264 - 964

7/31/2008

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

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 3 1 2008

Mel Toliver Bayer CropScience P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Subject: Raxil 2.6 F Seed Treatment Fungicide EPA Registration No. 264-964 Your submission dated July 11, 2008 – Adding new uses

Dear Mr. Toliver:

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

- 1) On Page under your ingredients statement, please change "INERT INGREDIENTS" to read "OTHER INGREDIENTS".
- 2) On page 2, under "Seed Labeling Requirements", change the sentence "To meet U.S. Federal Seed Act requirements, all seed treated with RAXIL 2.6F should be labeled:" to read "To meet U.S. Federal Seed Act requirements, all seed treated with RAXIL 2.6F must be labeled:". Directly after this statement, revise the following sentence to read "Treated with Tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethyl)-1H-1,2,4-triazole-1-ethanol)(RAXIL).
- 3) On page 2 under "SEED TREATMENT", revise the first sentence to read "Apply RAXIL 2.6F as a water based slurry..."
- 4) On page 3 under "Application Directions", revise the sentence to read "Refer to the SEED TREATMENT section on this label for the specified method of treating seed".

One copy of the label stamped "Accepted, with comments" is enclosed for your records. Please submit one copy of the final printed label before the product is released for shipment. If you have any questions, please contact Tracy Keigwin of my team at (703) 305-6605 and/or via email at keigwin.tracy@epa.gov.

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Sincerely,

Mary J. Waller

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

Enclosure

RAXIL[®] 2.6FSeed Treatment Fungicide

FOR USE ONLY BY COMMERCIAL SEED TREATERS

FOR CONTROL OF SPECIFIED DISEASES ON BARLEY, CORN, OATS, TRITICALE AND WHEAT

ACTIVE INGREDIENTS:

EPA Reg. No. 264-964

| Tebuconazole, Alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol | 28.3% |
|--|--------------|
| INERT INGREDIENTS: | <u>71.7%</u> |
| TOTAL | 100.0% |

Contains 2.6 lbs. tebuconazole per gallon

EPA Est.

STOP – READ THE LABEL BEFORE USE KEEP OUT OF REACH OF CHILDREN CAUTION

For <u>MEDICAL</u> And <u>TRANSPORTATION</u> Emergencies <u>ONLY</u> Call 24 Hours A Day 1-800-334-7577 For <u>PRODUCT USE</u> Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

| | Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by poison control center or doctor Do not give anything by mouth to an unconscious person. | ACCEPTED with COMMENTS In EPA Letter Dated |
|----------------------------|---|---|
| IF ON SKIN OR CLOTHING: | 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. | 7 / 31/ 2008 Under the Federal Insecticity Fungicide, and Rodenticide A |
| IF IN EYES: | 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 INHALED: | Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. | |

PRECAUTIONARY STATEMENTS

CAUTION HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed, inhaled or absorbed through the skin. Avoid contact with skin, eyes and clothing. Avoid breathing vapor or spray mist. Wear long sleeved shirt, long pants or coveralls, and chemical-resistant gloves made of waterproof material. Remove contaminated clothing and wash before reuse. Wash thoroughly with scap and water after handling.

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

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, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

SEED LABELING REQUIREMENTS

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

"Treated with alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-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."

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

SEED TREATMENT: It is recommended that RAXIL 2.6F be applied 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 CO DISEASE | RATE FL. OZ. / 100 POUNDS OF SEED | DIRECTIONS FOR USE | |
|---|--------------------------------------|---|--|
| Soilborne and Seedborne Fusraium | 0.075 - 0.1 | Apply as a seed treatment using standard slurry o | |
| Soilborne and Seedborne Head smut (Sphacelotheca reiliana) | 0.37 – 0.74 | 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. | |

| APPLICATION RATE | | | | | | |
|---|--|--|--|--|--|--|
| CROP & DISEASE | RATE OF RAXIL 2.6F | APPLICATION DIRECTIONS | | | | |
| 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 | 0.1 fluid ounce per 100 pounds of seed | Refer to the SEED TREATMENT section on this label for the recommended method of treating seed. | | | | |
| 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 | | | | | | |
| 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 | - | | | | | |

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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. 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 (PENDING) 06/25/08, resub 07/08/08