

264-977

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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

JUN 15 2011

Product Name: TOPS MZ Gaucho Potato Seed Piece Treatment
EPA Reg. No.: 264-977
Subject: Notification dated May 10, 2011: Deletion of "Notice to Buyer" statement
EPA Decision Number: 449236

Dear Dr. Huang:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10.

The Agency acknowledges the deletion of the Notice to Buyer statement.

The label submitted with the application has been stamped "Notification" and will be placed in our records. If you have any questions, please contact Erin Malone at (703) 347-0253 or via email at malone.erin@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Mary L. Waller".

Mary L. Waller
Product Manager (21)
Fungicide Branch
Registration Division (7504P)



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-977	2. EPA Product Manager Mary L. Waller	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) TOPS MZ Gaucho Potato Seed Piece Treatment	PM# Team 21	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

REGFEE: Notification per PRN 98-10
Justifications: Submit an amended label to delete "Notice to Buyer - Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside the United States" from the 7/27/2009 approved label via Notification per PR Notice 98-10. See attached cover letter.
CONTACT: Jamin Huang, jamin.huang@bayer.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 40 lbs		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Jamin Huang, Ph.D.	Title Senior Regulatory Manager	Telephone No. (Include Area Code) (919) 549-2634
2. Signature 		6. Date Application Received (Stamped)
3. Title Senior Regulatory Manager		
4. Typed Name Jamin Huang, Ph. D.	5. Date May 10, 2011	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		

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])*.....	2.50%
Mancozeb: A coordination product of zinc ion and manganese ethylene bisdithiocarbamate.....	6.00%
In which the ingredients are:	
Manganese++	1.20%
Zinc++	0.15%
Ethylene bisdithiocarbamate ion (C ₄ H ₆ N ₂ S ₄)	4.65%

OTHER 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

NOTIFICATION

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. 	<p>JUN 15 2011</p>
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.

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 (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' 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 ≥ 50,000 cwt (≥ 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. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. 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

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of the 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 demonstrated 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.

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 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.

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 the treated areas during restricted entry interval (REI) of 48 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, chemical resistant head-gear for overhead exposure and chemical-resistant footwear plus socks.

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 taping 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.

PESTS CONTROLLED

Potato Seed-Piece – To aid in control of insects including aphids, Colorado potato beetle, flea beetle, potato leafhopper, psyllids, *wireworms *Limonius 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. 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 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.

Do not use this product at higher than specified rate.

APPLICATION DIRECTIONS

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 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.

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 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 restrictions if there will be no contact with treated surface.”

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 must 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, except soybean) Lettuce Mustard seed Okra Pepino Pepper	Popcorn Potato Rapeseed Sorghum Soybean Strawberry Sugar beet Tomatillo Tomato Triticale Turnip greens Watercress Wheat Veg. root & tuber
30-Day Plant-Back		
Cereals (Including buckwheat, millet, oats, popcorn, rice, rye, and triticale) 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 specified rates.

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

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.

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.

NET CONTENTS:

GAUCHO and TOPS are registered trademarks of Bayer



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)**

TOPS-MZ-GAUCHO Potato Seed-Piece Treatment (MASTER) 07/27/2009, Notification 06/09/2011