

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505C) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration</p> <p>(under FIFRA, as amended)</p>	EPA Reg. Number: 264-704	Date of issuance: AUG 13 2004
	Term of issuance: Conditional	
	Name of Pesticide Product: Pyrimethanil Technical Fungicide	
Name and Address of Registrant (include ZIP Code): Bayer Crop Science LP P.O. Box 12014 2 T.W. Alexander Drive Research Triangle Park, NC 27709 Attention: Gregory C. Mattern		
<p>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.</p>		
<p>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.</p> <p>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.</p> <p>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you:</p> <ol style="list-style-type: none"> Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. Make the following label change: Revise the EPA Registration Number to read, "EPA Reg. No. 264-704". 		
Signature of Approving Official: <i>Mary L. Waller</i> Mary L. Waller, Product Manager (21)		Date: 8/13/04

3. Submit the following health effects data:
 - a. Guideline 860.1300: Nature of Residues - Livestock. Neither the dates of sample extraction or analysis nor evidence of storage stability were provided. If the samples were stored for longer than 6 months, evidence of storage stability must be submitted by February 2006.
 - b. Guideline 860.1380: Storage Stability. Storage stability data requirements are outstanding for wheat, almonds and cattle commodities. Submit storage stability data demonstrating the stability of pyrimethanil for the following intervals: wheat commodities - 21 months, almonds - 5 months, milk - 6 months, beef muscle - 5 months, beef liver - 5 months, beef kidney - 6 months and beef fat - 4 months. Storage stability must also be submitted for residues of AEC621312 in wheat commodities, AEC614276 in beef tissues and AEC614277 residues in milk for the aforementioned intervals. Studies due by August 2006.
 - c. Guideline 870.3465: 90-day inhalation study. This study must be submitted to address concerns for exposure associated with greenhouse use by November 2005.
 - d. Guideline 870.4200: Carcinogenicity. A mouse carcinogenicity study is required because the high dose in the existing study was judged to be inadequate for assessing the carcinogenic potential of pyimethanil. Due by October 2008.
4. Submit the following environmental fate and effects data:
 - a. Guidelines 850.4225 and 850.4250 (123-1a and b): Terrestrial Plant Seedling Emergence and Vegetative Vigor Tier II. These tests must be conducted using SCALA (37.4% ai formulation). Product labeling bears phytotoxicity warnings for cherries and warnings of crop injury if misused. No phytotoxicity data were submitted so the risk to terrestrial plants is considered probable but undefined. Due May 2005.
 - b. Guideline 850.1400 (72-4): Estuarine/marine Fish Early Life Stage. This study should be performed using the sheepshead minnow. The study is required since the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent. Due November 2005.

- c. Guideline 850.1500(72-5): Freshwater Fish Life Cycle. This study should be conducted using the fathead minnow. This study is required since pyrimethanil is expected to be transported to water from use sites. Due November 2006.
 - d. Guidelines 850.1735: Whole Sediment 10-day Toxicity to Freshwater Invertebrates. Testing using the TGAI should be performed to determine the toxicity and bioaccumulation potential of pyrimethanil to benthic organisms in freshwater sediments. Testing is required since the chemical is moderately toxic to aquatic invertebrates, is expected to reach freshwater environments under normal use, will partition into the soil/sediment of aquatic systems, and may be persistent in the upper layer of sediment and stable at deeper layers. Due August 2006.
 - e. Guidelines 850.1740: Whole Sediment 10-day Toxicity To Estuarine/Marine Invertebrates. Test using the TGAI for the reasons stated above for freshwater invertebrates. Due August 2006.
 - f. Guidelines 850.1730 (165-4): Bioaccumulation in Fish. This study is required ^{because} ~~is~~ significant concentrations of pyrimethanil or its degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms. Based on the characteristics of this chemical it is expected that there would be at least some degree of bioconcentration in fish. Due August 2005.
5. You will submit production information (pounds or gallons produced) for this product for the fiscal year in which the product is conditionally registered, in accordance with FIFRA section 29. The fiscal year begins October 1 and ends September 30. The production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year. This information should be submitted to:

U.S. Environmental Protection Agency
Office of Pesticide Programs (7505C)
Document Processing Desk
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Submit one copy of the final printed label for the record.

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

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A stamped copy of the label is enclosed for your records.

Sincerely yours,



Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division(7505C)

Enclosure

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PYRIMETHANIL Technical

For Formulation Of Fungicides Only.

Formulators who use this product are responsible for obtaining EPA supplemental distributor registration for their formulated products.

ACTIVE INGREDIENT:

Pyrimethanil: 4,6-dimethyl-N-phenyl-2-pyrimidinamine.....98.5%

INERT INGREDIENTS:.....1.5%

EPA Reg. No. 264-XXX

EPA Est. No.

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 1-888-AVENTIS (1-888-283-6847).

FIRST AID

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 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 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. • Call a poison control center or doctor for treatment advice.
<p style="text-align: center;">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.</p>	
<p>NOTE TO PHYSICIAN: Possible mucosal damage may contraindicate the use of gastric lavage. May pose an aspiration pneumonia hazard.</p>	

PRECAUTIONARY STATEMENTS

CAUTION

HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Avoid contact with skin and clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to invertebrates. 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 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.

DIRECTIONS FOR USE

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

For use only by manufacturers in the formulation of fungicides. Subsequent formulators are responsible for providing documentation to support registration of their product. This product requires further mixing before use.

Only For Formulation Into a Fungicide, for the Following Uses: tree nuts, bulb vegetables, grapes, stone fruit (except cherries), pome fruits, tuberous and corm vegetables, strawberries and tomatoes. This product may be used to formulate product for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s).

This product is not registered for use at residential sites.

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

8/13/04

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

264-704

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STORAGE AND DISPOSAL

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

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

CONTAINER DISPOSAL: Completely empty bag into application equipment. Then dispose of bags in a sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned, stay out of smoke.

DISCLAIMER AND INDEMNITY FOR FORMULATORS' USES

THE MANUFACTURER EXPRESSLY DISCLAIMS ALL LIABILITY FOR CLAIMS AND ACTIONS (WHETHER BASED ON CONTRACT, TORT, STRICT LIABILITY OR BREACH OF WARRANTY) ARISING OUT OF, RESULTING FROM OR CONNECTED WITH A FORMULATION CONTAINING THIS PRODUCT WHEN USED FOR ANY PURPOSE OTHER THAN THOSE USES SET FORTH IN (1) ABOVE. THE MANUFACTURER HAS NOT DEVELOPED SCIENTIFIC DATA TO SUPPORT, NOR HAS IT EXPLICITLY OR IMPLICITLY APPROVED, ANY USES OTHER THAN THOSE IN (1) ABOVE.

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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 should 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 Aventis CropScience. All such risks shall be assumed by the user or buyer.

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Aventis CropScience USA LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

Pyrimethanil Technical (PENDING) Submitted 3/27/02.