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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

PC Code: 113961
DP Barcode: 324660
Decision #: 341716

MEMORANDUM

November 6, 2006

SUBJECT: **Prothioconazole Section 3:** Revised Environmental Fate and Ecological Risk Assessment

TO: Tony Kish, Product Manager
Lana Coppolino, Product Manager
Registration Division (7505C)

FROM: Christopher Salice, Biologist
Roxolana Kashuba, Environmental Scientist
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507C)

THROUGH: Elizabeth Behl, Branch Chief
Thomas Steeger, Senior Biologist
R. David Jones, Senior Agronomist
Environmental Risk Branch IV
Environmental Fate and Effects Division (7507C)

Environmental Fate and Effects Division (EFED) has completed revisions of its ecological risk assessment for the new fungicide prothioconazole and its end-use product PROLINE® 480SC (41.0% a.i.). The fungicide is initially proposed for use on wheat, barley, oil seed (except sunflower and safflower), dried shell pea and bean (except soybean), peanut, and rice. A total toxic residues approach (including prothioconazole and two primary degradates: prothioconazole-desthio and prothioconazole-S-methyl) was used to estimate ecological exposure levels. Combined residues of concern are expected to be persistent and moderately mobile.

The results of this revised screening-level assessment indicate that there is a potential for direct adverse acute effects to non-target fresh- and saltwater non-vascular plants, freshwater vascular plants, and saltwater invertebrates other than mollusks at the proposed application rates for some uses. The results also indicate a potential for adverse effects associated with chronic exposures to mammals for all proposed uses of prothioconazole. For listed species, acute risk levels of

2053921

concern were exceeded for estuarine/marine invertebrates, semi-aquatic plants, aquatic plants, and freshwater fish. Listed species chronic risk levels of concern were exceeded for mammals.

Prothioconazole Recommended Label Language:

> "Prothioconazole-desthio (a degradate of prothioconazole) is toxic to shrimp. 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."
>
> "Prothioconazole-desthio (a degradate of prothioconazole) is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."
>
> "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff for several months or more after application. Poorly draining soils and soils with shallow watertables are more prone to produce runoff that contains this product. A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."

Status of Fate and Ecotoxicity Data for Prothioconazole:

Tables 1 and 2 list all of the available environmental fate and ecological effect studies, respectively, and the acceptability of each study. The major uncertainties in characterizing the environmental fate of prothioconazole involve non-rigorous soil extraction procedures, lack of complete information on the fate of the 1,2,4-triazole degradate, and inability to calculate parent adsorption coefficient and bioaccumulation factor. The major uncertainties in characterizing effects of prothioconazole and/or prothioconazole-desthio are associated with the toxicity of prothioconazole-desthio to estuarine/marine invertebrates, the lack of an acceptable sediment toxicity test, and the lack of data on the effects of the 1,2,4-triazole degradate. However, in general, all of the studies contained sufficient information on the fate and effects of prothioconazole for EFED to complete an ecological risk assessment of the chemical.

Table 1. Status of environmental fate data adequacy for prothioconazole.

Guideline		Description	MRID	Title	Substrate	Study Classification
161-1	835.212	Hydrolysis	46246505	Hydrolysis of [Phenyl-UL-^{14}C] JAU6476 in Sterile Aqueous Buffer Solutions.	Prothioconazole; phenyl label	Acceptable

Guideline		Description	MRID	Title	Substrate	Study Classification
161-1	835.212	Hydrolysis	46246506	SXX0665: Hydrolysis in Buffers.	Prothioconazole-desthio; phenyl label	Supplemental
161-2	835.224	Photolysis in Water	46246507	Photolysis of JAU6476 in Sterile Aqueous Buffer.	Prothioconazole; phenyl and triazole labels	Supplemental
161-3	835.241	Photolysis on Soil	46246510	Photolysis of JAU6476 on Soil Surface.	Prothioconazole; phenyl label	Acceptable
161-4	835.237	Photolysis in Air	---	---		Not required
162-1	835.42	Aerobic Soil Metabolism	46246511	Proazolthion (proposed) [JAU6476]: Degradation and Metabolism of JAU6476 in Aerobic Soils.	prothioconazole	Acceptable
162-1	835.42	Aerobic Soil Metabolism	46246512	Aerobic Degradation of JAU6476 in Two Soils	prothioconazole	Acceptable
162-1	835.42	Aerobic Soil Metabolism	46246513	Degradation of JAU6476-desthio (SXX0665) in Four Soils under Aerobic Conditions.	prothioconazole-desthio	Supplemental
162-1	835.42	Aerobic Soil Metabolism	46246514	Degradation of JAU6476-S-methyl (WAK7861) in Four Soils Under Aerobic Conditions.	prothioconazole-S-methyl	Supplemental
162-2	835.42	Anaerobic Soil Metabolism	---	---		Not required
162-3	835.44	Anaerobic Aquatic Metabolism	46246516	Anaerobic Aquatic Metabolism of JAU6476.	prothioconazole	Acceptable
162-4	835.43	Aerobic Aquatic Metabolism	46246515	Aerobic Degradation and Metabolism of the Active Ingredient JAU6476 in the Water/Sediment System	prothioconazole	Supplemental
163-1	835.1230 835.1240	Mobility	46246450	Adsorption/Desorption of [phenyl-UL-^{14}C] SXX0665 on Four Different Soils	prothioconazole-desthio	Acceptable
163-1	835.1230 835.1240	Mobility	46246501	Adsorption/Desorption of S-methyl-JAU6476 on Four Different Soils.	prothioconazole-S-methyl	Acceptable
163-1	835.1230 835.1240	Mobility	46246504	Aged Soil Column Leaching of JAU6476.	prothioconazole	Acceptable
163-1	835.1230 835.1240	Mobility	46246539	Leaching behaviour of JAU6476 formulated as 250 EC in soil (parent leaching).	prothioconazole (formulated product)	Supplemental
163-2	835.141	Laboratory Volatility	---	---		Not required
164-1	835.61	Terrestrial Field Dissipation	46246517 46246518 46246519	Terrestrial Field Dissipation of JAU6476 in California Soil, 1999. Terrestrial Field Dissipation of JAU6476 in Georgia Soil, 1999. Terrestrial Field Dissipation of JAU6476 in New York Soil, 1999.	prothioconazole (formulated product)	Supplemental Supplemental Supplemental

Guideline		Description	MRID	Title	Substrate	Study Classification
164-2	835.62	Aquatic Field Dissipation	46246522 46246523 46246524	Aquatic Field Dissipation of JAU6476 in a California Rice Field, 2000. Aquatic Field Dissipation of JAU6476 in an Arkansas Rice Field, 2000. Aquatic Field Dissipation of JAU6476 in a cropped Arkansas Rice Field, 2000.	prothioconazole (formulated product)	Supplemental Supplemental Supplemental
165-4	850.173	Accumulation in Laboratory Fish	46246034	(Carbon 14)-JAU6476-Bioconcentration and Biotransformation in Bluegill (Lepomis macrochirus) Under Flow-Through Conditions.	prothioconazole	Supplemental
165-4	850.173	Accumulation in Laboratory Fish	46246035	(Carbon 14)-JAU6476-Desthio - Bioconcentration and Biotransformation in Bluegill (Lepomis macrochirus) Under Flow-Through Conditions.	prothioconazole-desthio	Acceptable

Table 2. Status of ecological effects data adequacy for prothioconazole.

Guideline		Description	MRID	Title	Substrate	Study Classification
71-1	850.2100	Avian acute oral	462460-36 462460-37	Acute oral toxicity study with the Bobwhite	TGAI. SXX0665.	Acceptable Acceptable
71-2	OECD 205	Avian acute dietary	462460-38 462460-39	A dietary LC50 study with the Northern Bobwhite	TGAI. Desthio..	Acceptable
71-2	OECD 205	Avian acute dietary	462460-40	A dietary LC50 study with the Mallard	TGAI.	Acceptable
71-4a	--	Avian repro	462460-42 462460-43	Avian reproduction study in Northern Bobwhite	TGAI. Desthio. No.	Acceptable Acceptable
71-4b	--	Avian repro	462460-44 462460-45	Avian reproduction study in Mallard	TGAI. No. Desthio. No.	Acceptable Supplemental
72-1		Freshwater fish acute	462460-18 462460-19 462460-20 462460-21	An acute toxicity study with the Rainbow trout	TGAI. No. 480SC SXX0665. No. *S*-methyl.	Acceptable Acceptable Acceptable Acceptable
72-1		Freshwater fish acute	462460-22 462460-23	Acute toxicity to Bluegill sunfish	TGAI. 480SC	Acceptable Acceptable
Non-guideline	Non-guideline	Freshwater fish acute	462460-25	Acute toxicity to common carp	TGAI. No.	Supplemental
72-1a		Freshwater fish acute	462460-26	Acute toxicity to Fathead minnow	Desthio.	Acceptable

Guideline		Description	MRID	Title	Substrate	Study Classification
72-1a		Freshwater fish acute	462460-24	Acute toxicity to Golden orfe	SXX0665.	Invalid
72-2	OECD 202	Freshwater invertebrate acute	462460-09 462460-10 462460-11 462460-12	An acute toxicity study with the daphnid	TGAI. No. 480SC. SXX0665. *S*-methyl.	Acceptable Acceptable Supplemental Acceptable
Non-guideline	Non-guideline		462460-13	Acute toxicity study with crayfish	Desthio. No	Invalid
72-3a		Estuarine/ marine fish acute	462460-27	Acute toxicity study with the Sheepshead minnow	TGAI	Acceptable
72-3b		Oyster shell deposition	462460-14	Acute toxicity to Eastern Oyster	TGAI	Acceptable
72-3c		Estuarine/ marine invertebrate acute	462460-16 462460-17	Acute toxicity to Mysids	TGAI. No. Desthio. No.	Acceptable Acceptable
72-4a		Fish early life stage	462460-31 462460-32	Toxicity to the early life stages of the Rainbow trout	TGAI Desthio	Invalid Invalid
72-4b		Freshwater invertebrate life cycle	462460-28 462460-29	21-d chronic toxicity with the Daphnid	TGAI Desthio	Acceptable Acceptable
72-4c		Estuarine/ marine invertebrate life cycle	462460-30	Life cycle toxicity test with the Mysid	Desthio. No.	Acceptable
72-5		Estuarine/ marine fish life cycle	462460-33	Life-cycle toxicity test with the Fathead minnow	Desthio	Supplemental
122-1		Non-target plants seedling emergence/vegeta tive vigor	462460-49	Tier I seedling emergence/vegetative vigor	480SC	Acceptable
123-2a		Non-target plants, Tier II seedling emergence	462460-50	Tier II seedling emergence	480SC	Acceptable
123-2		Non-target plants; aquatic vascular plant toxicity test	462461-01 462461-02 462461-04	Toxicity to duckweed	TGAI 480SC. Desthio	Acceptable Acceptable Acceptable
123-2		Non-target plants; freshwater non-vascular plant toxicity test	462461-09	Acute toxicity to the freshwater diatom	TGAI	Acceptable

Guideline		Description	MRID	Title	Substrate	Study Classification
123-2		Non-target plants; marine non-vascular plant toxicity test	462461-10	Growth inhibition test with the marine diatom	TGAI	Acceptable
123-2		Non-target plants; freshwater non-vascular plant toxicity test	462461-05 462461-07 462461-08	Growth inhibition test with freshwater blue-green alga	TGAI *S*-methyl. SXX0665. No.	Acceptable Supplemental Acceptable
123-3		Non-target plants; freshwater non-vascular plant toxicity test	462461-03 462461-06	Toxicity to the freshwater green alga	TGAI 480SC	Acceptable Acceptable
141-1		Non-target insect contact toxicity test	462460-46 462460-48	Acute oral and contact toxicity tests with the honeybee	480SC TGAI	Acceptable Acceptable
N/A		Sediment-dwelling invertebrate toxicity test	462461-31 462461-32	Development and emergence of Chironomus larvae	TGAI SXX0665	Supplemental Supplemental