

100-739

5-16-2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ruhi Rezaaiyan
Syngenta Crop Protection, Inc
P.O Box 18300
Greensboro, NC 27419

MAY 16 2008

Dear Ms. Rezaaiyan:

Subject: Difenoconazole Technical
Label Amendment to add new uses: fruiting vegetables, pome fruit, sugar beet, potatoes, all vegetables in tuberous and corm subgroup crops, **and all ornamental uses except crops grown commercially in the greenhouse or nursery.**
EPA Registration No. 100-739
Your Application Dated 10/03/2006

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable providing you fully satisfy the conditional requirements listed below.

860.1340 Residue Analytical Methods - Livestock Commodities

1. Confirmatory analysis procedures (a second MS/MS ion transition) are needed for REM 147.07 for both parent and the metabolite as specified by ACB (memo, Charles J. Stafford, ACB Project # B07-26, 10/29/07). Submit by 1/16/09.
2. Analytical standards for the metabolites of metabolite CGA are currently not available in the National Pesticide Standards Repository [Source: memo, Charles J. Stafford, ACB Project # B07-26, 10/29/07]. Analytical reference standards of metabolite CGA must be supplied and supplies replenished as requested by the Repository. Submit by 6/16/08.
3. The petitioner must revise the method to correct all references to "crop matrices" as the method is intended for livestock commodities. Submit by 1/16/09.

860.1380 Storage Stability

4. Data must be submitted depicting the stability of residues of difenoconazole and CGA 205375 in milk and cattle tissues during frozen storage for up to 10 months for milk and

9 months for tissues. The studies cited by the petitioner (report numbers ABR-93012 and 202/99), which contain storage stability data for difenoconazole and CGA 205375, must be submitted. Submit by 1/16/2010.

5. Data must be submitted depicting the stability of residues of difenoconazole and CGA 205375 in egg and poultry tissue samples during frozen storage for up to 7 months for egg and 6 months for tissue samples. The studies cited by the petitioner (report numbers ABR-93012 and 202/99), which contain storage stability data for difenoconazole and CGA 205375, must be submitted. Submit by 1/16/2010.
6. Storage stability data for residues of 1,2,4-T, TA, and TAA have not been submitted in conjunction with the subject petitions. However, storage stability data for these compounds has been requested as part of the Human-Health Aggregate Risk Assessment for 1,2,4-T, TA and TAA (M. Doherty, *et. al.* 2/7/06). Submission of the data requested in the 2/7/06 document will satisfy storage stability data requirement for the subject petitions. Submit by 1/16/09, unless required earlier in other EPA documents.

860.1500 Crop Field Trials

7. The submitted residue data for fruiting vegetables are not adequate to fulfill data requirements as an insufficient number of crop field trials was conducted for tomatoes; two additional trials must be conducted in Zone 3. The submitted crop field trial data did not include any small varieties of tomato; therefore, the requested trials must be conducted on a cherry tomato or varieties of tomatoes in which the mature fruits will be less than 2 inches in diameter. Submit by 1/16/2010.

860.1850 Confined Accumulation in Rotational Crops

8. The available confined rotational crop data are not adequate to support the proposed uses, as the studies were conducted at <0.3x the proposed maximum seasonal rate to annual crops, and there are no data delineating the metabolism of the phenyl portion of the molecule in rotational crops. The petitioner should must new confined rotational crop studies reflecting application of [¹⁴C]difenoconazole, labeled in the phenyl ring, at 0.46 lb ai/A (1x the proposed maximum seasonal rate to annual crops). The studies should be conducted according to the requirements specified in OPPTS 860.1850. Submit by 1/16/2011.

9. 850.1350 Mysid Chronic Toxicity Test. Submit by 1/16/09.

10. 850.1735 Whole Sediment 10 day toxicity (freshwater invertebrates) or 850.1760 Whole sediment life cycle toxicity test with Chironomous tentans. Submit by 1/16/09.

In the Agency's risk assessment for 1,2,4-triazole and its metabolites triazole alanine, and

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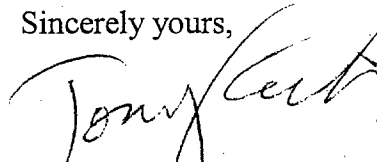
triazole acetic acid, dated February 7, 2006 (see docket number 2005-0497 at <http://www.regulations.gov>), the Agency identified additional data that are needed for triazole-derivative active ingredients which have the 1,2,4,-triazole ring. The Agency plans to issue a Data Call-In for all triazole-derivative 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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Submit one copy of the final printed label within 45 days from this notice. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A copy of the label (version 2-6-08) stamped "Accepted with comments" is enclosed for your records

Sincerely yours,



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

Enclosure

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Difenoconazole Technical

For Formulation into End-Use Fungicide Products

Active Ingredient:	
Difenoconazole*	95.0%
Other Ingredients:	5.0%
Total:	100.0%

*CAS No. 119446-68-3

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements on label.

EPA Reg. No. 100-739

EPA Est.

Product ID 22578

110.1 Pounds (50 kg)
Net Weight

**ACCEPTED
with COMMENTS
in EPA Letter Dated
MAY 16 2008**

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

100-739

FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call 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 the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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 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 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 by mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN	
If ingested induce emesis or lavage stomach. Treat symptomatically.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
HOT LINE NUMBER	
For 24-Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call 1-800-888-8372	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if swallowed, inhaled, or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Environmental Hazards

This pesticide is toxic to fish, mammals, and aquatic invertebrates. Drift and runoff may be hazardous to aquatic **estuarine/marine** organisms in water adjacent to treated area. Do not apply directly to water, areas where surface water is present, or intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

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.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and of Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE

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

This product is intended for the formulation of crop protection products. This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA data submission requirements regarding the support of such use(s).

This product is intended for formulation into fungicides for the following seed treatment uses: cereals (wheat, barley, triticale), cotton, sweet corn, and canola.

This product is intended for formulation into fungicides for the following foliar uses: fruiting vegetables, pome fruit, sugar beet, potatoes, all vegetables in tuberous and corm subgroup crops, and all ornamental uses except crops grown commercially in the greenhouse or nursery.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage, disposal or cleaning of equipment.

Pesticide Storage

Store in a cool dry place.

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

Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then 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.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

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For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured For:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300
www.syngenta-us.com

SCP 739A-

DIF TEC 739A- Feb Amend - bb - 2-6-08

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