

264-940

8/7/2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

AUG 07 2009

Mr. Larry R. Hodges
Bayer CropScience LP
2 T.W. Alexander Drive,
Research Triangle Park, NC 27709

SUBJECT: Label Notification(s) for Pesticide Registration Notice PRN 2007-4
Request Storage and disposal changes
EPA Reg. No. 264-940
Application Dated June 24, 2009

Dear Registrant:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 dated 6/24/2009 for the product **Vitavax-PCNB Flowable Fungicide**. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2007-4 and finds that the action(s) requested does not clearly fall within the scope of PRN 2007-4 and will require additional administrative review of the related files. A summary of our findings include:

The statements for rigid non-refillable containers larger than 5 gallons and the refillable statements are not exact as in the PR Notice. Modified statements must be reviewed as an amendment.

Therefore, the RD has determined that this action is denied and will be further processed as an amendment and our records have been updated accordingly. The label submitted with the application is considered proposed drafts and has been forwarded to Mary Waller (PM 21) for further processing.

If you have any questions, please call me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269

Sincerely,

Rachel C. Holloman
for

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

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United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 264-940	2. EPA Product Manager NOTIF	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Vitavax-PCNB Flowable Fungicide	PM# 21	
5. Name and Address of Applicant (Include ZIP Code) Bayer CropScience LP 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 _____	

NOTIFICATION

AUG 07 2009

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application.
 Notification - Explain below. Other - Explain below.

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

"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's 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 the amended label 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."

Section - III

1. Material This Product Will Be Packaged In:

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	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) poly drum
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container
5, 50, 200, 400 gal.

5. Location of Label Directions

6. Manner in Which Label is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Larry R. Hodges	Title Registration Manager - Insecticides	Telephone No. (include Area Code) 919-549-2870
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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.

2. Signature
L. R. Hodges

3. Title
Registration Manager - Insecticides

4. Typed Name
Larry R. Hodges

5. Date
June 24, 2009

6. Date Application Received (Stamped)

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VITAVAX[®]-PCNB Flowable Fungicide

Contains 1.68 lbs. carboxin and 1.68 lbs PCNB per U.S. gallon.

ACTIVE INGREDIENTS:

Carboxin: 5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide..... 17%
 Pentachloronitrobenzene (PCNB)..... 17%

OTHER INGREDIENTS: 66%
 Contains petroleum distillates TOTAL 100%

EPA Reg. No. 264-940

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"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to 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.
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.

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.

Note to Physcian: May pose an aspiration pneumonia hazard. Contains petroleum distillates.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

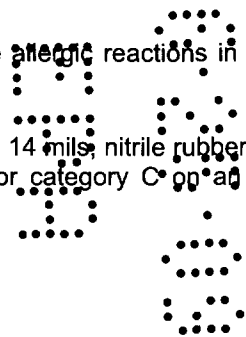
CAUTION: Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE):

Some materials that are chemical-resistant to this product are barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, and neoprene rubber ≥ 14 mils. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

All mixers, 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 mixing, 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 clothing.

ENGINEERING CONTROLS

When handlers use closed systems designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people AND the system is functioning properly and is used and maintained in accordance with the manufacturer's written operating instructions, the handlers need not wear the chemical-resistant apron and gloves. However, the chemical-resistant apron and gloves must be immediately available for use in an emergency, such as a spill or equipment breakdown.

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 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.

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

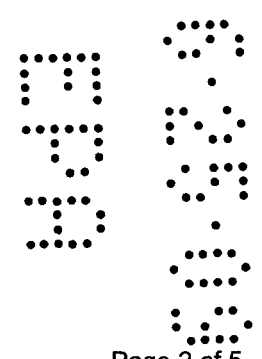
ENDANGERED SPECIES

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.

DIRECTIONS FOR USE

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

Not for use on agricultural establishments in hopper-box, planter-box, slurry-box, or other seed treatment applications at or immediately before planting.



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal or by cleaning of equipment. Open dumping is prohibited..

PESTICIDE STORAGE

Store in a cool, dry, secure, location. Do not store in direct hot sunlight. Keep container closed when not in use.

CONTAINER DISPOSAL

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons).

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.

Once container is rinsed, offer for recycling if available, or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons).

Non-refillable container. Do not reuse or refill this container. After emptying product from container, contact Bayer CropScience Customer Service Center (1-800-527-4781) with return authorization for container return instructions. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

Refillable container.

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. After emptying product from container, contact Bayer CropScience Customer Service Center (1-800-527-4781) with return authorization for container return instructions. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned stay out of smoke.

LABELING OF TREATED SEED

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 carboxin and pentachloronitrobenzene (PCNB).
- Do not use for feed, food or oil purposes.
- Store away from feeds and foodstuffs.
- When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves.
- Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds.
- 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.
- After the 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 subsurface.
- Do not graze or feed livestock on treated areas of wheat, barley, or oats for six weeks after planting. Do not graze or feed livestock on forage or hay grown from treated cotton or soybean seed.

VITAVAX-PCNB Flowable Fungicide combines the systemic action of carboxin with the surface action of PCNB to control various seed and seedling diseases. It is particularly effective against *Rhizoctonia solani*.

COMPATIBILITY

VITAVAX-PCNB Flowable Fungicide should not be tank mixed with any pesticide unless adequate physical and compatibility and phytotoxicity tests have been completed and proved to be satisfactory.

USE RESTRICTIONS

Do not use treated seed for food, feed or oil purposes. Do not graze or feed livestock on treated areas of wheat, barley, or oats for six weeks after planting. Do not graze or feed livestock on forage or hay grown from treated cotton or soybean seed. Care must be exercised in the handling of treated seed.

Since this product does not contain a dye, all seed treated with this product 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.

BARLEY, WHEAT AND OATS:

Use 3-4 fl oz of VITAVAX-PCNB Flowable Fungicide per 100 lbs of seed. VITAVAX-PCNB Flowable Fungicide should be applied as a slurry treatment by machine. Use the higher rate under conditions of expected heavy disease pressure.

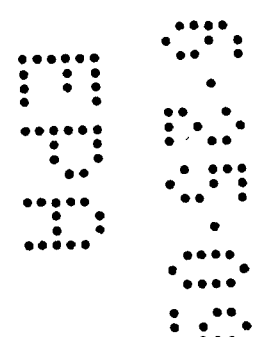
In addition, loose smut (*Ustilago nuda*) and covered smut (*Ustilago hordei*) are controlled on barley, and loose smut (*Ustilago tritici*) and common bunt (*Tilletia caries*) are controlled on wheat by VITAVAX-PCNB Flowable Fungicide.

COTTON:

Use 5 to 7 fl oz of VITAVAX-PCNB Flowable Fungicide per 100 lbs of seed as a slurry treatment by machine. Use the higher rate under conditions of expected heavy disease pressure.

SOYBEANS

Use 2 fl oz of VITAVAX-PCNB Flowable Fungicide per bushel of seed or 4 fl oz per 100 lbs of seed. VITAVAX-PCNB Flowable Fungicide should be applied as a slurry treatment by machine.



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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:

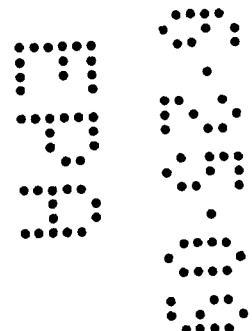
VITAVAX® is a registered trademark of Chemtura, Inc.

Produced for



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)



VITAVAX-PCNB Flowable Fungicide (PENDING) 06/11/09