

264-966

02/21/2009

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

FEB 21 2009

Mr. Melvin K. Tolliver  
Bayer CropScience (LP)  
Po Box 12014, 2 T.W. Alexander Drive,  
Research Triangle Park, NC 27709

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated February 9, 2009 for:

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**EPA Registration 264-966 Raxil XT Wettable Powder Fungicide**

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and finds that the label change(s) requested falls within the scope of PRN-2007-4. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-966	2. EPA Product Manager Mary Waller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Raxil XT Wettable Powder Fungicide	PM# Team 21	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

NOTIFICATION  
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Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4. See attached.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information  
 Label  Container

4. Size(s) Retail Container  
10 and 50 lbs

5. Location of Label Directions

6. Manner in Which Label is Affixed to Product  
 Lithograph Paper glued Stenciled  Other \_\_\_\_\_

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Melvin K. Tolliver	Title Registration Product Manager, Fungicides	Telephone No. (Include Area Code) (919) 549-2631
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**Certification**  
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature  
*Melvin K. Tolliver*

3. Title  
Registration Product Manager, Fungicides

4. Typed Name  
Melvin K. Tolliver

5. Date  
February 9, 2009

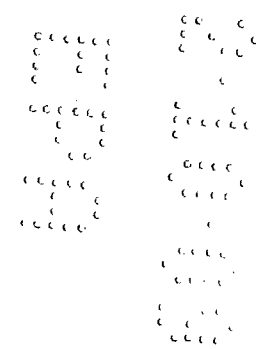
5. Date Application Received (Stamped)

Raxil XT Wettable Powder Fungicide  
EPA Reg. No. 264-966

Section II - Continued

Raxil XT Wettable Powder Fungicide is currently registered with the Agency as a seed treatment product for control of fungi infecting cereals. With this application form, we are notifying the Agency of label changes per PR Notice 2007-4. As required by PR Notice 2007-4 for a notification, we are using the exact wording contained the PR Notice. We are enclosing one copy of draft labeling, dated 02/04/09, in which the text of the PR Notice is highlighted in yellow. In addition, we are also enclosing two copies of final printed labeling. There are no changes in rates, timing of application, number of applications, or PHI from what is currently registered.

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."



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# Bayer CropScience



Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S4900  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

February 9, 2009

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
RTP, NC 27709  
Phone: (919) 549-2000

Subject: Raxil XT Wettable Powder Fungicide, EPA Reg. No. 264-966  
Notification per PR Notice 2007-4

Dear Sir/Madam:

Raxil XT Wettable Powder Fungicide is currently registered with the Agency as a seed treatment product for control of fungi infecting cereals. With this application form, we are notifying the Agency of label changes per PR Notice 2007-4.

Since this is a notification, no fee under PRIA is required.

If you have any questions or need additional information, please contact me by phone at (919) 549-2631 or by e-mail at [mel.tolliver@bayercropscience.com](mailto:mel.tolliver@bayercropscience.com).

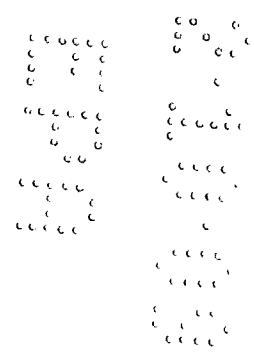
Sincerely,

*Melvin K. Tolliver*

Melvin K. Tolliver  
Registration Product Manager, Fungicides

Enclosure:

1. EPA application form 8570-1
2. Draft labeling with changes highlighted in yellow
3. Final Printed labeling (two copies)



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NOTIFICATION

FEB 21 2009

Highlighted Copy

# RAXIL<sup>®</sup> XT Wettable Powder Fungicide

## ACTIVE INGREDIENTS:

Tebuconazole [Alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol] ..... 15.0%  
 Metalaxyl: [N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester] ..... 20.0%

INERT INGREDIENTS: ..... 65.0%  
**TOTAL 100.0%**

EPA Reg. No. 264-966

EPA Est.

## KEEP OUT OF REACH OF CHILDREN

### CAUTION

See Additional Precautionary Statements

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 SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</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>In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577.          Have a product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	

## PRECAUTIONARY STATEMENTS

### CAUTION

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Wash thoroughly with soap and water after handling. Causes eye injury (irritation). Avoid contact with eyes or clothing.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

### USER SAFETY RECOMMENDATIONS

**USER SAFETY RECOMMENDATIONS:** Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish, estuarine and marine invertebrates. 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 cleaning equipment or disposing of equipment washwater or rinsate. Exposed treated seed may be hazardous to birds and other wildlife. Dispose of all excess treated seed and seed packaging by burial away from bodies of water. Cover or incorporate spilled treated seeds.

**Groundwater Advisory:** Metalaxyl is known to leach through soil into groundwater under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

## DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

### STORAGE AND DISPOSAL

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

#### PESTICIDE STORAGE

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat.

#### PESTICIDE DISPOSAL

Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance

#### CONTAINER DISPOSAL

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 50 lbs) WATER SOLUBLE POUCH CONTAINER:

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, offer for recycling, if available or dispose of in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

POWDER CONTAINER: Non-refillable container. Do not reuse or refill this container. Completely empty box into application equipment. Then, offer for recycling, if available or dispose of empty box in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agriculture pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours. Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: coveralls, chemical-resistant gloves made of any waterproof material and shoes plus socks.

### SEED LABELING

To meet U.S. *Federal Seed Act* requirements, all seed treated with RAXIL XT Wettable Powder should be labeled:

- **TREATED SEED.**
- **DO NOT USE FOR FOOD, FEED OR OIL PURPOSES.**
- Treated with Alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol (Tebuconazole) and Metalaxyl.

Seed labeling must contain the following restriction:

- "Barley, wheat, oat and triticale green forage may be grazed or harvested for hay 31 days after seeding."

RAXIL XT Wettable Powder Fungicide is a combination of systemic fungicides. Tebuconazole and Metalaxyl aid in the control or suppression of the following seed, seedling and soilborne diseases of wheat, barley, oats and triticale:

**Wheat, Triticale**— Stinking smut, Flag smut, Loose smut, Early season *Septoria* disease complex, Early season *Rhizoctonia* root rot, Early season common root rot, Early season *Fusarium* foot rot, Early season suppression of powdery mildew, Early season suppression of wheat leaf rust, Seedborne *Fusarium* scab, General seed rots and *Pythium* damping-off;

**Barley** – Covered smut, Loose smut, Barley stripe (suppression), Early season *Rhizoctonia* root rot, Early season common root rot, Early season *Fusarium* foot rot, Early season suppression of powdery mildew, Early season suppression of barley leaf rust, Seedborne *Fusarium* scab, General seed rots and *Pythium* damping-off;

**Oats** – Loose smut, Early season *Rhizoctonia* root rot, Early season common root rot, Early season *Fusarium* foot rot, Early season suppression of powdery mildew, Early season suppression of crown rust, seedborne *Fusarium* scab, General seed rots and *Pythium* damping-off.

Consult your area agronomist regarding planting depth recommendations for the particular variety to be planted.

**In California – Only for use in commercial seed treating establishments. Not allowed for “on-farm” use.**

**APPLICATION DIRECTIONS FOR WATER SOLUBLE POUCHES**

The pouches of RAXIL XT Wettable Powder are water soluble. Do not allow pouches to become wet prior to adding to the mix tank. Do not handle pouches with wet hands or wet gloves. Do not cut or puncture the pouches. Use the entire water-soluble bag. Do not break pouches or use partial pouches.

Prepare no more slurry than is needed for immediate treating. Mechanical agitation is required for proper mixing of RAXIL XT Wettable Powder. Agitate thoroughly before and during application. Add all of the required water to the mix tank. With agitation running, drop the required number of pouches into the tank. If this product is packaged with separate colorant pouches, add one colorant pouch with each RAXIL XT Wettable Powder pouch used. One 0.5 pound pouch of RAXIL XT Wettable Powder and one 0.5 pound pouch of dry colorant should be used to treat 40-50 hundredweights of seed. This equates to a use rate of from 0.16\* - 0.20 ounces per hundredweight of seed and will deliver from 15-18.75 parts per million of tebuconazole and from 20-25 parts per million of metalaxyl. (One full case of product can treat from 960 – 1200 hundredweights of seed). **\*(Only the low rate of 0.16 ounces per hundredweight is registered for use in California.)** Product should be diluted with sufficient water to give an applied slurry rate of 9 to 20 fluid ounces per 100 pounds of seed. Applications should be made using standard slurry or mist-type seed treatment equipment. Uniform application to seed is necessary to ensure seed safety and best disease control. Seed should be sound and well cured prior to treatment.

**APPLICATION DIRECTIONS FOR POWDER**

Apply RAXIL XT Wettable Powder at the recommended rate of application using a closed system metering apparatus with standard slurry or mist-type seed treatment equipment. Product should be diluted with sufficient water to give an applied slurry rate of 9 to 20 fluid ounces per 100 pounds of seed. Mechanical agitation is required for proper mixing of RAXIL XT Wettable Powder. Agitate thoroughly before and during application. Uniform application to seed is necessary to ensure seed safety and best disease control. Seed should be sound and well cured prior to treatment. Apply RAXIL XT Wettable Powder at 0.16\* - 0.20 ounces per hundredweight of seed. This rate will deliver from 15 – 18.75 parts per million of tebuconazole and from 20 – 25 parts per million of metalaxyl. **\*(Only the low rate of 0.16 ounces per hundredweight is registered in California.)**

NOTE: This product is undyed. The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as food for man or feed for animals. Refer to 12CFR, Part 2.25. Any dye added to treated seed must be cleared for use under 40CFR 180.1001.

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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.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

**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 Bayer CropScience. To the extent allowable under State law, all such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** BAYER CROPSCIENCE MAKES NO 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. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** 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.

**NOTICE TO BUYER**

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

**NOTIFICATION**  
FEB 21 2009

**NET CONTENTS:**

RAXIL is a registered trademark of Bayer



**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)

