United States Environmental Protection Agency

Office of Prevention, Pesticides and Toxic Substances (7501 P)

Pesticide Fact Sheet

Name of Chemical: **Prothioconazole**
Reason for Issuance: **New Chemical**
Tolerances Established
Date Issued: **March 14, 2007**

Description of Chemical

Generic Name:	Prothioconazole (2-(2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl)-1,2-dihydro-3*H*-1,2,4-triazole-3-thione)
Common Name:	Prothioconazole
Trade Name:	PROLINE ® 480 SC Fungicide
Chemical Class:	Triazolinthione
EPA Chemical Code:	113961
CAS Number:	178928-70-6
Registration Status:	New Chemical Registration
Pesticide Type:	Fungicide
U.S. Producer:	Bayer CropScience 2 T. W. Alexander Drive Research Triangle Park, NC 27709

Tolerances Established

Tolerances were established for prothioconazole in the 40 CFR §180.626 section as summarized below:

Tolerances for combined residues of prothioconazole and its desthio metabolite:

Barley, grain	0.35 ppm
Barley, hay	7.0 ppm
Barley, straw	4.0 ppm
Grain, aspirated grain fractions	11
Pea and bean, dried shelled, except soybean, subgroup 6C	0.90 ppm
Peanut, nutmeat	0.02 ppm

Peanut, hay	6.0 ppm
Rapeseed, seed	0.15 ppm
Wheat, grain	0.07 ppm
Wheat, forage	6.0 ppm
Wheat, hay	4.5 ppm
Wheat, straw	5.0 ppm

Tolerances for prothioconazole, the desthio metabolite, and conjugates convertible to these compounds by acid hydolysis, calculated as parent:

Cattle, fat	0.1 ppm
Cattle, meat	0.02 ppm
Cattle, meat byproducts	0.20 ppm
Goat, fat	0.1 ppm
Goat, meat	0.02 ppm
Goat, meat byproducts	0.20 ppm
Hog, meat byproducts	0.05 ppm
Horse, fat	0.1 ppm
Horse, meat	0.02 ppm
Horse, meat byproducts	0.20 ppm
Milk	0.02 ppm
Poultry, liver	0.02 ppm
Sheep, fat	0.1 ppm
Sheep, meat	0.02 ppm
Sheep, meat byproducts	0.20 ppm

Use Patterns and Formulations

Prothioconazole is a broad-spectrum systemic fungicide produced by Bayer CropScience for the control of diseases caused by ascomycetes, basidiomycetes, and deuteromycetes. Prothioconazole may be applied alone or as a tank mix with other fungicides, insecticides, or herbicides. Application through any type of irrigation system is prohibited.

EPA and the Pest Management Regulatory Agency (PMRA) of Canada jointly reviewed prothioconazole. The crops proposed for joint review include barley, canola, chickpeas, the oilseed crop group, the dried shell and bean subgroup, lentils and wheat. Uses on peanuts were proposed for the U.S. only.

Prothioconazole is formulated as a 4 lb/gal suspension concentrate (equivalent to a flowable concentrate; FlC) formulation (Proline® 480 SC Fungicide, 41% active ingredient). The product is applied as broadcast post emergence foliar or soil sprays (application to soil for peanuts only) using ground or aerial equipment at 0.088-0.178 lb ai/A/application (0.100-0.200 kg ai/ha/application). The proposed maximum seasonal rates range 0.285-0.713 lb ai/A (0.320-0.800 kg ai/ha), and the proposed retreatment intervals are 5-21 days. The PHIs range from 7 days for dried shelled peas and beans to 36 days for oilseed crops. The directions for use of prothioconazole are summarized in Table 1.

Table 1. Summary of Directions for Use of Prothioconazole						
Applic. Timing, Type, and Equip.	Applic. Rate (lb ai/A) [fl oz/A]	Max. No. Applic. per Season	Retreatment Interval (days)	Max. Seasonal Applic. Rate (lb ai/A) [fl oz/A]	PHI (days)	Use Directions and Limitations
Barley (for Fusarium Head Blight)						
Broadcast foliar spray; Ground or aerial	0.134 -0.178 [4.3 - 5.7]	2	7 to 14	0.293 [9.37]	32	Apply as a preventative foliar spray within the time period when 70 to 100% of the barley heads on the main stem are fully emerged when weather conditions are favorable for disease development and up to 3 to 5 days after full head emergence.
Barley (for Leaf and Stem Diseases)						
Broadcast foliar spray; Ground or aerial	0.0875 – 0.134 [2.8 - 4.3]	2	7 to 14	0.269 [8.6]	32	Apply as a preventative foliar spray when the earliest disease symptoms appear on the leaves or stems.
Chickpea						
Broadcast foliar spray; Ground or aerial	0.134 -0.178 [4.3 - 5.7]	3	10 to 14	0.534 [17.1]	7	Apply at first sign of disease. Use higher use rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.
Dried Shelled Peas and Beans Subgroup, except Soybean (Grain, Sweet, White and White Sweet lupins; Field, Kidney, Dry lima, Pinto and Tepary beans; Adzuki bean, Blackeyed pea, Catjang, Cowpea, Crowder pea, Moth bean, Mung bean, Rice bean, Southern pea and Urd bean; Dry broad bean; Guar; Lablab bean; Pea [including Field pea] and Pigeon pea)						
Broadcast foliar spray; Ground or aerial	0.134 -0.178 [4.3 – 5.7]	3	5 to 14	0.534 [17.1]	7	Apply at the first sign of disease. Use higher use rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.
Lentils						
Broadcast foliar spray; Ground or aerial	0.134 -0.178 [4.3 – 5.7]	3	10 to 14	0.534 [17.1]	7	Apply at early flower or at the first sign of disease. Use higher use rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.
Rapeseed (Canola), Indian rapeseed, and Crambe						
Broadcast foliar spray; Ground or aerial	0.134 -0.178 [4.3 – 5.7]	2	5 to 7	0.356 [11.4]	36	Apply when the crop is 20 to 50% bloom stage (not after the 50% bloom stage). Utilize higher rate for fields with history of heavy disease pressure or for dense crop stands.
Peanut						

Table 1. Summary of Directions for Use of Prothioconazole						
Applic. Timing, Type, and Equip.	Applic. Rate (lb ai/A) [fl oz/A]	Max. No. Applic. per Season	Retreatment Interval (days)	Max. Seasonal Applic. Rate (lb ai/A) [fl oz/A]	PHI (days)	Use Directions and Limitations
Broadcast foliar spray; Ground or aerial	0.156 -0.178 [5.0 – 5.7]	4	14 to 21	0.713 [22.8]	14	Use higher rate when conditions are favorable for severe disease pressure and/or when growing less disease resistant varieties.
Wheat (spring, durum and winter; for Fusarium Head Blight)						
Broadcast foliar spray; Ground or aerial	0.134 -0.178 [4.3 – 5.7]	2	7 to 14	0.293 [9.37]	30	Apply within the time period from when at least 75% of the wheat heads on the main stem are fully emerged to when 50% of the heads on the main stem are in flower. Optimal timing of application may be at or around 15% flower.
Wheat (spring, durum and winter; for Leaf and Stem Diseases)						
Broadcast foliar spray; Ground or aerial	0.134 -0.156 [4.3 - 5.0]	2	7 to 14	0.293 [9.37]	30	Apply as a preventative foliar spray or when the earliest disease symptoms appear on the leaves or stems.

Science Findings

The Agency has completed a human health risk assessment for the uses of the new active ingredient prothioconazole. For the approved crops, the risk estimates from acute and chronic dietary (food + water) exposures do not exceed the Agency's LOC.

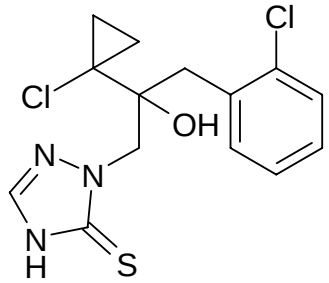
The toxicology database is extremely large, especially the number of complex toxicology studies. The toxicity database for prothioconazole (and its metabolites) is considered complete and deemed adequate for endpoint selection for exposure and risk assessment, for FQPA evaluation, and to support the approved uses and tolerances.

With respect to cancer, EPA has concluded prothioconazole and its metabolites are not carcinogenic, and are classified "Not likely to be Carcinogenic to Humans."

Available product chemistry and toxicology data supporting the proposed tolerance are summarized below.

Physical/Chemical Structure:

Prothioconazole -



Prothioconazole-Desthio –

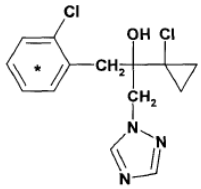


Table 2. Prothioconazole Nomenclature.	
Empirical Formula	$C_{14}H_{15}Cl_2N_3OS$
Common name	Prothioconazole
Company experimental name	JAU 6476
IUPAC name	2-[(2*RS*)-2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2*H*-1,2,4-triazole-3(4*H*)-thione
CAS name	2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3*H*-1,2,4-triazole-3-thione
CAS registry number	178928-70-6
End-use product/EP	PROLINE ® 480 SC Fungicide
Chemical Class	Triazolinthione
Known Impurities of Concern	None

The physical and chemical properties of prothioconazole are summarized in Table 3.

Table 3. Physicochemical Properties of the Technical-Grade Prothioconazole.		
Parameter	**Value**	**Reference**
Molecular Weight	344.26 g/mol	
Melting point	139.1 - 144.5 °C	MRID 46246003
Density (g/ml at 20^0C)	1.36 (pure active ingredient)	MRID 46246003
	1.17 at 20 °C (end use product)	MRID 46246003

Table 3. Physicochemical Properties of the Technical-Grade Prothioconazole.		
Parameter	**Value**	**Reference**
Water solubility (g/L)	5.0 pH 4 buffer at 20 °C 0.3 pH 8 buffer at 20 °C 2.0 pH 9 Buffer at 20 °C	MRID 46246003
Solvent solubility at 20 °C (g/L)	g/L at room temp acetone >250 acetonitrile 10-100 dichloromethane 100-250 dimethylsulfoxide 100-250 ethyl acetate <250 n-heptane <0.1 1-octanol 10-100 polyethylene glycol >250 2-propanol 10-100 xylene 1-10	MRID 46246003
Vapor pressure (Pa at 20 or 25 °C)	$<4 \times 10^{-7}$	MRID 46246003
Dissociation constant, pK_a	6.9	MRID 46246003
Octanol/water partition coefficient, Log(K_{OW})	at 20 °C unbuffered: K_{ow} = 11300; log K_{ow} = 4.05 pH 4: K_{ow} = 14600; log = 4.16 pH 7: K_{ow} = 6600; log = 3.82 pH 9: K_{ow} = 100; log = 2.00	MRID 46246003
UV/visible absorption spectrum	Peak maxima at 275 nm. No absorption at >300 nm.	MRID 46246003

Toxicological Characteristics

In addition to prothionconazole *per se*, the major metabolite prothioconazole-desthio is of toxicological interest. Residues of prothioconazole-desthio, the major metabolite/degradate in plants, together with residues of its 4-hydroxy metabolites, may also be found in edible ruminant tissues and milk. Because of the toxicological significance of the parent prothioconazole and prothioconazole-desthio, this Fact Sheet provides summaries of the available toxicity information for both compounds.

Table 4. Acute Toxicity of Prothioconazole Technical				
Guideline No.	**Study Type**	**MRID No.**	**Results**	**Toxicity Category**
870.1100	Acute oral toxicity (rat)	46246230	LD_{50} >= 6200 mg/kg (M, F)	IV
870.1200	Acute dermal toxicity (rat)	46246244	LD_{50} >= 2000 mg/kg (M, F)	III
870.1300	Acute inhalation toxicity (rat)	46246246	LC_{50} >= 4.99 mg/L (M, F)	IV
870.2400	Primary eye irritation (rabbit)	46246249	Not an irritant	IV

Table 4. Acute Toxicity of Prothioconazole Technical				
Guideline No.	**Study Type**	**MRID No.**	**Results**	**Toxicity Category**
870.2500	Primary skin irritation (rabbit)	46246302	Not an irritant	IV
870.2600	Dermal sensitization (Guinea pig)	46246305	Not a sensitizer	Negative

Table 5. Acute Toxicity of Prothioconazole-desthio				
Guideline No.	**Study Type**	**MRID No.**	**Results**	**Toxicity Category**
870.1100	Acute oral toxicity (rat)	46246231	LD_{50} = 2806 mg/kg (M, F) (approximate)	III
870.1100	Acute oral toxicity (mouse)	46246242	LD_{50} = 2235 mg/kg (M) LD_{50} = 3459 mg/kg (F)	III
870.1200	Acute dermal toxicity (rat)	46246243	LD_{50} >= 5000 mg/kg (M,F)	IV
870.1300	Acute inhalation toxicity (rat)	46246247	LC_{50} >= 5.077 mg/L (M,F)	IV
870.2400	Primary eye irritation (rabbit)	46246250	Slight irritant (iritis, discharge)	III
870.2500	Primary skin irritation (rabbit)	46246250	Not an irritant	IV
870.2600	Dermal sensitization (Guinea pig)	46246304	Not a sensitizer	Negative

Table 6. Toxicity Profile for Prothioconazole Technical		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3700a Prenatal develop-mental in rats – oral	46246316 (1996) 0, 80, 500, 1000 mg/kg/day Acceptable/Guideline	**Maternal Toxicity** NOAEL = 80 mg/kg/day LOAEL = 500 mg/kg/day based on increased urination and water consumption, and decreased body weight gain. **Developmental Toxicity** NOAEL = 80 mg/kg/day LOAEL = 500 mg/kg/day based on increased incidence of delayed ossification, increased incidence of dysplastic pubic bone, and increased incidence of left punctiform 14th rib.

Table 6. Toxicity Profile for Prothioconazole Technical		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3700a Prenatal develop-mental in rats – oral	46246317 (2002) 0, 40, 200, 1000 mg/kg/day Acceptable/Nonguideline	Range finding study for above, no endpoints were determined.
870.3700a Prenatal develop-mental in rodents (rat) - dermal	46246323 (2001) 0, Technical 1000 mg/kg/day, 62.5 mg/kg/day diluted EC 250 formulation, 250 mg/kg/day EC 250 formulation Acceptable/Nonguideline	**Maternal Toxicity** NOAEL > 1000 mg/kg/day LOAEL > 1000 mg/kg/day **Developmental Toxicity** NOAEL = 1000 mg/kg/day LOAEL > 1000 mg/kg/day
870.3700a Prenatal develop-mental in rats – oral	46923601 (2004) 0, 20, 80, 750 mg/kg/day Acceptable/Nonguideline	**Maternal Toxicity** NOAEL = 80 mg/kg/day LOAEL = 750 mg/kg/day based on increased water consumption, decreased food consumption and decreased body weight gain. **Developmental Toxicity** NOAEL = 80 mg/kg/day LOAEL = 750 mg/kg/day based on increased incidence of rudimentary ribs (comma-shaped).
870.3700b Prenatal develop-mental in nonrodents (rabbit)	46246330 (1997) 0, 80, 100, 300, 480 mg/kg/day pilot study Acceptable/Nonguideline	**Maternal Toxicity** NOAEL < 80 mg/kg/day LOAEL = 80 mg/kg/day based on reduced food consumption and body wts. **Developmenta**l NOAEL = 300 mg/kg/day LOAEL = 480 mg/kg/day based on decreased body wt, and small fetuses.
870.3700b Prenatal develop-mental in nonrodents (rabbit)	46246328 (1998) 0, 10, 30, 80, 350* mg/kg/day * Additional group added after start of study Acceptable/Guideline	**Maternal Toxicity** NOAEL = 80 mg/kg/day LOAEL = 350 mg/kg/day based on decreased body wt and decreased food consumption. **Developmental Toxicity** NOAEL = 80 mg/kg/day LOAEL = 350 mg/kg/day based on abortions, total resorptions, and lower fetal body weight
870.4100a Chronic toxicity rodents (rat)	46246335 (2000) 0, 5, 50, 750 mg/kg/day Rat, 53 weeks Acceptable/Guideline	NOAEL = 50 mg/kg/day LOAEL = 750 mg/kg/day based on decreased body weight and body weight gain, alterations in hematology and clinical chemistry parameters indicative of liver and kidney damage, increased liver and kidney weights, and accompanying histopathological alterations in the liver, kidney and urinary bladder. FOB conducted at 27 and 52 weeks.

Table 6. Toxicity Profile for Prothioconazole Technical		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.4100b Chronic toxicity non-rodent (dog)	46246336 (2001) 0, 5, 40, 125 mg/kg/day one year Acceptable/Guideline	NOAEL = 5 mg/kg/day LOAEL = 40 mg/kg/day based on decreased T3 and T4 thyroid hormones, increased urine volume, and increased incidence of chronic inflammation and pigmentation in the kidneys of the male animals, and decreased T4 thyroid hormone, increased spleen weight, increased incidence of spleen pigmentation, and increased incidence of crystals present in the kidneys of the female animals.
870.4200 Carcinogenicity rats	46246338 (2001) M: 0, 5, 50, 750/500 mg/kg/day F: 0,5,50,750/625 mg/kg/day 106 weeks Unacceptable/Guideline for Carcinogenicity because dose levels too high.	NOAEL = 50 mg/kg/day LOAEL = 500/625 (M/F) mg/kg/day based **on increased mortality** and decreased body weight/body weight gain, changes in clinical chemistry (APh, creatinine, urea) and hematological parameters, increased liver and kidney weights, and liver (hypertrophy and eosinophilic/clear cell focus) and kidney/urinary bladder pathology.
870.4300 Carcinogenicity mice	46246339 (2001) 0, 10, 70, 500 mg/kg/day 80 weeks Acceptable/Guideline	NOAEL = 10 mg/kg/day LOAEL = 70 mg/kg/day based on kidney (tubular degeneration/regeneration in males) effects. **no evidence of carcinogenicity**

Table 7. Toxicity Profile for Prothioconazole-Desthio (SXX0665)		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3700a Prenatal develop-mental in rodents (rat) - dermal	46246326 (1991) 0, 30 mg/kg/day Pilot study, used with 46246325 Acceptable/Nonguideline	**Discussed in appendix 1 of MRID 46246325** **Maternal Toxicity** NOAEL = 30 mg/kg/day LOAEL > 30 mg/kg/day **Developmental Toxicity** NOAEL = 30 mg/kg/day LOAEL > 30 mg/kg/day
870.3700a Prenatal develop-mental in rodents (rat) - dermal	46246325 (1991) 0, 100, 300, 1000 mg/kg/day Acceptable/Guideline When combined with 46246326	**Maternal Toxicity** NOAEL = 1000 mg/kg/day LOAEL > 1000 mg/kg/day **Developmental Toxicity** NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on structural alterations (14^{th} rib)
870.3700a Prenatal develop-mental in rodents (rat) - oral	46246322 (1991) 0, 1, 3 mg/kg/day Acceptable/Nonguideline results combined with 46246321	**Maternal Toxicity** NOAEL = 3 mg/kg/day LOAEL > 3 mg/kg/day **Developmental Toxicity** NOAEL = 3 mg/kg/day LOAEL > 3 mg/kg/day Combined with 46246321

Table 7. Toxicity Profile for Prothioconazole-Desthio (SXX0665)		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.3700a Prenatal develop-mental in rodents (rat) - oral	46246321 (1991) 0, 10, 30, 100 mg/kg/day Acceptable/Guideline results combined with 46246322	**Maternal Toxicity** NOAEL = 30 mg/kg/day LOAEL = 100 mg/kg/day based on decreased body weight gains, increased liver weight with histopathology **Developmental Toxicity** NOAEL < 10 mg/kg/day LOAEL < 10 mg/kg/day based on structural alterations (supernumery ribs) and incomplete/delayed ossification at all levels. Combined with 46346322
870.3700a Prenatal develop-mental in rodents (rat) - oral	46246320 (1990) 0, 100 mg/kg/day Acceptable/Nonguideline	**Maternal Toxicity** NOAEL = 100 mg/kg/day LOAEL > 100 mg/kg/day **Developmental Toxicity** NOAEL <100 mg/kg/day LOAEL = 100 mg/kg/day based on developmental delays
870.3700a Prenatal develop-mental in rodents (rat) - oral	46246319 (1992) 0, 30 mg/kg/day oral Acceptable/Nonguideline	**Maternal Toxicity** No NOAEL or LOAEL were determined **Developmental Toxicity** No NOAEL or LOAEL were determined, observations included structural abnormalities, developmental delays, death, shows 14th rib not completely reversible after birth. Follow up of MRID 46246320, 46246321.
870.3700b Prenatal developmental in nonrodents (rabbit) - oral	46246327, (1991) 0, 2, 10, 50 mg/kg/day Acceptable/Guideline	**Maternal Toxicity** NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on decreased body wt gain, decrease food consumption, increased resorptions, decreased number of fetuses, liver histopathology. **Developmental Toxicity** NOAEL = 2 mg/kg/day LOAEL = 10 mg/kg/day based on structural alterations including malformed vertebral body and ribs, arthrogryposis, and other multiple malformations.
870.3700b Prenatal developmental in nonrodents (rabbit) - dermal	46246329 (1991) 0, 100, 300, 1000 mg/kg/day dermal pilot study Acceptable/Nonguideline	**Maternal Toxicity** NOAEL = 300 mg/kg/day LOAEL = 1000 mg/kg/day based on local dermal toxicity **Developmental Toxicity** NOAEL = 1000 mg/kg/day LOAEL > 1000 mg/kg/day
870.4100b Chronic toxicity dogs	46246337 (2001) 0, 40, 300, 2000 ppm 0, 1.35/1.55, 10.1/11.1, 69.9/77.1 (M/F) mg/kg/day 30 weeks Unacceptable/Guideline Not tested at high enough doses GLP deficiencies	NOAEL = 69.9/77.1 (M/F) mg/kg/day LOAEL > 69.9/77.1 (M/F) mg/kg/day

Table 7. Toxicity Profile for Prothioconazole-Desthio (SXX0665)		
Guideline No./ Study Type	**MRID No. (year)/ Classification /Doses**	**Results**
870.4200 Carcinogenicity rats	46246342 (1999) 0, 20, 140, 980 ppm 0, 1.1/1.6, 8.0/11.2, 57.6/77.4 (M/F) mg/kg/day Acceptable/Guideline	NOAEL = 1.1/1.6 (M/F) mg/kg/day LOAEL = 8.0/11.2 (M/F) mg/kg/day based on clinical chemistry, histopathology (liver). **no evidence of carcinogenicity**
870.4300 Carcinogenicity mice	46246340 (2000) 46246341 (2001) 0, 12.5, 50, 200 ppm 0, 3.1/5.1, 12.8/20.3, 51.7/80.0 (M/F) mg/kg/day 105 weeks Acceptable/Guideline	NOAEL =12.8/20.3 (M/F) mg/kg/day LOAEL = 51.7/80.0 (M/F) mg/kg/day based on decreased body weight gain in males, decreased triglyceride levels in both sexes, decreased cholesterol levels in males, changes in glucose levels in males, increased liver weights in both sexes, increased incidence of histopathological findings in the liver hepatocytes in both sexes, decreased blood urea levels in females, increased kidney weights in females, and increased incidence of eosinophilic droplets in the cortical tubules of the kidneys of females. **no evidence of carcinogenicity**
870.6300 Developmental neurotoxicity rats	46246418 (2004) 0, 40, 160, 500 ppm 0, 3.6, 15.1, 43.3 mg/kg/day during gestation 0, 8.1, 35.7, 104.6 during lactation Acceptable/Nonguideline	**Maternal Toxicity** NOAEL = 15.1 mg/kg/day LOAEL = 43.3 mg/kg/day based on dystocia **Developmental Toxicity** NOAEL = 3.6 mg/kg/day LOAEL = 15.1 mg/kg/day based on deviated snout and malocclusion **Offspring Neurotoxicity** potential could not be determined - Brain morphometric changes and increased incidence of peripheral nerve lesions were observed at high dose level, but not measured at mid- and low-dose levels.

Toxicological Endpoints

Table 8. Summary of Toxicological Doses and Endpoints for Prothioconazole desthio for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty/FQPA Safety Factors**	**RfD, PAD, Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dietary and Non-Occupational Human Health Risk Assessments				
Acute Dietary (Females 13 – 49)	NOAEL = 2.0 mg/kg/day	UF_A=10x UF_H=10x FQPA SF=10x (UF_{DB})	Acute RfD = 0.002 mg/kg/day aPAD = 0.002 mg/kg/day	**Developmental Toxicity study in rabbits** LOAEL = 10 mg/kg/day, based on structural alterations including malformed vertebral body and ribs, arthrogryposis, and multiple malformations.
Acute Dietary (General Population, including infants and children)	None	None	None	**An appropriate study was not identified**

Table 8. Summary of Toxicological Doses and Endpoints for Prothioconazole desthio for Use in Human Health Risk Assessments				
Chronic Dietary (All Populations)	NOAEL=1.1 mg/kg/day	UF_A=10x UF_H=10x FQPA SF=10x (UF_{DB})	Chronic RfD = 0.001 mg/kg/day cPAD = 0.001 mg/kg/day	**Chronic/Oncogenicity study in rats** LOAEL = 8.0 mg/kg/day based on liver histopathology (hepatocellular vacuolation and fatty change (single cell, centrilobular, and periportal)).
Incidental Oral Short- and Intermediate-Term (1-30 days and 1-6 months)	N/A	N/A	N/A	Incidental oral exposure endpoint not identified because residential exposure is not anticipated.
Dermal Short- and Intermediate-Term (1-30 days and 1-6 months)	N/A	N/A	N/A	Dermal endpoints are not applicable because residential exposure is not anticipated.
Inhalation Short- and Intermediate-term (1-30 days and 1-6 months)	N/A	N/A	N/A	Inhalation endpoints are not applicable because residential exposure is not anticipated
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			
Occupational Human Health Risk Assessments				
Dermal Short- and Intermediate-Term (1-30 days and 1-6 months)	NOAEL=30 mg/kg/day	UF_A=10x UF_H=10x UF_{DB} = 10x	Occupational LOC for MOE = 1000	**Dermal developmental study in rats** LOAEL = 100 mg/kg/day based on an increased incidence of supernumerary rib (14th rib).
Inhalation Short- and Intermediate-term (1-30 days and 1-6 months)	NOAEL=2.0 mg/kg/day Inhalation absorption are assumed to be 100%	UF_A=10x UF_H=10x UF_{DB} = 10x	Occupational LOC for MOE = 1000	**Developmental Toxicity study in rabbits** LOAEL = 10 mg/kg/day, based on structural alterations including malformed vertebral body and ribs, arthrogryposis, and multiple malformations.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

For acute and chronic dietary (food and water) risk assessments, the 10x FQPA SF has been retained in the form of an UF_{db} (10x) for the lack of NOAEL and a LOAEL from the developmental neurotoxicity study, regarding some neurotoxic endpoint (peripheral nerve lesions and brain morphometrics).

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

The LOC for occupational exposure to prothioconazole desthio is based on the conventional uncertainty factor of 100x (UF_A = 10x and UF_H = 10x) and an additional UF_{DB} (10x) for the lack of NOAEL and a LOAEL from the developmental neurotoxicity study, regarding some neurotoxic endpoint (peripheral nerve lesions and brain morphometrics).

Food Quality Protection Act Considerations:

There are adequate data in the prothioconazole (including metabolites) database to characterize the potential for pre-natal or post-natal risks to infants and children: two-generation reproduction studies in rats; developmental studies in rats and rabbits; and a developmental neurotoxicity study in rats. The effects seen in these studies suggest that pups are more susceptible: pup effects were seen at levels below the LOAELs for maternal toxicity and, in general, were of comparable or greater severity compared to the effects observed in adults. In addition, since the developmental effects seen in the developmental neurotoxicity study were investigated at the high dose level only, there is uncertainty concerning the LOAEL/NOAEL for developmental effects in this study. Thus, the FQPA factor is retained at 10X. EPA is currently regulating at doses lower than the lowest dose in the DNT. It is unlikely that the lowest dose tested in the DNT will be a LOAEL.

Exposure Assessment:

Acute Dietary Exposure and Risk: A moderately refined acute dietary exposure assessment was conducted for prothioconazole using empirical processing factors (PFs), livestock maximum residues, and 100 percent crop treated (%CT). An acute endpoint was identified only for females, 13-49 years of age. Dietary risk estimates were determined considering exposures from food plus upper bound surface water EDWC point estimates based on the bean application scenario.

The dietary exposure analyses result in acute dietary risk estimates that are below the Agency's level of concern for food and drinking water. The most conservative exposure estimate, using upper bound water residues from the bean application scenario resulted in exposure estimates at the 95th percentile of 0.001192 mg/kg/day, which utilized 60% of the aPAD for females 13-49 years of age.

Chronic Dietary Exposure and Risk: A moderately refined chronic dietary exposure assessment assumed empirical processing factors, average residues, livestock maximum residues, and 100%CT. Dietary risk estimates were determined considering exposures from food plus upper bound surface water EDWC point estimates based on the bean application scenario. The dietary exposure analysis results in chronic dietary risk estimates that are below the Agency's level of concern for food plus drinking water. The highest exposure and risk estimates were for all infants and children 1-2 years old. The highest exposure and risk estimates for food plus upper bound water were for the all infants population subgroup, with an estimated exposure of 0.000948 mg/kg/day, which utilized 86% of the cPAD.

Cancer Exposure and Risk: The available toxicology studies in the mouse and rat showed no increase in tumor incidence, and therefore the Agency concluded that prothioconazole or its metabolites are not carcinogenic, and classified "Not Likely to be Carcinogenic to Humans" according to the 2005 Cancer Guidelines. Therefore, a dietary cancer assessment was not performed.

Residential Exposure and Risk: Residential exposures are not expected, since there are no proposed residential uses.

Aggregate Exposure and Risk: In accordance with the FQPA, the Agency must consider aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. Consequently, an aggregate assessment adds together exposures from relevant sources and compares the resulting estimate of **total** exposure to numerical estimates of hazard (e.g., a NOAEL or PAD); alternatively, the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure.

Based on the Section 3 food crop uses, dietary aggregate exposures (i.e. food plus drinking water) are expected. The Agency does not expect residential exposures at this time because no residential uses have been proposed. Therefore, dietary (food plus drinking water) exposures sufficiently define aggregate exposures for assessment of risks from the use of prothioconazole. Estimates of pesticide residues in drinking water were incorporated directly into the dietary exposure analysis to assess aggregate acute and chronic risk.

Cumulative Exposure and Risk: Prothioconazole is a member of the triazole-containing class of pesticides, often referred to as the conazoles. EPA is not currently following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. At this time, there is not sufficient evidence to determine whether conazoles share common mechanisms of toxicity. Without such understanding, there is no basis to make a common mechanism of toxicity finding for the diverse range of effects found. For information regarding EPA's procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA's website at http://www.epa.gov/pesticides/cumulative.

To support existing tolerances and to establish new tolerances for conazole pesticides, including prothioconazole, EPA conducted human health risk assessments for exposure to 1,2 4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of triazole-containing pesticides (as of 9/1/05), including prothioconazole. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with the common metabolites (e.g., use of maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high-end estimates of both dietary and non-dietary exposures). Acute and chronic aggregate risk estimates associated with these compounds are below the Agency's level of concern for all durations of exposure and for all population subgroups, including those of infants and children. The Agency's risk assessment for these common metabolites is available in the propiconazole reregistration docket at http://www.regulations.gov, Docket Identification (ID) Number EPA-HQ-OPP-2005-0497.

Occupational Exposure and Risk: Occupational exposure to prothioconazole is limited to use of the formulation PROLINE® 480 SC Fungicide, which is for application on barley, oilseed crops, dried bean and pea crops, peanuts, and wheat. Short- and intermediate-term dermal and inhalation exposures are expected from handler activities, and short- and intermediate-term dermal exposures are expected from postapplication activities. The short- and intermediate-term dermal exposure scenarios are assessed using the NOAEL of 30 mg/kg/day from the dermal

developmental toxicity study in the rat. The short- and intermediate-term inhalation exposure scenarios are assessed using the NOAEL of 2 mg/kg/day from the rabbit developmental toxicity study.

EPA did not use a submitted prothioconazole-specific handler exposure study because the unit exposure information was inappropriate for estimating exposure, the small scale of the study, the choice of activity, and the use of Bayer employees as study subjects. An ethics review of this study was completed (K.Sherman, 9/27/06) concluded that the study does not violate current ethical standards. Although it was considered scientifically valid for qualitative purposes, the study not meet HED's scientific standards for quantitative use in risk assessment

Short-/Intermediate-Term Handler Risk: Handlers are assumed to have potential short- (1-30 consecutive days) and intermediate-term (31-180 consecutive days) dermal and inhalation exposure to prothioconazole and its degradates when mixing, loading and applying PROLINE® 480 SC Fungicide. Short- and intermediate-term risk is not of concern if the MOE attains or exceeds the LOC of 1000.

PROLINE® 480 SC is applied aerially and by ground equipment. MOEs for mixers and loaders reached or exceeded the LOC of 1000 for all scenarios except for wheat for aerial application, even when engineering controls/PPE were applied (closed system and gloves). The LOC of 1000 was reached for mixers/loaders for groundboom application with single-layer PPE plus gloves. Representative handler exposure scenarios include mixing and loading (M/L) for aerial and groundboom equipment, application with aerial and groundboom equipment, and flagging for aerial applications. Total MOEs range from 870 (closed M/L for aerial application to wheat) to 5,000. The MOE of 870 is not considered a significant departure from the target LOC of 1000. Aerial and groundboom application exposure scenarios reach MOEs of 1000 with baseline clothing and no gloves. With appropriate PPE and engineering controls (for aerial M/L activities), the target MOE of 1000 is attained or exceeded for all handler activities.

Short-/Intermediate-Term Postapplication Risk: Postapplication workers are assumed to have potential short- and intermediate-term dermal exposure (but not inhalation exposure) from the uses of PROLINE® 480 SC Fungicide in low- to medium-height crops from activities such as scouting, irrigation, hand weeding and hand harvesting. The quantitative hazard estimate of 30 mg/kg/day (LOAEL from the dermal developmental study in the rat) as used in the handler assessment (see previous section) is used in the postapplication assessment. Postapplication Risk: Currently available exposure and toxicity data support an interim 48 hour REI for all crops; therefore, the postapplication worker risk assessment indicates no risk concerns for scouting and irrigation. The interim 48 hour REI could change based on the requested brain morphometric data from lower doses of the DNT.

Environmental Fate Characteristics/Ecological Effects

Environmental Fate Summary: Environmental risk assessments utilized environmental fate and toxicity data for prothioconazole and two primary degradates; the prothioconazole-desthio and prothioconazole-S-methyl. Risks were estimated using a total toxics residue approach for exposure levels for aquatic organisms and to derive estimated concentrations in drinking water.

In addition, for characterization purposes, unbound residues alone were used to estimate exposures. The lowest available toxicity endpoint among prothioconazole and the two primary degradates was used to evaluate risk.

Prothioconazole possesses a potential for direct adverse acute effects to non-target fresh- and saltwater non-vascular plants, freshwater vascular plants, and saltwater invertebrates other than mollusks at some of the proposed application rates. The results also indicate a potential for adverse effects associated with chronic exposures to mammals for all proposed uses of prothioconazole and a potential for adverse effects to semi-aquatic plant species.

Overall, potential risks appear to be greatest for estuarine/marine invertebrates, nonvascular plants, and terrestrial mammals. Estimated risks may translate to reduced survival, reproduction, or growth in affected species with subsequent effects at higher levels of biological organization. Aquatic exposure estimated assuming ground application is 8 – 27 percent lower than when the pesticide is applied aerially, which does not alter the overall risk conclusions.

For listed species, acute risk levels of concern were exceeded for estuarine/marine invertebrates, semi-aquatic plants, aquatic plants, and freshwater fish. Listed species chronic risk levels of concern were exceeded for mammals. Because aquatic plant risk quotients are above the endangered species level of concern, the Agency considers this indicative of a potential for adverse effects to those listed species that rely on a specific plant species (plant species obligate). However, given the uncertainties in the screening level assessment, the levels of exceedance are not deemed significant.

a. Hydrolysis

Prothioconazole is stable to hydrolysis at environmentally relevant pH's and temperatures. In a study conducted in darkness for 7 days at 50°C, radio-labeled prothioconazole did not hydrolyze in sterile aquatic buffer solutions (pH 7 and 9); radio-labeled prothioconazole was hydrolyzed with a half-life of 120 days in sterile pH 4 aqueous buffer solution. Extrapolating from these results, the half-life of prothioconazole at 25°C at pH 4 was estimated as between 679 days and >10 years. No major transformation products were detected in any pH solution.

The metabolite prothioconazole-desthio is stable to hydrolysis at environmentally relevant pH's and temperatures. In a study conducted in darkness for 30 days at 25°C, radio-labeled prothioconazole-desthio did not hydrolyze in sterile pH 5, 7 and 9 aqueous buffer solutions.

b. Photolysis

Aqueous – Prothioconazole is rapidly photodegraded to prothioconazole-desthio in water under favorable light conditions; however, prothioconazole-desthio is persistent under further irradiation. Radio-labelled prothioconazole photodegrades with a half-life of approximately 9.7 days in sterile pH 7 aqueous buffered solution maintained at 25^{O}C and irradiated with the equivalent of 93 days of summer sunlight. Together, prothioconazole and prothioconazole-desthio photodegrade with a half-life of 101.9 days. Prothioconazole-desthio, together with two other major degradates, prothioconazole-thiazocine and 1,2,4-triazole, have maximum

concentrations of 55.7%, 14.1%, and 11.9% of the applied, observed on the 11th, 5th, and 18th day of incubation, respectively. No significant information was obtained for six minor transformation products or several unidentified compounds. Photodegradation is expected to be a potential route of dissipation for prothioconazole and prothioconazole-desthio together in the environment when the compounds are present in clear, shallow surface water.

Soil – Prothioconazole together with prothioconazole-desthio are considered stable to photodegradation on loamy sand soil. Prothioconazole photodegradation on soil is insignificant compared to metabolism. The major transformation product detected in both dark and irradiated samples is prothioconazole-desthio. Prothioconazole and prothioconazole-desthio were added together in the half-life calculations. Apparently, no significant transformation products are specifically generated by phototransformation on soil surfaces. Photodegradation on soil is not expected to be a potential route of dissipation for prothioconazole and prothioconazole-desthio in the environment.

c. Metabolism

Aerobic soil metabolism –Prothioconazole rapidly dissipates from aerobic soil systems. Relatively high amounts of prothioconazole-desthio and unextracted material were observed in environmental fate studies, and are assumed to have similar toxicities. It is possible that toxic, unextracted residues will become bioavailable in the environment. Calculated aerobic biotic degradation of prothioconazole and prothioconazole-desthio was very slow in silt, loamy sand, silty loam, and silty clay loam soils, with half-lives ranging from 533 to 1386 days. When incubated in darkness for up to one year at 20 ^{O}C, maintained at 75% of 1/3 bar moisture, prothioconazole degraded to prothioconazole-desthio, prothioconazole-S-methyl, 1,2,4-triazole, prothioconazole-sulfonic acid, prothioconazole-triazolinone, prothioconazole-3, 4, 5, and 6-hydroxy-desthio, 2-chlorobenzoic acid, and CO_2. However, the estimates of the aerobic soil metabolism half-lives are uncertain given the assumptions associated with the unextracted residues. Consequently, the Agency's estimates of prothioconazole's persistence in the soil may be overestimated.

Aerobic aquatic metabolism – The aerobic aquatic metabolism of prothioconazole can not be calculated adequately because prothioconazole quickly degrades to prothioconazole-desthio. Furthermore, both chemicals are of similar toxicity and there is considerable unextracted material in the studies. In addition to prothioconazole-desthio, prothioconazole degrades to prothioconazole-S-methyl, 1,2,4-triazole, prothioconazole-triazolinone, prothioconazole-triazolylketone, and CO_2. Prothioconazole-desthio appears to degrade more quickly in aerobic water/sediment systems than in aerobic soil alone; half-lives in various water/sediment systems range from 17.4 to 75.3 days. The Agency believes that the unextracted residues may consist of parent and may be bioavailable in the environment. The Agency's calculations are conservative because of the uncertainty associated with these unextracted residues. Thus, the Agency's estimate of the persistence of prothioconazole and prothioconazole-desthio may be overstated.

Anaerobic aquatic metabolism – Prothioconazole and prothioconazole-desthio degraded slowly, with half-lives ranging from 61.9 to 231 days in an anaerobic pond/sandy clay loam sediment system. Prothioconazole degraded extensively in this system to prothioconazole-S-methyl.

d. Adsorption/Desorption

Prothioconazole's rapid degradation made it impossible to calculate adsorption coefficients. Nonetheless, prothioconazole-desthio is expected to be mobile in most soils, although it might bind to some benthic sediments in aquatic environments. Soil binding is strongly correlated to the soil organic carbon content. Prothioconazole-S-methyl, another significant degradate of prothioconazole, is expected to have low to slight mobility, as indicated from high sorption coefficients (Kd of 15.6-64.1 mg/L, K_{OC} of 1973-2995 mL/g_{OC}). Mobility may be greater in relatively coarse-grained, well-drained soils. Prothioconazole may be mobile in typical agricultural soils.

e. Mobility

Prothioconazole's rapid degradation makes it impossible to determine its soil-water partition coefficient. Qualitatively, however, prothioconazole may exhibit low potential of leaching, likely to its rapid degradation. In contrast, prothioconazole-desthio has soil-water coefficients ranging from 4.13 to 13.38 mg/L in four different soils, indicating moderate to high mobility. Prothioconazole-desthio has a K_d less than 5 in some soils and is persistent (hydrolysis half-life greater than 25 weeks). Furthermore, its photolysis half-life is greater than 1 week, aerobic soil metabolism half-life is greater than 2-3 weeks, it is not volatile, and shows movement to 45 cm during field dissipation studies. Together, these parameters indicate potential for groundwater contamination.

f. Terrestrial Field Dissipation

In three terrestrial field dissipation studies, prothioconazole alone dissipated from the top layer of soil with a DT_{50} of less than 2 or 3 days, but prothioconazole-desthio dissipated from the top layer of soil with extremely variable DT_{50} of 28-422 days. Moderate amounts of prothioconazole-S-methyl were detected above the level of quantitation (LOQ) in 0-15 cm soil, and 1,2,4-triazole was detected at all soil depths, albeit not above the LOQ. Prothioconazole was not detected below 15 cm in any of the three fields in California, Georgia or New York. In contrast, prothioconazole-desthio was detected at levels above the LOQ down to 30 cm and at levels above the minimum detection limit [MDL] but below the LOQ down to 45 cm in one replicate in the California field study, and at levels below the LOQ at one to two sampling times in the Georgia and New York field studies

g. Aquatic Field Dissipation

In three aquatic field dissipation studies, prothioconazole and prothioconazole-desthio dissipated with long half-lives in sediment (203.9 days, 121.6 days, and 90.0 days in California, Arkansas, and Arkansas cropped aquatic fields, respectively). Dissipation half-lives in paddy water were extremely short (1.7 days, 0.9 days, and 0.6 days in California, Arkansas, and Arkansas cropped aquatic fields, respectively), likely more due to adsorption than degradation. Prothioconazole was detected in only three sampling intervals below LOQ but above the MDL in sediment below 3 inches. Prothioconazole-desthio was detected at 3-6 inch deep sediment through 28 DAT in the

Arkansas flooded field and through 60 DAT in the Arkansas flooded and cropped field.

h. Bioaccumulation

Bioaccumulation factors (BCF) for prothioconazole and prothioconazole-desthio could not be definitively calculated due to lack of clear accumulation plateaus. Nonetheless, there is minimal uncertainty in the conclusion that neither chemical bioaccumulates. Despite prothioconazole's very hydrophobic octanol-water partition coefficient (unbuffered log K_{OW} of 4.05), significant bioaccumulation in aquatic organisms is not anticipated due to its quick degradation. The octanol-water partition coefficient for prothioconazole-desthio is unknown. The BCFs in fish for prothioconazole and prothioconazole-desthio can not be definitively quantified; however, the studies indicate that it is likely that prothioconazole-desthio does not bioaccumulate.

Exposure Characterization: Prothioconazole degrades rapidly to prothioconazole-desthio via most degradation processes, and prothioconazole-desthio has a similar toxicological profile to that of its parent. Therefore, this assessment is conducted considering prothioconazole and prothioconazole-desthio jointly as the toxic moiety. Based on registrant-submitted environmental fate data, prothioconazole is expected to degrade quickly to prothioconazole-desthio, which is expected to be persistent with moderate mobility in the soil. Prothioconazole-desthio is stable to hydrolysis, very slowly degraded by aerobic soil metabolism, anaerobic aquatic metabolism, and aqueous photolysis, and moderately degraded by aerobic aquatic metabolism. Transport to surface water of prothioconazole residues is predicted, and, in some soils, transport to groundwater is also predicted, particularly in areas with porous soil of low organic carbon content.

Effects Characterization: Prothioconazole and the prothioconazole-desthio are practically non-toxic to birds, mammals, and honeybees under acute exposure conditions and only slightly toxic to fish and freshwater aquatic invertebrates. Prothioconazole-desthio is very highly toxic to aquatic plants and estuarine/marine invertebrates following acute exposure. Prothioconazole-desthio is slightly more toxic to birds and mammals under chronic exposure conditions compared to the parent compound based on the respective study-determined effect levels. In birds, chronic exposure to prothioconazole-desthio did not cause any significant effects in adults or offspring. In mammals, chronic effects of prothioconazole-desthio included decreased viability of offspring and decreased offspring body weights.

Ecological Risk Summary: Overall, potential risks appear to be greatest for estuarine/marine invertebrates and nonvascular plants, and terrestrial mammals. Functionally, estimated risks may translate to reduced survival, reproduction, or growth in affected species with subsequent effects at higher levels of biological organization. Aquatic exposure estimated assuming ground application is 8 – 27 percent lower than when the pesticide is applied aerially. The exposure estimates associated with ground application would not alter overall risk conclusions although for some specific combination of crop and taxa, risk quotients may be below the LOC.

For listed species, acute risk levels of concern were exceeded for estuarine/marine invertebrates, semi-aquatic plants, aquatic plants, and freshwater fish. Listed species chronic risk levels of concern were exceeded for mammals. Because aquatic plant risk quotients are above the

endangered species level of concern, the Agency considers this to be indicative of a potential for adverse effects to those listed species that rely on a specific plant species (plant species obligate).

Because of the national extent of the proposed uses of prothioconazole, there is a potential to affect some listed plant species and the species which depend upon listed or non-listed plant species. Indirect effects in this case may not be limited to aquatic species as terrestrial animals that rely on aquatic food items have potential to be affected indirectly.

Conclusions: Prothioconazole degrades rapidly to prothioconazole-desthio via most degradation processes, and prothioconazole-desthio has a similar toxicological profile to that of its parent. Prothioconazole-desthio is expected to be persistent with moderate mobility in the soil. Prothioconazole-desthio is stable to hydrolysis, very slowly degraded by aerobic soil metabolism, anaerobic aquatic metabolism, and aqueous photolysis, and moderately degraded by aerobic aquatic metabolism. Transport to surface water of prothioconazole residues is predicted, and, in some soils, transport to groundwater is predicted, particularly in areas with porous soil of low organic carbon content.

Prothioconazole and the prothioconazole-desthio are practically non-toxic to birds, mammals, and honeybees under acute exposure conditions and only slightly toxic to fish and freshwater aquatic invertebrates. Prothioconazole-desthio is very highly toxic to aquatic plants and estuarine/marine invertebrates following acute exposure. Prothioconazole-desthio is slightly more toxic to birds and mammals under chronic exposure conditions compared to the parent compound based on the respective study-determined effect levels. In birds, chronic exposure to prothioconazole-desthio did not cause any significant effects in adults or offspring. In mammals, chronic effects of prothioconazole-desthio included decreased viability of offspring and decreased offspring body weights.

a. Risk to Aquatic Organisms

Regarding freshwater fish, aquatic-phase amphibians, and freshwater invertebrates potentially exposed to prothioconazole for uses on wheat, bean, canola, and peanut, the RQs do not exceed non-listed or listed species acute or chronic risk LOCs.

For estuarine/marine fish and invertebrates potentially exposed to prothioconazole for uses on wheat, canola, bean, and peanuts, the RQs for estuarine/marine fish do not exceed any acute risk LOCs with all RQs less than 0.01; chronic toxicity data were not available for a representative fish species so RQs could not be calculated. The RQs for estuarine/marine mollusks similarly did not exceed any acute risk LOCs with all RQs<0.01. Based on mysid shrimp toxicity data, the listed species acute risk LOC of 0.05 is exceeded for estuarine/marine invertebrates for all modeled scenarios while the acute non-listed species LOC of 0.5 is exceeded for use on beans and peanuts (RQs = 0.55 & 0.57, respectively). Chronic RQ values were only calculated for non-molluskan invertebrates since this was the only taxa with chronic toxicity data. The listed and non-listed species chronic risk LOC (RQ≥1.0) for estuarine marine invertebrates is exceeded for all modeled uses with RQs ranging from 2.4 to 6.4. These risks are summarized in Table 9.

Table 9. Risk Quotients for Estuarine/Marine Fish and Invertebrates Exposed to Prothioconazole								
Use	**Application Rate lbs ai/A (#app/ interval (d))**	**EECs (ppb)**			**Fish RQs LC_{50} = >10300 NOAEC = N/A**	**Invertebrate RQs LC_{50} = 60 NOAEC = 5.2**		**Mollusk RQs EC_{50}= 3000**
		Peak	**21-day**	**60-day**	**Acute**	**Acute**	**Chronic**	**Acute**
Wheat	0.178 (2/7)	20.5	20.2	19.8	<0.01	**0.34***	**3.94**	<0.01
Canola	0.178 (2/5)	12.8	12.5	12.0	<0.01	**0.21***	**2.40**	<0.01
Bean	0.178 (3/5)	33.2	32.7	32.2	<0.01	**0.55****	**6.29**	<0.01
Peanut	0.178 (4/14)	34.4	33.3	32.2	<0.01	**0.57****	**6.40**	<0.01

*Exceeds the listed species acute risk LOC (RQ≥0.05)
**Exceeds the non-listed species acute risk LOC (RQ>0.50) and the listed species acute risk LOC
Bolded chronic RQs exceed the listed and non-listed species chronic risk LOC (RQ≥1.0)

For both vascular and non-vascular aquatic plants, the listed species acute risk LOC of 1.0 is exceeded for all scenarios, with RQs ranging from 1.20 to 5.9 (Table 10).

Table 11 lists the RQs for estuarine/marine non-vascular plants potentially exposed to prothioconazole. These RQs exceed the listed species acute risk LOC for all uses (1.8 to 4.7) and exceed or equal the non-listed species acute risk LOC at all proposed application rates except canola (1.0 to 1.6).

Table 10. Risk Quotients for Freshwater Aquatic Plants Exposed to Prothioconazole						
Use	**Application Rate lbs a.i./A (#app/interval (d))**	**EECs (ppb)**	**Vascular Plant RQs EC_{50} = 35 NOAEC = 5.8**		**Non-Vascular Plant RQs EC_{50} = 0.074 EC_{05} = 0.011**	
		Peak	**Acute**	**Acute Listed Species**	**Acute**	**Acute Listed Species**
Wheat	0.178 (2/7)	20.5	0.59	**3.5**	0.28	**1.9**

Table 10. Risk Quotients for Freshwater Aquatic Plants Exposed to Prothioconazole						
Use	**Application Rate lbs a.i./A (#app/interval (d))**	**EECs (ppb)**	**Vascular Plant RQs EC_{50} = 35 NOAEC = 5.8**		**Non-Vascular Plant RQs EC_{50} = 0.074 EC_{05} = 0.011**	
		Peak	**Acute**	**Acute Listed Species**	**Acute**	**Acute Listed Species**
Canola	0.178 (2/5)	12.8	0.37	**2.2**	0.17	**1.2**
Bean	0.178 (3/5)	33.2	0.95	**5.7**	0.45	**3.0**
Peanut	0.178 (4/14)	34.4	0.98	**5.9**	0.46	**3.1**
Aquatic plant acute risk LOC (RQ ≥ 1.0); applies to non-listed and listed species						

Table 11. Risk Quotients for Estuarine/Marine Non-Vascular Plants Exposed to Prothioconazole				
Use	**Application Rate lbs ai/A (#app/interval (d))**	**EECs (ppb)**	**Non-Vascular Plant RQs EC_{50} = 21 NOAEC = 7.3**	
		Peak	**Acute**	**Acute Listed Species**
Wheat	0.178 (2/7)	20.5	**1.0**	**2.9**
Canola	0.178 (2/5)	12.8	0.62	**1.8**
Bean	0.178 (3/5)	33.2	**1.6**	**4.5**
Peanut	0.178 (4/14)	34.4	**1.6**	**4.7**
Aquatic plant acute risk LOC (RQ ≥ 1.0); applies to non-listed and listed species				

b. Risk to Avian Species (Acute/Chronic)

No RQs exceed non-listed or listed species acute risk LOCs with RQs ranging from <0.01 to 0.05. No acute or chronic LOCs are exceeded for any proposed uses. Acute dietary-based RQs range from <0.01 to 0.01 and dietary-based chronic RQs ranged from 0.01 to 0.18.

c. Risk to Mammalians (Acute/Chronic)

For mammals, no acute risk LOCs are exceeded with RQs ranging from <0.01 to 0.01. Table 12 summarizes the chronic mammalian RQs for the proposed uses of prothioconazole. The non-listed and listed species chronic risk LOC (RQ>1.0) is exceeded for all proposed uses of prothioconazole. However, LOC exceedances are specific to food item with no exceedances associated with mammals that consume seeds or fruits/pods/large insects with RQs ranging from 0.01 to 0.23. For all other food items, the chronic risk LOCs are exceeded, particularly for smaller mammals. The highest RQs are for mammals that consume short grass with RQs ranging from 1.0 to 3.8 followed by mammals that consume broadleaf plants/small insects (RQs = 0.56 to 2.1) and tall grass (RQs = 0.45 to 1.7).

Table 12. Mammalian Dose-Based Chronic RQ Values for Uses of Prothioconazole; Based on Rat NOAEL of 9.5 mg/kg bw and Upper-Bound Kenaga Residues

Use	Application Rate lbs ai/A #app/interval (d)	Body Weight (g)	Avian Acute RQs for Specified Food Items				
			Short Grass	Tall Grass	Broadleaf Plants/Small Insects	Fruits/Pods / Lg Insects	Seeds
Barley/ Wheat (Fusarium head blight)	0.178 (2/7)	15	**2.9**	**1.3**	**1.6**	0.18	0.04
		35	**2.4**	**1.1**	**1.4**	0.15	0.03
		1000	**1.3**	0.60	0.74	0.08	0.02
Barley (leaf & stem)	0.134 (2/7)	15	**2.2**	0.99	**1.2**	0.13	0.03
		35	**1.8**	0.85	**1.0**	0.12	0.03
		1000	0.99	0.45	0.56	0.06	0.01
Canola & Oilseed crop	0.178 (2/5)	15	**3.1**	**1.4**	**1.7**	0.19	0.04
		35	**2.6**	**1.2**	**1.5**	0.16	0.04
		1000	**1.4**	0.65	0.80	0.09	0.02
Chickpea & Lentils	0.178 (3/10)	15	**2.8**	**1.3**	**1.6**	0.18	0.04
		35	**2.4**	**1.1**	**1.4**	0.15	0.03
		1000	**1.3**	0.60	0.73	0.08	0.02
Peanut	0.178 (4/14)	15	**2.5**	**1.2**	**1.4**	0.16	0.03
		35	**2.1**	0.98	**1.2**	0.13	0.03
		1000	**1.1**	0.52	0.64	0.07	0.02
Dried shell peas & beans	0.178 (3/5)	15	**3.8**	**1.7**	**2.1**	0.23	0.05
		35	**3.2**	**1.5**	**1.8**	0.20	0.04
		1000	**1.7**	0.79	0.97	0.11	0.02
Wheat	0.156	15	**2.5**	**1.2**	**1.4**	0.16	0.03

Table 12. Mammalian Dose-Based Chronic RQ Values for Uses of Prothioconazole; Based on Rat NOAEL of 9.5 mg/kg bw and Upper-Bound Kenaga Residues							
Use	**Application Rate lbs ai/A #app/interval (d)**	**Body Weight (g)**	**Avian Acute RQs for Specified Food Items**				
			Short Grass	**Tall Grass**	**Broadleaf Plants/Small Insects**	**Fruits/Pods / Lg Insects**	**Seeds**
(leaf & stem)	(2/7)	35	**2.2**	0.98	**1.2**	0.13	0.03
		1000	**1.2**	0.53	0.65	0.07	0.02
Bolded values exceed the chronic risk LOC (RQ≥1.0) for non-listed and listed mammalian species							

Chronic dietary-based mammalian RQs for proposed uses of prothioconazole are based on effects levels associated with chemical concentrations in feed. The dietary-based RQs do not exceed the chronic risk LOCs for any proposed uses of prothioconazole with RQs ranging from 0.02 to 0.51.

d. Risk to Terrestrial and Semi-aquatic Plants

Risk quotients for terrestrial and semi-aquatic plant (Table 13) for proposed uses of prothioconazole exceed the acute plant risk LOC (RQ≥1.0) for semi-aquatic listed plants; no other LOCs are exceeded. Risk quotients for non-listed terrestrial and semi-aquatic plant species are not calculated because an EC_{25} (>0.272 lbs a.i./A, highest test level) could not be estimated from the Tier II plant study.

Table 13. RQ Values for Listed Terrestrial and Semi-Aquatic Plants Exposed to Prothioconazole					
Use(s)	**Single Application Rate Lbs a.i./A**	**RQs Based on Tier II Study on Cucumber (EC_{25}>0.272; NOAEC/EC_{05} = 0.03)**			
		Adjacent		**Semi-Aquatic**	
		Ground spray	**Aerial spray**	**Ground spray**	**Aerial spray**
Barley, Canola, Chickpea, Dried shell peas & beans, Lentils, Oilseed crops, Peanut, Wheat	0.178	0.36	0.59	**3.0**	**3.3**
Barley (leaf & stem)	0.134	0.27	0.45	**2.3**	**2.5**
Wheat (leaf & stem)	0.156	0.31	0.52	**2.6**	**2.9**
Bolded values exceed listed plant acute risk LOC (RQ≥1.0)					

Uncertainties and Data Gaps

The major uncertainty in characterizing effects of prothioconazole and/or prothioconazole-desthio is associated with the toxicity of prothioconazole-desthio to estuarine/marine invertebrates and the lack of an acceptable sediment toxicity test. For estuarine/marine invertebrates, toxicity tests for prothioconazole-desthio indicated that both the LC_{50} and the chronic NOAEC are approximately 60 ppb based on mysid shrimp toxicity tests. This suggests that chronic and acute thresholds are the same, a conclusion that is incongruent with typical toxicological patterns. Risks to sediment dwelling invertebrates could not be estimated since the submitted studies did not meet guideline requirements. It is recommended that guideline sediment toxicity tests be submitted.

The environmental fate data submitted to the Agency are complete. However, because of the considerable uncertainty surrounding soil extraction procedures, the unextracted material in the aerobic soil, aerobic aquatic, and anaerobic aquatic metabolism studies was added to parent in calculation of half-lives used in environmental fate modeling and fate characterization. Therefore, the persistence and bioavailability of prothioconazole may be overestimated; resulting in conservative estimated aquatic exposure. Importantly, Tier II modeling using the 90^{th} percentile unextracted-material-incorporated half-lives did not change risk estimates for aquatic animals or aquatic plants relative to modeling using upper 90^{th} percentile confidence bounds on the mean half-lives calculated without incorporating unextracted material. In neither case do aquatic concentrations approach levels-of-concern for aquatic animals; however, aquatic concentrations are sufficiently high to result in risk quotients that exceed levels-of-concern for aquatic plants. Finally, the adsorption coefficient (K_d or K_{OC}) of prothioconazole could not be calculated from submitted data because of the chemical's quick degradation in the systems. Therefore, conclusions about the mobility of prothioconazole combined residues of concern are drawn only from degradates. Similarly, bioaccumulation factors (BCF) of prothioconazole and prothioconazole-desthio could not be definitively calculated due to lack of clear accumulation plateaus. Therefore, there is also minimal uncertainty in the conclusion that neither chemical bioaccumulates.

DATA GAPS

For the Developmental Neurotoxicity Study (MRID 46246418), brain morphometric measurements from the mid and low dose animals must be submitted as well as addressing the other deficiencies listed in the DER to allow the reconsideration of the FQPA database uncertainty factor.

Data must be generated and submitted to confirm the degree of stability of the prothioconazole-4-hydroxy in ruminant fat for a duration of 45 days.

The final report of the ongoing storage stability study with prothioconazole and desthio-prothioconazole in plant commodities (interim results for which were reported in MRID 46477701) must be submitted.

Based on the proposed tolerance expressions and the proposed enforcement methods, analytical reference standards of the following compounds must be provided:

- prothioconazole-desthio
- prothioconazole sulfonic acid potassium salt
- [triazole-^{15}N-^{13}C]prothioconazole
- [triazole-^{15}N-^{13}C]prothioconazole-desthio
- [triazole-^{15}N-^{13}C]prothioconazole sulfonic acid

Environmental Fate and Effects

Repeating the sediment toxicity study following Agency guidelines in which the chemical is first added to the sediment would reduce some uncertainty associated with assessing risks to sediment dwelling invertebrates.

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Disclaimer: The information in this Pesticide Fact Sheet is a summary only and is not to be used to satisfy any data requirements for pesticide registration or reregistration.

GLOSSARY OF TERMS AND ABBREVIATIONS

ai	Active Ingredient
ARTF	Agricultural Reentry Task Force
°C	Degrees Celsius
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSFII	Continuing Surveys of Food Intakes by Individuals
d	Day(s)
DEEM-FCID	Dietary Exposure Evaluation Model - Food Consumption Intake Database
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Concern
EC_{50}	Effective Concentration - concentration of chemical in water at which an effect is seen in 50% of the exposed population
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor and Testing Advisory Committee
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentrations
EFED	Environmental Fate and Effects Division, Office of Pesticide Programs
EPA	United States Environmental Protection Agency
F	Female
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FQPA	Food Quality Protection Act
g	Gram
HED	Health Effects Division, Office of Pesticide Programs
Ha	Hectare
hr	Hour
K_d	Partition coefficient
kg	Kilogram
K_{ow}	Octanol/Water Partition Coefficient
lb	Pound
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation.). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.

LOAEL	Lowest Observed Adverse Effect Level
LOAEC	Lowest Observed Adverse Effect Concentration
LOC	Level of Concern
LOD	Limit of Detection
LOQ	Limit of Quantitation
M	Male
m^3	Cubic meter
mg/kg/day	Milligrams per kilogram (body weight) per day
mg/L	Milligrams per Liter
ml	Milliliter
MOE	Margin of Exposure
MRID	Master Record Identification Number
MTD	Maximum Tolerated Dose
NA	Not Applicable
NOAEL	No Observed Adverse Effect Level
NOAEC	No Observed Adverse Effect Concentration
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SOP	Standard Operating Procedure
TC	Transfer Coefficient
TGAI	Technical Grade Active Ingredient
TTR	Turf Transferable Residue
UF	Uncertainty Factor
µg	Micrograms
µg/L	Micrograms per Liter
USDA	United Stated Department of Agriculture
WPS	Worker Protection Standard

Study Information For Ingredient
113961 / 178928-70-6/Prothioconazole

MRID	Citation	Receipt Date
46246000	Bayer CropScience (2004) Submission of Product Chemistry, Efficacy, Toxicity and Fate Data in Support of the Applications for Registration of Prothioconazole Technical Fungicide and Proline 480 SC Fungicide and the Petition for Tolerance of Prothioconazole on Barley, Oilseed Crop Group (Except Sunflower and Safflower), Dried Shell Pea and Bean (Except Soybean) Crop Subgroup, Peanut, Rice, and Wheat. Transmittal of 50 of 298 Studies.	01-Apr-2004
46246001	Schneider, J. (2001) Physical and Chemical Properties of JAU6476. Project Number: 14/0120/0950. Unpublished study prepared by Bayer Ag Institut fuer Ruckstands-Analytik. 298 p.	01-Apr-2004
46246002	Fontaine, L. (2004) Product Chemistry of Prothioconazole Technical. Project Number: BR/2281, ANR/02904, ANR/03004. Unpublished study prepared by Bayer Corp., Bayer Ag Institut fuer Ruckstands-Analytik and Bayer Ag, Institute of Product Info. 409 p.	01-Apr-2004
46246003	Fontaine, L. (2004) Product Chemistry of Prothioconazole Technical. Project Number: BR/2282, 14/0210/0950, 2001/08/08. Unpublished study prepared by Bayer Ag Institut fuer Ruckstands-Analytik, Bayer Corp. and Bayer Ag, Institute of Product Info. 140 p.	01-Apr-2004
46246004	Frank, J. (2004) Product Chemistry of Proline 480 SC. Project Number: BR/2283, ANR/02804, 200420/1. Unpublished study prepared by Bayer Corp. 202 p.	01-Apr-2004
46246005	Bulman, P. (2004) Prothioconazole 480 SC Fungicide for Control of Diseases in Pulse Crops, Cereal Crops, Canola and Rapeseed: Volume 1 - Wheat. Project Number: BYFCAN005, BYFCAN005/1. Unpublished study prepared by Bayer CropScience. 596 p.	01-Apr-2004
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46246009	Heimbach, F. (2001) Acute Toxicity of JAU6476 (tech.) to Water Fleas (Daphnia magna). Project Number: E/3201675/4, HBF/DM212. Unpublished study prepared by Bayer Ag Institut fuer Ruckstands-Analytik. 50 p.	01-Apr-2004
46246010	Kern, M.; Lam, C. (2003) Acute Toxicity of JAU 6476 480 SC Formulation to the Waterflea (Daphnia magna) Under Static-Renewal Conditions. Project Number: EBJAX072, J6820701, 200514. Unpublished study prepared by Bayer Corp. 34 p.	01-Apr-2004
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46246017	Drottar, K.; Palmer, S.; Kendall, T.; et. al. (2002) Desthio JAU 6476: A 96-Hour Flow-Through Acute Toxicity Test with the Saltwater Mysid (Mysidopsis bahia). Project Number: 149A/129, J6833102, 110979. Unpublished study prepared by Wildlife International, Ltd. 39 p.	01-Apr-2004
46246018	Dorgerloh, M. (1999) JAU6476 - Acute Toxicity (96 hours) to Rainbow Trout (Oncorhynchus mykiss) in a Static Test. Project Number: E/2501657/6, DOM/99076. Unpublished study prepared by Bayer Ag Institut fuer Ruckstands-Analytik. 51 p.	01-Apr-2004
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46246021	Dorgerloh, M.; Sommer, H. (2001) JAU6476-S-Methyl - Acute Toxicity (96 hours) to Rainbow Trout (Oncorhynchus mykiss) in a Semi-Static Test. Project Number: E/2802052/9, DOM/21047, 00699. Unpublished study prepared by Bayer Ag Institut fuer Ruckstands-Analytik. 47 p.	01-Apr-2004
46246022	Dorgerloh, M. (1999) JAU6476 - Acute Toxicity (96 Hours) to Bluegill (Lepomis macrochirus) in a Static Test. Project Number: E/2521695/0, DOM/99090, 00586. Unpublished study prepared by Bayer Ag Institut fuer Ruckstands-Analytik. 48 p.	01-Apr-2004
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46246030	Blankinship, A.; Kendall, T.; Krueger, H. (2003) Desthio JAU-6476: A Flow-Through Life Cycle Toxicity Test with the Saltwater Mysid (Mysidopsis bahia). Project Number: 149A/130A, J6843101, 200485. Unpublished study prepared by Wildlife International, Ltd. 107 p.	01-Apr-2004
46246031	Dorgerloh, M.; Sommer, H. (2001) JAU6476 - Early Life Stage Toxicity to Rainbow Trout (Oncorhynchus mykiss) Under Flow-through Conditions. Project Number: E/2841699/9, DOM/20028, 00586. Unpublished study prepared by Bayer Ag Institut fuer Ruckstands-Analytik. 102 p.	01-Apr-2004
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46246100	Bayer CropScience (2004) Submission of Environmental Fate and Residue Data in Support of the Applications for Registration of Prothioconazole Technical and Proline 480 SC Fungicide and the Petition for Tolerance of Prothioconazole on Barley, Oilseed Crop Group (Except Sunflower and Safflower), Dried Shelled Pea and Bean (Except Soybean) Crop	01-Apr-2004

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