



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

November 12, 2008

Larry Hodges
Product Registration Manager
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Subject: Vortex
EPA Reg. No. 264-988
Your Submission Dated January 31, 2007
Label Amendment to Add Food Uses (EPA Decision No. 376228)

Dear Mr. 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 conditions met:

1. Acute and Subchronic Neurotoxicity (870.6200) and Immunotoxicity (870.7800) studies as required for all food and non-food use pesticide registrations per the revised 40 CFR Part 158 are submitted by November 30, 2010.
2. For the soybean study reported in MRID 45542243 and 45542248, the petitioner must provide the sample analysis dates. In addition, evidence must be provided that the identity of residues did not change during the period between collection and final analysis by November 30, 2010.
3. For the wheat study reported in MRID 47048924, the petitioner must provide the sample storage conditions for all samples and extracts and provide all sample combustion and analysis dates. The petitioner must explain the discrepancy between their statement that all extractions were completed within 84 days of harvest and the reported extraction dates in Appendix IV of the submission, which indicated that extractions were not completed until 286 days after harvest. Evidence must be provided that the identity of residues did not change during the period between collection and final analysis by November 30, 2010.
4. Additional storage stability data/information must be submitted for the extracts of certain barley and wheat commodities samples. For the barley and wheat crop field trial studies reported in MRIDs 47048925 and 47048930, the petitioner must submit the conditions of extract storage, and provide storage stability data to support the storage of extracts for durations up to 36 days (barley commodities) or 43 days (wheat commodities). If the

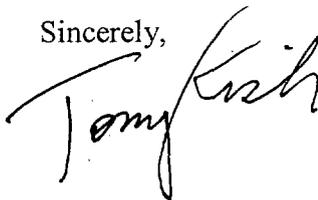
petitioner can provide data demonstrating that the extracts of fortified untreated samples for concurrent method recovery analyses were stored for the same durations and under the same conditions as the extracts of treated samples, these data will be considered adequate to support the extended extract storage conditions by November 30, 2010.

5. The method, as written, does not meet the general requirement as a confirmatory method since only one MS/MS ion transition is documented. The method must be revised to include a second, confirmatory ion transition to provide unambiguous confirmation of analyte identity by November 30, 2010.
6. The radiotracer study for peanuts must be submitted into the Agency for database completeness by December 31, 2008.
7. A new Chronic Exposure study on *Daphnia magna* to address this data gap must be submitted by November 30, 2010.
8. Submit a revised generic data matrix which correctly addresses all required generic data. Please contact us to discuss the revisions required for the subject matrix by December 31, 2008.

Also, bear in mind, in the Agency's risk assessment for 1,2,4-triazole and its metabolites triazole alanine, and triazole acetic acid, dated February 7, 2006 (see docket number 2005-0497 at <http://www.regulations.gov>), the Agency identified additional data that are needed for triazole-derivative active ingredients which have the 1,2,4,-triazole ring. The Agency plans to issue a Data Call-In for all triazole-derivative active ingredients which will identify all data needs for these active ingredients listed in the February 7, 2006 risk assessment. The Data Call-In will not address data needs that are related to parent-only data requirements.

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 before the product is released for shipment. If you have any questions, please contact Tawanda Maignan by phone at (703) 308-8050 or via email at Maignan.tawanda@epa.gov.

Sincerely,



Tony Kish
Product Manager (22)
Fungicide Branch
Registration Division (7505P)

Enclosure

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ACCEPTED
with COMMENTS
In EPA Letter Dated

NOV 12 2008

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
264-988

VORTEX® Seed Treatment Fungicide

ACTIVE INGREDIENT:		
Ipconazole (CAS No. 125225-28-7)	40.7%
OTHER INGREDIENTS:	59.3%
	TOTAL	100.0%

Contains 3.77 pounds active ipconazole per U.S. gallon

EPA Reg. No. 264-988

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:

- 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.

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

CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category A on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves, such as natural rubber. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

For terrestrial uses, 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 apply when weather conditions favor drift from treated areas. Do not contaminate water when disposing of equipment washwater or rinsate. This fungicide may persist in soil, and long-term use in the same field may result in an accumulation of active ingredient.

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, disposal or cleaning of equipment.

PESTICIDE STORAGE

Store in a cool dry location. Do not store in direct hot sunlight.

PESTICIDE DISPOSAL

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

CONTAINER DISPOSAL

28 ounces, 2.5 gallon, 15 gallon

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Offer for reconditioning, if appropriate. Triple 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 1/4 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.

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, follow instructions for cleaning. Then 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.

Federal law requires that bags containing treated seeds shall be labeled with the following information:

"This seed has been treated with Ipconazole. Do not use for feed, food or oil purposes. Store away from feeds and foodstuffs."

FAILURE TO FOLLOW DIRECTIONS ON THIS LABEL MAY RESULT IN CROP INJURY OR POOR DISEASE CONTROL.

VORTEX is a systemic broad-spectrum fungicide seed dressing specifically for protection against soilborne and seedborne disease of crop plants. VORTEX is active against *Rhizoctonia*, *Fusarium*, and *Phomopsis*. In addition, VORTEX provides activity against weakly pathogenic fungi such as *Mucor*, *Rhizopus*, *Aspergillus*, *Penicillium*, *Alternaria*, and *Cladosporium*. VORTEX does not provide activity against *Pythium* spp. or *Phytophthora* spp. To provide best seedling protection against a wide array of fungal pathogens, apply VORTEX as a tank mix with ALLEGIANCE-FL. Consult the ALLEGIANCE-FL label to assure registration on crop, or if not labeled, use another labeled seed treatment product that has activity against *Pythium* or *Phytophthora*. Consult the label for appropriate use rate and follow all use instructions for the products. Do not use with other seed treatment products unless previous experience assures compatibility.

NOTE: This product is undyed. The purchaser of this product is responsible for ensuring that all seed treated with this product are adequately dyed with a suitable color to prevent its accidental use as food for man or feed for animals. Refer to 21CFR, part 2.25. Any dye added to treated seed must be cleared for use under 40CFR, Part 153.155.

VORTEX may be applied as a water-based slurry with other registered seed treatment insecticides and fungicides through standard slurry or mist-type commercial seed treatment equipment.

ROOT VEGETABLES

Beet (garden), beet (sugar), burdock (edible), carrot, celeriac, chervil (turnip-rooted), chicory (roots), chufa, dandelion (roots), ginseng, parsley (turnip-rooted), parsnip, radish, radish (oriental), rutabaga, salsify, salsify (black), salsify (Spanish), skirret, turnip and yam bean.

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.051 – 0.34 fl.oz. of VORTEX per 100 lbs of seed or propagating root or tuber material.

LEAFY VEGETABLES (Except Brassica Vegetables)

Amaranth (leafy, Chinese spinach, tampala), arugula, cardoon, celery (including Chinese), celtuce, chervil, chrysanthemum (edible-leaved and garland), corn salad, cress (garden and upland), dandelion, dock, endive, fennel (Florence, finocchio), lettuce (head and leaf), orach, parsley, purslane (garden and winter), radicchio, rhubarb, spinach, spinach (New Zealand), spinach (vine), and Swiss chard.

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.051 – 0.34 fl. oz. of VORTEX per 100 lbs of seed.

BRASSICA (COLE) LEAFY VEGETABLE GROUP

Broccoli, broccoli (Chinese), broccoli (raab), Brussels sprouts, cabbage (including Chinese bok choy, Chinese napa, and Chinese mustard), cauliflower, cavalo broccolo, collards, kale, kohlrabi, mizuna, mustard greens, mustard spinach, and rape greens.

For protection against seedborne and soilborne fungi that cause seed decay, damping off, and seedling blight, apply 0.051 – 0.34 fl oz of VORTEX per 100 lbs of seed.

CUCURBIT VEGETABLES

Chayote, Chinese waxgourd, citron melon, cucumber, gherkin, gourd edible (includes hyotan, cucuzza, hechima, Chinese okra), *Momordica*, all muskmelon, pumpkin, squash and watermelon.

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.051 – 0.34 fl oz of VORTEX per 100 lbs of seed.

CEREAL GRAINS (Includes Forage And Silage)

Corn (field corn, popcorn, and sweet corn) and sorghum.

Corn (Field Corn and Popcorn): For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.085 fl oz of VORTEX per 100 lbs of seed.

Sweet corn: For protection against seedborne and soilborne fungi which cause seed decay, damping-off and seedling blight, apply 0.085 fl oz of VORTEX per 100 lbs of seed.

Sorghum: For protection against seedborne and soilborne fungi which cause seed decay, damping-off and seedling blight, apply 0.051 – 0.17 fl oz of VORTEX per 100 lbs of seed.

COTTON

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.085 – 0.34 fl oz of VORTEX per 100 lbs of seed.

SUNFLOWER

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.051 – 0.085 fl oz of VORTEX per 100 lbs of seed.

MUSTARD, RAPE, CANOLA

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, as well as for protection against *Phoma lingam* causing blackleg, apply 0.051 – 0.34 fl oz of VORTEX per 100 lbs of seed.

ORNAMENTAL FLOWERS

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.051 – 0.34 fl oz of VORTEX per 100 lbs of seed.

CONIFERS

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.051 – 0.34 fl oz of VORTEX per 100 lbs of seed.

TURF GRASS

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.051 – 0.085 fl oz of VORTEX per 100 lbs of seed.

Peanut

For protection against seedborne and soilborne fungi that cause seed decay, damping-off, and seedling blight, apply 0.085 fl oz of VORTEX per 100 lbs of seed. **(For commercial application only.)** Do not graze or feed livestock on treated areas or on hay grown from treated seed.

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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.

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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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1-866-99BAYER (1-866-992-2937)

VORTEX Seed Treatment Fungicide. (PENDING 01/31/07) BASED ON MASTER Approved 08/01/06, Notification 08/25/06, Resub 11/04/08