

264-997

8/21/2008

186



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 21 2008

Jamin Huang, Ph.D
Bayer CropScience
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

SUBJECT: Reregistration Label Amendment Per Imazalil RED
Raxil MD Extra W Seed Treatment
EPA Reg. No. 264-997
Your Submission Dated February 8, 2008

Dear Dr. Huang:

EPA determined that you fulfilled the requirements of the Imazalil RED for the subject product. However, we are unable to reregister the product under FIFRA 4(g)(2)(c) at this time, because it also contains the active ingredients Metalaxyl, Tebuconazole and Imidacloprid. This product will be reregistered once the data requirements have been satisfied for this product under the Metalaxyl, Tebuconazole and Imidacloprid REDs.

Within thirty (30) days from the date of this letter, you must submit a revised master label which adds the following changes. If these conditions are not complied, with the registration will be subject to cancellation in accordance with FIFRA section 6(e).

1. On page 1, User Safety Recommendations, line three, the second sentence must read "As soon as possible, wash thoroughly and change into clean clothing." Also delete this same sentence which repeats at the end of this section.
2. Delete "Wear protective eyewear" in the Precautionary Statements because it is not needed as per the acute tox review, and it is not in the PPE section.

3. On page 2 in the Storage and Disposal section, the subheading "Storage" should be changed to "Pesticide Storage."

4. Delete "Do not enter or allow....soil/media subsurface." on page 2 because it's in the Agricultural Use Requirements section.

5. On page 2, in the Seed labeling section, the second sentence must read "This bag contains seed treated with Imazalil, Tebuconazole, Metalaxyl and Imidacloprid....resistant gloves. Place right quotation mark at the end of the following sentence to indicate end of labeling required on seed bag: Store away from feeds and foodstuffs." Thus each seed bag begins/ends with "This bag....foodstuffs."

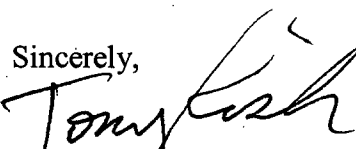
6. On page 2, in the Seed Labeling section, delete the sentence "Treated with Tebuconazole, Metalaxyl, Imazalil and Imidacloprid."

7. On page 3, in the Application Directions, subheading Rotational Crops, delete "Treated areas...listed crops" and replace it with "Areas planted with treated seeds may be replanted with wheat, barley, and triticale immediately. The following plant back intervals must be observed for listed crops." Also, change second asterisk in table deleting "an Imidacloprid" and replace with "this".

8. On page 3, in the chart at the bottom of the page, you have popcorn listed twice, Once in the immediate plant-back and again in the 30 day plant back. You can only list it once and you must delete the one in the 30 day plant back column.

9. On page 3, under Application Directions, change "This product is not intended for direct application into a planter box" to the following; "Do not use for direct at plant applications into planter or hopper boxes."

Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions. One copy of the label stamped "Accepted with comments" is enclosed for your records. 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 703-308-9443 or via email at kish.tony@epa.gov.

Sincerely,

Tony Kish
Product Manager (22)
Fungicide Branch
Registration Division (7504P)

RAXIL[®] MD EXTRA W Seed Treatment

ACTIVE INGREDIENTS:

Imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-Imidazolidinimine).....	1.384%
Tebuconazole (Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethyl-ethyl)-1H-1,2,4-triazole-1-ethanol).....	0.415%
Metalaxyl: (N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester).....	0.560%
Imazalil (1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1H Imidazole).....	0.965%
INERT INGREDIENTS:	96.676%

TOTAL 100.00%

EPA Reg. No. 264-997

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.
--------------------	---

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

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

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 and long pants, shoes plus socks, chemical-resistant gloves (such as nitrile rubber ≥ 14 mils, butyl rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, barrier laminate ≥ 14 mils, polyvinyl chloride (PVC) ≥ 14 mils and Viton ≥ 14 mils), except for bag sewers and planters, and 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 clothes. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into 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 product is highly toxic to birds and aquatic invertebrates and toxic to fish. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Exposed treated seeds may be hazardous to birds. In the event that treated seeds are spilled and cannot be salvaged, completely cover them with soil. Do not contaminate water when disposing of equipment washwaters or rinsate.

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

PROHIBITIONS

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited. Do not reuse empty containers.

STORAGE

Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Store in a cool dry location. Protect from excessive heat.

PESTICIDE DISPOSAL

Pesticide 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 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 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. Personal protective equipment required for early entry to treated areas that involve 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 labeling:

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 for Food, Feed, or Oil Purposes.

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.

Cover or collect spilled seeds.

Treated with Tebuconazole, Metalaxyl, Imazalil, and Imidacloprid.

Do not graze or feed livestock on treated areas for 45 days after planting.

Store away from feeds and foodstuffs.

NOTE: Use with an EPA-approved dye that imparts an unnatural color to the treated seed.

PRODUCT INFORMATION

RAXIL MD EXTRA W is a combination of the insecticide, imidacloprid and the systemic fungicides, tebuconazole, metalaxyl and imazalil that aid in the control or 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 season *Fusarium* foot rot, early season suppression of powdery mildew and rust. Imidacloprid offers suppression of wireworm activity on seed and young seedlings.

APPLICATION DIRECTIONS

Wheat, Barley, Triticale:

Use 5.14 fluid ounces of RAXIL MD EXTRA W per 100 pounds of seed. Applications should be made using standard slurry or mist-type seed treatment equipment. In some cases, a water and chemical slurry dilution may enhance coverage. A 1-part RAXIL MD EXTRA W 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 pest 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.

ROTATIONAL CROPS: Treated areas may be replanted with any crop specified on the RAXIL MD EXTRA W label, or for any crop for which a tolerance exists for imidacloprid, as soon as practical following the last application. The following plant-back intervals should be observed for listed crops:

ROTATIONAL PLANT-BACK INTERVALS*				
IMMEDIATE PLANT-BACK				30-DAY PLANT-BACK
Artichoke	Cranberry	Mustard seed	Sugar beet	Cereals (Including buckwheat, millet, oats, popcorn, rice and rye) Safflower
Barley	Cucurbits	Okra	Tomatillo	
Brassica (cole) leafy veg.	Eggplant	Pepinos	Tomato	
Canola	Ground cherry	Pepper	Triticale	
Cilantro	Leaf petiole veg.	Popcorn	Turnip greens	
Corn, Field	Leafy veg.	Potato	Veg. Root and Tuber	
Corn, Sweet	Legume veg. (succulent or dried)	Rapeseed	Watercress	
Cotton		Sorghum	Wheat	
		Soybean		
		Strawberry		
* Cover crops for soil building or erosion control may be planted any time, but do not graze or harvest for food or feed.				
* All other crops not listed on an Imidacloprid label, or for crops for which no tolerance for the active ingredient have been established, a 12-month plant-back interval should be observed.				

6 7 6

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 allowed by 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

**ACCEPTED
with COMMENTS
In EPA Letter Dated
— AUG 21 2008**

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

264-997

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 W Seed Treatment (PENDING) Submitted 02/13/06, Resubmitted 02/08/08