

264-967

5/24/2010

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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

MAY 24 2010

Subject: Raxil Allegiance MD Fungicide
EPA Reg. No. 264-967
Your amendment dated November 19, 2009
EPA Decision Number 415873

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 1 move the line "Contains 0.039 pounds....per U.S. gallon" to below the Total line in the list of ingredients.
2. On page 1 immediately below the header **PRECAUTIONARY STATEMENTS** move the word CAUTION to below the subheader HAZARDS TO HUMANS AND DOMESTIC ANIMALS.
3. On page 1 change "Groundwater advisory: Metalaxyl is known...." to "Groundwater Advisory: Metalaxyl and tebuconazole are known...."
4. On page 1 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."
5. On page 2 add the following text below the subheader **Refillable Containers** before the sentence "After emptying product from container, either return....": "Do not remove tamper evident cables or one way valves or clean the container if the container is equipped with one way valves and refilling or returning is planned."

6. On page 3 in the first line below the header **SEED LABELING** change "...should be labeled:" to "...must be labeled:"
7. On page 3 in the last line of the NOTE under the header **SEED LABELING** change "...40CFR, part 180.1001." to "...40CFR parts 180.910, 180.920, or 180.950.
8. On page 3 in the first line below the header **APPLICATION DIRECTIONS** change "Applications should be made using standard slurry...." to "Make applications using standard slurry...."
9. On page 3 in the third and fourth lines below the header **APPLICATION DIRECTIONS** change "This product is not intended for direct application...." to "Do not use this product for direct application...."
10. On page 3 move the last paragraph **Refillable Containers**

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.

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

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RAXIL[®] ALLEGIANCE[®] MD

Fungicide

Contains 0.039 pounds Tebuconazole and 0.051 pounds Metalaxyl per U.S. gallon.

ACTIVE INGREDIENTS:

Tebuconazole: Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol	0.48%
Metalaxyl: N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester	0.64%

OTHER INGREDIENTS:	98.88%
TOTAL	100.00%

EPA Reg. No. 264-967

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)

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.

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear: Long-sleeved shirt, 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

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 clothes. 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 highly 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 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.

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.

ACCEPTED
with **COMMENTS**
In EPA Letter Dated
MAY 24 2010

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

264-967

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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

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.

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 seed is treated with the product and the treated seed 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, shoes plus socks.

SEED LABELING

To meet U.S. *Federal Seed Act* requirements, all seed treated with RAXIL ALLEGIANCE MD 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 ALLEGIANCE MD Fungicide is a combination of the systemic fungicides, Tebuconazole and metalaxyl which aids in the control or suppression of the following seed, seedling and soilborne diseases of wheat, barley, oats 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 season *Fusarium* foot rot, early season suppression of powdery mildew and rust.

In California – Registered only for use in commercial seed treating establishments. Not allowed for "on-farm" use.

NOTE: If 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 a food for man or feed for animals. Refer to 21 CFR, Part 2.25. Any dye added to treated seed must be cleared for use under 40CFR, part 180.1001.

APPLICATION DIRECTIONS

Use 5 – 6.5 fluid ounces of RAXIL ALLEGIANCE MD per 100 pounds of seed. Applications should 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 ALLEGIANCE MD with 1 part water dilution may be used. This product is for commercial or on-farm application. This product is not intended 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.

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Bayer CropScience

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RAXIL ALLEGIANCE MD Fungicide (PENDING) 05/05/09, resub 11/16/09