

264-978

05-24-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 24 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dr. Jamin Huang
Bayer CropScience
P.O. Box 12014, 2 T.W. Alexander Drive
Reserch Triangle Park, NC 27709

Subject: Amended Label to Delete Notice to Buyer Statement

Dear Dr. Huang:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated May 10, 2011 for:

EPA Reg. No. 264-978

Gaicho MZ Potato Seed Piece Treatment

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN-98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, call me at 703 305-5409 or electronically at daniel.dani@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be "Dani Daniel".

Dani Daniel
Registration Division (7504P)
Insecticide/Rodenticide Branch



United States
Environmental Protection Agency
Washington, DC 20460

 Registration
 Amendment
 Other

OPP Identifier Number

NOTIFICATION

Application for Pesticide - Section I

1. Company/Product Number 264-978	2. EPA Product Manager Mary L. Waller	3. Proposed Classification MAY 24 2011 <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Gaucho MZ 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 9/28/2009 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
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	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 <input type="checkbox"/> 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	
Certification 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.			6. Date Application Received (Stamped)
2. Signature 	3. Title Senior Regulatory Manager		
4. Typed Name Jamin Huang, Ph. D.	5. Date May 10, 2011		

CERTIFICATION
MAY 24 2011

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GAUCHO[®]-MZ Potato Seed-Piece Treatment

ACTIVE INGREDIENTS:

Imidacloprid (1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine).....	1.25%
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 (C ₄ H ₆ N ₂ S ₄).....	4.65%

OTHER INGREDIENTS:	92.75%
TOTAL	100.0%

EPA Reg. No. 264-978

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.
<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>	

PRECAUTIONARY STATEMENTS

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT

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.

USER SAFETY 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, and must be provided with, have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown: 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.

When handlers use closed systems 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 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 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. 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 the specified 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

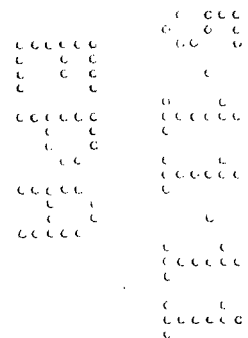
Store in cool, dry location. Do not store in direct, hot sunlight. Protect from freezing temperatures.

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 instruction, contact your State Pesticide or Environmental Control Agency, or 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 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, shoes plus socks, and protective eyewear.

RESISTANCE MANAGEMENT

NOTE: 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.

PESTS CONTROLLED

Potato Seed-Piece – To aid in control of insects including aphids, Colorado potato beetle, flea beetles, potato leafhopper, psyllids and *wireworms (*Limoniussp.*, and *Melanotus sp.*) (seed-piece protection only) and *Fusarium* (dry rot).

*GAUCHO-MZ 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.

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.

Seed Tag Labeling Requirements

Seed-pieces that have been treated with this product that are then packaged or bagged for future use must contain the following labeling on the outside of the seed/seed-piece package or bag:

“Treated Seed/Seed-Pieces – Do Not Use for Food, Feed, or Oil Purposes.

This bag contains potato seed pieces treated with imidacloprid and mancozeb. When opening this bag or pouring the treated seed/seed-pieces, wear 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 the seeds/seed pieces have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours. Exception: Once the seeds/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.”

“Observe the following rotational plant-back intervals:”

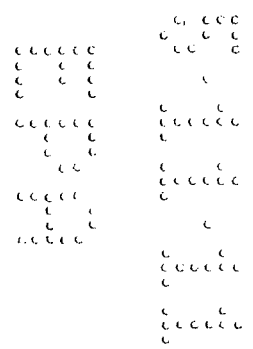
ROTATIONAL PLANT-BACK INTERVALS ¹				
IMMEDIATE PLANT-BACK			30-DAY PLANT-BACK	12-MONTH PLANT-BACK
Artichokes	Gound cherry	Popcorn	Cereals	All Other Crops
Barley	Leaf Petiole Veg.	Potato	(Including buckwheat, millet, oats, rice, rye, and triticale)	
Brassica (cole) leafy veg.	Leafy Veg.	Rapeseed	Soybeans	C C C C C
Canola	Legume veg.	Sorghum	Safflower	C C C C C
Cilantro	(succulent or dried, except soybean)	Strawberry		C C C C C
Corn, Field	Lettuce	Sugar beet		C C C C C
Corn, Sweet	Mustard seed	Tomatillo		C C C C C
Cotton	Okra	Tomato		C C C C C
Cranberry	Pepino	Turnip greens		C C C C C
Cucurbit	Pepper	Watercress		C C C C C
Eggplant		Wheat		C C C C C
		Veg. root & tuber		C C C C C

¹Cover crops for soil building or erosion control may be planted anytime, but do not graze or harvest for food or feed.
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 labeled rates.

APPLICATION RATES

Apply at 0.5 – 0.75 pounds 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 recommendation 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.



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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.

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:

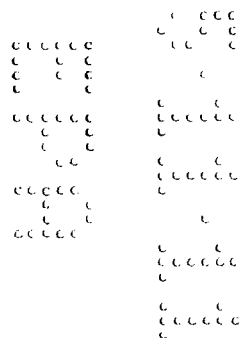
GAUCHO is a registered trademark of Bayer

Produced for



Bayer CropScience

**Bayer CropScience LP
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1-866-99BAYER (1-866-992-2937)**



GAUCHO® -MZ Potato Seed-Piece Treatment (MASTER) 09/28/09, Notification 05/10/2011