

264-977

07-27-2009

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 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE: <input type="checkbox"/> Registration <input checked="" type="checkbox"/> Reregistration (under FIFRA, as amended)</p>	<p>EPA Reg. Number: 264-977-</p>	<p>Date of Issuance: JUL 27 2009</p>
	<p>Term of Issuance: Unconditional</p>	
	<p>Name of Pesticide Product: Tops-MZ-Gaicho® Potato Seed-Piece Treatment</p>	
<p>Name and Address of Registrant (include ZIP Code): Bayer CropScience LP P.O. Box 12014 Research Triangle Park, NC 27709</p>		
<p>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.</p>		
<p>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.</p> <p>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:</p> <ol style="list-style-type: none"> In the list of ingredients on page 1 line up the decimal points and change "INERT INGREDIENTS" to "OTHER INGREDIENTS" 		
<p>Signature of Approving Official: <i>Mary L. Waller</i> Mary Waller, Product Manager (21) Fungicide Branch, Registration Division (7505P)</p>		<p>Date: 7/27/2009</p>

2. On page 2 change the header **PERSONAL PROTECTIVE EQUIPMENT** to "**PERSONAL PROTECTIVE EQUIPMENT (PPE)**"
3. 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 ..."
4. On page 2, revise the **ENVIRONMENTAL HAZARDS** section as follows: "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.

Imidacloprid demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination."
5. Change the second sentence in the paragraph following the header **DIRECTIONS FOR USE** to "Do not use this product at higher than specified rate." and relocate the sentence to the **RESTRICTIONS** section on page 3.
6. On page 3, move the **AGRICULTURAL USE REQUIREMENTS** box above the Storage and Disposal box.
7. 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.*]
8. 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".
9. In the **AGRICULTURAL USE REQUIREMENTS** box add "chemical resistant head-gear for overhead exposure" to the early entry PPE.
10. On page 3 in the **NOTE** following the header **RESISTANCE MANAGEMENT** delete the sentence "Therefore, Bayer CropScience cannot assume liability for crop damage resulting from resistant strains of fungi."
11. On page 3 in the second paragraph of the section **RESTRICTIONS** change "Apply only on areas...." to "Apply only in areas...."

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12. On page 3, change the header **RECOMMENDED APPLICATION** to **APPLICATION DIRECTIONS**.

13. 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 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 and the insecticide imidacloprid. 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.

ROTATIONAL PLANT-BACK INTERVALS ¹		
Immediate Plant-Back		
Artichoke	Ground cherry	Sorghum
Barley	Leaf Petiole Veg.	Soybean
Brassica (cole) leafy veg.	Leafy Veg.	Strawberry
Canola	Legume Veg. (succulent or dried)	Sugar beet
Cilantro	Lettuce	Tomatillo
Corn, Field	Mustard seed	Tomato
Corn, Sweet	Okra	Triticale
Cotton	Pepino	Veg. Root and Tuber
Cranberry	Pepper	Turnip greens
Cucurbit	Popcorn	Watercress
Eggplant	Potato	Wheat
	Rapeseed	Veg. root & tuber
30-Day Plant-Back		
Cereals (Including buckwheat, millet, oats, popcorn, rice, rye,)		
Legumes (Including soybeans, beans and peas)		
Safflower		
12-Month Plant-Back		
All Other Crops		
¹ Cover crops for soil building or erosion control may be planted any time, but do not graze or harvest for food or feed.		

14. On page 4 in the line above the table change “...interval should be observed.” to “...interval must be observed.”

15. On page 4 in the first note below the table change "...at recommended rates." to "...at specified rates."

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 and alternate Confidential Statements of Formula (CSFs) dated 3/17/08, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable. These CSFs supersede 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 (mancozeb) dated May 2, 2008
PRB Label Review (thiophanate-methyl) dated February 28, 2007
Acute Toxicity Review DP352007 dated April 29, 2008
Product Chemistry Review DP352006 dated April 28, 2008

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TOPS[®]-MZ-GAUCHO[®] Potato Seed-Piece Treatment

ACTIVE INGREDIENTS:

Imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine)..... 1.25%
 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: 90.25%
TOTAL 100.00%

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

EPA Reg. No. 264-977

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 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.
<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>	

**ACCEPTED
with COMMENTS
in EPA Letter Dated
JUL 27 2009**

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act
 as amended, for the pesticide
 registered under EPA Reg. No.
 264-977

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

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

PERSONAL PROTECTIVE EQUIPMENT

Some materials that are chemical-resistant to this product are made of waterproof materials. 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-21 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' 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 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. 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. Exposed treated seed-pieces may be hazardous to birds. Dispose of all excess treated seed-pieces and seed packaging by burial away from bodies of water.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This labeling must be in the possession of the user at the time of application. 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 or disposal.

PESTICIDE STORAGE

Store in cool, dry location. Do not store in direct, hot sunlight. Protect from freezing temperatures.

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 by tapping sides to dislodge residues. 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 not 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.

PESTS CONTROLLED

Potato Seed-Piece – To aid in control of insects including aphids, Colorado potato beetle, flea beetle, potato leafhopper, psyllids, *wireworms *Limoni* sp., and *Melanotus* sp.), and diseases including *Fusarium* (dry rot), *Rhizoctonia* (black scurf and stem canker), *Helminthosporium solani* (silver scurf) and to 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. Consult your local extension potato specialist for detailed information about controlling silver scurf in your area.

*TOPS-MZ-GAUCHO when used at the label rate can reduce wireworm damage in seed pieces, and can also reduce the amount of damage in the daughter tubers.

**TOPS-MZ-GAUCHO is not efficacious against systemic seed-piece infections or airborne (secondary) inoculum.

RESISTANCE MANAGEMENT

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 resistant strains 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. This pesticide will not control bacterial diseases or other diseases not claimed on the 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.

Some insects are known to develop resistance to insecticides after repeated use. As with any insecticide, the use of this product should conform to resistance management strategies established for the use area. Consult your agricultural advisor for resistance management strategies and recommended pest management practices for your area.

RESTRICTIONS

Do not use treated seed-pieces for food, feed, or fodder.

Regardless of the type of application (seed-piece treatment, soil or foliar) do not apply more than 0.25 pounds a.i. (imidacloprid) per acre per year.

Apply only on 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.

RECOMMENDED APPLICATION

Apply at 0.75 pound per 100 pounds of cut seed-pieces. Apply using a seed dust metering applicator so that cut seed-pieces are thoroughly covered with the mixture. Thoroughly clean and sanitize cutting machines, knives, trays, tables, barrels, equipment, trucks

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and planters before cutting and planting seed-pieces. Plant seed-pieces as soon as possible after cutting and treating in accordance with the recommendations of your local extension potato specialist. Avoid prolonged exposure of treated seed-pieces to sunlight.

The length of control will vary depending on the rate used. Consult your local Bayer CropScience representative or dealer for information relevant to your area.

ROTATIONAL CROPS

Treated areas may be replanted with any crop specified on an imidacloprid label, or any crop for which a tolerance exists for the active ingredient, as soon as practical following the last application.

For crops not listed on an imidacloprid label, or for crops for which no tolerances for the active ingredient have been established, a 12-month plant-back interval should be observed.

ROTATIONAL PLANT-BACK INTERVALS¹		
Immediate Plant-Back		
Artichoke Barley Brassica (cole) leafy veg. Canola Cilantro Corn, Field Corn, Sweet Cotton Cranberry Cucurbit Eggplant	Ground cherry Leaf Petiole Veg. Leafy Veg. Legume Veg. (succulent or dried) Lettuce Mustard seed Okra Pepino Pepper	Popcorn Potato Rapeseed Sorghum Soybean Strawberry Sugar beet Tomatillo Tomato Triticale Veg. Root and Tuber Turnip greens Watercress Wheat Veg. root & tuber
30-Day Plant-Back		
Cereals (Including buckwheat, millet, oats, popcorn, rice, rye.) Legumes (Including soybeans, beans and peas) Safflower		
12-Month Plant-Back		
All Other Crops		
¹ Cover crops for soil building or erosion control may be planted any time, but do not graze or harvest for food or feed.		

Notification of the crop rotational restrictions must be conveyed to the grower through the distribution of this label on all commercially treated seed.

NOTE: Federal regulations have established official tolerances for certain pesticide residues. In order that residues on food and forage crops will not exceed established tolerances, use only at recommended rates.

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

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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. 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.

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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:

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Produced for



Bayer CropScience

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TOPS-MZ-GAUCHO Potato Seed-Piece Treatment (PENDING) Submitted 10/28/05, Resub 01/22/08, Resub 03/07/08, Resub 08/08/08