

264-824

03/27/2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

264-824

Date of Issuance:

MAR 27 2007

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Prothioconazole Technical
Fungicide

Name and Address of Registrant (include ZIP Code):

Bayer CropScience (Attention Mr. Mel Tolliver)
P.O.Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C), provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4.

2. You must submit the following conditional data listed below, on or before the associated due dates:

A. For the Developmental Neurotoxicity Study (MRID 46246418), brain morphometric measurements from the mid and low dose animals must be submitted by December 1, 2007, as well as addressing the other deficiencies listed in the DER to allow the reconsideration of the FQPA database uncertainty factor.

B. The final report of the ongoing storage stability study with prothioconazole and desthio-prothioconazole in plant commodities (interim results for which were reported in MRID 46477701) must be submitted by March 31, 2008.

C. Submit a poultry feeding study with prothioconazole by June 30, 2008.

Signature of Approving Official:

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Cynthia Giles-Parker, Chief
Fungicide Branch
Registration Division (7505P)

Date:

MAR 27 2007

D. Data must be generated and submitted by December 1, 2007 to confirm the degree of stability of the prothioconazole-4-hydroxy in ruminant fat for a duration of 45 days.

E. Based on the proposed tolerance expressions and the proposed enforcement methods, analytical reference standards for the following compounds must be submitted by July 1, 2007, and supplies replenished as requested by the EPA Pesticide Repository:

prothioconazole-desthio [JAU6476-desthio; α -(1-chlorocyclopropyl)- α -[(2-chlorophenyl)methyl]-1*H*-1,2,4-triazole-1-ethanol]

prothioconazole sulfonic acid potassium salt [potassium salt of JAU6476 sulfonic acid; 1-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1*H*-1,2,4-triazole sulfonic acid, potassium salt]

[triazole-¹⁵N-¹³C]prothioconazole

[triazole-¹⁵N-¹³C]prothioconazole-desthio

[triazole-¹⁵N-¹³C]prothioconazole sulfonic acid

F. Submit raw data from field fortifications in MRID 46246447 (in addition to the percent conversions reported in the study), by December 1, 2007.

G. The proposed data collection and enforcement methods for livestock commodities must be validated for poultry commodities. The EPA labs validated the livestock method for liver and milk. If the poultry method is the same or essentially the same, then the registrant at a minimum must present an argument and confirm (in writing, not in the lab) that the cow liver LOQ covers chicken liver. At a maximum, the registrant must validate the method for poultry commodities, including a demonstration of the LOQs. Presumably that would be done as part of the poultry feeding study. In no case is an ILV needed; no further work is needed by EPA labs. These data/information must be submitted by June 30, 2008.

H. In the Agency's risk assessment for 1,2,4-triazole and its metabolites triazole alanine, and triazole acetic acid, dated February 7, 2006 (see docket number 2005-0497 at <http://www.regulations.gov>), the Agency identified additional data that are needed for triazole-derivative active ingredients which have the 1,2,4,-triazole ring. The Agency plans to issue a Data Call-In for all triazole-derivative active ingredients which will identify all data needs for these active ingredients listed in the February 7, 2006 risk assessment. The Data Call-In will not address data needs that are related to parent-only data requirements.

I. The sediment toxicity study using chironomids was classified as SUPPLEMENTAL because it did not follow Agency guidelines and because not all exposure levels were analytically verified. Therefore, submit by December 1, 2007, a repeat study following Agency guidelines in which the chemical is first added to the sediment. This is expected to reduce some uncertainty associated with assessing risks to sediment dwelling invertebrates.

3. You must submit two copies of a final printed label within 45 days from the date of this Notice, or sooner if shipped before 45 days, which makes the following changes:

A. In the chemical name, change the left and right parentheses to brackets as shown below:

2-[2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione

B. Change the EPA Reg No. from 264-IEU to 264-824.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

If you have any questions about this notice, please feel free to call Tony Kish at 703-308-9443. A copy of the label stamped "Accepted with comments" is enclosed for your records.

MAR 27 2007

Prothioconazole Technical Fungicide

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
264-824

For use in the manufacture of fungicides

ACTIVE INGREDIENT: Prothioconazole, 2-(2-(1-chlorocyclopropyl)-3-(2-Chlorophenyl)-2-hydroxypropyl)-1,2-dihydro-3H-1,2,4-triazole-3-thione.....	97.7%
INERT INGREDIENTS:	2.3%
TOTAL:	100%

EPA Reg. No. 264-IEU

EPA Est. No.

STOP – Read the label before use
KEEP OUT OF REACH OF CHILDREN
CAUTION

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF INHALED:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: No specific antidote is available. Treat symptomatically.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if absorbed through the skin, swallowed, or inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, and clothing, and avoid breathing dust. Wash thoroughly with soap and water after handling, and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

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.

STORAGE & DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Store in original container and out of the reach of children, preferably in a locked storage area.

Handle and open container in a manner as to prevent spillage. If the container is leaking or material spilled for any reason or cause, carefully sweep material into a pile. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Dispose of pesticide as directed below. In spill or leak incidents, keep unauthorized people away. You may contact the Bayer CropScience Emergency Response Team for decontamination procedures or any other assistance that may be necessary. The Bayer CropScience Emergency Response Telephone No. is 1-800-334-7577.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Detailed information on chemical and physical properties and other formulating recommendations for Prothioconazole are available upon request from Bayer CropScience. Obtain and read this information before undertaking the formulation of Prothioconazole in order to avoid formulation hazards and insure a satisfactory finished product.

Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency. For specific information on federally registered uses, contact Bayer CropScience. Any variance from the federally registered labeling for products containing Prothioconazole will have to be supported by data provided by the formulator.

Prothioconazole Technical Fungicide is intended for formulation into end-use products for

- 1) **Terrestrial Food Crops:** barley, canola, dried shelled pea and bean (except soybean) subgroup, peanuts, rapeseed, Indian rapeseed, field mustard, crambe and wheat.
- 2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration or,
- 3) Uses for experimental purposes that are in compliance with USEPA requirements

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCES ELECTION, THE REPLACEMENT OF PRODUCT.

NET WEIGHT:

PRODUCED FOR

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)

Prothioconazole Technical (PENDING) 01-08-07