



264-1017

09/22/2008

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 <p><b>U.S. ENVIRONMENTAL PROTECTION AGENCY</b> 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>	EPA Reg. Number:  <b>264-1017</b>	Date of Issuance:  <b>SEP 22 2008</b>
	Terms of Issuance: <b>Unconditional</b>	
	Name of Pesticide Product: <b>IMIDACLOPRID- VITAVAX-METALAXYL SEED TREATMENT</b>	
<b>Name and Address of Registrant (include ZIP Code):</b> Bayer CropScience LP P.O. Box 12014 2 T.W. Alexander Dr. Research Triangle Park, NC 27709		
<p><b>Note:</b> 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 Reregistration Eligibility Document(s) for <b>Carboxin</b>, EPA has reregistered the product listed above provided that the following changes are made to the label:</p> <ol style="list-style-type: none"> <li>1. On page 1, in the ingredient statement, revise "Inert Ingredient" to read "Other Ingredients:"</li> </ol>		
Signature of Approving Official:   Mary L. Waller, Product Manager (Team 21) Fungicide Branch, Registration Division		Date:  <b>SEP 22 2008</b>

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2. On page 2, revise the **Environmental Hazard** section as follows:

“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 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.

This product contains metalaxyl that is known to leach through soil into groundwater under certain condition 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.”

3. Move the **Product Information** and **Seed Tag Labeling** so that it follows the **Storage and Disposal** section in the Directions for Use.
4. Add the following sentence to the **PRODUCT INFORMATION** section:

“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.”
5. In the **Labeling of Treated Seed** section, add another bullet and the following statement:

“This product contains metalaxyl that is known to leach through soil into groundwater under certain condition 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.”
6. Because the REI for Metalaxyl is 24 hours, in the **Seed Tag Labeling**, in the seventh bullet, revise the restricted-entry interval (REI) to read “24 hours.”
7. On page 3, in the **Agricultural Use Requirements** box, revise the REI of “12 hours” to read “24 hours.”

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- 8. On page 3, delete "PROHIBITIONS, Do not contaminate water, food, or feed by storage, disposal, or cleaning of equipment. Do not reuse empty container. Open dumping is prohibited." and add "Do not contaminate water, food, or feed by storage and disposal." under **Storage and Disposal** header.
- 9. On page 3, immediately after **Container Disposal** heading, add "Do not reuse empty container."
- 10. On page 3, in the **Storage and Disposal** section, revise the subheading "Storage" to "Pesticide Storage".
- 11. Submit an amendment by 2/1/2009 in accordance with PR Notice 2007-4: Labeling Revisions Required by the Final Rule *Pesticide Management and Disposal; Standards for Pesticide Containers and Containment*.
- 12. On page 4, add another note which reads as follows:  
  

"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."
- 13. On page 4, revise the two sentences "Use only at the recommended rate." to read "Use only at the specified rate."
- 14. On page 4, revise the first and second sentence to read as follows: "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 the listed crops:"
- 15. On page 5, revise the last sentence under **Conditions** to read "To the extent consistent with applicable law all such risks shall be assumed by the buyer."

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.

Submit one (1) copy of final printed labeling incorporating the above changes before the product is released for shipment. A copy of your label stamped "Accepted with Comments" is enclosed for your records.

Notice of Pesticide Reregistration  
IMIDACLOPRID-VITAVAX-METALAXYL Seed Treatment  
EPA Reg. No. 264-1017  
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The revised basic and alternate Confidential Statements of Formula (CSF) dated 9/18/07 submitted in connection with reregistration under the Federal Insecticide, Fungicide and Rodenticide Act as amended are acceptable. These CSFs supersede all CSFs previously accepted for this product.

If you have questions concerning this letter, you may contact me at 703-308-9354.

Sincerely,



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

Enclosure:

Label stamped "Accepted with Comments"  
PRB Preliminary Label Assessment dated December 4, 2007  
Product Chemistry Review DP344884 dated October 29, 2007  
Acute Toxicity Review DP344887 dated October 9, 2007

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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%

INERT 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

<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<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

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated**

**SEP 22 2008**

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No. 264-1017**

- 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**

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 by disposal of wastes. 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.

**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.

**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.

**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 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.
- 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 12 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.

### 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 12 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

**PROHIBITIONS:** Do not contaminate water, food or feed by storage, disposal or cleaning of equipment. Open dumping is prohibited. Do not reuse empty containers.

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

**Field Corn, Sweet Corn, Popcorn:** Use at a rate of 1.5 ounces per 42 pounds of seed.

**Sorghum:** Use at a rate of 5.0 ounces per 100 pounds of seed.

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

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

**Soybeans:** Apply at a rate of 1.5 oz. canister per 37 pounds 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 recommended 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 pounds of seed.

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

**Soybeans:** Use two scoops full (1.5 oz.) per 37 pounds 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 recommended 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 imidacloprid, as soon as practical following the last application. The following plant-back intervals should 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. 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.

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PRODUCED FOR



**Bayer CropScience**

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IMIDACLOPRID-VITAVAX®-METALAXYL Seed Treatment (PENDING) SUBMITTED TO EPA 09/24/07