

264-1109

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



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

FEB 24 2011

Robyn Kneen  
Regulatory Affairs  
Bayer CropScience  
P.O. Box 12014  
Research Triangle Park, NC 27709

Subject: Label amendment – Add Increased Seed Treatment Use Rate on Cotton  
EPA Reg. No. 264-1109  
Submissions dated May 18, 2010  
EPA Decision No. 434092

Dear Ms. Kneen:

The proposed labeling referred to above, EPA Reg. No. 264-1109, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided the registrant satisfies the following conditional data requirements:

- 1) 835.4300 (Old GL 162-4) Aerobic Aquatic Metabolism study. Although a previous aerobic aquatic metabolism study was submitted (MRID 45422324) and deemed to be supplemental, a new study is required. See the enclosed Agency review dated 12/3/10 for further specifics. The data are due to the Agency within 24 months of the date of this letter.
- 2) 850.5400 Algal Toxicity. Data on four species of non-vascular aquatic plants are required. A study on only one species has been submitted to date on green algae (*Pseudokirchneriella subcapitata*; formerly *Selenastrum capricornutum*). The three remaining species of non-vascular plant data are due to the Agency within 12 months of the date of this letter.
- 3) 850.3040 Field Test for Pollinators. There are uncertainties regarding the potential effects of clothianidin on insect pollinators and specifically the honey bee (*Apis mellifera*). These uncertainties have not been adequately addressed by the currently available studies. Also, there have been advances in pollinator study designs which were discussed at last month's global Pellston workshop supported by the Society of Environmental Toxicology and Chemistry (SETAC). Honey bee study design elements from the Pellston may be able to address some of the uncertainties surrounding the potential effects of clothianidin. Options are being evaluated for requesting additional data to further evaluate potential effects due to chronic exposure pending review of the

field pollinator data that have already been submitted to EPA. EPA will also consider study design recommendations which may be forthcoming from the SETAC Pellston. Therefore this data requirement is placed in **reserve** at this time until EPA has had an opportunity to review the available data and study design options.

Please submit two copies of your final printed label before you release the product for shipment. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

A stamped copy is enclosed for your records. If you have any questions, please contact Marianne Lewis at (703) 308-8043 or [lewis.marianne@epa.gov](mailto:lewis.marianne@epa.gov).

Regards,



Venus Eagle  
Product Manager 01  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosures

# PONCHO<sup>®</sup>/VOTIVO<sup>™</sup>

**A systemic insecticide and biological seed treatment for use on corn, cotton, sorghum, and soybean for the control of listed insect pests and listed soil plant pathogenic nematodes**

**ACTIVE INGREDIENTS:**

Clothianidin .....	40.3%
<i>Bacillus firmus</i> I-1582 .....	8.1%

<b>OTHER INGREDIENTS:</b> .....	51.6%
<b>TOTAL:</b> .....	100.0%

Contains 4.17 pounds clothianidin per U.S. gallon

Contains 0.84 pounds *Bacillus firmus* per U.S. gallon (contains a minimum of 2 X10<sup>9</sup> cfu/ml)

**EPA Reg. No. 264-1109**

**EPA Est.**

## KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

**For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577  
For PRODUCT USE Information Call 1-800-331-2867**

### 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 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.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p><b>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.</b></p>	

**NOTE TO PHYSICIAN:** No specific antidote is available. Treat the patient symptomatically.

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMAN AND DOMESTIC ANIMALS

##### CAUTION

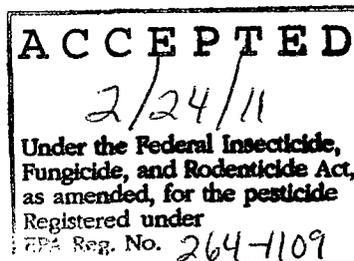
Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing.

##### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are **barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton**. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Workers involved with treating the seed (e.g. connecting and disconnecting hoses and transfer pumps, mixing, equipment calibration, etc.) and others exposed to the concentrate, and cleaners/repairers of seed treatment equipment must wear a long-sleeve shirt and long pants, shoes plus socks, chemical-resistant gloves, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95.

Baggers and bag sewers must wear a long-sleeve shirt and long pants, shoes plus socks, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95.



**ENGINEERING CONTROLS STATEMENT**

When handlers use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS. 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**

This product is toxic to aquatic invertebrates. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters. Do not apply where runoff is likely to occur. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Apply this product only as specified on the label.

This chemical has properties and characteristics associated with chemicals detected in ground water. This chemical may leach into ground water if used in areas where soils are permeable, particularly where the water table is shallow. Therefore contain any product spills or equipment leaks and dispose of wastes according to the disposal instructions on this label.

**DIRECTIONS FOR USE**

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

**Read entire label before using this product.**

For use only in commercial seed treatment equipment. Not for use in hopper box, planter box, slurry box, or other on-farm seed treatment applications.

Read the entire label and observe all label directions and precautions before use. Do not use this product except as directed on this label or on other Bayer CropScience supplemental labeling for this product.

**USE INFORMATION**

PONCHO/VOTiVO is a combination insecticide and biological seed treatment that, when applied to seed, protects the seed and seedling against certain early season insects and provides early season protection from listed plant pathogenic nematodes that attack the root system. As a result of the dual protection, there is an improvement in plant vigor, which often results in more uniform plants and greater yields. In areas of high nematode infestation additional control measures may be warranted.

**COMPATIBILITY**

It is essential that before using PONCHO/VOTiVO seed treatment in any tank mixture the compatibility of the mixture be established. Add PONCHO/VOTiVO at the labeled rate to a clean quart jar containing approximately one-half the amount of water intended for a final slurry application rate. Next, follow with all other tank mix components that will be used in the total slurry application. Add last the remaining balance of water. The total amount of volume is determined by the seed size and how much is necessary to ensure complete and uniform coverage and distribution on the seed, as well as the type of commercial seed treating application equipment that will be used.

DO NOT USE MIXTURES THAT CURDLE, PRECIPITATE, OR GEL. USE TANK MIXTURES IMMEDIATELY AFTER MIXING WITH ADEQUATE AGITATION.

**DIRECTIONS FOR SEED TREATMENT**

All seed treated with this product must be colored with an EPA-approved dye or colorant that imparts an unnatural color to the seed to help prevent the inadvertent use of treated seed for food, feed or oil purposes.

**FOR USE AS A SEED TREATMENT**

Apply PONCHO/VOTiVO as a commercial water-based slurry either alone or with other registered seed treatment insecticides and fungicides through standard slurry or mist commercial seed treatment equipment. Follow the most restrictive of the labeling limitations and precautions of all products used in mixtures. Treated seed must be labeled in accordance with the requirements of the Federal Seed Act.

### MIXING INSTRUCTIONS

When applied with seed treatment application equipment designed to treat seed utilizing a treatment slurry mixture, add approximately 1/2 to 2/3 of the required water to the treatment slurry tank followed by the accompanying seed treatment products and PONCHO/VOTIVO. The order of product addition is dependant on the accompanying seed treatment products and application equipment used. Allow each slurry component to disperse completely prior to the next addition until a uniform suspension is obtained. After all slurry components have been added and dispersed completely add the remaining 1/2 to 1/3 of required water for proper slurry volume and mix until uniform. Do not store mixed slurries for greater than 72 hours. Maintain adequate agitation until treatment slurry is applied. For additional instructions for use, slurry component mixing order, and other application suggestions contact your Bayer CropScience representative.

### APPLICATION RATES

May be used in combination with other registered Bayer CropScience seed treatment fungicides and insecticides. Pre-test for compatibility with other seed treatment products.

CROP	INSECT PESTS	NEMATODE PESTS	RATE PONCHO/VOTIVO
Corn (including field, sweet and pop)	Chinch bug Corn flea beetle Corn leaf aphid Cutworm, black Grape colaspis Seedcorn maggot Southern corn leaf beetle Southern corn rootworm Southern green stinkbug Storage pests <sup>1</sup> (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle) Sugarcane beetle White grub (including European, Chafer larvae, May/June beetle larvae, Japanese beetle larvae) Thrips Wireworm	Soil Nematodes including Dagger Nematode Lance Nematode Needle Nematode Pin Nematode Ring Nematode Root Knot Nematode Root Lesion Nematode Spiral Nematode Sting Nematode Stubby Root Nematode Stunt Nematode	<b>To deliver 0.25 mg ai/seed of clothianidin:</b>  Use PONCHO/VOTIVO at 1.35 fl oz / 80,000 seeds.  <b>To deliver 0.50 mg ai/seed of clothianidin:</b>  Use PONCHO/VOTIVO at 2.7 fl oz / 80,000 seeds  Do not apply more than 0.5 mg ai of clothianidin per seed through the application of PONCHO/VOTIVO.
Cotton, delinted, only	Early season thrips Cutworm, black Aphids Storage pests <sup>1</sup> (including Indian meal moth, Lesser grain borer, Red flour beetle, Rice weevil, Rusty grain beetle)	Columbia Lance Nematode Reniform Nematode Root Knot Nematode	2.4 fl oz / 100,000 seed (or 0.424 mg total ai / seed)
Sorghum	Cutworm, black Aphid (including Greenbug, Yellow sugarcane aphid, Corn leaf aphid, and English grain aphid) Chinch bugs White grub Wireworms	Ring Nematode Root Knot Nematode Root Lesion Nematode Sting Nematode Stubby Root Nematode	6.13 fl oz/cwt (100 pounds of seed)
Soybean	Aphids Bean leaf Beetle Grape Colaspis Leafhoppers Seed Corn Maggot Three Cornered Alfalfa Hopper Thrips White Grubs Wireworm	Reniform Nematode Root Knot Nematode Soybean Cyst Nematode	0.13 mg ai/seed <sup>2</sup>

<sup>1</sup> It is recommended that seed with existing populations of storage pests be fumigated prior to treating and bagging seed.

<sup>2</sup> For Soybean:

- Foliar spray of clothianidin can be applied 45 days after planting PONCHO/VOTIVO treated soybean seeds for mid-to-late season foliar insects.
- Do not graze or feed soybean forage and hay to livestock

**RESTRICTIONS:**

Regardless of type of application (seed treatment or foliar), do not apply more than 0.2lbs (Soybean), 0.1lbs (corn), 0.2lbs (cotton) or 0.02lbs (sorghum) of active ingredient clothianidin per acre per season.

**Resistance Management**

The components in Poncho/VOTIVO belong to multiple chemistry classes. Because resistance development cannot be predicted, the use of this product should conform to resistance management strategies established for the crop and use area. Such strategies may include rotating and/or tank mixing with products having different modes of action; or limiting the total number of applications per season. Use labeled rates. Contact your local extension specialist, certified crop advisor, and/or manufacturer for fungicide/insecticide resistance management and/or integrated pest management recommendations for specific crops and pest populations. Bayer CropScience encourages responsible product stewardship to ensure effective long-term control of pests on this label.

**SEED BAG TAG**

The Federal Seed Act requires that the container of seed treated with PONCHO/VOTIVO must be labeled with the following statements:

- This seed has been treated with PONCHO/VOTIVO, which contains 40.3% clothianidin and 8.1% *Bacillus firmus* I-1582.
- Do not use treated seed for food, feed, oil production or ethanol production.
- Use planting equipment that will plant treated seed into the soil to a minimum depth of 0.5 inch.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with PONCHO/VOTIVO:

- Regardless of type of application (seed treatment or foliar), do not apply more than 0.2lbs (Soybean), 0.1lbs (corn), 0.2lbs (cotton) or 0.02lbs (sorghum) of active ingredient clothianidin per acre per season.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound may be highly toxic to bees exposed directly (contact). Ensure that planting equipment is functioning properly in accordance with manufacturing recommendations to minimize seed coat abrasion during planting to reduce dust which can drift to blooming crops or weeds.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- For Field Corn, Popcorn and soybeans: **Immediate Plant-back:** Cereal grains, Field corn, popcorn, sweet corn, cotton, rapeseed, canola, soybeans, root and tuber vegetable, **30-Day Plant-back:** Grasses, non-grass animal feeds, dry beans, **8-Month Plant-back:** Sugar cane, **12-Month Plant-back:** Any crops without an earlier plant-back interval.
- For Cotton, Sweet corn, and Sorghum: **Immediate Plant-back:** Cereal grains, Field corn, popcorn, sweet corn, cotton, rapeseed, soybeans, canola, sorghum, root and tuber vegetables, **30-Day Plant-back:** Grasses, non-grass animal feeds, dried beans, **4-Month Plant-back:** Any crop without an earlier plant-back interval
- In soybean, foliar sprays of clothianidin can be applied 45 days after planting Poncho/Votivo treated seeds for mid-to-late season foliar insects.
- Do not graze or feed soybean forage and hay to livestock.

## STORAGE AND DISPOSAL

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

### PESTICIDE STORAGE

Store in cool, dry conditions.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

#### Containers with capacities equal to or less than 5 gallons

Non-refillable container. Do not reuse or refill this container. 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.

Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or by incineration.

#### Containers that are too large to shake (i.e., with capacities greater than 5 gallons)

Non-refillable containers - Do not reuse or refill this container. After emptying product from container, either return container to Bayer CropScience per instructions from Bayer CropScience Customer Service Center (1-800-527-4781), or rinse and either recycle or dispose of the container as follows:

##### Bottom Discharge IBC (e.g. – Schuetz Caged IBC or Snyder Square Stackable

Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. To pressure rinse the container before final disposal, empty the remaining contents from the IBC into application equipment or mix tank. Raise the bottom of the IBC by 1.5 inch on the side which is opposite of the bottom discharge valve to promote more complete product removal. Completely remove the top lid of the IBC. Use water pressurized to at least 40 PSI to rinse all interior portions.

Continuously pump or drain rinsate into application equipment or rinsate collection system while pressure rinsing. Continue pressure rinsing for 2 minutes or until rinsate becomes clear. Replace the lid and close bottom valve.

##### Top Discharge IBC, Drums, Kegs (e.g.– Snyder 120 Next Gen, Bonar B120, Drums, and Kegs).

Triple rinsing the container before final disposal is the responsibility of the person disposing of the container. To triple rinse the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container at least 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Rinse all interior surfaces. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this procedure two more times.

Once container is rinsed, offer for recycling if available or puncture and dispose of in a sanitary landfill

## 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 the user must follow directions. 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:

Produced for



**Bayer CropScience**

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