

264-964

10-22-2010

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

OCT 22 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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 2001-5

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2001-5 dated September 27, 2010 for:

EPA Registration 264-964 Raxil 2.6F Seed Treatment Fungicide

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2001-5 and finds that the label change(s) requested falls within the scope of PRN-2001-5. 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 703-305-5335 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

A handwritten signature in cursive script that reads "Rachel C. Holman".

Paul Mastradone, Acting Leader *for*
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-964	2. EPA Product Manager Mary Waller	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Raxil 2.6F Seed Treatment 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. NOTIFICATION Product Name OCT 2 2 2010	

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 to add resistance management per PR Notice 2001-5. See attached for explanation.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper 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 <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> 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
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.		8. Date Application Received (Stamped)
2. Signature <i>Melvin K. Tolliver</i>	3. Title Registration Product Manager, Fungicides	
4. Typed Name Melvin K. Tolliver	5. Date September 27, 2010	

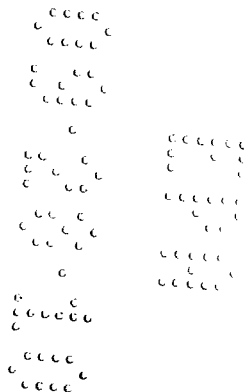
Rail 2.6F Seed Treatment Fungicide
EPA Reg. No. 264-964

Section II - Continued

The South Dakota Department of Agriculture requires registrants to add resistance management language per PR Notice 2001-5 to seed treatment labels before registering the product in South Dakota. Therefore, with this application form, we are notifying the Agency that we are adding the appropriate mode/target site of action classification to page 1 and our own resistance management language on page 4 of the attached draft labeling.

As required for notifications we are enclosing one copy of draft labeling, dated 09/24/2010, in which the mode/target site of action classification and Bayer CropScience's resistance management language are 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 that which is currently registered.

This notification is consistent with the provision of PR Notice 2001-5 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of 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 this notification is not consistent with the terms of PR Notice 2001-5 and 40 CFR 152.46, 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.



ENVIRONMENTAL HAZARDS

This pesticide is toxic to mammals, fish and aquatic 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. Runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

Ground Water Advisory: Tebuconazole is known to leach through soil into ground 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.

Surface Water Advisory: 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 water tables are more prone to 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 within 48 hours.

DIRECTIONS FOR USE

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

Not for use on agricultural establishments in hopper-box, planter-box, slurry-box or other seed treatment applications at or immediately before planting.

STORAGE AND DISPOSAL

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

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

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons).

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. 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.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Once container is rinsed, offer for recycling if available, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 lbs)

Non-refillable Containers

Non-refillable containers - Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

Refillable Containers

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781) or rinse and either recycle or dispose of the container as follows:

Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable)

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inches on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions. Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

Top Discharge IBC, Drums, Kegs (e.g. – Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To triple rinse the containers before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill or by incineration.

SEED LABELING REQUIREMENTS

To meet U.S. *Federal Seed Act* requirements, all seed treated with RAXIL 2.6F must be labeled:

“Treated with Tebuconazole (alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1*H*-1,2,4-triazole-1-ethanol) (RAXIL). Do not use treated seed for feed, food or oil purposes. Barley, wheat and oat green forage may be grazed or harvested for hay 31 days after seeding.”

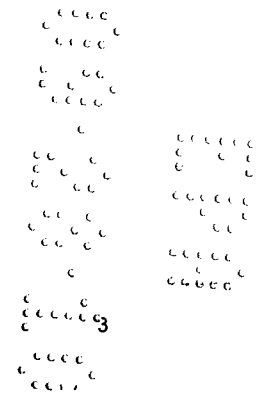
Resistance Management

The component in Raxil 2.6F Seed Treatment Fungicide belongs to resistance group 3 (see resistance group number on front panel of label). Because resistance development cannot be predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotating and/or tank mixing with products having different modes of action; or limiting the total number of applications per season. Use labeled rates. Contact your local extension specialist, certified crop advisor, and/or manufacturer for fungicide/insecticide resistance management and/or integrated pest management recommendations for specific crops and pest populations. Bayer CropScience encourages responsible product stewardship to ensure effective long-term control of pests on this label.

RAXIL controls or suppresses certain designated seed and soilborne diseases of barley, corn, oats, triticale and wheat.

SEED TREATMENT: Apply RAXIL 2.6F as a water-based slurry through standard slurry or mist-type commercial seed treatment equipment. Prepare a slurry by mixing the specified dosage in 9 to 20 fl oz of water per 100 lbs of seed. Add dye** to the resulting slurry. Mix the slurry thoroughly with the seeds to provide uniform coverage.

**21 CFR Chapter I, Section 2.25 requires grain seed treated with poisonous substances in excess of recognized tolerances be suitably colored with an EPA approved dye, such as one of the dyes listed in 40 CFR Section 180.1001 (c) and (d), to prevent their subsequent inadvertent use as a food for man or feed for animals.

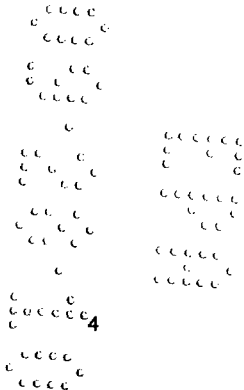


CORN (SWEET CORN, FIELD CORN, FIELD CORN GROWN FOR SEED, AND POPCORN)		
DISEASE	RATE fl oz/100 lbs OF SEED	DIRECTIONS FOR USE
Soilborne and Seedborne <i>Fusarium</i>	0.075 – 0.1	Apply as a seed treatment using standard slurry or mist-type seed treatment equipment. Uniform application of seed is necessary to ensure seed safety and best disease protection. Seed should be sound and well cured prior to treatment. Product should be diluted with sufficient water ensure complete seed coverage. Add dye to the resulting slurry. Consult a seed treatment specialist regarding slurry rates recommended for the crop to be treated with RAXIL 2.6F. The length of control will vary depending on the rate used.
Soilborne and Seedborne Head smut (<i>Sphacelotheca reiliana</i>)	0.37 – 0.74	

APPLICATION RATE		
CROP & DISEASE	RATE OF RAXIL 2.6F	APPLICATION DIRECTIONS
<p>Wheat and Triticale: Stinking Smut, Flag Smut, Loose Smut, Early Season <i>Septoria</i> Disease Complex, Early Season <i>Rhizoctonia</i> Root Rot, Early Season Common Root Rot, Early Season <i>Fusarium</i> Foot Rot, Early Season, Suppression of Powdery Mildew, Early Season Suppression of Wheat Leaf Rust</p> <p>Barley: Covered Smut, Loose Smut, Barley Stripe (suppression), Early Season <i>Rhizoctonia</i> Root Rot, Early Season Common Root Rot, Early Season <i>Fusarium</i> Foot Rot, Early Season Suppression of Powdery Mildew, Early Season Suppression of Barley Leaf Rust</p> <p>Oats: Loose Smut, Pythium Damping-off, Early Season <i>Rhizoctonia</i> Root Rot, Early Season Common Root Rot, Early Season <i>Fusarium</i> Foot Rot, Early Season Suppression of Powdery Mildew, Early Season Suppression of Crown Rust</p>	0.1 fl oz/100 lbs of seed	Refer to the SEED TREATMENT section on this label for the specified method of treating seed.

Refillable Containers

End users are authorized to remove tamper evident cables as required to remove the product from the container unless the container is equipped with one way valves and refilling or returning is planned. If this is the case, end users are not authorized to remove tamper evident cables, one way valves or clean container. See Container Disposal instructions under Storage and Disposal.



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 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 allowable under State 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 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.

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.

NET CONTENTS:

RAXIL is a registered trademark of Bayer

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)**

RAXIL 2.6F Seed Treatment (MASTER) Approved 03/25/10 NOTIFICATION 09/24/2010

