

U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460

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Date of Issuance:

264-1072

EPA Reg. Number:

APR 9 2009

Term of Issuance:

Conditional

Name of Pesticide Product:

Proceed MD Fungicide

NOTICE OF PESTICIDE:

x Registration

Reregistration (under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(B) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4.
- 2. Submit a GLP one-year storage stability study (830.6317) and corrosion characteristics study (830.6320) by March 31, 2010.
- 3. Submit revised enforcement methods, by January 1, 2010, for the LC/MS/MS Method RPA JA/03/01 for plants, and LC/MS/MS Method Bayer Report No. 200537 for ruminants, which must include at least two multiple reaction monitoring (MRM) transitions to preclude the need for a confirmatory method.

Signature of Approving Official:

Tony Kish

Product Manager, Team 22

Fungicide Branch

Registration Division (7505P)

Date:

APR 9 2009

- 4. By May 1, 2011, a valid immunotoxicity study must be submitted to the Agency to satisfy guideline requirement (OPPTS 870.7800). An earlier study (MRID 42626438) in the Prothioconazole data base was reviewed by the Agency, and found to be unacceptable.
- 5. Before releasing the product for shipment, revise the EPA Registration Number to read, "EPA Reg. No. 264-1072." Submit a final printed label, within 45 days of the date hereon, making the following changes:
 - A. On page 1, change "Wear protective eyewear" to "Wear protective eyewear (goggles, face shield or safety)"
 - B. Under the "Environmental Hazards" section, in the "Groundwater Advisory" subsection, revise its first sentence, by inserting "metalaxyl." In the second sentence of this subsection, replace "chemical" with "product." Delete the remaining sentences in this subsection: "Metalaxyl is known...in groundwater contamination."
 - C. Delete the "Surface Water Advisory" subsection, including its text, under the "Environmental Hazards" section.
 - D. In the 'Seed labeling' section, replace the first sentence with, "Seed that has been treated with this product that is then packaged or bagged for future use must contain the following additional labeling on the outside of the seed package or bag."
 - E. From the fourth bullet, in the 'Seed Labeling' section, delete "Seed labeling must contain the following restriction," and the pair of quotation marks used in the second sentence, "Barley, wheat and triticale...after seeding."
 - F. The final bullet statement in the 'Seed Labeling' section must be revised as "Cover or collect spilled treated seed." This statement reads more legibly, by replacing 'incorporate' with 'collect', because both 'incorporate' and 'cover' have comparable meanings.
 - G. Under 'Application Directions', delete 'water and' from the fourth sentence, so that the guidance may become more legible than the current statement.
 - H. In the 'Application Directions' section, revise the fourth from the last sentence to read as follows or a variation thereof, "Do not apply this product with a hopper box, planter box, slurry box or any other at-plant methods."

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I. Replace the second to last sentence in the 'Application Directions' section with "Only use seed that is sound and well cured prior to treatment."

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release of the shipment of your product constitutes acceptance of these conditions.

A copy of the label stamped "Accepted with Comments" is enclosed for your records.

Enclosures

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PROCEED MD Fungicide

| ACTIVE INGREDIENTS: | |
|--|----------------------|
| Prothioconazole: 2-[2-(1- Chlorocylocpropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]- 1,2- dihydro-3H-1,2,4-tr | iazole-3-thione1.47% |
| Tebuconazole: (Alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1- ethanol) | 0.29% |
| Metalaxyl: N- (2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester | |
| OTHER INGREDIENTS: | |
| | TOTAL:100.00% |

Contains 0.128 pounds Prothioconazole, 0.025 pounds Tebuconazole and 0.052 pounds Metalaxyl per U.S. gallon.

EPA Reg. No. 264-RNTE

EPA Est.

KEEP OUT OF REACH OF CHILDREN WARNING AVISO

See Additional Precautionary Statements

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

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

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|---------------|--|--|--|--|
| 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 SWALLOWED: | Immediately call a poison control center or doctor for treatment advice. | | | |
| | Have person sip a glass of water if able to swallow. | | | |
| | Do not induce vomiting unless told to do so by a poison control center or doctor. | | | |
| | Do not give anything by mouth to an unconscious person. | | | |
| 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. | | | |
| IF ON SKIN OR | Take off contaminated clothing. | | | |
| CLOTHING: | Rinse skin immediately with plenty of water for 15-20 minutes. | | | |
| | Call a poison control center or doctor for treatment advice. | | | |

NOTE TO PHYSICIAN: No specific antidote. Treat symptomatically.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

Causes substantial but temporary eye injury. Harmful if swallowed, inhaled, or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear. Avoid contact with skin and breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

ACCEPTED
with COMBIENTS
In EPA Letter Dated

APR 9 2000

Under the Federal Insecticide, Fundicide, and Redemicide Act as mesended, for the pesticide

264- 1072

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PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical resistant gloves (such as Natural Rubber, selection Category A)
- Shoes plus socks
- Protective eyewear (goggles, face shield, or safety glasses)

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Control Statements

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

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.

Users should 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 toxic to mammals, fish, aquatic invertebrates, and freshwater/estuarines/marine aquatic plants. 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.

Cover or incorporate spilled treated seed.

Groundwater Advisory: Prothioconazole-desthio(a degradate of prothioconazole) and tebuconazole are known to leach through soil into ground water 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. 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.

Surface Water Advisory: This product may contaminate water through drift of spray in wind. Drift and runoff are hazardous to aquatic organisms in water adjacent to treated areas. 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 produce 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 to occur within 48 hours.

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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.

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

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.

SEED LABELING

To meet U.S. Federal Seed Act requirements, all seed treated with PROCEED MD should be labeled:

- TREATED SEED.
- DO NOT USE FOR FOOD, FEED OR OIL PURPOSES.
- Treated with prothioconazole, tebuconazole and metalaxyl.
- Seed labeling must contain the following restriction: "Barley, wheat and triticale green forage may be grazed or harvested for hay 31 days after seeding."
- Do not enter or allow worker entry into treated areas 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.
- · Cover or incorporate spilled treated seed.

PRODUCT INFORMATION

PROCEED MD Fungicide is a combination of the systemic fungicides, prothioconazole, tebuconazole and metalaxyl which aids 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 (7.5 fluid ounce rate only) and rust.

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

APPLICATION DIRECTIONS

Apply this product only as specified on this label. Use 5.0 – 7.5 fluid ounces of PROCEED MD 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 PROCEED MD with 1 part water dilution may be used. This product is for commercial or on-farm application. Do not apply this product with a hopper box, planter box, or slurry 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.

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 CONSISTENT WITH APPLICABLE 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.

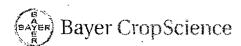
NOTICE TO BUYER

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:

PROCEED is a trademark of Bayer CropScience LP

PRODUCED FOR



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)

PROCEED MD Fungicide (PENDING) 10/26/07, resub 07/07/08, resub 04/01/09