524304, ORTF# OMA004, New Data Requirement (Paint, Wood Preservative Uses)
875.1300	232	Estimation of Inhalation Exposure, Outdoor Sites		45524304, 45469502, New Data Requirement (Paint Use)
875.1400	234	Estimation of Inhalation Exposure, Indoor Sites		45524304, 46513901, New Data Requirement (Paint, Wood Preservative Uses)
875.1200	132-1A	Foliar (Dislodgeable) Residue Dissipation		00133390, 42564003, 44959701, 44959702, 45288601

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis		0067901, 0067911, 133409, 93194052
835.2240	161-2	Photodegradation - Water		41811901, 0067911, 133409
835.2410	161-3	Photodegradation - Soil		41811902, 0067911, 133409
835.4100	162-1	Aerobic Soil Metabolism		00129912, 00129914, 00133375
835.4400	162-3	Anaerobic Aquatic Metabolism		42415702
835.4300	162-4	Aerobic Aquatic Metabolism		42347901
835.1240	163-1	Leaching/Adsorption/Desorption		Data Gap (MRIDs 41727001, 44701801 are both supplemental)
835.6100	164-1	Terrestrial Field Dissipation		00155642, 00159691, 45528702, 45528703
835.6200	164-2	Aquatic Field Dissipation		452560501, 452560502
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue - Plants	A,B	00074496, 00074498 , 00074499, 00074500 , 00074501, 00074502, 00129915 , 00155645 , 44049601, 44381402, 93194062

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
860.1300	171-4B	Nature of Residue - Livestock	A,B	00067905, 00074503, 00074504, 41823301, 41823302, 41823304, 42564006, 42983001, 93194085
860.1340	171-4C	Residue Analytical Method - Plants	A,B	00137150, 40154501, 40180701, 40692203, 40692204, 40692206, 40783306, 41063801, 41063802, 41486801, 41823305, 42061301, 42182901, 42564005, 42605801, 42634101, 43424601, 43434201, 43825401, 44411201, 44411206, 44411207, 44411208, 93194064
860.1340	171-4D	Residue Analytical Method - Animals	A,B	40150701, 40154501, 40180702, 41823304, 44411204, 93194067
860.1380	171-4E	Storage Stability	A,B	00074510, 00074511, 00133385, 40692201, 41063801, 41063802, 41486802, 42605801, 43314201, 43825402, 44411205, 93194068, 40150701, 42983001
860.1650	171-13	Analytical Reference Standards	A,B	Data Gap
860.1480	171-4J	Magnitude of Residues - Meat/Milk/Poultry/Egg		

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
		- Milk and the Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	A,B	00137861, 40150701 , 93194070
		- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	A,B	00137861, 40150701 , 93194070
860.1500	171-4K	Crop Field Trials (Stone Fruits Group)		
		- Apricots	A,B	41063802
		- Cherries	A,B	43655609
		- Nectarines	A,B	41063802
		- Peaches	A,B	41063802
		- Plums	A,B	41063802
		- Prunes, fresh	A,B	41063802
860.1500	171-4K	Crop Field Trials (Tree Nuts Group)		
		- Pecans	A,B	00074495 , 00074508 , 00074509 , 00153327
860.1500	171-4K	Crop Field Trials (Cereal Grains Group)		
		- Barley, grain	A,B	93194072
		- Corn, field, grain and aspirated grain fractions	A,B	40783303, 42564004, 42564005
		- Corn, sweet (kernels plus cobs with husks removed)	A,B	40783303, 42564004, 42564005
		- Oats, grain	A,B	42182901, 43314202
		- Rice, grain	A,B	00137861, 42915601, 44411208, 93194075
		- Wheat, grain and aspirated grain fractions	A,B	44411206, 44411207, 93194072
		- Wild rice	A,B	41063801, 42511401
860.1500	171-4K	Crop Field Trials (Fodder, Forage, Hay, and Straw of Cereal Grains Group)		

Requirement		Study Title	Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number			
		- Barley, hay and straw	A,B	93194072
		- Corn, field, forage and stover	A,B	40783303, 42564004, 42564005
		- Corn, sweet, forage and stover	A,B	40783303, 42564004, 42564005
		- Oats, forage, hay, and straw	A,B	42182901, 43314202
		- Rice, straw	A,B	00137861, 44411208, 93194075
		- Wheat, forage, hay, and straw	A,B	44411206, 44411207, 93194072
860.1500	171-4K	Crop Field Trials (Grass Forage, Fodder, and Hay Group)		
		- Grass, seed screenings, forage, hay, and straw	A,B	40890701, 41823305, 42634101, 42634102, 93194073
860.1500	171-4K	Crop Field Trials (Miscellaneous Commodities)		
		- Bananas	A,B	00137150, 93194071
		- Mint	A,B	42061301, 43424601
		- Mushrooms	A,B	43434201
		- Peanut, nutmeat and hay	A,B	40692201
		- Pineapple	A,B	40783305
		- Sugarcane	A,B	44142401, 93194077
860.1520	171-4L	Magnitude of Residue in Processed Food/feed		
		- Corn, field	A,B	40783303, 42564005
		- Mint	A,B	42061301, 43424601
		- Oat	A,B	42182901
		- Peanut	A,B	40692201, 42605801
		- Pineapple	A,B	40783305, Data Gap

Requirement			Use Pattern	MRID Citation(s)
New Guideline Number	Old Guideline Number	Study Title		
		- Plum	A,B	41063802
		- Rice	A,B	00137861, 42915601, 93194079
		- Wheat	A,B	44411206, 44411207, 44757208, 93194080
835.1850	165-1	Confined Rotational Crop	A,B	00074498, 00129915, 00138266, 00155644, 00155645, 00164802, 41102001
860.1950	165-4	Bioaccumulation in Fish	A,B	44411206
OTHER				
Non-	Guideline	Rat developmental Toxicity		40425002
Non-	Guideline	Tumor Promotion – rat 2000 ppm dietary up to 8 weeks		
Non-	Guideline	Mechanistic studies:Hepatic Biochemical Parameters – Male CD-1 mice	00151517 45215803	
Non-	Guideline	Mechanistic studies:Hepatocellular Proliferation - Mouse		
Non-	Guideline	Catfish Acute Toxicity	45215802	00132930, 00067924, 00244273

Appendix C: Bibliography of Studies Considered in the Propiconazole RED

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark,

the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word "received."
 - (2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

Product Chemistry

- 00067961 Heinrichs, L. (1981) Complete Analysis of CGA-64250 Technical by Liquid Chromatography, Gas Chromatography, and Thin Layer Chromatography. Method no. PA-227R dated Jan 20, 1981. (Unpublished study received Jan 28, 1981 under 100-618; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:244267-B)
- 40583701 Brown, R.; Lail, L. (1988) Product Chemistry: CGA-64250 Technical: Study No. PC-87-026. Unpublished compilation prepared by Ciba- Geigy Corp. 81 p.
- 40583702 Brown, R.; Lail, L. (1988) Product Chemistry: CGA-64250 Technical: Study No. PC-87-026. Unpublished compilation prepared by Ciba- Geigy Corp. 98 p.
- 40583703 Brown, R.; Lail, L. (1988) Product Chemistry: CGA-64250 Technical: Study No. PC-87-026. Unpublished compilation prepared by Ciba- Geigy Corp. 81 p.
- 42030201 Lail, L. (1991) Product Chemistry of CGA-64250 Technical: Lab Proj- ect Number: PC-91-024. Unpublished study prepared by Ciba-Geigy Corp. 5 p.
- 43420701 McCain, P. (1994) CGA-64250 Technical: Supplement to Product Chemistry: (Manufacturing Process). Unpublished study prepared by Ciba-Geigy Corp. 70 p.
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APPENDIX D: Technical Support Documents for Propiconazole

Additional documentation in support of this RED is maintained in EPA's Pesticide Docket under docket number EPA-HQ-OPP-2005-0497. This docket may be viewed, in paper form, in the OPP docket room located at Room S-4900, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA. The docket is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m. All documents in this docket may also be viewed or downloaded via the Internet at <http://www.regulations.gov>, under the docket number listed above.

The Preliminary Risk Assessments for Propiconazole, which were made publicly available on February 15, 2006, and public comments on these risk assessments, are also available under docket number EPA-HQ-OPP-2005-0497. Registrant requests to amend their propiconazole registrations to delete certain uses, and the March 8, 2006 *Federal Register Notice* announcing receipt of this are also available under this docket number.

Final revised risk assessment documents supporting the reregistration eligibility decision for propiconazole are listed below. These documents may also be viewed in the Pesticide docket, or viewed or downloaded from the Internet as described above.

Human Health Risk Assessment Documents

1. *Propiconazole: Phase 4, HED Chapter of the Reregistration Eligibility Decision Document (RED)*. June 28, 2006.
2. *Propiconazole: Phase IV, revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document (RED)*. June 15, 2006.
3. *Propiconazole: Amendment to the Propiconazole Reregistration Eligibility Decision (RED) Document for Children's Postapplication Exposure Treated Structures*. June 20, 2006.
4. *Propiconazole Revised Acute and Chronic Dietary Exposure Assessments for Reregistration Evaluation [sic] Decision (RED) – Phase 4*. June 7, 2006.
5. *Propiconazole (122101): Reregistration Eligibility Decision (RED) Document; Revised Residue Chemistry Considerations*. June 15, 2006.

Environmental Fate and Ecological Effects Documents

6. *Environmental Fate and Effects Division Revised RED for the Reregistration of Propiconazole*. June 29, 2006.
7. *Terrestrial Plant Runoff Risk Assessment for Propiconazole on Turf Using PRZM*. July 14, 2006.
8. *Revised Drinking Water Assessment of Propiconazole*. June 7, 2006.

Risk Assessments and Related Documents for the Free Triazoles

9. *Meeting Summary: EPA/FDA Joint Teleconference on July 11, 2006 to Discuss 1,2,4-Triazole (Free TRiazole) as a Common Metabolite of Triazole Derivative Fungicides and Anastrozole, a Drug*. July 18, 2006.
10. *EPA 1,2,4-Triazole Consult Response*. Memo from John Lazor, Director, FDA Division of Clinical Pharmacology 4, to Debra Edwards, Director, Special Review and Reregistration Division. May 19, 2006.

11. *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*. Michael Doherty et al. February 7, 2006.
12. *Response to Triazole Task Force Comments on the FQPA Drinking Water Assessment for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), and Triazole Acetic Acid (TAA)*. June 15, 2006.

Documents on Propiconazole Use and Usage

13. *Usage Report Package in Support of Reregistration for the Fungicide Propiconazole (122101)*. April 26, 2006.

APPENDIX E: Generic Data Call-In (DCI) for Propiconazole

This is a placeholder for the Generic DCI for the pesticide active ingredient propiconazole. The Generic DCI has not yet been issued and will be issued at a future date. Generic data requirements for propiconazole are listed in the RED document.

APPENDIX F: Product-specific Data Call-In (DCI) for Propiconazole

This is a placeholder for the Product DCI for all pesticide products containing the pesticide active ingredient propiconazole. The Product DCI has not yet been issued and will be issued at a future date.

APPENDIX G: Batching of Propiconazole Products for Meeting Acute Toxicity Testing Data Requirements

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Seventy nine products were found which contain Propiconazole as the active ingredient. These products have been placed in fourteen batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

Batch 13: Studies should be conducted on EPA Reg. No. 60061-119

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

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

Batch 1	EPA Reg. No.	Percent Active Ingredient
	100-618	95.0
	43813-13	95.0
	62719-347	93.8
	66222-59	93.0
	74054-2	93.0
	74054-3	93.0

Batch 2	EPA Reg. No.	Percent Active Ingredient
	43813-21	50.0
	43813-37	50.0

Batch 3	EPA Reg. No.	Percent Active Ingredient
	100-780	45.0
	100-781	45.0
	100-1153	45.0

Batch 4	EPA Reg. No.	Percent Active Ingredient
	100-736	41.8
	100-737	41.8

Batch 5	EPA Reg. No.	Percent Active Ingredient
	100-617	41.8
	100-702	41.8
	100-1233	41.8
	62719-346	41.8
	66222-42	41.8
	66222-118	41.8

Batch 6	EPA Reg. No.	Percent Active Ingredient
	43813-15	23.6
	43813-16	23.6

Batch 7	EPA Reg. No.	Percent Active Ingredient
	43813-41	15.0
	43813-42	15.0

Batch 7	EPA Reg. No.	Percent Active Ingredient
	53883-174	14.3
	66222-41	14.3

Batch 8	EPA Reg. No.	Percent Active Ingredient
	100-741	14.3
	100-772	14.3
	228-396	14.3
	34704-879	14.3
	53883-129	14.3
	60063-27	14.3
	66330-325	14.3
	69117-3	14.3
	72112-3	14.3
	79676-8	14.3

Batch 9	EPA Reg. No.	Percent Active Ingredient
	43813-19	9.7
	75506-3	9.7

Batch 10	EPA Reg. No.	Percent Active Ingredient
	70227-6	4.5
	71406-1	4.5

Batch 11	EPA Reg. No.	Percent Active Ingredient
	100-773	1.55
	100-952	1.55
	53883-128	1.55
	53883-184	1.55

Batch 12	EPA Reg. No.	Percent Active Ingredient
	43813-43	Propiconazole: 34.0 IPBC: 16.0
	43813-44	Propiconazole: 34.0 IPBC: 16.0

Batch 13	EPA Reg. No.	Percent Active Ingredient
	60061-103	Propiconazole: 0.21 IPBC: 0.21 Tebuconazole: 0.21
	60061-109	Propiconazole: 0.10 IPBC: 0.10 Tebuconazole: 0.10
	60061-119	Propiconazole: 0.98 IPBC: 0.98;Tebuconazole: 0.98

Batch 14	EPA Reg. No.	Percent Active Ingredient
	74405-1	Propiconazole: 0.70 Permethrin: 0.35 Tebuconazole: 0.70
	75101-1	Propiconazole: 0.50 Permethrin: 0.43 Tebuconazole: 0.51

No Batch	EPA Reg. No.	Percent Active Ingredient
	100-641	14.30
	100-1178	Propiconazole: 11.70 Azoxystrobin: 7.00
	100-1192	Propiconazole: 2.90 Chlorothalonil: 38.50
	100-1216	Propiconazole: 9.54 Azoxystrobin: 5.73
	100-1231	Propiconazole: 4.70 Chlorothalonil: 29.90 Fludioxonil: 1.20
	100-1244	32.40
	264-778	Propiconazole: 20.90 Trifloxystrobin: 25.00
	264-779	Propiconazole: 11.40 Trifloxystrobin: 11.40
	352-699	Propiconazole: 45.00 Fentin Hydroxide: 40.00
	1022-585	Propiconazole: 3.00 IPBC: 6.00
	1448-394	8.00
	1448-414	Propiconazole: 5.00 Bardac 2280: 25.00
	5383-114	Propiconazole: 7.00 IPBC: 21.60
	5383-120	Propiconazole: 6.00 IPBC: 17.40

No Batch	EPA Reg. No.	Percent Active Ingredient
	9198-227	Propiconazole: 0.62 Chlorothalonil: 3.90 PCNB: 7.50
	57227-3	Propiconazole: 4.94 Bardac 2280: 46.25
	57227-6	40.00
	60061-102	10.00
	60061-107	Propiconazole: 5.00 Bardac 2280: 46.25
	60061-112	Propiconazole: 3.50 Diiodomethyl-p-tolyl sulfone: 0.95 IPBC: 3.50
	60061-114	4.50
	60061-115	Propiconazole: 0.977 IPBC: 0.979 Tebuconazole: 0.979
	60061-121	Propiconazole: 5.00 IPBC: 5.00
	70227-4	20.00
	71711-17	Propiconazole: 6.00 Flutolanil: 32.00
	71711-24	Propiconazole: 1.80 Chlorothalonil: 21.65 Flutolanil: 17.20
	72616-1	Propiconazole: 5.00 IPBC: 5.00 Maquat: 50.00
	75506-1	Propiconazole: 0.40 Boric Acid: 9.74 Copper Carbonate: 18.18
	75506-7	Propiconazole: 5.00 Imidacloprid: 0.50 Tebuconazole: 5.00

APPENDIX H: List of Registrants Sent the Generic and Product-Specific DCIs for Propiconazole

This is a placeholder for the list of registrants sent the generic and product DCIs for propiconazole. The final list of registrants will be compiled when the DCIs are issued (at a future date).

Appendix I: List of Available Related Documents and Electronically Available Forms

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

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

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

Instructions:

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

Document Processing Desk (distribution code)*
Office of Pesticide Programs (7504P)
Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

* Distribution Codes are as follows:
(APPL) Application for product registration
(AMEND) Amendment to existing registration
(CAN) Voluntary Cancellation
(EUP) Experimental Use Permit
(DIST) Supplemental Distributor Registration
(SLN) Special Local Need
(NEWCO) Request for new company number
(NOTIF) Notification
(PETN) Petition for Tolerance
(XFER) Product Transfer

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

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov. If you want these forms mailed or faxed to you, please contact Lois White, white.lois@epa.gov or Floyd Gayles, gayles.floyd@epa.gov.

If you have any questions concerning how to complete these forms, please contact OPP’s ombudsperson for conventional pesticide products: Linda Arrington, (703) 305-5446

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit <http://www.epa.gov/pesticides/registrationkit/>

Dear Registrant:

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

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

- a. 83-3 Label Improvement Program-Storage and Disposal Statements
- b. 84-1 Clarification of Label Improvement Program
- c. 86-5 Standard Format for Data Submitted under FIFRA
- d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
- e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
- f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
- g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
- h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/oppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

- a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
- b. EPA Form No. 8570-4, Confidential Statement of Formula
- c. EPA Form No. 8570-27, Formulator's Exemption Statement
- d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
- e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

- a. Registration Division Personnel Contact List
- b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
- c. Antimicrobials Division Organizational Structure/Contact List
- d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
- e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
- f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
- g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

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

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

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

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

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

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

- Date of receipt
- EPA identifying number
- Product Manager assignment

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

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