

264-949

11/20/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

NOV 20 2008

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

Subject: Reregistration: Vitavax[®] PC Peanut Seed Treatment Fungicide
EPA Reg. No. 264-949
Your 8-month submission dated September 24, 2007
EPA Decision Number 373925

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. On Page 1, based on toxicity review, First Aid statements must be placed in the following order:
"IF IN EYES:...
IF ON SKIN OR CLOTHING:...
IF INHALED:...
IF SWALLOWED:..."
2. On page 1, in the IF INHALED section, add the word "advice" to the last line after the word "treatment".
3. On page 1, move the signal word "Danger" so that it appears below the subheading "HAZARDS TO HUMANS AND DOMESTIC ANIMALS".
4. On page 1, delete the paragraph under the HAZARDS TO HUMAN AND DOMESTIC ANIMALS heading and add "Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals."
5. On page 2, under PPE, revise "chemical resistant gloves except when bagging or sewing bags" to read "chemical resistant gloves".
6. On page 2, revise the Engineering Controls section to read, "When handlers use closed systems designed by the manufacturer to enclose the pesticides 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 or gloves. However, the chemical-resistant gloves and apron must be immediately available for use in an emergency, such as a spill or equipment breakdown."

7. On page 2, Under the ENVIRONMENTAL HAZARDS, delete current statement and add "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 SEED LABELING:
 - a. Remove the quotation marks surrounding the statements in the first and second bullets.
 - b. Revise the first bullet to read: This bag contains seed treated with captan, carboxin, and PCNB.
 - c. Delete the first sentence in the third bullet.
 - d. Add a sixth bullet with the following statement: Do not graze or feed livestock on treated area.
9. On page 3, replace the heading "DIRECTIONS FOR USE" with "Applications Instructions".
10. 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.
11. On page 3, immediately after Container Disposal heading, add "Do not reuse empty container."
12. On page 4, under Conditions, revise the last sentence to read "To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer."
13. In accordance with PR Notice 2007-4, submit an amendment before February 1, 2009 to comply with the labeling revisions required by the Final Rule for pesticide management and disposal.

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.

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.

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 ingredient 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:

- Label stamped "Accepted with Comments"
- PRB Preliminary Label Assessment dated November 27, 2007
- Product Chemistry Review DP344803 dated November 2, 2007
- Acute Toxicity Review DP344804 dated October 9, 2007
- PRB Preliminary Label Assessment dated February 22, 2005

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VITAVAX[®] PC Peanut Seed Treatment Fungicide

For Use Only By Commercial Seed Treaters

ACTIVE INGREDIENTS:

| | |
|--|---------------------|
| Captan: N-trichloromethylthio-4-cyclohexene-1,2-dicarboximide..... | 45.0% |
| Related Derivatives..... | 1.0% |
| Pentachloronitrobenzene (PCNB)..... | 15.0% |
| Carboxin..... | 10.0% |
| INERT INGREDIENTS: | 29.0% |
| | TOTAL 100.0% |

EPA Reg. No. 264-949

EPA Est.

KEEP OUT OF REACH OF CHILDREN DANGER

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 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. |
| 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. |
| 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. |

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

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.

PRECAUTIONARY STATEMENTS

DANGER HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Do not get in eyes or on clothing. Avoid contact with skin. Avoid breathing dust. Wear long-sleeved shirt and long pants, socks and shoes, goggles or face shield and chemical resistant gloves (such as or made out of any waterproof material, Selection Category A). Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum using tobacco or using the toilet.

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

NOV 20 2008

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

264-949

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are made of natural rubber, neoprene rubber, barrier laminate and Viton. If you want more options, follow the instructions for category A on an EPA Chemical resistance category selection chart.

All mixers, loaders, applicators and other handlers must wear:

Long-sleeved shirt and long pants, shoes and socks, chemical-resistant gloves except when bagging or sewing bags of treated seeds, chemical-resistant apron when loading, cleaning up spills, or cleaning equipment, goggles or face shield, and a NIOSH-approved dust mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH approved respirator with any N², R, P, or HE filter.

Persons drying or bagging treated seeds or sewing bags of treated seeds are handlers and must wear handler personal protective equipment.

See Engineering Controls for additional options.

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.

ENGINEERING CONTROLS

When handlers use closed systems designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers and 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 only wear long-sleeved shirt, long pants, chemical-resistant gloves, shoes and socks. However, the respirator must be immediately available for use in an emergency, such as a spill or equipment breakdown.

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

This pesticide is toxic to fish. Do not apply 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 washwaters or rinsate. 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. Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application.

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

SEED LABELING

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 bag contains seed treated with captan. Persons opening this bag or loading/pouring the treated seed must wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves."
- "TREATED SEED. DO NOT USE FOR FOOD, FEED OR OIL PURPOSES."
- 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.
- 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/media subsurface.

DIRECTIONS FOR USE

VITAVAX PC Peanut Seed Treatment Fungicide is a special formulation developed for dry application to peanut seed. It is used for protection against seed rot and damping-off diseases, including *Rhizoctonia solani*, *Rhizopus* and *Aspergillus spp.*, that attack germinating seeds and seedlings.

Peanuts:

Use 4-5 ounces per 100 pounds of seed. Apply with a standard commercial treating machine designed for dry formulations which provides uniform coverage to seed. Use of the higher rate is recommended under conditions of heavy disease pressure.

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 container.

STORAGE

Keep pesticide in original container. Do not put concentrate or dilute into food or drink containers. Store in a cool, dry place at temperatures which do not exceed 90°F. Protect from excessive heat. Do not store or transport near feed or food.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. 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

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Do not reuse container. Dispose of liner in a sanitary landfill, or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

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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.

Produced for



Bayer CropScience

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

Vitavax PC Peanut Seed Treatment Fungicide (PENDING) SUBMITTED TO EPA 09/24/07