UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Pesticide Fact Sheet

Name of Chemical: Metconazole
Reason for Issuance: Registration
Date Issued: September, 2007

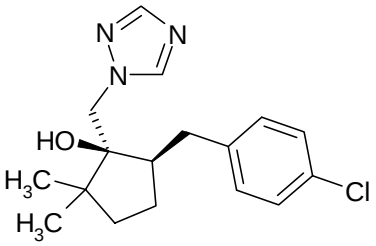
1. Description of Chemical

Chemical Name: 5-[(4-Chlorophenyl)methyl]-2,2-dimethyl-1-(1*H*-1,2,4-triazol-1-ylmethyl)cyclopentanol

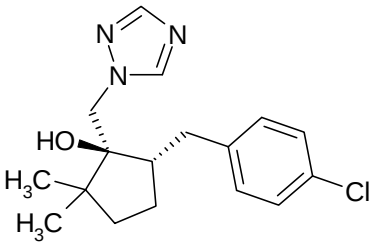
Common Name: Metconazole

Chemical Formula:

cis-Metconazole



trans-Metconazole



EPA PC Code: 125619

Chemical Abstracts Service (CAS) Number: 125116-23-6

Year of Initial Registration: 2007

Pesticide Type: Fungicide

Chemical Class: Sterol biosynthesis inhibitor – DMI-Fungicide

U.S. Producer: Kureha Corporation and Valent USA

II. Use Patterns and Formulations

Application Sites: Turf and ornamentals

Types of Formulations: Metconazole Technical (72078-1)
V-10116 VPP Fungicide (59639-144)

Application Methods And Rates: Metconazole may be applied at an application rate of 0.25 to 0.6 lb a.i./A per year. It may be applied by ground spray only.

III. Physical and Chemical Properties:

Table 1 – Physical and Chemical Properties of Metconazole

Table 1. Physicochemical Properties of the Technical Grade Metconazole		
Parameter	Value	Reference
Molecular Weight	319.837	44721503
Melting point/range	100.0-108.4^{0}C (using Electrothermal Digital Melting Point Apparatus) (AC900,768 technical grade)	44721505
pH	No data were submitted.	
Relative density (20^{0}C)	1.14 (relative density to water at 4 deg C, using capillary-stoppered, density-specific gravity bottle) (Lot No. AC 8879-140B)	44721505
Water solubility (20^{0}C)	Using shake flask method: 18.7±1.0 mg/L (*cis*-isomer, WL148271, KNF-S-474m) 13.6±1.7 mg/L (*trans*-isomer, WL148271, KNF-S-474m)	44721505

Table 1. Physicochemical Properties of the Technical Grade Metconazole		
Parameter	Value	Reference
Solvent solubility (g/L) at 20^0C	hexane: 1.40 toluene: 103 2-propanol: 132 ethyl acetate: 260 dichloromethane:481 methanol: 403 acetone: 363	44721505
Vapor pressure (20^0C)	Using gas-saturation method at 20^0C: < 1.23×10^{-5} Pa or 9.23×10^{-8} mm Hg (AC 900,768) < 1.04×10^{-5} Pa or 7.80×10^{-8} mm Hg (*cis*-isomer, CL 354,801) < 1.96×10^{-6} Pa or 1.47×10^{-8} mm Hg (*trans*-isomer, CL 354,802)	44721505
Dissociation constant (pK_a)	11.38±0.03 and 1.06±0.03 (in water using spectrophotometric method) (Lot No. AC 8879-140B)	44721505
Octanol/water partition coefficient Log (K_{ow})	K_{ow} (log K_{ow}) = 7090±989 (3.85) (using flask shaking method) (Lot No. AC 8879-140B) (TGAI) K_{ow} (log K_{ow}) = 7150±803 (3.85) (using flask shaking method) (*cis*-isomer, CL 354,801) K_{ow} (log K_{ow}) = 6800±1700 (3.8) (using flask shaking method) (*trans*-isomer, CL 354,802)	44721505
UV/visible absorption spectrum	Not required for TGAI; required for pure active ingredient	

IV. HUMAN HEALTH RISK ASSESSMENT

A. Toxicity

1. **Acute Toxicity:** Metconazole has low or minimal acute toxicity via the oral (Category III-IV), dermal (Category III), and inhalation routes of exposure (Category IV). It is moderately irritating to the eye (Category III), and minimally irritating to the skin (Category IV); it is not a skin sensitizer.

Table 2 – Acute Toxicity

Table A.2 Acute Toxicity Profile – Metconazole Technical				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute oral [mouse]	44721512	LD_{50} = >566 mg/kg	III
870.1100	Acute oral [rat]	44721512	LD_{50} = >566 mg/kg	III
870.1100	Acute oral [rat]	44721513	LD_{50} = >1459 mg/kg	III

870.1100	Acute oral [rat]	44721514	LD_{50} = >5000 mg/kg	IV
870.1200	Acute dermal [rat]	44721512	Dermal LD_{50} > 2000	III
870.1200	Acute dermal [rabbit]	44721512	Dermal LD_{50} > 2000	III
870.1200	Acute inhalation [rat]	44721512	LD_{50} = >5.6 mg/L	IV
870.2400	Acute eye irritation [rat]	44721513	moderate irritant	III
870.2500	Acute dermal irritation [rabbit]	44721513	mild irritant	IV
870.2600	Skin sensitization [guinea pig]	44721513	neg.	-

2. **Subchronic Toxicity:** A 28-day oral toxicity study in rats showed decreased body weight gain and food consumption at 1000 and 3000 ppm, as well as effects on blood cells, increased liver enzyme levels, decreased glucose and decreased cholesterol levels at 3000 ppm. Increased liver, spleen, and kidney weights were observed at 1000 and 3000 ppm. Increased fatty vacuolation and hepatocellular hypertrophy at 1000 and 3000 ppm were also observed, indicating that the liver is the primary target organ for metconazole toxicity. 90-day oral toxicity studies in rat and mouse showed similar effects, with hisotpathological changes again demonstrating that the liver is the primary target organ for metconazole. A 90-day oral toxicity study in dogs showed a decrease in food consumption at 600 ppm in females, and at 6000 ppm in males, with a corresponding decrease in body weight gain. All dogs at the high (6000 ppm) dose had cataracts by the end of the study. Effects on blood cells were observed in males at 600 ppm, and in both sexes at 6000 ppm. High dose animals also showed histopathological changes in the liver, kidney, and spleen. Subchronic dermal exposure in rats (21 days) did not result in effects on body weight gain, food consumption, eyes, hematology, or blood chemistry. Liver weights were increased in females at 500 ppm, and in both sexes at 1000 ppm, as well as decreased thymus weights in males at 500 and 1000 ppm, but these were not considered adverse since the histopathology of these organs was normal.

3. **Chronic Toxicity:** A chronic toxicity study in rats showed increased liver weights in males at 12 months and in females at 24 months, as well as an increase in females' spleen weights at 24 months at doses of 13.1 mg/kg/day in males and 53.8 mg/kg/day in females. Increased hepatocellular lipid vacuolation and centrilobular hypertrophy in both males and females at these doses. A chronic toxicity study in dogs showed a decrease in body weight gain during the first 13 weeks in males, increased incidence of Kupffer cell pigmentation in females, and increased alkaling phosphatase activity in both sexes at 38.5 and 36.8 mg/kg/day in males and females, respectively.

4. **Carcinogenicity:** There were no treatment-related increases in tumors in rat and mouse carcinogenicity studies after exposure to metconazole.

5. **Developmental Toxicity/Developmental Neurotoxicity:** A pre-natal development study in rats showed reduced maternal food consumption at 30 and 75 mg/kg/day, correlating with poor weight gain, but no increase in pre-implantation loss. Post-implantation loss was significantly increased at 75 mg/kg/day, and an increase in fetal visceral abnormalities was also seen at this level. An increase in skeletal abnormalities, including extra lumbar ribs, cervical ribs and extra pre-sacral vertebrae, was observed at 30 and 75 mg/kg/day. A pre-natal development study in rabbits showed a reduction in maternal body weight gain at 40 mg/kg/day, again corresponding to a decrease in food consumption. An increase in maternal liver weight was also seen at that dose, along with decreased red blood cell parameters and increased alkaline phosphatase levels. The 40 mg/kg/day dose also showed increased fetal resorptions and a slight decrease in fetal body weight.

   There was no evidence of neurotoxicity observed in the toxicology database.

6. **Reproductive Toxicity:** An acceptable new two-generation reproduction study in rats (MRID 46808447) using cis/trans metconazole was submitted and reviewed by HED. This study replaces the two–generation reproduction study with cis-only metconazole (MRID 44721608) that was used in the human health risk assessment for proposed tolerance on imported bananas (Memo Date: 7/06/06). In the new study, parental systemic toxicity was evident at 750 ppm, and included decreased body weight and decreased weight gain in male and female parental animals, increased incidence of fatty hepatocyte change in male parental animals, and increased incidence of spleen congestion in F_1 parental females. Offspring toxicity was also evident at 750 ppm as decreased viability index on lactation day 0 and reduced body weight in F_2 offspring. Reproductive toxicity was evident at 750 ppm as prolonged duration of gestation and decreased gestation index driven by dystocia (maternal deaths during delivery).

   Available evidence (two developmental toxicity studies and one two-generation reproductive toxicity study) suggest there is no concern for pre- and/or post-natal toxicity resulting from exposure to metconazole, because the pre and postnatal effects observed in rats and rabbits occurred only at maternally toxic dose levels.

7. **Metabolism:** Metabolism studies in rats indicated that metconazole is excreted primarily in the feces with greater than 90% of the administered dose excreted by three days post-dosing. Biliary excretion is the major route of elimination. Plasma kinetic studies show a low potential for bioaccumulation following single or multiple dosing regimens and the plasma half-life of low- and high-dose rats was slightly shorter in males than females. In an experiment in which the triazole ring was labeled, a single high (200 mg/kg) dose of metconazole showed approximately 5% of the parent compound was excreted as free triazole.

8. **Mutagenicity:** There is no mutagenicity concern for metconazole. When the genotoxic potential of metconazole was tested in several *in vitro* and *in vivo* mutagenicity assays, all tests were negative with the exception of the chromosomal aberration assay (in the presence of S-9 mix (metabolic activation)). Overall, metconazole is considered to be non-genotoxic.

9. **Toxicology Profile:** The toxicological profile for metconazole is discussed in Table 3 below:

Table 3 – Toxicology Profile

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
870.3100		44721515 (1990)	NOAEL (M/F) = 9.1/10.1

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
	28-Day oral toxicity rodents (rat)	M/F: 0, 30, 100, 1000, 3000 ppm M: 0, 2.7, 9.1, 90.5, 261.1 mg/kg/day F: 0, 3.1, 10.1, 97, 287.4 mg/kg/day Acceptable/guideline	mg/kg/day LOAEL (M/F) = 90.5/97 mg/kg/day based on depression of body weight in M, liver and kidney weight increases with associated histopathological effects (hypertrophy and fatty vacuolation) in liver only.
870.3100	90-Day oral toxicity rodents (rat)	44721517 (1991) M/F: 0, 30, 100, 300, 1000, 3000 ppm M: 0, 1.94, 6.4, 19.2, 64.3, 192.7 mg/kg/day F: 0, 2.1, 7.2, 22.1, 71.4, 208.0 mg/kg/day Acceptable/guideline	NOAEL (M/F) = 6.4/7.2 mg/kg/day LOAEL (M/F) = 19.2/22.1 mg/kg/day based on increased spleen weight in females and hepatic vacuolation in males.
870.3100	90-Day oral toxicity rodents (mouse)	44721519 (1991) M/F: 0, 30, 300, 3000 (wk 1)/2000(wk 2-13) ppm M: 0, 9.58, 50.5, 341.1 mg/kg/day F: 0, 6.94, 60.7, 438.5 mg/kg/day Acceptable/guideline	NOAEL (M/F) = 9.58/6.94 mg/kg/day LOAEL (M/F) = 50.5/60.7 mg/kg/day based on increase in absolute and relative liver weights, hepatocellular hypertrophy and vacuolation, and increase in relative spleen weight (F), elevated AST and ALT activity.
870.3150	28-Day oral toxicity non-rodents (dog)	44721520 (1991) M/F: 0, 100, 1000, and 7000-10000 ppm in diet Unacceptable/non-guideline (some preliminary test data provided)	NOAEL (M/F) = 100 ppm in diet LOAEL (M/F) = 1000 ppm in diet (increase in relative and absolute thyroid wt. in one/two females) Deficiencies: low n (2M/2F per dose); decrease in food consumption means low exposure to test compound; actual dose received per dose group not provided.
870.3150	90-Day oral toxicity non-rodents	44721521 (1991) M/F: 0, 60, 600, 6000	NOAEL (M/F) = 2.5/2.6 mg/kg/day

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
	(dog)	ppm in diet M: 0, 2.5, 24.4, 225.2 mg/kg/day F: 0, 2.6, 24.3, 206.6 mg/kg/day Acceptable/guideline	LOAEL (M/F) = 24.4/24.3 mg/kg/day based on decreased food consumption and body weight gain in females and elevated platelets and reticulocytes in males.
870.3200	21-day Dermal Toxicity	46808439 (2006) 0, 250, 500, 1000 mg/kg/day Acceptable/guideline	**NOAEL**: 1000 mg/kg **LOAEL**: > 1000 mg/kg No evidence of dermal toxicity
870.6200	Subchronic (13-week) Oral Neurotoxicity- rat	46808440 (2002) 0, 50, 170, 500 ppm M: 0, 4.84, 15.69, 47.08 mg/kg/day F: 0, 5.10, 17.62, 49.82 mg/kg/day Acceptable/Non-guideline	**Systemic** NOAEL (M/F) = 4.84/5.10 mg/kg/ **Systemic** LOAEL (M/F) = 15.69/ 17.62 mg/kg/ based on decreases in body weight and food consumption. **Neurotoxicity** NOAEL (M/F) ≥ 47.08/49.82 mg/kg/day
870.3700	Prenatal development in rodents (rat)	44721522 (1991) 0, 12, 30, 75 mg/kg/day Gavage Acceptable/Guideline	**Maternal** NOAEL = 12 mg/kg/day LOAEL = 30 mg/kg/day based on decrease in body weight gain. **Developmental** NOAEL = 12 mg/kg/day LOAEL = 30 mg/kg/day based on increased incidence of skeletal variations (predominantly lumbar ribs).
870.3700	Prenatal development in rodents (rat)	46808443 (2002) 0, 1, 4, 16, 64 mg/kg/day Gavage Acceptable/Guideline	**Maternal** NOAEL= 16 mg/kg/day LOAEL= 64 mg/kg/day based on decreased body weight and food consumption, increased placental weight and increased incidence of swollen placentae

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
			Developmental NOAEL= 16 mg/kg/day LOAEL= 64 mg/kg/day based on based on an increase in early and late resorptions, decreased fetal body weight and increased incidence of incomplete ossification of sternebrae.
870.3700	Prenatal developmental in non-rodents (rabbit) Definitive Study	44721602 (1997) 0, 5, 10, 20, 40 mg/kg/day gavage Acceptable/Guideline	**Materna**l NOAEL = 20 mg/kg/day LOAEL = 40 mg/kg/day based on reductions in body weight gain, food consumption, and changes in various hematology parameters (reductions in hematocrit, hemoglobin, mean corpuscular volume and increases in platelet counts and alkaline phosphatase activity). **Developmenta**l NOAEL = 20 mg/kg/day LOAEL = 40 mg/kg/day based on increases in post-implantation losses.
870.3700	Prenatal developmental in non-rodents (rabbit)	44721603 (1991) 0, 4, 10, 25, 62.5 mg/kg/day (Exp. #1) 0, 2, 4, 10 mg/kg/day (Exp. #2) Acceptable/Guideline	**Materna**l NOAEL = 25 mg/kg/day LOAEL = 62.5 mg/kg/day based on body weight changes and slight clinical signs (anorexia/reduced or altered fecal output, cold ears). **Developmenta**l NOAEL = 4 mg/kg/day LOAEL = 10 mg/kg/day based on examining data from the two experiments. Effects at 62.5 mg/kg/day show total litter loss, decreased live fetuses, increased early and late resorptions.

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
			Effects at 25 mg/kg/day show some malformations: hydrocephaly (4 fetuses from 4 different litters, but NOT seen at 62.5 mg/kg/day) and limb effects (2 fetuses from 2 different litters, with one fetus with same effect at 62.5 mg/kg/d). Hydrocephaly and limb effects were observed at 10 mg/kg/day in Experiment #2, but not at that same dose in Experiment #1.
870.3800	Reproduction and fertility effects 2-generation- rat	46808447 (2002) 0, 30, 150 and 750 ppm M/F: 0/0, 2/2, 10.8/10.6, 53.2/53.0 mg/kg/day Acceptable/Guideline	**Parental/Systemic** NOAEL (M/F) = 9.8/10.8 mg/kg/day LOAEL (M/F) = 49.4/53.2 mg/kg/day based on: decreased body weight and decreased weight gain in male and female parental animals, increased incidence of fatty hepatocyte change in male parental animals, and increased incidence of spleen congestion in F1 parental females. **Reproductive** NOAEL (M/F) = ≥49.4/ 10.8 mg/kg/day LOAEL (M/F) = 53.2 mg/kg/day based on increased gestation length and decreased gestation index driven by dystocia (difficult labor). **Offspring** NOAEL (M/F) = 9.8/10.8 mg/kg/day LOAEL (M/F) = 49.4/53.2 mg/kg/day based decreased viability on lactation day 0 and decreased body weight in F2 offspring.
870.4100a	Chronic toxicity rodents (rat)	44721609 (1992) 0, 10, 100, 300, 1000	NOAEL = (M/F) = 4.3/16.0 mg/kg/day

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
		ppm M: 0, 0.44, 4.3, 13.1, 43.9 mg/kg/day F: 0, 0.52, 5.3, 16.0, 53.8 mg/kg/day Acceptable/Guideline	LOAEL = (M/F) = 13.1/ 53.8 mg/kg/day based on an increase in mean adjusted liver weights at 12 months (M) and 24 months (F), increase in spleen weights at 24 months (F), and increased hepatocellular lipid vacuolation (M/F) and centrilobular hypertrophy (M/F).
870.4100b	Chronic toxicity-dog	44721610 0, 30, 300, 1000, 3000 ppm in diet M: 0, 1.1, 12.0, 38.5, 110.0 mg/kg/day F: 0, 1.1, 10.3, 36.8, 113.7 mg/kg/day Acceptable/Guideline	NOAEL (M/F) = 12.0/10.3 mg/kg/day LOAEL (M/F) = 38.5/36.8 mg/kg/day based on decreased body weight gain weeks 1-13 (males), increased alkaline phosphatase activity (both sexes) and increased incidence of Kupffer cell pigmentation (females).
870.4200	Carcinogenicity - rat	44721611 (1992) 0, 100, 300, 1000 ppm M: 0, 4.6, 13.8, 46.5 mg/kg/day F: 0, 5.5, 16.6, 56.2 mg/kg/day Acceptable/Guideline	Non-neoplastic findings at (M/F) 13.8/56.2 mg/kg/day: increased incidence of hepatocellular lipid vacuolation (M/F), centrilobular hypertrophy (M/F), liver pigment deposition (M), histiocytic foci in the spleen (M/F),and increase in severity of chronic renal nephropathy (M). Evidence of mononuclear cell leukemia (F).
870.4300	Carcinogenicity-mouse	44721612 (1992) 0, 30, 300, 1000 ppm M: 0, 4.5, 39.5, 166.9 mg/kg/day F: 0, 5.9, 58.1, 195.5 mg/kg/day Acceptable/Guideline	Non-neoplastic findings at (M/F) 166.9/58.1 mg/kg/day: increase in vacuolation, hypertrophy, splenic atrophy and adrenal corticomedullary pigmentation, sinusoidal hypercellularity/single cell necrosis. Neoplastic findings: increase in liver cell

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
			tumors at high dose (M/F): Increased incidence of hepatocellular adenomas in males and hepatocellular carcinomas in females.
870.5500	*Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay	44721613 (1990) Up to limit dose of 5000 µg/ plate (*S. typhimurium*) and (*E. coli*) in the presence and absence of metabolic activation (± S9) Acceptable/Guideline	Test material was not cytotoxic with or without S9 activation in five *S. typhimurium* strains and one strain of *E. coli*, and did not induce a genotoxic response in any strain.
870.5300	*In vitro* Mouse Lymphoma Mutagenesis Assay WL136184* **cis* only isomer	44721615 (1991) Six doses up to 125 µg/ml (toxicity was observed above that dose) in the presence and absence of metabolic activation (± S9) Acceptable/Guideline	There was no evidence of biologically significant induction of mutant colonies.
870.5375	*In vitro* Cytogenetics Test	44721616 (1991) From 6.25 to 400 µg/ml, with and without metabolic activation (± S9) Acceptable/Guideline	Weakly positive (induced chromosome aberrations in Chinese hamster ovary cells) in the presence of S9 activation, negative without S9 activation.
870.5395	*In vivo* Mammalian Erythrocyte Micronucleus Test: Mouse	44721618 (1995) Up to the limit dose of 2000 mg/kg Acceptable/Guideline	There was no statistically significant increase in the frequency of micronucleated polychromatic erythrocytes in mouse bone marrow at any dose or collection time.
870.5550	*In vivo*/*in vitro* Mammalian UDS test	44721620 (1995) Up to the limit dose of 2000 mg/kg	Negative for unscheduled DNA synthesis.

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
	Rat	Acceptable/Guideline	
870.7485	Metabolism and pharmacokinetics: rat	44721622 (1992) single high dose: 164 mg/kg Radiolabel: (cyclopentyl-^{14}C) Acceptable/Guideline	Approximately 94% of radioactivity in excreta after five days: feces (males - 81.3%, females - 65.5%) and urine (males - 13.6%, females - 28.4%)
870.7485	Metabolism and pharmacokinetics: rat	44721622 (1992) single high dose: 164 mg/kg Radiolabel: (cyclopentyl-^{14}C) Acceptable/Guideline	Approximately 94% of radioactivity in excreta after five days: feces (males - 81.3%, females - 65.5%) and urine (males - 13.6%, females - 28.4%)
870.7485	Metabolism and pharmacokinetics: rat	44721623 (1991) single low dose: 2 mg/kg Radiolabel: (cyclopentyl-^{14}C) Acceptable/Guideline	Approximately 94% of radioactivity in excreta after 72 hrs: feces (males - 80%, females - 67%) and urine (males - 14.8%, females - 26%). Metabolite information presented.
870.7485	Metabolism and pharmacokinetics: rat WL136184* **cis* only isomer	44721624 (1991) single high dose: 200 mg/kg (males only) Radiolabel: (Triazole - ^{14}C) Acceptable/Guideline	Approximately 96% of radioactivity in excreta after seven days: feces (76%) and urine (20%). Metabolite information presented.
870.7485	Metabolism and pharmacokinetics: rat WL136184* **cis* only isomer	44721625 (1991) single low dose: 2 mg/kg Radiolabel: (Cyclopentyl - ^{14}C) Acceptable/Guideline	Excretion/retention in bile-duct cannulated rats. Approximately 80% of radioactivity was excreted in the bile after 48 hrs: males (78.7%) and females (83.3%).
870.7485	Metabolism and pharmacokinetics: rat	46808449 (2002) male/female rat single low dose: 2 mg/kg single high dose: 200 mg/kg repeated dose: 2 mg/kg	Low potential for bioaccumulation following single or multiple dosing regimen. The time to maximum plasma concentration for male and female rats treated with either 2 mg/kg or 200 mg/kg was the

Table 3. Subchronic, Chronic and Other Toxicity Profile for Metconazole Technical[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification /Doses**	**Results**
		Acceptable/Non-guideline	earliest sampling interval, 0.25 hours and 4 hours, respectively The plasma half-life of low- and high-dose rats was slightly shorter in males than females, ~20-25 hours and ~34 hours, respectively.
870.7485	Effects on rat/mice liver enzymes WL136184* *cis only isomer	44721626 (1991) 0, 300 ppm in diet (mice) and 0, 1000 ppm in diet (rats) for seven or 28 days Acceptable/Non-guideline	Increased liver weight, cytochrome P450, ethoxycoumarin O-deethylase, ethylmorphine N-demethylase, and lauric acid 11-hydroxylase in both rats and mice. No effect on ethoxyresorufin O-deethylase, palmitoyl-CoA oxidation, or peroxisome proliferation (in terms of peroxisome number or morphology).
	14-day Mechanistic Study	46665402 (2005) 0, 30, 300, 1000 ppm in diet (mice) for 14 days. F: 4.5, 48, 151 mg/kg/day Acceptable/*Non-guideline*	Increased liver weight (300 and 1000 ppm); increased hepatic drug metabolizing enzymes (300 and 1000 ppm) after 7 days; enlarged livers (1000 ppm) at days 3, 7 and 14; hepatic hypertrophy and vacuolation (300 and 1000 ppm) at day 14; increased ALT and AST activities at 1000 ppm (day 14); increased lipid peroxide (300 and 1000) at day 14; increased PCNA labeling at 1000 ppm at day 3 and 7.
870.7600	In Vivo Dermal Penetration Study	46808450 (1990) Acceptable/Non-guideline	Dermal absorption= 16% (72 hrs)

[1] cis/trans ratio is 85:15. All studies used cis/trans mixture unless otherwise noted.

10. FQPA Hazard Considerations: The toxicology risk assessment team addressed the potential enhanced sensitivity to infants and children as required by FQPA, in accordance with the 2002 OPP 10x Guidance document, and recommended reducing the 10X FQPA Safety Factor to 1X for the dietary and residential risk assessments. The recommendation is based on the following:

- There is no evidence of susceptibility following *in utero* exposure in the rat and rabbit developmental toxicity studies and following both *in utero* and post-natal exposure in the two-generation rat reproduction study.

- There is no evidence of increased susceptibility in the offspring based on the result of the two-generation reproduction study.

- The residue levels used in the dietary assessment were the established tolerance levels for banana, soybean commodities, and livestock commodities, and assumed 100% crop treated (actions completed previously). Therefore, the acute and chronic dietary, food only, exposure is considered an upper bound conservative estimate. The contribution from drinking water is minimal. The Agency concludes that the acute and chronic exposure estimates in this analysis are unlikely to underestimate actual exposure.

- The drinking water component of the dietary assessment utilizes water concentration values generated by model and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded.

- While there is potential for postapplication residential exposure, the best data and approaches currently available were used in the metconazole residential assessment. The Agency used the current conservative approaches for residential assessment. The Agency believes that the calculated risks represent conservative estimates of exposure because maximum application rates are used to define residue levels upon which the calculations are based. Exposures are unlikely to be under estimated because the assessment was a screening level assessment.

11. Toxicological Endpoints: A summary of the toxicological endpoints and doses chosen for the relevant exposure scenarios for dietary and occupational human health risk assessments is provided in the table below. The conventional interspecies extrapolation (10X) and intraspecies variation (10X) uncertainty factors were applied for all exposure scenarios. As stated above, the FQPA SF for increased susceptibility was reduced to 1X for all exposures scenarios. A summary of the toxicological endpoints are shown below in Table 4:

Tables 4a and 4b -- Summary of Toxicological Doses and Endpoints for Metconazole for Use in Human Health Risk Assessments

Table 4a. Summary of Toxicological Doses and Endpoints for Metconazole for Use in Dietary and Non-Occupational 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**
Acute Dietary (General Population, including Infants and Children)	An appropriate dose/endpoint attributable to a single dose was not observed in the available oral toxicity studies reviewed.			
Acute Dietary (Females 13-49 years of age)	NOAEL= 12 mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x	Acute RfD = 0.12 mg/kg/day aPAD= 0.12 mg/kg/day	**Developmental toxicity in rats:** LOAEL= 30 mg/kg/day based on increases in skeletal variations.
Chronic Dietary (All Populations)	NOAEL= 4.3 mg/kg/day	UF_A=10x UF_H= 10x FQPA SF= 1x	Chronic RfD = 0.04 mg/kg/day cPAD = 0.04 mg/kg/day	**Chronic oral toxicity study in rats:** LOAEL = 13.1 mg/kg/day based on increased liver (M) weights and associated hepatocellular lipid vacuolation (M) and centrilobular hypertrophy(M). Same effects seen in F at 54 mg/kg/day, plus increased spleen wt.
Incidental Oral Short-Term (1-30 days)	NOAEL= 9.1 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Residential LOC for MOE = 100	**28-Day oral toxicity study in rats:** LOAEL = 90.5 mg/kg/day based on decreased body weight (M), increased liver and kidney weight and hepatocellular hypertrophy and vacuolation (M/F).
Incidental Oral Intermediate-Term (1-6 months)	NOAEL= 6.4 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Residential LOC for MOE = 100	**90-Day oral toxicity study in rats:** LOAEL = 19.2 based on increased spleen wt (F) and hepatic vacuolation (M).
Dermal Short-Term (1-30 days)	Quantification of dermal risk is not required due to lack of systemic or dermal toxicity at the Limit Dose in a 21-day dermal toxicity study in the rat and the lack of target organ toxicity, neurotoxicity, developmental or reproductive toxicity.			
Dermal				

Table 4a. Summary of Toxicological Doses and Endpoints for Metconazole for Use in Dietary and Non-Occupational 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**
Intermediate-Term (1-6 months)				
Inhalation Short- Term (1-30 days)	NOAEL= 9.1 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Residential LOC for MOE = 100	**28-Day oral toxicity study in rats:** LOAEL = 90.5 mg/kg/day based on decreased body weight (M), increased liver and kidney weight and hepatocellular hypertrophy and vacuolation (M/F).
Inhalation Intermediate-Term (1-6 months)	NOAEL= 6.4 mg/kg/day	UF_A= 10x UF_H=10x FQPA SF= 1x	Residential LOC for MOE = 100	**90-Day oral toxicity study in rats:** LOAEL = 19.2 mg/kg/day based on increased spleen wt (F) and hepatic vacuolation (M).
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans"			

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 (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). 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 date (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.

Table 4b. Summary of Toxicological Doses and Endpoints for Metconazole for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Dermal Short-Term (1-30 days)	Quantification of dermal risk is not required due to lack of systemic or dermal toxicity at the Limit Dose in a 21-day dermal toxicity study in the rat and the lack of target organ toxicity, neurotoxicity, developmental or reproductive toxicity.			
Dermal Intermediate-Term (1-6 months)				
Inhalation Short-Term (1-30 days)	NOAEL=9.1 mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = 100	**28-Day oral toxicity study in rats:** LOAEL = 90.5 mg/kg/day based on decreased body weight (M), increased liver and kidney weight and hepatocellular hypertrophy and

Table 4b. Summary of Toxicological Doses and Endpoints for Metconazole for Use in Occupational Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
				vacuolation (M/F).
Inhalation Intermediate-term (1-6 months)	NOAEL=6.4 mg/kg/day	UF_A=10x UF_H=10x	Occupational LOC for MOE = 100	**90-Day oral toxicity study in rats:** LOAEL = 19.2 mg/kg/day based on increased spleen wt (F) and hepatic vacuolation (M).
Cancer (oral, dermal, inhalation)	Classification: "Not Likely to be Carcinogenic to Humans"			

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 date (i.e., lack of a critical study). MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

B. Dietary Exposure and Risk

1. **Dietary Exposure from Food and Drinking Water:** Acute and chronic dietary (food and drinking water) exposure assessments were conducted for the proposed uses on turf and ornamentals, and all registered food uses (imported bananas, and Section 18 on soybeans), and drinking water. The residue levels used in the assessment were the established tolerance levels for banana, soybean commodities, and livestock commodities, and assumed 100% crop treated. Therefore, the dietary, food only, exposure is considered an upper bound conservative estimate.

   Estimated concentrations of metconazole in drinking water from the proposed uses on turf and ornamentals were provided by EFED and incorporated directly into the acute and chronic assessments.

   A Tier II drinking water assessment for the proposed uses on turf and ornamentals was performed using PRZM/EXAMS modeling with index reservoir (IR) scenarios and percent cropped area (PCA) adjustment factors. For the acute assessment the 1 in 10 year annual peak concentration of metconazole in drinking water was used, and is not expected to exceed 45.48 µg /L. For the chronic assessment, the 1 in 10 year annual average concentration of metconazole in drinking water was used, and is not expected to exceed 31.25 µg /L.

2. **Aggregate Risk Exposures:** Based on the proposed uses on turfgrass, and that fact that common toxicity endpoints exist for the incidental oral, and acute and chronic dietary routes of exposure, then acute, chronic, and short-term aggregate exposure and risk assessments are required.

3. **Acute Aggregate Risk:** Acute aggregate exposures include food plus drinking water exposures. The acute dietary exposure estimate at the 95th percentile is 2% aPAD for

females 13-49 years old, the only population subgroup of concern, which is below the Agency's level of concern.

4. **Chronic Aggregate Risk:** Chronic aggregate exposures include food plus drinking water exposures. The chronic dietary (food and drinking water) exposure to metconazole is below the Agency's level of concern for the general U.S. population and all population subgroups. The chronic dietary exposure estimates are 4% cPAD for the general U.S. population and 10% cPAD for all infants (<1 year old), the most highly exposed population subgroup.

5. **Short- and Intermediate Term Aggregate Risk:** Dietary, incidental oral and inhalation routes of exposure have the same toxicity endpoints, and therefore, can be aggregated. The short- and intermediate-term aggregate risk assessments take into account average (chronic) exposure estimates from dietary consumption of metconazole (food and drinking water) and non-occupational/residential use on turf (dermal for adults, and dermal plus incidental oral for children). Postapplication exposures from the use on turf are considered predominantly short-term (1-30 days). Although exposures are expected via the dermal route, quantification of dermal risk is not required, since a dermal endpoint was not identified for short-, or intermediate-term exposures. Therefore, short- and intermediate-term postapplication aggregate risk assessments were conducted only for average dietary and incidental oral exposures to toddlers.

   The short-and intermediate-term aggregate MOEs from dietary exposure (food + drinking water) and non-occupational/residential handler exposure (inhalation) for adults are 3,000 and 2,900, respectively; which are not of concern, since they are greater than the level of concern MOE of 100. The short-and intermediate-term aggregate MOEs from dietary exposure (food + drinking water) and non-occupational/residential exposure (incidental oral) for children 1-2 years old are 470 and 520, respectively; which are not of concern, since it is greater than the level of concern MOE of 100.

   These aggregate exposure assessments are considered conservative estimates, that should not underestimate risks, because of the following inputs: 1) dietary inputs used crop specific (turf) screening level drinking water modeling data (i.e., Tier II surface water model); 2) maximum application rates and minimum application intervals were used; and 3) conservative SOPs and upper level estimates of exposure were employed.

6. Cancer Aggregate Risk: There were no treatment-related tumors observed in carcinogenicity studies in rats and mice. As a result, a cancer assessment was not conducted.

7. Cumulative Risk: Section 408(b)(2)(D)(v) of the FFDCA 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." Unlike

other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to metconazole and any other substances. For the purposes of this action, therefore, EPA has not assumed that metconazole has a common mechanism of toxicity with other substances. 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 concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

B. Handler and Worker Risk Assessments

1. Occupational: Short- (1 - 30 days) and intermediate-term (1 – 6 months) exposures are possible for occupational metconazole handlers. Only inhalation toxicity endpoints were identified for these anticipated exposure durations. A Margin of Exposure (MOE) ≥100 is adequate to protect occupational pesticide handlers. All metconazole occupational handler MOEs are estimated to be >100 for the proposed uses, and therefore, do not cause concern for HED.

There is the possibility for agricultural workers to have postapplication exposure to metconazole following its use on commercially grown ornamentals in nurseries and greenhouses, as well as golf course turf. However, because dermal toxicity endpoints for the appropriate durations of exposure were not identified, and because inhalation exposure is considered to be insignificant for postapplication exposures, no occupational postapplication exposure assessment was conducted.

2. Residential: There is potential adult short-term dermal and inhalation exposure to metconazole from its proposed use on turf and ornamentals. However, because dermal toxicity endpoints for the appropriate duration of exposure were not identified, only residential handler inhalation exposures/risks have been assessed.

An MOE ≥100 is adequate to protect residential pesticide handlers. All metconazole residential handler MOEs are estimated to be >100 for the proposed uses, and therefore, do not cause concern.

Adults, adolescents and toddlers may be exposed to metconazole from its proposed residential uses. Adults and adolescents may experience short- and intermediate-term dermal exposure from golfing and other activities on treated turf, as well as from tending treated ornamentals. Toddlers may experience short- and intermediate-term dermal and incidental oral exposure from activities on treated turf. Because dermal toxicity endpoints for the appropriate durations of exposure were not identified, and because inhalation exposure is considered to be insignificant for postapplication exposures, only toddler incidental oral postapplication exposures have been assessed. Chemical-specific turf transferable residue studies were submitted for use in estimating postapplication

exposures.

Postapplication risks to toddlers following the application of metconazole to home lawns were calculated for short- and intermediate-term exposures. All MOEs for the toddler lawn exposure scenarios were >100, and therefore, are not of concern. In addition the total MOE for combined toddler exposures (i.e., hand-to-mouth, object-to-mouth, and incidental ingestion of soil) is >100, and therefore, is not of concern.

III. ENVIRONMENTAL RISK ASSESSMENT

A. Environmental Fate Characterization: Metconazole is stable to hydrolysis under environmental conditions. It is moderately to slightly degradable by direct photolysis in water. However, photodegradation in water is not expected to be a major route of dissipation in aquatic systems as metconazole has been shown to partition rapidly to the sediment (DT_{50} in water ranged from 1-15 days) and slowly degrade while in sediment (DT_{50} for total system ranged from 116-814 days). Aerobic soil metabolism is the only significant route of degradation of metconazole. Based on three aerobic soil metabolism studies, the half-life values are in the range of 192.5 days to 660 days. In a soil photolysis study, metconazole degraded with an estimated half-life of 72 days. Field dissipation studies indicate that metconazole dissipated with a DT_{50} ranging from 33 to 138 days. Adsorption/desorption studies of metconazole in four soils (pH 5.8-7.6, 0.74-2.29 % OC) produced K_{oc} values ranging between 1026 and 2723 ml/g. This K_{oc} range suggests the chemical is slightly mobile (FAO Classes). The ranges of BCFs for edible tissue, nonedible tissue, and whole fish indicate a low potential for bioconcentration in fish. Also, given the relative short depuration time, it is considered that the risk for bioaccumulation of metconazole in fish is low.

B. Exposure Characterization: Metconazole has potential to reach surface water via run-off and spray drift and to reach ground water via leaching. However, the submitted terrestrial field dissipation studies show no significant leaching of metconazole, and ground water modeling estimate a concentration of less than 1 ppb.

Estimated environmental concentrations (EECs) in surface water were calculated for metconazole using the Tier II PRZM/EXAMS models and employing maximum application rates for metconazole usage on turf, small grains, soybeans, sugar beets, peanuts, stone fruits, and tree nuts. The peak (1-in-10 year) surface water EECs were between 2.89 and 88.19 µg/L (dependent on scenario and application method). For the terrestrial assessment, EECs for metconazole were calculated using the terrestrial Tier I model T-REX using the maximum application rate for the evaluated uses. Upper bound dietary EECs ranged from approximately 1.53 ppm for metconazole residues on fruits, pods, seeds, and large insects for soybean application to 446 ppm on short grass for turf application.

C. Effects Characterization: Results of acute toxicity studies in freshwater and estuarine/marine fish indicate that metconazole is moderately toxic on an acute basis.

The LC_{50} = 1.71 mg ai/L for freshwater fish (28-day study, OECD204) and the LC_{50} = 6.3 mg ai/L for estuarine/marine fish. The NOAEC for freshwater fish was 0.00291 mg ai/L based on dry and wet weights and length. For the eastern oyster, the EC_{50} = 2.0 mg ai/L based on shell growth. Acceptable or supplemental toxicity data for estuarine/marine fish (chronic) and for invertebrates (freshwater and estuarine/marine, acute and chronic) were not provided to the Agency. In lieu of these data, toxicity data from other conazole pesticides were use to characterize the risks, assuming that metconazole toxicity was similar to the other conazoles.

Metconazole is classified as slightly toxic to birds based on gavage (LD_{50} = 777 mg ai/kg-bwt) and dietary (LC_{50} 1078 mg ai/kg-diet) studies in bobwhite quail. Adverse effects were observed in a reproduction study using bobwhite quail (reduction in live 3-week embryos, hatching success, chick survival, chick body weights, and adult female body weight gain), resulting in a NOAEC of 58 mg ai/kg-diet. the acute toxicity tests for mammals produced definitive LD_{50}s (combined for males and females) of 566, 660, and 1459 mg ai/kg-bwt as well as one non-definitive LD_{50} of >5000 mg ai/kg-bwt (no mortalities). The parental, offspring, and reproductive NOAEC for the 2-generation rat study was 150 mg ai/kg-diet. Significant effects were categorized as parental, reproductive, and offspring. Parental effects include decreased body weight and decreased weight gain in male and female parental animals, increased incidence of fatty hepatocyte change in male parental animals, and increased incidence of spleen congestion in F1 parental females. Reproductive effects included increased gestation length and decreased gestation index driven by dystocia. Offspring effects included decreased viability on lactation day 0 and decreased body weight in F2 offspring. Results of available toxicity studies indicate that metconazole is practically non-toxic to honey bees on an acute contact basis.

Seedling emergence studies and vegetative vigor studies were conducted for ten species using two different end-use products (Caramba and Metconazole 50 WDG). The studies with Caramba did not provide any definitive EC_{25}s (all were > 0.097 lbs ai/acre, the highest concentration tested). For the seedling emergence study conducted with Metconazole 50 WDG, the most sensitive monocot was ryegrass (EC_{25} = 0.78 lbs ai/acre and NOAEC = 0.30 lbs ai/acre), and the most sensitive dicot was the radish (EC_{25} = 0.15 lbs ai/acre and NOAEC = 0.075 lbs ai/acre). For the vegetative vigor study conducted with Metconazole 50 WDG, there were no reductions in growth parameters based on the EC_{25} (> 0.60 lbs ai/acre) and NOAEC (0.60 lbs ai/acre) in the four tested monocots, and the most sensitive dicot was radish (EC_{25} = 0.44 lbs ai/acre, NOAEC < 0.038 lbs ai/acre, and EC_{05} = 0.0036 lbs ai/acre).

Contact toxicity studies on the effects of metconazole to honey bees indicate that there are no effects at concentrations less than 95.3 µg ai/bee.

The most sensitive EC_{50} values for aquatic vascular plants and non-vascular plants are 0.022 and 0.081 mg ai/L, respectively. The respective NOAECs are 0.00051 and 0.031 mg ai/L.

D. Potential Risks to Non-Target Organisms:

1. **Aquatic**: Based on this analysis, direct toxic exposure is expected for estuarine/marine fish (chronic), and freshwater and estuarine/marine invertebrates (acute and chronic). Available toxicity data for aquatic plants coupled with the results of this screening-level assessment show that use of metconazole is likely to result in direct toxic exposure to vascular aquatic plants (proposed application to turf and ornamentals only) and to non-vascular aquatic plants (proposed application to ornamentals only). Labeling restrictions limiting number of applications and requiring a buffer zone will reduce these risks. The specific labeling language addressing these concerns is provided below.

2. **Terrestrial**: Results of this screening-level assessment using available toxicity data suggest that use of metconazole is likely to result in toxic exposure to birds and mammals on an acute basis and to mammals on a chronic basis.). Labeling restrictions limiting number of applications will reduce these risks. The specific labeling language addressing these concerns is provided below. The Tier I terrestrial plant model, TERRPLANT, was used to assess risks to terrestrial and semi-aquatic plants. Results of this screening-level assessment suggest that use of metconazole is likely to result in toxic exposure to semi-aquatic dicots.). Labeling restrictions limiting number of applications and requiring a buffer zone will help reduce these risks. The specific labeling language addressing these concerns is provided below.

   The results of this risk assessment suggest that the patterns of metconazole use are such that they coincide in time and space to areas frequented by avian and mammalian wildlife. These areas have been of demonstrated use by wildlife as sources of food and cover. The potentially problematic wildlife food items suggested by this risk assessment are likely to be present in and around the treated areas. In addition, there is potential for indirect effects to all taxonomic groups due to changes in habitat caused by vegetation changes.

   A considerable uncertainty in this assessment comes from the fact that metconazole (94% purity used in formulation) comprises two geometric isomers; *cis and trans,* with a typical ratio of 85:15 *cis:trans*. The technical grade material is 94 % pure with a minimum of 80 % *cis* isomer. The submitted data do not provide information on the differences in degradation rates between the two geometric isomers or the relative contribution of each isomer to the total amount of residues identified in each of the environmental fate studies. Therefore, the environmental concentrations presented in this risk assessment assume fate properties and degradation rates are the same for both isomers.

   Estimated levels of metconazole in the environment, when compared with minimum toxicity values, are likely to result in direct risks to Federally Listed Threatened and Endangered ("listed") and non-listed species from several different taxa. Indirect risks are also identified for listed and non-listed species. Labeling restrictions limiting number of applications and requiring will reduce these risks. The specific labeling language addressing these concerns is provided below.

IV. PROPOSED REGULATORY DECISION

A. Unconditional Registration: We recommended registration of metconazole for control of diseases in turfgrass and ornamentals.

1. Conditional Data:

850.1075/72-1a,c: Freshwater fish LC_{50}, both cold and warm water fish
850.1010/72-2a: Freshwater invertebrate LC_{50}
850.1055/72-3c: Estuarine/marine invertebrate LC_{50}
850.1300/72-4a: Fish early life stage (estuarine/marine)
850.1400/72-4b: Aquatic invertebrate Life cycle Freshwater and Estuarine/marine
850.1735: Whole Sediment Acute Toxicity invertebrates, freshwater

B. Tolerances: No tolerances are required for the proposed non-food uses of metconazole on turf and ornamentals**.**

C. Required Label Statements: End use products containing metconazole as an active ingredient will be required to add the following protective language on the product labeling:

1. Environmental Hazards: "Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. "

2. Directions for Use:

- "Do not make more than three applications per year (2 lbs active ingredient/year)."

Contact Person at EPA

Mary Waller
Product Manager
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs
Environmental Protection Agency
Aerial Rios Building
1200 Pennsylvania Ave., NW
Washington, DC 20460

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Product Registration - Section 3
59639-RUU

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