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



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Date: November 2, 2006

MEMORANDUM

SUBJECT: Section 3 Request for Tebuconazole Uses on Pome Fruit Crop Group, Wheat and

Barley, Tree Nut Group and Pistachio, Corn (including Corn Seed Treatment) and soybean, Stone Fruits Except Cherries, Turnips (IR-4 Petition), Hops (IR-4 Petition), Cucurbits (IR-4 Petition), Sunflower (IR-4 Petition), Okra (IR-4 Petition), Lychee

(IR-4 Petition), Turf, and Ornamentals.

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Attached please find the Environmental Fate and Effects Division's (EFED) environmental risk assessment for the proposed registration of tebuconazole as a fungicide on the following: (1) pome fruit crop group, (2) wheat and barley, (3) tree nut group and pistachio, (4) corn (including corn seed treatment) and soybean, (5) stone fruits except cherries, (6) turnips (IR-4 petition), (7) hops (IR-4 Petition), (8) cucurbits (IR-4 petition), (9) sunflower (IR-4 petition), (10) okra (IR-4 petition), (11) lychee (IR-4 petition), (12) turf, (13) and ornamentals. This document addresses only the tebuconazole parent compound.

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Tebuconazole is a sterol demethylation inhibitor (DMI) fungicide. It is systemic and shows activity against rusts (*Puccinia spp.*) and powdery mildew infecting grasses grown for seed. Tebuconazole provides protective activity by preventing completion of the infection process. It is rapidly absorbed by plants and is translocated systemically in the young growing tissues. The proposed maximum annual rate ranges from 4.42 lb ai/ac for turf use to 0.23 lb ai/ac for wheat and barley uses. The proposed trade names for products containing tebuconazole include Lynx 45 WG, Lynx 2, Elite 45 DF, and Folicur 3.6F. Formulations come in water-soluble granule and water-soluble liquid concentrate. Depending on the crop being treated, products containing tebuconazole as an active ingredient can be applied by aerial or ground foliar spray, and chemigation (Lynx 45 WG and Lynx 2 on turf only). Exposure to aquatic organisms is predominantly from release to the environment by surface runoff and spray drift. Exposure to terrestrial organisms is predominantly from release to the environment by spray drift.

The terrestrial risk assessment was based on the EFED's T-REX model (version 1.2.3) and the water resource assessment was based on the PRZM/EXAMS modeling.

Risk Conclusions

Freshwater Animals and Aquatic Plants

Chronic risk RQs exceed the listed species LOCs for freshwater fish for use on ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, almond, bean, sunflower, soybean, cotton, and asparagus. The chronic RQs range from 1.1 to 8.0. The estuarine/marine invertebrate acute RQs exceed the listed species LOCs for use on ornamentals, turf, pome fruit, stone fruit, and corn, and beans and range from 0.08 to 0.12. There is much uncertainty about these RQs because the acute toxicity value of 1166 µg/L was derived from the acute to chronic ratio for freshwater invertebrates. The chronic RQs ranging from 1.2 to 4.0 for freshwater invertebrates exceeds the LOCs for the same uses. The aquatic vascular plant RQs exceed the listed species LOCs for the ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, and bean uses and range from 1.1 to 2.8. However, it must be pointed out that there is a great uncertainty here because the only data submitted for non-vascular plants was green algae.

Birds

Bird acute risk listed species level of concern is exceeded for turf, ornamental, pome fruit and stone fruit uses for small birds. Chronic concerns are identified for turf, ornamental and stone fruit uses.

Mammals

Acute risk to mammals based on an adjusted LD_{50} of 1404 mg/kg-bw only triggered risks to the turf use for 15 and 35 g mammals foraging on short grass, and these risks were marginal (RQ = 0.16 and 0.13, respectively). These risks could be easily mitigated by a slight reduction the use rate.

Chronic risk to mammals from dose-based RQs exceed the chronic LOCs for use on turf, pome fruit, stone fruit, almond, pecan, pistachio, hops, lychee, cotton, okra, beans, asparagus, sunflower and soybean. These RQs range from 14.78 for all weight classes of mammals when used on turf to a RQ of 1.09 for 15 g mammals when used that the use on sunflower.

Terrestrial Plants

Results of seedling emergence tests indicate that risk quotients from single applications to turf exceed the acute LOCs for non-listed plants found in semi-aquatic areas for both aerial and ground applications (RQs = 4.13 and 3.37, respectively). Listed plant single application RQs exceed the LOCs for many other uses. In addition to turf, these uses include pome fruit, stone fruit, almonds, pistachio, cotton, lychee, corn, bean, okra, asparagus, turnip, sunflower, wheat, and barley. The RQs range from 1.02 to 22.05 and include plants found adjacent to treated areas as well as plants in semi-aquatic areas.

Multiple application RQs exceed acute risk LOCs for most all of the use sites when the sums of the exposure from each application is used to calculate the RQs for terrestrial plants. The acute RQs to non-listed plants that exceed the LOCs range from 1.04 to 12.98 and the listed species RQs range from 1.48 to 78.75. It should also be noted that the total additive exposure would have to be greater than 20 lb ai/A in order for the vegetative vigor RQs to exceed the LOCs. In addition, the monocot seedling emergence additive exposure rate would have to be just below 2.0 lb ai/A to bring the turf RQs below the LOCs.

Summary of Potential concerns for Listed Species

The following table summarizes the areas of potential concern for direct and indirect adverse effects to federally-listed threatened or endangered plants and animals (listed species).

Listed Taxon	Direct Effects		Indirect Effects	
	Use sites	Finding	Use Sites	Finding
Terrestrial and semi- aquatic plants - monocots	Turf,	Yes	All uses	Yes Direct effects to terrestrial invertebrates based on insufficient data to preclude concern
Terrestrial and semi- aquatic plants - dicots	Turf, pome fruit, stone fruit, almond, pistachio, cotton, corn, lychee, okra, bean, asparagus, turnip, sunflower	Yes	All uses	Yes Direct effects to terrestrial invertebrates based on insufficient data to preclude concern
Terrestrial invertebrates	All uses	Insufficient data to preclude concern		
Birds	Turf, ornamentals, pome/stone fruit	Yes Acute and/or chronic concerns	All uses	Yes Direct effects to plants Direct effects to terrestrial invertebrates based on insufficient data to preclude concern

Listed Town	Dire	ect Effects	Indire	ect Effects
Listed Taxon	Use sites	Finding	Use Sites	Finding
Terrestrial phase amphibians	Turf, ornamentals pome/stone fruit	Yes Based on avian results	Turf, pome fruit, stone fruit, almond, pistachio, cotton, corn, lychee, okra, bean, asparagus, turnip, sunflower	Yes Direct effects to plants
Reptiles	Turf, ornamentals pome/stone fruit	Yes Based on avian results	Turf, pome fruit, stone fruit, almond, pistachio, cotton, corn, lychee, okra, bean, asparagus, turnip, sunflower	Yes Direct effects to plants
Mammals	All uses	Yes Acute and/or chronic concerns	Turf, ornamentals, pome/stone fruit Turf, pome fruit, stone fruit, almond, pistachio, cotton, corn, lychee, okra, bean, asparagus, turnip, sunflower	Yes Direct effects to terrestrial invertebrates based on insufficient data to preclude concern Yes Direct effects on birds,amphibians, reptiles Yes Direct effects to plants
Aquatic plants	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, and bean	Yes (vascular) No(nonvascular)	Not applicable	Not applicable
Freshwater fish	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, almond, bean, sunflower, soybean, cotton, asparagus	Yes Predominantly chronic effects	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, and bean	Yes Direct effects on aquatic plants

Listed Taxon	Direct Effects		Indirect Effects	
	Use sites	Finding	Use Sites	Finding
Aquatic phase amphibians	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, almond, bean, sunflower, soybean, cotton, asparagus	Yes Based on Fish results	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, and bean	Yes Direct effects on aquatic plants
Freshwater crustaceans	All uses	No	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, and bean	Yes Direct effects on aquatic plants
Freshwater mollusks	All uses	No Surrogate is most sensitive invertebrate tested	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, almond, bean, sunflower, soybean, cotton, asparagus	Yes Direct effects on fish
Marine/estuarine fish	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, almond, bean, sunflower, soybean, cotton	Yes Predominantly chronic effects	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, and bean	Yes Direct effects on aquatic plants
Marine/estuarine invertebrates	Ornamentals, turf, pome fruit, stone fruit, corn, beans (all)	Yes Predominantly chronic effects	Ornamentals, turf, pome fruit, stone fruit, corn, hops, pecan, pistachio, cucumber, and bean	Yes Direct effects on aquatic plants

Environmental Fate

Tebuconazole is persistent in soil (aerobic metabolism $T_{1/2} = 796$ days) and moderately mobile to relatively immobile (adsorption K_{DS} range from 7.69 to 16.39, adsorption K_{DS} range from 906 to 1251 ml/g). Tebuconazole has little potential to reach ground water, except in soils of high sand and low organic matter content. During a runoff event, tebuconazole adsorbed onto the soil particles could enter adjacent bodies of surface water via runoff. During an application, tebuconazole may drift off site into the surface water.

Tebuconazole is resistant to hydrolysis ($T_{1/2} >> 28$ days or stable at pH 5, 7, and 9), aqueous and soil photodegradation [$T_{1/2}$ = stable (extrapolated $T_{1/2}$ = 590 days and 192.5 days, respectively)], and soil metabolism (aerobic metabolism $T_{1/2}$ = 796 days).

Terrestrial field dissipation half-lives varied from about 1.6 to 4 months and beyond (i.e. 10 months). A supplemental study on bare ground in Florida showed leaching of tebuconazole into a lower soil horizon. In sand soil of Vero Beach, FL (sand = 92%, silt = 0.4%, clay = 7.6%, and organic matter = 1%) tebuconazole was detected up to 0.12 ppm in the depth of 6 to 12 inches 30 days after surface application of - 1.5 lb. a.i./acre (lower depths were not sampled, MRID 40700963). In addition, tebuconazole has a low potential for bioaccumulation in fish tissues (BCFs = 25X, 228X, and 99X for edible, nonedible, and whole fish tissues).

Based on registrant-submitted tebuconazole field residue studies, tebuconazole foliar dissipation half-life ranged from 1.2 days in wheat forage to 8.4 days in soybean forage.

Uncertainties and Data Gaps

The following uncertainties have been identified on the environmental fate properties and exposure models for tebuconazole. .

- 1. Formulation effects on the dissipation of tebuconazole in the environment are not known at this time. For purposes of the risk assessment, it is assumed that formulation types do not alter dissipation rates and pathways when compared to the technical product.
- 2. The water column metabolism parameter used by EXAMS was estimated from the aerobic soil metabolism by multiplying the aerobic soil metabolism input parameter by 2 to reflect the uncertainty in this extrapolation.
- 3. In the PRZM/EXAMS modeling, to describe soil:water partition coefficient, the lowest non-sand K_D values was used for sandy loam since there was no statistically significant relationship between K_D values and the organic carbon content (the coefficients of determination $r^2 = 0.75$, lower 95% confidence level = -16.4, upper 95% confidence level = 22.0, and P = 0.14, n=4). The graphical analysis, however, illustrates a positive linear relationship between SOC and K_D . In addition, the lack of significance of the regression equation can be attributed to low sample size (n=4). Therefore, the input parameter of the average K_{oc} value was used in the second round of the model simulations to account for the uncertainty in the selection of the lowest non-sand K_D as the partition coefficient.
- 4. Tier II modeling indicates tebuconazole accumulation in the surface water. This is due to the high persistence of tebuconazole in aquatic and soil environments as well as the static nature (no flow) of the EFED small pond scenario. To account for the uncertainties associated with the static nature of the small pond scenario in the model, the RQs were estimated for the first year and the 1-in-10 year concentrations. While the RQs obtained for the first year concentrations are underestimating the risk, the RQs obtained for the 1-in10 year concentrations are potentially overestimating the risk.

- 5. Within each scenario, a change of tebuconazole application dates or rainfall pattern may be an important influence on the modeling results. Tebuconazole application dates were selected based on the expected disease pressure within the standard scenario region.
- 6. The assessment addresses the risk from the parent only. The ecological risk from tebuconazole degradate 1,2,4-trizole and tebuconazole intermediate degradates were not discussed in this document. Based on laboratory and field studies submitted to date, tebuconazole transformation products were detected at levels below ten percent of the applied parent. 1,2,4-Triazole degradate was detected at the maximum of 9% of the applied tebuconazole (Bayer Report # 103804).

A number of areas of uncertainty have been identified in the ecological risk portion of the assessment; since the majority of the risk appears to be with mammals and birds, these risk uncertainties have been identified as important in the risk assessment.

- 1. Other exposure routes are possible for birds in treated areas. These routes include ingestion of contaminated soils, ingestion of contaminated drinking water, preening, dermal contact, and inhalation.
- 2. The risk assessment only considers the most sensitive species tested.
- 3. The risk assessment assumes 100% of the avian diet is assigned to single food types foraged only from treated fields. Given that several food item residue estimates exceed levels of concern, assigning complex dietary mixtures of these components to modeled birds would not likely alter the risk assessment conclusions.
- 4. The exposure assessment used 95th percentile reside values. Values selected from points lower on the distribution would yield lower exposure estimates and lower RQs.

The environmental fate and transport database is complete with the exception of the aerobic and anaerobic aquatic metabolism data. The data would be beneficial in characterizing tebuconazole dissipation in the aquatic environment. It would also eliminate the uncertainty associated with the selection of the water column parameter for aquatic modeling. The submission of acute estuarine/marine data that could produce a valid EC₅₀ could reduce acute risk below the LOCs. Risk to terrestrial plants may potentially be underestimated due to the lack of definitive NOAELs for most of the crop species tested. The submission of Tier 2 data could greatly reduce the uncertainty of effects to terrestrial plants.