

264-824

05/28/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

May 28, 2010

Melvin K. Tolliver  
Registration Product Manager  
Bayer CropScience LP  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

Subject: Prothioconazole Technical Fungicide  
EPA Registration Number 264-824  
Amendment submitted September 26, 2008; Decision No. 403608  
Pesticide Petition No. 8F7485; Decision No. 403615  
Cereal Crop Groups 15 & 16 (except Sorghum, Rice)

Dear Mr. Tolliver,

The label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided within 45 days you submit two copies of a revised final printed label complying with condition #1 below, and satisfy the other conditions herein.

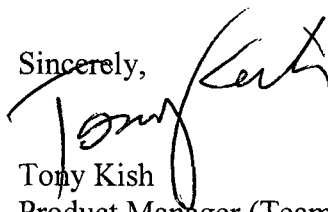
1. On page 2 of the label version dated 5/27/10, under the "Directions For Use" in the item #1 list of uses, delete "cereal grain group 16 (except sorghum and rice)". It is not needed because the product is applied to the grain crops in group 15 and not applied separately to the group 16 forage, fodder, and straw from these grain crops, which have separate higher tolerances. Also delete "sweet corn" because it is already included in group 15.

2. As per the EPA letter dated 4/9/09 for EPA Reg 264-825, by May 1, 2011, submit a valid immunotoxicity study which satisfies guideline requirement 870.7800. An immunotoxicity study is required to meet current guideline requirements. The previously submitted immunotoxicity study (MRID 42626438) in the mouse is part of the existing data base, but this study as reported does not satisfy the current guideline requirements for an immunotoxicity study.

3. 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 like prothioconazole 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.

A copy of the label stamped "Accepted with Comments" is enclosed for your records. Should you have any questions please contact Tawanda Maignan at (703) 308-8050 or via e-mail at [Maignan.Tawanda@epa.gov](mailto:Maignan.Tawanda@epa.gov).

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Prothioconazole Technical Fungicide  
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Sincerely,  
  
Tony Kish  
Product Manager (Team 22)  
Fungicide Branch  
Registration Division (7504P)

ACCEPTED  
with COMMENTS  
In EPA Letter Dated

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MAY 28 2010  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
264-824

# Prothioconazole Technical Fungicide

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. 264-824

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

<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>Immediately call a poison control center or doctor for treatment advice.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
<p>For <b>MEDICAL</b> Emergencies Call 24 Hours A Day 1-800-334-7577.</p> <p>Have the product container or label with you when calling a poison control center or doctor or going for treatment.</p>	
<p><b>NOTE TO PHYSICIAN:</b> No specific antidote is available. Treat symptomatically.</p>	

## 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.

### 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:** Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. 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, cereal grain group 15 (except sorghum, and rice), cereal grain group 16 (except sorghum, and rice), dried shelled pea and bean (except soybean) subgroup, peanuts, rapeseed, Indian rapeseed, field mustard, crambe, soybean, sugar beets, sweet corn, 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.

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**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 CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

**NET WEIGHT:**

**PRODUCED FOR**



**Bayer CropScience**

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)