

264-1017

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

AUG 18 2009

Dr. Jamin Huang
Product Registration Manager
Bayer CropScience LP
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: IMIDACLOPRID-VITAVAX[®]-METALAXYL SEED TREATMENT
EPA Reg. No. 264-1017
Notification Application Dated July 21, 2009.

Dear Dr. Huang:

The Agency has received your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4, dated July 21, 2009, for the product Imidacloprid-Vitavax[®]-Metalaxyl Seed Treatment, EPA Reg. No. 264-1017. The Registration Division (RD) has reviewed this request and finds that the action requested falls within the scope of PR Notice 2007-4. The label submitted with the application has been stamped "Notification" and will be placed in our records.

Although we do not routinely review entire labels that are submitted with Notifications, I noticed that the words "This product contains metalaxyl" are missing from the first sentence of the third paragraph under "**ENVIRONMENTAL HAZARDS**" on the labels that you submitted with your Notification of July 21, 2009. Make sure that the full sentence appears on printed labels.

If you have any questions, please call me directly at 703-305-6406.

Sincerely,

William W. Jacobs
Insecticide-Rodenticide Branch
Registration Division (7505P)
Office of Pesticide Programs

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United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-1017	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Imidacloprid-Vitavax-Metalaxyl seed treatment	PM# Team 01	
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.

NOTIFICATION

AUG 18 2009

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

REGFEE: Notification, Fee amount due: \$ 0

Justifications: Submit an amended Imidacloprid-Vitavax-Metalaxyl seed treatment to update container disposal statement per PRN 2007-4. No new data needed to be reviewed by the Agency. See my cover letter for certification in compliance with PR Notice 2007-4.

CONTACT: Jamin Huang, jamin.huang@bayercropscience.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	Other (Specify) _____	
		If "Yes" Package wgt.	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1.5 oz, 4 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 Product Registration Manager, Insecticides	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 Product Registration Manager, Insecticides	
4. Typed Name Jamin Huang, Ph. D.	5. Date July 21, 2009	

Bayer CropScience



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July 21, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Linda Arrington (Team leader, Notifications & Minor Formulation)

Re: Notification to Update Container Disposal Statement per PR Notice 2007-4 for Imidacloprid-Vitavax-Metalaxyl Seed Treatment (EPA Reg. No. 264-1017)

Dear Ms. Arrington,

Byaer CropScience is herein submitting a Notification to update the container disposal statement per PR Notice 2007-4 on the 09/22/2008 EPA latest approved label for Imidacloprid-Vitavax-Metalaxyl Seed Treatment. Three copies of the amended label dated 07/21/2009 are attached.

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000

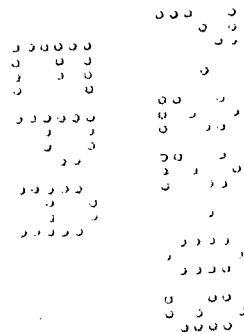
"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA regulations at 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the requirements of 40 CFR 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Please let me know at jamin.huang@bayercropscience.com or at 919-549-2634 if you have any questions regarding this submission.

Sincerely,

A handwritten signature in black ink that reads 'Jamin Huang'.

Jamin Huang, Ph.D.
Product Registration Manager



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IMIDACLOPRID-VITAVAX[®]-METALAXYL

Seed Treatment

For the protection of Seeds and Seedlings of Field Corn, Sweet Corn and Popcorn against Seed and Seedling Diseases caused by *Pythium* and *Rhizoctonia*; also against Seed Corn Beetle, Seed Corn Maggots, and Wireworms. For the protection of Seeds and Seedlings of Sorghum against Seed and Seedling Diseases caused by *Pythium* and *Rhizoctonia*, also for suppression against Wireworm, Seed Corn Maggot, and White Grub, and protection of seed against Flea Beetle (up to first true leaf), Seed Corn Beetle, and Imported Fire Ants.

For the protection of Seeds and Seedlings of Soybeans against Seed and Seedling diseases caused by *Rhizoctonia* and *Pythium*; also suppression of Seed Corn Maggots and early season control of over-wintering Bean Leaf Beetles.

ACTIVE INGREDIENTS:

Imidacloprid	25.00%
Carboxin	14.00%
Metalaxyl	1.00%

OTHER INGREDIENTS 60.00%

TOTAL 100.00%

EPA Reg. No. 264-1017

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 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 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 swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are (barrier laminate, nitrile rubber or neoprene rubber). If you want more options, follow the instructions for category E, on an EPA chemical-resistance category selection chart.

All loaders, applicators and other handlers must wear:
-long-sleeved shirt and long pants
-socks plus shoes
-chemical resistant gloves, except when bagging or sewing bags of treated seeds,
-chemical resistant aprons when loading.

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.

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

For on Farm Use: Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

For Commercial Seed Treatment Facilities: 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 Eliminations 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 with out previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

that is known to leach through soil into groundwater under certain conditions as result of agricultural use. Use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds.

ENDANGERED SPECIES

This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult <http://www.epa.gov/espp> before each season's use of this product.

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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.

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 is 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 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, or treated seed is:

- Coveralls
- Shoes plus socks
- Chemical-resistant gloves made of any waterproof material

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Store in a cool dry location. Protect from excessive heat.

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 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 container into application equipment. Then dispose of empty container in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

PRODUCT INFORMATION

Imidacloprid-VITAVAX®-Metalaxyl may be used on seed previously treated with a full dosage of protective fungicide to give added protection against seedling blight, damping-off or seed decay.

Maximum usage when applying both metalaxyl and mefenoxam containing products to the same crop within the same season: Do not apply more than the maximum seasonal total for the active ingredient as stated on the label of the product containing the lowest seasonal total on that crop.

Note: Adjust the seed drill or planter to give the required rate of seed delivery with treated seed. Regularly inspect planter plates and clean as required. At the end of each day, clean the electric-eye monitors as directed by the manufacturer.

Note: Since this product does not contain a dye, all seed treated with this product which is not planted immediately must be colored with an EPA-approved dye (e.g., 40 CFR 180.1001) which imparts an unnatural color to the seed to help prevent the inadvertent use of treated seed as food for man or feed for animals.

Important: Treated seed must not be used for or mixed with food or animal feed, or processed for oil. Treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Do not store excess treated seed beyond planting time.

SEED TAG LABELLING

Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:

- This seed has been treated with imidacloprid, carboxin, and metalaxyl.
- Dispose of seed packaging in accordance with local requirements.
- This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species with out authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult <http://www.epa.gov/espp> before each season's use of this product.
- This product contains metalaxyl that is known to leach through soil into groundwater under certain conditions as result of agricultural use. Use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.
- Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds.
- When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves.
- Treated Seed- Do Not Use for Food, Feed, or Oil Purposes.
- After seeds 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 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.
- Areas planted with treated seed may be replanted immediately with artichoke, barley, brassica (cole) leafy veg., canola, cilantro, field corn, sweet corn, cotton cranberry, cucurbits, eggplant, ground cherry, leaf petiole veg., leafy veg., legume veg. (succulent or dried, including soybean), millet, mustard seed, oats, okra, pepinos, pepper, popcorn, potato, rapeseed, rye, sorghum, soybean, strawberry, sugarbeet, tomatillo, tomato, triticale, veg. root and tuber, watercress and wheat. These areas may also be replanted after 30 days with cereals, including: buckwheat, rice, safflower.
- Do not graze or feed livestock on forage and hay on treated areas for six weeks after planting soybeans. Do not graze or feed livestock on vines grown from treated soybean seed.
- Do not graze or feed livestock on treated areas for 45 days.

Field Corn, Sweet Corn, Popcorn: Use at a rate of 1.5 oz per 42 lbs of seed.

Sorghum: Use at a rate of 5.0 oz per 100 lbs of seed.

Soybeans: Use at a rate of 4.0 oz per 100 lbs of seed.

Mixing Instructions (1.5 oz canister)

Use as a dry mixture in the planter box as a seed treatment prior to planting. Apply Imidacloprid-VITAVAX®-Metalaxyl to seed at planting time with the canister applicator tube system.

Field corn, Sweet Corn, Popcorn: Apply at a rate of 1.5 oz canister per 42 lbs of seed.

Sorghum: Apply at a rate of 1.5 oz canister per 30.0 lbs of seed.

Soybeans: Apply at a rate of 1.5 oz canister per 37 lbs of seed.

For best results, fill planter box with seed, add Imidacloprid-VITAVAX®-Metalaxyl through applicator tube and mix so that all seeds are covered. **DO NOT MIX WITH BARE HANDS.** Use only at the specified rate. Lower amounts may not give desired control. Excessive amounts may cause seed injury.

Mixing Instructions (4-pound pail)

Use as a dry mixture in the planter box as a seed treatment prior to planting.

Field Corn, Sweet Corn, Popcorn: Use two scoops full (1.5 oz) per 42 lbs of seed.

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Sorghum: Use two scoops full (1.5oz) per 30 lbs of seed.

Soybeans: Use two scoops full (1.5 oz) per 37 lbs of seed.

For best results, fill planter box half full of seed, add half the required amount of Imidacloprid-VITAVAX®-Metalaxyl and mix thoroughly with a stick or paddle. Add remainder of the seed and Imidacloprid-VITAVAX®-Metalaxyl and mix again so that all seeds are covered. **DO NOT MIX WITH BARE HANDS.** Use only at the specified rate. Lower amounts may not give desired control. Excessive amounts may cause injury.

NOTE: Do not graze or feed livestock on forage and hay on treated areas for six weeks after planting soybeans. Do not graze or feed livestock on vines grown from treated soybean seed.

NOTE: Do not graze or feed livestock on treated areas for 45 days.

ROTATIONAL CROPS

Treated areas may be replanted with any crop specified on the Imidacloprid-Vitavax®-Metalaxyl label, or for any crop for which a tolerance exists for each active ingredient. The following plant-back intervals must be observed for listed crops:

ROTATIONAL PLANT-BACK INTERVALS*				
IMMEDIATE PLANT-BACK				30-DAY PLANT-BACK
Artichoke	Cucurbits	Oats	Soybean	Cereals, including: buckwheat rice Safflower
Barley	Eggplant	Okra	Strawberry	
Brassica (cole) leafy veg.	Ground cherry	Pepinos	Sugarbeet	
Canola	Leaf petiole veg.	Pepper	Tomatillo	
Cilantro	Leafy veg.	Popcorn	Tomato	
Corn, Field	Legume veg. (succulent or dried, including soybean)	Potato	Triticale	
Corn, Sweet	Millet	Rapeseed	Veg. Root and Tuber	
Cotton	Mustard Seed	Rye	Watercress	
Cranberry		Sorghum	Wheat	

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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 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.

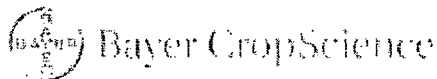
NOTICE TO BUYER

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:

VITAVAX® is a registered trademark of Chemtura USA Corporation

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)**

IMIDACLOPRID-VITAVAX®-METALAXYL Seed Treatment (MASTER) EPA APPROVED 09/22/08, NOTIFICATION 07/21/09