

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Melvin K. Tolliver
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

JUL 2 2008

SUBJECT: Reregistration Label Amendment per Imazalil Red
Raxil Md Extra Fungicide
EPA Reg. No. 264-976
Your Submission Dated February 5, 2008

Dear Mr. Tolliver:

The amended labeling 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, in the Environmental Hazards section, delete the second sentence.
2. On page 2, delete the Agricultural Use Requirements box.
3. On page 2, Seed Labeling section, the second sentence should read "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.

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This bag contains seeds 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 live stock on treated areas for six weeks after planting."

The last paragraph in that section remains the same.

3. On page 3, first line of the Application Directions section, delete the word "made" and change to "must" in the second sentence and the third line should read as follows: "1 part water dilution may be used. This product is for commercial or on-farm application. Do not use for direct".

4. On page 4 in the Conditions section, last line delete "allowable under State" and replace with "consistent with applicable".

5. On page 4 in the Limitations of Liability section, first sentence delete the word "allowed" and replace with "consistent with applicable."

Submit one copy of your final printed labels before you release the product for shipment.

If you have any questions regarding this correspondence, contact Rose Kearns of my staff by phone at 703-305-5611 or via email at kearns.rosemary@epa.gov or myself at 703-305-7740 or via email at giles-parker.cynthia@epa.gov.

Sincerely,



Cynthia Giles-Parker, Chief
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 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. 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

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning, 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.

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 agricultural 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 48 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.

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 treated areas during the restricted entry interval (REI) of 48 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. 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.

Treated with Tebuconazole, Metalaxyl, and Imazalil.

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 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 MD EXTRA 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.

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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: TO THE EXTENT ALLOWED BY 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

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

JUL 2 2008

**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) Submitted 02/13/06, Resubmitted 08/07/06, Resubmitted 01/31/08.