



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 WASHINGTON, DC 20460

OFFICE OF
 PREVENTION, PESTICIDES AND
 TOXIC SUBSTANCES

Larry Hodges
 Registration Manager, Insecticide
 Bayer CropScience
 2 T.W. Alexander Drive
 P.O. Box 12014
 Research Triangle Park, NC 27709

SEP 23 2008

Subject: Reregistration: Vitavax®-PCNB
 EPA Reg. No. 264-940
 Your 8-month submission dated September 24, 2007
 EPA Decision Number 373922

Dear Dr. Hodges:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is acceptable provided the following changes are made:

1. Add the following immediately below the ingredients statement: "Contains petroleum distillates"
2. In the **FIRST AID** box, change the **IF SWALLOWED** first aid statements to read:
 - 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
3. Add the following statement in the **FIRST AID** box: "Note to Physician: May pose an aspiration pneumonia hazard. Contains petroleum distillates."
4. Revise the **HAZARDS TO HUMANS AND DOMESTIC ANIMALS** statement to read: "CAUTION: Harmful if swallowed. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."
5. In the PPE section, delete the text "...or participating in dip treatments" because this product is not applied as a dip.
6. On page 2, revise the Engineering Controls section to read as follows: 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.

7. On page 2, revise the Environmental Hazards section to read as follows:

“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.

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

8. On page 2, under the Endangered Species section, delete the first sentence.
9. On page 2, in the Storage and Disposal section, revise the subheading “Storage” to read “Pesticide Storage”, and revise the first sentence to read “Store in a cool, dry, secure location.”
10. Submit an amendment by 2/1/2009 to amend the product labeling in accordance with the Pesticide Registration Notice 2007-4: Labeling Revisions Required by the Final Rule “Pesticide Management and Disposal; Standards for Pesticide Containers and Containment.”
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11. On page 2, delete the Agricultural Use Requirements box as this product is not subject to the Worker Protection Standard.
12. On page 3, under the Labeling of Treated Seed section, correct the spelling of “seed” in the fourth bullet and delete the first sentence in the sixth bullet.
13. On page 4, in the Conditions section, revise the last sentence to read “To the extent consistent with applicable law, all such risks shall be assumed by the buyer.”

One copy of the label stamped “Accepted with comments” is enclosed for your records. This label supersedes all labels previously accepted for this product. Please submit one copy of the final printed label that incorporates the required changes before the product is released for shipment.

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The basic and alternate Confidential Statements of Formula (CSF) dated 9/18/07 referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended are acceptable. These CSFs supersede all CSFs previously accepted for this product.

The Agency has completed its review of the one year storage stability and corrosion characteristics data (MRID 474639-01) and has determined that the data requirements for guidelines 830.6317 and 830.6320 are satisfied. A copy of the Product Chemistry Review DP474639-01 is enclosed for your records. This fulfills the data requirement finding number 4 of the Product Chemistry Review DP472383 dated October 22, 2007.

EPA determined that you fulfilled the requirements of the carboxin RED for the subject product. However, we are unable to reregister the product under FIFRA 4(g)(2)(c) at this time since it also contains the active ingredients PCNB for which a reregistration eligibility decision was signed in July 2006. This product will be reregistered once the data requirements have been satisfied for this product under the PCNB RED.

If you have any questions, please contact Robert Westin by phone at (703) 305-5721 or via email at westin.robert@epa.gov.

Sincerely,



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

Enclosure:

- PRB Preliminary label review dated July 25, 2008
- Acute Toxicity Review DP344678 dated October 5, 2007
- Product Chemistry Review DP354419 dated July 15, 2008
- Product Chemistry Review DP344688 dated October 22, 2007

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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%

INERT INGREDIENTS: 66%
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"> • 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.
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

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed, inhaled or absorbed through the skin. May cause irritation of nose, throat, eyes and skin. Avoid contact with skin, eyes or clothing. Avoid breathing vapors or spray mist

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, or participating in dip treatments.

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. However, the chemical-resistant gloves must be immediately available for use in an emergency, such as a spill or equipment breakdown.

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.

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

PROHIBITIONS

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

STORAGE

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

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

Triple rinse (or equivalent) and offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

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

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 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.
- 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 fluid ounces of VITAVAX-PCNB Flowable Fungicide per 100 pounds 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 fluid ounces of VITAVAX-PCNB Flowable Fungicide per 100 pounds of seed as a slurry treatment by machine. Use the higher rate under conditions of expected heavy disease pressure.

SOYBEANS

Use 2 fluid ounces of VITAVAX-PCNB Flowable Fungicide per bushel of seed or 4 fluid ounces per 100 pounds 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. 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.

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

**SEP 23 2008
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.**

264-940



Bayer CropScience

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VITAVAX-PCNB Flowable Fungicide (PENDING) SUBMITTED TO EPA 09/24/07.