

264-958

07/13/2009

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

264-958

Date of Issuance:

JUL 13 2009

NOTICE OF PESTICIDE:

Registration
[X] Reregistration
(under FIFRA, as amended)

Term of Issuance:
Unconditional

Name of Pesticide Product:
Tops-MZ Potato Seed Piece
Treatment Fungicide

Name and Address of Registrant (include ZIP Code):

Bayer CropScience LP
P.O. Box 12014
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 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.

Based on your response to the thiophanate-methyl and mancozeb Reregistration Eligibility Documents, EPA has reregistered the product listed above provided that the following changes are made to the label:

- 1. In the list of ingredients on page 1 change "INERT INGREDIENTS" to "OTHER INGREDIENTS"

Page 1 of 3

Signature of Approving Official:

Mary L. Waller

Date:

7/13/2009

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

2. On page 2 move the signal word “CAUTION” so that it appears below the subheading **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**.
3. On page 2 in the section **HAZARDS TO HUMANS AND DOMESTIC ANIMALS** change “Harmful if absorbed trough the skin.” to “Harmful if absorbed through the skin.”
4. Correct the typographical error on page 2 of 5, in the first sentence of the **Engineering controls** text, “...seed pieces that prevents dust form contacting ...” to “...seed pieces that prevents dust from contacting ...”
5. On page 2, revise the **ENVIRONMENTAL HAZARDS** section as follows: “This pesticide is toxic to aquatic organisms. Dispose of all excess treated seed by burial away from bodies of water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.”
6. Change the first sentence on page 3 to read “Do not use this product at higher than the specified rate.”
7. On page 3, move the **AGRICULTURAL USE REQUIREMENTS** box to above the Storage and Disposal box.
8. The REI text in the **AGRICULTURAL USE REQUIREMENTS** box must be revised to read “Do not enter or allow worker entry into the treated areas during restricted entry interval (REI) of 48 hours.” *[Note: This reflects the more restrictive REI found in the RED for thiophanate-methyl.]*
9. In the **AGRICULTURAL USE REQUIREMENTS** box, delete the statement “Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas”.
10. On page 3 in the first **Note** following the header **GENERAL INFORMATION** delete the sentence “Therefore, Bayer CropScience cannot assume liability for crop damage resulting from resistant strains of fungi.”
11. On page 3, change the header **APPLICATION** to **APPLICATION DIRECTIONS**.

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12. Add the following text to the **APPLICATION DIRECTIONS**:

Seed pieces that have been treated with this product that are packaged or bagged for future use must be colored with an EPA approved dye to impart an unnatural color and must contain the following labeling on the outside of the seed-piece or bag:

“Treated seed pieces. Seed pieces have been treated with the fungicides thiophanate-methyl and mancozeb. When opening this bag or loading/pouring the treated seed pieces, wear a long-sleeved shirt, long pants, shoes, socks, chemical resistant gloves, and a NIOSH approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC 21C, *or* any N, R, P, or HE filter. After seeds have been planted, do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours. Exception: Once seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no contact with the treated subsurface.”

13. You must comply with PR Notice 2007-4 by notification or by amendment.

This action is taken under the authority of section 4(g)(2)(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

A copy of your label stamped “Accepted with Comments” is enclosed for your records. Please submit one copy of the revised final printed label for the record before the product is released for shipment.

The basic Confidential Statements of Formula (CSF) dated 3/17/08, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable. This CSF supersedes all CSFs previously accepted for this product.



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

Enclosure:

Label stamped “Accepted with Comments”
PRB Label Review dated May 2, 2008
Acute Toxicity Review DP352002 dated April 29, 2008
Product Chemistry Review DP352001 dated April 29, 2008

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TOPS[®] MZ Potato Seed-Piece Treatment Fungicide

ACTIVE INGREDIENTS:

Thiophanate-methyl: (dimethyl[(1,2-phenylene) bis (iminocarbonothioyl)]bis[carbamate])*2.5%
 Mancozeb: A coordination product of zinc ion and manganese ethylene bisdithiocarbamate.....6.0%
 In which the ingredients are:
 Manganese++1.2%
 Zinc++0.15%
 Ethylene bisdithiocarbamate ion (C₄H₆N₂S₄).....4.65%

INERT INGREDIENTS:91.5%
TOTAL 100.00%

*Also known as dimethyl 4,4'-o-phenylenebis[3-thioallophanate]

EPA Reg. No. 264-958 **EPA Est.**
 Covered under U.S. Patent Number 5007953

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 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.
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 SWALLOWED:	<ul style="list-style-type: none"> • 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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF INHALED	<ul style="list-style-type: none"> • 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.

In case of emergency call toll free the Bayer CropScience Emergency Response Telephone No. 1-800-334-7577.
 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

JUL 13 2009

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

264-958

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are made out of any waterproof material. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.

Loaders, applicators and other handlers must wear:

Long-sleeved shirt and long pants,

shoes plus socks,

chemical-resistant gloves made of any waterproof material and

a NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or any N, R, P, or HE filter.

See engineering controls for additional requirements.

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. Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

Engineering Controls: Large scale seed piece treatment facilities that, on any given week in the current year or in the past year, treated $\geq 50,000$ cwt ($\geq 2,500$ tons) must use a dust collection system during the treatment of the seed pieces that prevents dust from contacting handlers or other persons.

Handlers using the dust collection system must wear:

Long-sleeved shirt and long pants,

shoes plus socks,

chemical-resistant gloves and must be provided with, have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown:

a NIOSH-approved respirator with a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or any N, R, P, or HE filter.

Planters/operators planting potato seed that has been treated with dust must be in an enclosed cab. When handlers use closed systems or enclosed cabs 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/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. 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 fish and aquatic organisms. Drift and runoff from treated areas may be hazardous to aquatic organisms. 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 from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Dispose of all excess treated seed-pieces and seed packaging by burial away from bodies of water.

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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 use this product at higher than recommended rate.

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 and disposal.

PESTICIDE STORAGE

Store in cool, dry location. Do not store in direct, hot sunlight.

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

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by 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 24 hours. Exception: Once the seed pieces are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface. PPE required for early reentry 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 over long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material and chemical-resistant footwear plus socks.

Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.

NOTICE

This pesticide will not control bacterial diseases or other diseases not claimed on this label. Consult your local extension potato specialist for variety and treatment information, and for recommendations specific to your area on how to minimize the potential expression of seed-piece decay and potato diseases.

GENERAL INFORMATION

Note: Thiophanate-methyl is a systemic fungicide having a specific mode of action which has been subject to development of resistant strains of fungi. Development of resistance cannot be predicted. Therefore, Bayer CropScience cannot assume liability for crop damage resulting from resistant strains of fungi. Consult with your local extension potato specialist for guidance and ways to control any possible resistant strains of fungi which may occur.

NOTE: This pesticide is to be sold ONLY in this original unbroken package.

Do not use treated seed-pieces for food, feed, or fodder. Plant as soon as possible after cutting and treating in accordance with the basic recommendations of your local extension potato specialist.

Apply only in areas with adequate ventilation or dust collection and control equipment installed. Do not substitute fans for ventilation in areas where application is made to cut potatoes.

APPLICATION

TOPS MZ aids in the suppression of potato seed-piece diseases caused by *Fusarium* (dry rot), *Rhizoctonia* (black scurf and stem canker), and *Helminthosporium solani* (silver scurf) and will help reduce the *spread of *Phytophthora infestans* (late blight) that may occur from surface infestation resulting from seed-piece to seed-piece contact during the handling, cutting and planting process. [*TOPS MZ is not efficacious against systemic seed-piece infections or airborne (secondary) inoculum.] Use 0.75-1.0 pound TOPS MZ per 100 pounds of cut seed-pieces. Apply by means of a seed dust metering applicator or dust attachment positioned over the belt so that the cut seed-pieces are thoroughly covered with TOPS MZ. Thoroughly clean and sanitize cutting machines, knives, trays, tables,

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barrels, equipment, trucks and planters before cutting and planting seed-pieces. Consult your local extension potato specialist for detailed information about controlling Silver Scurf in your area.

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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:

TOPS is a registered trademark of Bayer

Produced for



Bayer CropScience

**Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
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1-866-99BAYER (1-866-992-2937)**

TOPS MZ Potato Seed-Piece Treatment Fungicide(PENDING) Submitted 10/28/05, resub 01/22/08, resub 3/07/08, resub 08/08/08