

264-976

03-29-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Melvin K. Tolliver
Registration Manager, Fungicides
Bayer CropScience LP
P.O. Box 12014
Research Triangle Park, NC 27709

MAR 29 2010

Subject: Raxil MD Extra Fungicide
EPA Reg. No. 264-976
Your amendment dated November 19, 2009
EPA Decision Number 424236

Dear Mr. Tolliver:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable provided the following changes are made:

1. On page 2 change "Groundwater advisory: Metalaxyl is known...." to "Groundwater Advisory: Metalaxyl and tebuconazole are known...."
2. On page 2 add the following paragraph below the Groundwater Advisory paragraph: "**Surface Water Advisory**: 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."
3. On page 3 in the section **SEED LABELING**:
 - a. In the first line change "...**must contain the following:**" to "...**must contain the following labeling on the seed tag:**"
 - b. Add a quotation mark " at the beginning of the required text: "Seed that has been treated...."
 - c. Add a quotation mark " at the end of the required text: six weeks after planting."

One copy of the label stamped "Accepted with comments" is enclosed for your records. This label supersedes all labels previously accepted for this product. Please submit one copy of the final printed label that incorporates the required changes before the product is released for shipment.

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If you have any questions, please contact Robert Westin by phone at (703) 305-5721 or via email at westin.robert@epa.gov.

Sincerely,



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

Enclosure

RAXIL[®] MD EXTRA Fungicide

RAXIL MD EXTRA Fungicide contains three active ingredients: Tebuconazole, Metalaxyl and Imazalil

ACTIVE INGREDIENTS:

Tebuconazole: (Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol).....	0.43%
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester	0.58%
Imazalil: [1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1H Imidazole]	1.00%
INERT INGREDIENTS:	97.99%

TOTAL 100.00%

Contains 0.04 pounds Tebuconazole, 0.05 pounds Metalaxyl and 0.09 pounds Imazalil per U.S. gallon.
Contains Imazalil, an active ingredient from Janssen Pharmaceutica, N.V., Beerse, Belgium.

EPA Reg. No. 264-976

EPA Est.

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 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.
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.
<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

Causes eye irritation. Avoid contact with skin, eyes and clothing. Harmful if absorbed through skin.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

All handlers must wear: Long-sleeved shirt, long pants, shoes plus socks and chemical-resistant gloves, such as barrier laminate, butyl rubber > 14 mils, nitrile rubber > 14 mils, neoprene rubber > 14 mils, polyvinyl chloride (PVC) > 14 mils or Viton > 14 mils, except for bag sewers, planters, truck drivers, and sorters. All handlers must wear: Chemical resistant apron when mixing/loading, cleaning up spills, cleaning equipment, or otherwise exposed to the concentrate.

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

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove clothing/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 contaminate water when disposing of equipment washwaters. 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. Apply this product only as specified on this label.

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. 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 a cool, dry place and avoid excess heat.

PESTICIDE DISPOSAL

This pesticide's 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 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

Seed that has been treated with this product that is packaged or bagged for future use must contain the following:

Do not enter or allow worker entry into areas planted with treated seed during the restricted entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, workers may enter the treated area without restriction if there will be no contact with the soil/media subsurface.

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 is:

- Coveralls,
- Shoes plus socks,
- Chemical-resistant gloves made of any waterproof material, and
- Protective eyewear.

This bag contains seed treated with Imazalil, Tebuconazole, and Metalaxyl. When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves.

Treated Seed-Do Not Use of Food, Feed, or Oil Purposes.

Cover or collect spilled seeds.

Do not graze or feed livestock on treated areas for six weeks after planting.

RAXIL® MD EXTRA Fungicide is a combination of the systemic fungicides, tebuconazole, metalaxyl and imazalil which aid in the control of suppression of the following seed, seedling and soilborne diseases of wheat, barley and triticale: stinking smut, flag smut, loose smut, early season *Septoria* disease complex, general seed rots, *Pythium* damping-off, early season *Rhizoctonia* root rot, early season common root rot, seedborne *Fusarium* scab, early *Fusarium* foot rot, early season suppression of powdery mildew and early season suppression of leaf rust and barley stripe.

APPLICATION DIRECTIONS:

Use 5 fluid ounces of RAXIL MD EXTRA per 100 pounds of seed. Applications must be made using standard slurry or mist-type seed treatment equipment. In some instances, a water and chemical slurry dilution may enhance coverage. A 1 part RAXIL MD EXTRA with 1 part water dilution may be used. This product is for commercial or on-farm application. Do not use this product for direct application into a planter box. Uniform application to seed is necessary to ensure seed safety and best disease control. Seed should be sound and well cured prior to treatment. Consult your area agronomist regarding planting depth recommendations for the particular variety to be planted.

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.

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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 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 LP. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP 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 LP 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 LP 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 LP'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

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

MAR 29 2010

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

264-976

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 MD EXTRA Fungicide (PENDING) 05/05/09, resubmitted 11/16/09