United States
Environmental Protection
Agency

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

Pesticide Fact Sheet

Name of Chemical: Tetraconazole
Reason for Issuance: New Chemical
Date Issued: April 2005

Description of Chemical

Generic Name:	Tetraconazole (1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4-triazole)
Common Name:	Tetraconazole
Trade Name:	Eminent 125SL
Chemical Class:	Triazole
EPA Chemical Code:	120603
Chemical Abstracts Service (CAS) Number:	112281-77-3
Year of Initial Registration:	2005
Pesticide Type:	Fungicide
U.S. Producer:	Sipcam Agro USA, Inc., 300 Colonial Center Parkway, Roswell, GA 30076

Limitations: Time limited tolerance to expire Nov.30, 2012.
Use is limited to the states of CO, MI, MN, MT, ND, NE and WY

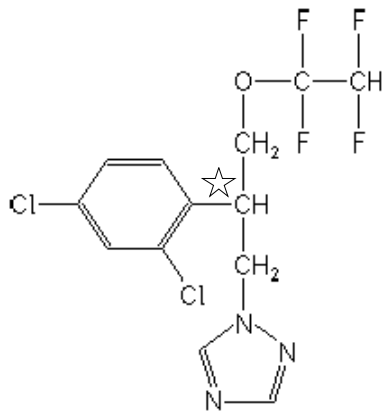
Use Pattern and Formulations

The end-use product, Eminent 125SL, contains 11.6% tetraconazole by weight and is a liquid fungicide for control of Cercospora leafspot and powdery mildew on sugar beets. The proposed application method is ground and aerial application as a foliar spray or by chemigation. The applications must by alternated with non-triazole fungicides. Applications should begin when disease conditions are favorable and be repeated at 21-28 day intervals. A maximum of two applications per growing season may be made using 13 fluid ounces of a 1pound per gallon product per acre. The preharvest interval is 14 days. The product is for agricultural use only. The pesticide's use is proposed in seven U.S. states: CO, MI, MN, MT, ND, NE, and WY.

Science Findings

Available product chemistry, toxicology, ecological effects and environmental fate data supporting the proposed uses are summarized below.

Physical/Chemical Structure:



(star denotes chiral carbon)

Table 1. Physical-Chemical Properties of Tetraconazole			
Parameter		**Value and Unit**	**Source**
Chemical Structure	1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4-triazole		
Chemical Name		Tetraconazole	
CAS Number		112281-77-3	
PC Code		120603	
Empirical Formula		$C_{13}H_{11}N_3O\ Cl_2F_4$	
Molecular Weight		372.16	
Appearance		Viscous liquid	
Color		Yellow	
Odor		Slight aromatic	
Density		1.4382 g/mL at 20 ^{0}C	
Boiling Point		decomposition at 240 ^{0}C	
Octanol/Water Partition Coefficient		log K_{ow} = 3.56 at 23 ^{0}C	
pH saturated solution		5.47	
Organic Solvents Solubility		Readily dichloromathane, acetone, and methanol	
Vapor pressure		1.35e^{-6} mm Hg	Exp VP (EPI Suite)
Water Solubility (pH 7, 20^{o}C)		159 mg/L	MRID 44268104
Henry's law constant (K_H)		4.24e^{-9} atm m^3/mole	Exp HLC (EPI Suite)
Hydrolysis		stable up to 30 days	MRID 44367002
Aerobic Soil Metabolism		stable	MRID 44367005
Aerobic Aquatic Metabolism ($t_{1/2}$)[1]		382 days (high organic) and 320 days (low organic)	MRID 44751319
Aquatic Photolysis $t_{1/2}$ (days) [2]		215 (sun in Sept) and 107 (July)	MRID 44367003
Partition Coefficient normalized to Organic Carbon Content (K_{oc})[3]		428 mL/g	MRID 44367006
Soil Photolysis $t_{1/2}$ (days)		106	MRID 44367004

[1] Half-life values calculated for water and sediment compartment together (382 days Mill stream pond-high organic), 320 days in Iron Hatch run-off aquatic system- low organic)

[2] a half-life adjusted for typical sunlight in Milano, Italy

RISK ASSESSMENT

Toxicological Endpoints:

- **Acute Toxicity**: Tetraconazole has low acute toxicity (Toxicity category III or IV) via the oral, dermal, and inhalation routes. It is a slight eye irritant, but is not a dermal irritant or a dermal sensitizer.

- **Chronic Toxicity**: The liver and kidney are the primary target organs of tetraconazole. In the subchronic, chronic, and reproduction rat studies, subchronic and carcinogenicity mouse studies, and the chronic dog study increases in liver weight, increases in liver serum enzymes, or gross and microscopic liver pathology were noted at various doses, providing evidence of liver toxicity.

- **Reproductive and Developmental Toxicity:** There is no evidence of increased susceptibility of rat or rabbit fetuses to in-utero exposure to tetraconazole. In the developmental toxicity study in rats, developmental effects were seen at the same dose that induced maternal toxicity. In the developmental toxicity study in rabbits, no developmental toxicity was seen at the highest dose tested. In the two generation reproduction study, offspring toxicity occurred at doses higher than the dose that induced parental/systemic toxicity.

- **Neurotoxicity:** No evidence of neurotoxicity was noted in any oral study. No acute or subchronic neurotoxicity studies were submitted.

- **Mutagenicity:** The Agency concluded that there is not a concern for mutagenicity resulting from exposure to Tetraconazole since it was not mutagenic in various mutagenic assays.

- **Cancer Classification:** Tetraconazole was classified as "likely to be carcinogenic to humans" based on the occurrence of liver tumors in male and female mice. The Carcinogenicity Assessment Review Committee recommended that a low dose extrapolation model be applied to the experimental animal tumor data and that quantification of risk be estimated for male and female mouse liver tumors for Tetraconazole. The most potent unit risk will be used for the purpose of lifetime cancer risk assessment by the Agency. In this case, the most potent unit risk, Q1*, is that for male mouse liver benign and/or malignant combined tumor rates at 2.30 x 10-2 in human equivalents.

HAZARD CHARACTERIZATION

Table 2. Summary of Toxicological Dose and Endpoints for Tetraconazole for Use in Human Risk Assessment

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Special Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary General Population (Infants and Children)	Not available	None	An end-point of concern attributable to a single dose was not identified. An acute **RfD** was not established.
Acute Dietary Females 13 - 50 years of age	NOAEL = 22.5 mg/kg/day UF = 100 **Acute RfD** = 0.225 mg/kg	FQPA SF = 1X **aPAD** = acute RfD / FQPA SF = 0.225 mg/kg	Oral developmental toxicity study - rat Developmental NOAEL = 22.5 mg/kg/day, based on increased incidence of small fetuses, and supernumerary ribs.
Chronic Dietary all populations	NOAEL= 0.73 mg/kg/day UP = 100 **Chronic RfD** = 0.0073 mg/kg/day	FQPA SF = 1X **cPAD** = chronic RfD / FQPA SF = 0.0073 mg/kg/day	Chronic oral toxicity - dog Systemic Toxicity LOAEL = 2.95/3.33 (M/F) mg/kg/day, based on absolute and relative kidney weights and histopathological changes in the male kidney.
Short-Term Dermal (1- 30 days) (Occupational/ Residential)	oral NOAEL = 5.9 mg/kg/day (dermal absorption rate = 12%)	**Occupational LOC for MOE** = 100 **Residential LOC for MOE** = 100	Oral 2-Gen Reproduction Toxicity Study - rat **Offspring LOAEL = 40.6 mg/kg/day**, based on decreased litter weight and mean pup weight in litters of all generations before weaning and increased relative liver weights at weaning in both sexes of all litters.
Intermediate-Term Dermal (1 - 6 months) (Occupational/ Residential)	oral NOAEL= 0.73 mg /kg/day (dermal absorption rate = 12%)	**Occupational LOC for MOE** = 100 **Residential LOC for MOE** = 100	Chronic oral toxicity - dog Systemic Toxicity LOAEL = 2.95/3.33 (M/F) mg/kg/day, based on increased absolute and relative kidney weights and histopathological changes in the male kidney.

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Special Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term Inhalation (1 day -30 days) (Occupational/ Residential)	oral NOAEL= 5.9 mg ai/kg/day (inhalation absorption rate = 100%)	**Occupational LOC for MOE** = 100 **Residential LOC for MOE** = 100	Oral 2-Gen Reproduction Toxicity Study - rat **Offspring LOAEL = 40.6 mg/kg/day**, based on decreased litter weight and mean pup weight in litters of all generations before weaning and increased relative liver weights at weaning in both sexes of all litters.
Intermediate-Term Inhalation (1 - 6 months) (Occupational/ Residential)	oral NOAEL = 0.73 mg/kg/day (inhalation absorption rate = 100%)	**Occupational LOC for MOE** = 100 **Residential LOC for MOE** = 100	Chronic oral toxicity - dog Systemic Toxicity LOAEL = 2.95/3.33 (M/F) mg/kg/day, based on increased absolute and relative kidney weights and histopathological changes in the male kidney.
Cancer (oral, dermal, inhalation)	"likely to be carcinogenic to humans"		Q_1^*= 2.30 x 10^{-2}, based on male mouse liver benign and/or malignant combined tumor rates.

[1] UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure

* ***NOTE:*** The Special FQPA Safety Factor recommended by the HIARC **assumes** that the exposure databases (dietary food, drinking water, and residential) are complete and that the risk assessment for each potential exposure scenario includes all metabolites and/or degradates of concern and does not underestimate the potential risk for infants and children.

Food Quality Protection Act Considerations:

FQPA Safety Factor:

Based on the following, EPA concluded that the additional safety factor for the protections of infants and children could be removed:

1. There is no quantitative or qualitative evidence of increased susceptibility of rat and rabbit fetuses to in

utero exposure in developmental studies. There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study.
2. There are no residual uncertainties for pre-/post-natal toxicity
3. The toxicological database is complete for FQPA assessment.
4. The chronic non-cancer dietary food exposure assessment utilizes anticipated residue data and assumed 100% crop treated. The chronic assessment will not underestimate exposure or risk since the refinement is based on reliable data derived from studies designed to produce worst-case residues.
5. At this time, only agricultural uses have been proposed for tetraconazole. There are no uses that would result in residential or recreational exposures.

Exposure Assumptions:

This action uses the conclusions of a dietary exposure assessment carried out for tetraconazole on soybeans which included the proposed uses of tetraconazole on sugar beets. These conclusions included the assumption that tetraconazole residues were present in soybeans as well as sugar beets.

Estimated Drinking Water Concentrations

Monitoring data were not available for tetraconazole. Thus, the Agency used the PRZM 3.12/ EXAMS 2.7.97 screening model to calculate the surface water EECs and the screening model SCI-GROW (Screening Concentrations in Ground Water) to calculate the groundwater EEC. The EECs of tetraconazole for acute exposures are estimated to be 8.38 parts per billion (ppb) for surface water, representing the 1 in 10 year annual peak concentrations. The surface water EECs are estimated to be 5.58 ppb for chronic non-cancer exposures (the 1 in 10 year annual average concentration) and 4.46 ppb for chronic cancer exposures (the 30 year annual average concentration). Based on the SCI-GROW model the ground water EECs for all exposures are estimated to be 0.5 ppb.

Aggregate Dietary Exposure

Aggregate exposure risk assessments were performed for the following scenarios: acute aggregate exposure (food + drinking water) for women 13-50 years of age, chronic non-cancer aggregate exposure (food + drinking water) for the general population and chronic cancer aggregate exposure (food + drinking water) for the general population. The Dietary Exposure Evaluation Model (DEEM™-FCID™) analysis evaluated the individual food consumption as reported by respondents in the USDA [1994-1996] Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

i. *Acute:* DWLOC's were calculated for acute aggregate exposure for women 13-50 years of age and chronic non-cancer aggregate exposure (food + drinking water)for the general population: the EEC's were found to fall below the DWLOC so that aggregate acute exposures do not exceed the level of concern. The acute exposure assessments used tolerance level residues for all sugarbeet and soybean commodities and it was assumed that 100% of all crops were treated.

ii. *Chronic non-cancer:* DWLOC's were calculated for chronic non-cancer aggregate exposure (food + drinking water)for the general population: the EEC's were found to fall below the DWLOC so that chronic non-cancer exposures do not exceed the level of concern. Tolerance

level residues were assumed for all soybean commodities, poultry liver, poultry meat, byproducts, and eggs. Anticipated residues were assumed for poultry fat, poultry meat, milk, and all sugar beet, cattle, goat, horse, sheep and swine commodities. It was assumed that 100% of all crops were treated.

iii. *Cancer:* The cancer dietary assessment was identical to the chronic dietary assessment except for the following additional refinements: drinking water was incorporated into the dietary analysis as a food commodity with the tetraconazole level set at 0.00446 ppm, (30-year average surface water concentration); lower anticipated residues were used for soybean seed and soybean oil (refined from 0.05 to 0.025); the concentration factor for soybean oil was refined from 12 to 4.6; it was estimated that 67% of the soybean crop would be treated and; it was estimated that 52% of the sugar beet crop would be treated. Using these added refinements, the aggregate cancer risk for the U.S. population was estimated to be 2.5 x 10-6, a value that falls within the Agency's risk standard as an acceptable cancer risk.

Residential Exposure and Risk

At this time, tetraconazole is not registered for any homeowner use, nor for any professional use that could result in residential post-application exposures. Therefore, the potential for residential exposure and risk is nil.

Occupational Exposure:

Tetraconazole is to be applied to sugar beets in Colorado, Michigan, Minnesota, Montana, Nebraska, North Dakota and Wyoming as a foliar spray by ground boom machinery, by aircraft and by chemigation including center pivot, lateral move, end tow, side (wheel) roll, traveler, big gun, solid set or hand move irrigation systems. The rate of application is 13 fluid ounces of product per acre (0.1 lb a.i./A) with a maximum application rate of two applications per season. Dilute spray volumes are 20 - 150 gallons of water per acre and concentrate sprays are delivered in 5 - 10 gallons of water per acre.

Handler risks do not exceed the Agency's level of concern when handlers wear the personal protective equipment (PPE) and clothing listed on the proposed labels (long-sleeved shirt, long pants, chemical resistant gloves, and shoes plus socks). The re-entry interval (REI) is 24 hours.

The highest estimated cancer risk is 6.7 x 10-4 for mixer/loaders working without gloves, However, the labeling requires gloves and the estimated cancer risk for mixer/loaders wearing gloves falls to 7.5 x 10-6. The remaining risks to agricultural workers applying tetraconazole to sugarbeets range from 7.5 x 10-6 - 7.7 x 10-7. Post-application cancer risk is 5.1 x 10-6 or lower, which does not exceed the Agency's level of concern.

ENVIRONMENTAL FATE AND EFFECTS

A. Environmental Fate Characterization

A racemic mixture of tetraconazole was used as the active ingredient in all laboratory and field studies with the exception of the hydrolysis study (MRID 44367002) where the (+) isomer was used as

the active ingredient. There are insufficient environmental fate data to evaluate the fate and transport properties of individual tetraconazole isomers.

Tetraconzole does not have a single predominant route of dissipation. The compound is expected to be persistent (laboratory and field half-lives ranged from 106 days to more than 1 year) and moderately to slightly mobile in soil (linearized Kd values ranged from 7.7 ml/g in sandy soil to 580 ml/g for clay loam soil). Successive applications will result in year to year soil accumulation. Tetraconazole has potential to reach surface water via run-off and spray drift, and is less likely to reach ground water.

Tetraconazole is stable to hydrolysis in sterile pH 5, 7 and 9 aqueous buffer solutions (MRID 44367002). It is stable to photolysis on soil (t1/2 = 106 days; MRID 44367004) and photolysis in water (t1/2 = 107-215 days; MRID 44367003). Photo degradates in soil were identified as M14360-acid (8.9% of applied), M14360-difluoroacetic acid (6.1% of applied), triazolylacetic acid (4.9% of applied), M14360-alcohol (4.3% of applied), 1,2,4-triazole (3.7% of applied), and M14360-dihydro-isoquinoline-triazole (0.91% of applied). In water, photo degradates were identified as hydroxy-triazolyl-isobutanoic acid (15.6% of applied), tetrafluoroethoxy-triazolyl-isobutanoic acid (10.3% of applied), M14360-dihydro-isoquinoline-triazole (9.3% of applied), and 1,2,4-triazole (6.7% of applied).

Tetraconazole is stable to aerobic soil metabolism (t1/2 > 1 year; MRID 44367005)) and aerobic aquatic metabolism (t1/2 = 382 days and 320 days; MRID 44751319). Aerobic soil metabolism data show that bound residues were up to 16% of applied radioactivity suggesting tetraconazole has a tendency to bind to soil particles. Aerobic aquatic metabolism data show that tetraconazole partitioned from the water phase into the sediment phase (t1/2 (in water) = 7.9 and 27 days). CO2 production in the laboratory studies was generally low (< 0.3% of applied radioactivity). The registrant proposed that tetraconazole degrades to form M14360-difluoroacetic acid and M14360-alcohol, which further degrade to form M14360-acid and 1,2,4-triazole.

Tetraconazole has slight to moderate mobility potential (McCall et al., 1980) in most soils (linearized Kd (Kdl) values were 7.7 mL/g in sandy soil, 7.0 mL/g in loamy sand, 10.7 mL/g in clay soil, and 580 mL/g in clay loam soil) (MRID 44367006). There is a strong correlation between soil organic carbon (% OC) and Kdl values for different soils (R2 = 0.99), which indicates tetraconazole sorption is dependent on soil organic carbon. Column leaching studies indicate that tetraconazole has a low potential for leaching. There were no residues detected in the leachate below a depth of 10 inches and the total residues in the leachate did not exceed 0.37% of applied radioactivity.

The results of terrestrial field dissipation studies conducted in the U.S. are consistent with laboratory findings. On bare ground plots in GA and CA, tetraconazole (Eminent 125SL) dissipated very slowly (t1/2 > 1 year) and did not show movement below a depth of 6-inches (MRID 44865405). The results indicate that tetraconazole has the potential to accumulate in soil with successive annual applications.

Tetraconazole has the potential to reach surface water due to its persistence and its tendency to accumulate in the top soil layer. Upon entering surface waters, tetraconazole is expected to readily partition from the water column into the sediment, sorb onto the sediment and then degrade very slowly (MRID 44751319), most likely forming polar compounds. Tetraconazole's slight to moderate mobility in soil imply a low potential to contaminate ground water. However, under some environmental conditions,

such as preferential flow conditions and in structural and sandy soils, tetraconazole residues may reach ground water resources.

Although tetraconazole has some potential to bioaccumulate in fish tissue (log Kow = 3.56 at 23 0 C), there was nearly complete elimination (> 98% of the accumulated [14C]residues) by day 2 for the 4 Fg/L dose or day 5 for the 40 Fg/L dose of the depuration period. The bioaccumulation factor in whole rainbow trout was 39-42x (MRID 44751320).

B. Ecological Effects Characterization

Tetraconazole is moderately toxic to freshwater and estuarine/marine fish; moderately toxic to freshwater invertebrates; and highly toxic to estuarine/marine invertebrates. At the proposed application rate, there were no statistically significant toxic effects to terrestrial or aquatic plants. Tetraconazole is practically non-toxic to honeybees on an acute contact basis. In addition, no toxic effects were observed in a honeybee oral acute study. Tetraconazole is slightly toxic to mammals on an oral acute basis. The chemical is moderately toxic to birds on an acute oral basis. It is highly toxic to the Mallard duck, but only moderately toxic to the bobwhite quail on a subacute dietary basis. Reproductive chronic effects were observed in birds and mammals. Tables 3, 4, and 5 summarize the most sensitive ecological toxicity endpoints for aquatic organisms, terrestrial organisms, and aquatic and terrestrial plants, respectively, which were used for risk characterization. Discussions of the effects of tetraconazole on aquatic and terrestrial taxonomic groups are presented below.

Table 3. Summary of Acute and Chronic Aquatic Toxicity Data used for Risk Quotient Calculation for Tetraconazole Application to Sugarbeets					
Species	**Acute Toxicity**			**Chronic Toxicity**	
	96-hr LC_{50} (mg/L)	**48-hr EC_{50} (mg/L)**	**MRID**	**NOAEC / LOAEC (mg/L)**	**Most Sensitive Endpoint (MRID)**
Bluegill sunfish *Lepomis macrochirus* Freshwater Fish	3.85	--	Moderately Toxic (443670-17)	--	--
Water flea *Daphnia magna* Freshwater Invertebrate	--	2.63	Moderately Toxic (443670-18)	0.19/0.29	Reproduction (458232-01)
Fathead minnow *Pimephales promelas* Freshwater Fish Early Life Stage	--	--	--	0.30/0.96	Growth (458232-08)
Sheepshead minnow *Cyprinodon variegatus* Estuarine/Marine Fish	> 3.4	--	Moderately Toxic (458232-06)	NOAEC = 0.26	Estimated value*
Eastern oyster *Crassostrea virginica* Estuarine/Marine Invertebrate	EC_{50} = 0.99	--	Highly Toxic (458232-02)	--	--
Mysid shrimp *Americamysis bahia* Estuarine/Marine Invertebrate	0.44	--	Highly Toxic (458232-03)	NOAEC = 0.032	Estimated value**

* A chronic estuarine/marine fish study was not proved. Estimated value is based on the assumption that the estuarine/marine fish acute to chronic ratio is similar to the freshwater fish acute to chronic ratio.

** A chronic estuarine/marine mysid study was not proved. Estimated value is based on the assumption that the estuarine/marine mysid acute to chronic ratio is similar to the freshwater invertebrate acute to chronic ratio.

Table 4. Summary of Aquatic and Terrestrial Plant Toxicity Data used for Risk Quotient Calculation for Tetraconazole Application to Sugarbeets			
Species	**Toxicity**	**NOAEC**	**Affected Endpoint (MRID)**
Duckweed *Lemna gibba*	EC_{50} = 0.31 mg/L	0.032 mg/L	Frond Number (458422-01)
Terrestrial plants, Seedling Emergence * Tier I Study	EC_{25} >0.1 lb a.i./A	0.1 lbs a.i./A	(458232-09) no statistically significant reduction in measured endpoints at the single application rate of 0.1 lbs/acre
Terrestrial plants, Vegetative Vigor * Tier I Study	EC_{25} >0.1 lb a.i./A	0.1 lbs a.i./A	(458232-10) no statistically significant reduction in measured endpoints at the single application rate of 0.1 lbs/acre

Table 5. Summary of Terrestrial Acute and Chronic Toxicity Data used for Risk Quotient Calculation for Tetraconazole Application to Sugarbeets						
Species	**Acute Toxicity**				**Chronic Toxicity**	
	LD_{50}	**Acute Oral Toxicity (MRID)**	**5-day LC_{50}**	**Subacute Dietary Toxicity (MRID)**	**NOAEC(L)/ LOAEC(L)**	**Affected Endpoints (MRID)**
Mallard duck *Anas platyrhynchos*	131 mg/kg-bwt	Moderately Toxic (443670-11)	382 mg ai/kg-diet	Highly Toxic (443670-12)	10/50 mg/kg diet	Survival and Growth (443670-14)
Laboratory rat *Rattus norvegicus* male	1030 mg/kg-bwt	Slightly Toxic (442681-12)	--	--	10/70 mg/kg bw	Parental mortality and reproductive toxicity (443053-06)

* species tested: monocot: corn, onion, ryegrass, wheat; dicot: bean, cabbage, lettuce, radish, soybean, tomato

IV. RISK CHARACTERIZATION

A. Risk Estimation - Integration of Exposure and Effects Data

Results of the exposure and toxicity effects data are used to evaluate the likelihood of adverse ecological effects on non-target species. For the assessment of tetraconazole risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The RQs are compared to the Agency's Levels of Concern (LOCs). These LOCs are the Agency's interpretive policy and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. These criteria are used to indicate when a pesticide's use as directed on the label has the potential to cause adverse effects on non-target organisms.

1. Nontarget Aquatic Animals, Invertebrates, and Plants

No LOCs are exceeded for aquatic organisms (freshwater and estuarine/marine fish and invertebrates and aquatic plants) on an acute or chronic basis. Acute and chronic RQs could not be calculated for estuarine/marine fish. Although a definitive LC50 for estuarine/marine fish was not available, the non-definitive LC50 (>3400 µg/L, MRID 458232-06) is comparable to the definitive freshwater fish LC50 (3850 µg/L, MRID 443670-17), suggesting similar or reduced acute sensitivity to tetraconazole.

2. Nontarget Terrestrial Animals

Avian Risk

For the single-oral dose scenario at the proposed label rate of two applications per year, small birds (20 g) consuming short grass exceeds the Acute Risk LOC (0.5), and small birds consuming tall grass and broadleaf plants and small insects exceed the Acute Restricted Use LOC (0.2). Medium-sized birds (100 g) consuming short grass exceed the Acute Restricted LOC. Small and medium-sized birds consuming all food groups except the fruits, pods, and large insects group, exceed the Acute Endangered LOC (0.1). For the alternative one application scenario, there are still exceedances for both small and medium sized birds. Acute Restricted Use LOC's are exceeded for small birds consuming short grass. Acute Endangered LOC's are exceeded for small birds consuming tall grass and broadleaf plants/small insects and medium sized birds consuming short grass. There are no exceedances for large birds (1000 g) for one and two applications. There are no exceedances for the food group, fruits, pods, and large insects for all sized birds and both application scenarios.

For the dietary-based scenario, the Acute Endangered LOC for birds consuming short grass is exceeded for two applications (RQ = 0.11). There are no acute LOC exceedances for birds when one application of tetraconozole is applied. For both single and double applications, avian chronic LOCs (1.0) are exceeded for all wildlife food types except fruits, pods, seeds, and large insects (exceeding RQs range from 1.12 to 4.06).

Mammalian Risk

There were no acute oral dose-based LOCs exceeded for mammals for both one and two applications per year. However, mammalian chronic oral dose-based LOCs are exceeded for all food types except seeds for both application rates. Exceeding RQs range from 1.14 to 21.16 for one application and 1.88 to 35.12 for two applications per year. The chronic oral dose-based RQs were greatest for small mammals consuming short grass.

Acute dietary-based LOCs were not determined because a subacute dietary laboratory test is not regularly performed. For both single and double applications, mammalian chronic dietary-based LOCs are exceeded for all food types except fruits, pods, seeds, and large insects, ranging from 1.86 to 4.06 for two applications.

B. Risk Description - Interpretation of Direct Effects

1. Risks to Aquatic Organisms and Plants

Freshwater fish and aquatic invertebrates are not at an acute or chronic risk from exposure to tetraconazole (RQs were orders of magnitude less than the LOCs) at the proposed application rate based on the Minnesota and California scenarios. Similar conclusions were reached for marine/estuarine fish and invertebrates, although chronic risk is based on an extrapolation using the acute-to-chronic ratios in freshwater species and the acute toxicity values for estuarine/marine species. Acute RQ values for aquatic plants are also well below the LOC for acute risk and acute endangered risk.

2. Risks to Terrestrial Organisms and Plants

Direct application of tetraconazole to the field leads to the conclusion that exposure is likely to terrestrial organisms that are foraging or nesting in or near the treated field. Birds and mammals in treated fields may be exposed to spray applications of pesticides by ingesting material directly with the diet. They may also be exposed by other routes, such as incidental ingestion of contaminated soil, dermal contact with treated plant surfaces and soil during activities in the treated areas, direct impingement of sprayed material on the body at the time of application, preening activities, inhalation of pesticide vapor and contaminated particulate, and ingestion of drinking water contaminated by the pesticide. Currently, acute exposures to birds and mammals are estimated only via the dietary route in the screening assessment.

C. Threatened and Endangered Species Concern

1. **Avian Species:** Four threatened and endangered birds, the bald eagle, whooping crane, piping plover, and interior least tern, were identified that are collocated within counties in the seven states where sugar beets. However, these species are not likely to be adversely altered by direct or indirect effects. These species usually do not forage or inhabit grasses or broadleaf plants near farm fields.

2. **Mammalian Species:** Four threatened and endangered mammals, the gray wolf, grizzly bear, black-footed ferret, and Preble's meadow jumping mouse, were identified that are collocated within counties in the seven states where sugar beets are grown. The gray wolf and the grizzly bear are not likely to be adversely altered by direct or indirect effects due to their diet and habitat preferences.

The US Fish and Wildlife Service is currently considering a petition to delist the Preble's mouse. This petition is based on the review of available information which indicates that the Preble's mouse is not a discrete taxonomic entity, does not meet the definition of a subspecies, and was listed in error. Risk refinements will not be necessary if this species is removed from the list. A final rule will be made in May 2005 (FR Vol. 70. No. 21. February 2, 2005).

The black-footed ferret is possibly collocated in a total of 13 counties in three states (MT, NE, and WY) based on EFED's LOCATES Database. There may be a potential for indirect adverse effects based on an endpoint of increased length of gestation. It is possible that the availability of prey for the black-footed ferret could be reduced. The black-footed ferret feed on prairie dogs and other small mammals that may chronically contain tetraconazole residues.

SUMMARY OF DATA GAPS

As a condition of registration, the registrant will be required to provide the following:

1. One side-by-side sugar beet field trial comparing two and six applications of Eminent® 125SL at 0.10 lb ai/acre/application.

2. 28-Day Inhalation study based on the current use pattern. This study can be performed as OPPTS Guideline 870.3465, 90-Day inhalation, but carried out only for 28 days rather than 90 days.

3. A study determining the toxicity of tetraconazole residues to benthic organisms (including chronomid) is requested (850.1790, Chironomid Sediment Toxicity Test).

4. Because tetraconazole accumulates and persists in the soil of treated fields, there are uncertainties associated with risks to soil invertebrates. A study determining the toxicity of tetraconazole residues to earthworms is requested (850.6200, Earthworm Subchronic Toxicity Test).

5. A new guideline adsorption/desorption study (163-1) is requested to address uncertainties in the risk assessment and satisfy the data requirements. The study should fulfill the following requirements:

a. One of the soils used should be the same type of soil used in the aerobic soil metabolism study. The aerobic soil metabolism study (MRID 44367005) used a sandy loam soil from Davidson, Georgia.

b. The study should avoid the use of soils with high organic matter content. Soils with high organic matter content may not be representative of the agricultural soils in intended use areas and may not be appropriate for assessing the mobility of the test material.

c. One of the soils used in the study should have an organic matter content of < 1%.

d. Soil columns should be leached with 0.01-0.02 N CaCl2 solution and not distilled water. The use of distilled water could cause particles to disperse, thereby decreasing the rate of infiltration and leaching. Also, the use of distilled water may lead to the removal of sorbed ions from soil particles, thereby affecting the degree of adsorption of the test material.

e. The soils used in the adsorption/desorption study should be characterized using the USDA soil textural classification system."

6. Well documented estimates of how many pounds of tetraconazole will be placed on the market to treat sugar beets;

7. Tetraconazole use reporting on sugar beets. This information should be reported as how many pounds tetraconazole will be applied per acre on sugar beets and how many acres of sugar beets will be treated.

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DISCLAIMER: The information in this Pesticide Fact Sheet is for information only and is not to be used to satisfy data requirements for pesticide registration. The information is believed to be accurate as of the date on the document.

APPENDIX I:

GLOSSARY OF TERMS AND ABBREVIATIONS

ADNT Acute delayed neurotoxicity
a.i. Active Ingredient
aPAD Acute Population Adjusted Dose
ARI Aggregate Risk Index
BCF Bioconcentration Factor
CAS Chemical Abstracts Service
ChE Cholinesterase
ChEI Cholinesterase inhibition
cPAD Chronic Population Adjusted Dose
%CT Percent crop treated
DAT Days after treatment
DEEM-FCID Dietary Exposure Evaluation Model - Food Consumption Intake Database
DNA Deoxyribonucleic acid
DNT Developmental neurotoxicity
DIT Developmental immunotoxicity
DWLOC Drinking Water Level of Comparison.
EC Emulsifiable Concentrate Formulation
EEC Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EPA U.S. Environmental Protection Agency
FQPA Food Quality Protection Act
GLC Gas Liquid Chromatography
GLN Guideline Number
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**
mg/kg/day	**Milligram Per Kilogram Per Day**
mg/L	**Milligrams Per Liter**
MOE	**Margin of Exposure**
MRID	**Master Record Identification (number), EPA's system of recording and tracking studies submitted**
MTD	**Maximum tolerated dose**
NA	**Not Applicable**
NOEC	**No Observable Effect Concentration**
NOEL	**No Observed Effect Level**
NOAEL	**No Observed Adverse Effect Level**
NOAEC	**No Observed Adverse Effect Concentration**
NPDES	**National Pollutant Discharge Elimination System**
OP	**Organophosphate**
OPP	**EPA Office of Pesticide Programs**
OPPTS	**EPA Office of Prevention, Pesticides and Toxic Substances**
PAD	**Population Adjusted Dose**
PAG	**Pesticide Assessment Guideline**
PAM	**Pesticide Analytical Method**
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**
RAC	**Raw Agriculture Commodity**
RBC	**Red Blood Cell**
RED	**Reregistration Eligibility Decision**
REI	**Restricted Entry Interval**
RfD	**Reference Dose**
SCI-GROW	**Tier I Ground Water Computer Model**
SF	**Safety Factor**
TGAI	**Technical Grade Active Ingredient**
UF	**Uncertainty Factor**
µg	**micrograms**
µg/L	**Micrograms Per Liter**
µL/g	**Microliter per gram**

USDA **United States Department of Agriculture**
WPS **Worker Protection Standard**

Appendix II

Citations Considered to be Part of the Data Base Supporting the Registration of Tetraconazole

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