

100-739

04-21-2010

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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 27419-8300

APR 21 2010

SUBJECT: Label Amendment
Difenoconazole Technical
EPA Reg. No. 100-739; Decision # 403560
Your Submission Dated November 14, 2008

Dear Ms. Rezaaiyan:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended which adds the following crops; bulb vegetables, brassica (cole) leafy vegetables, cucurbit vegetables, citrus fruit, grapes, tree nuts and pistachios,, is acceptable provided that you satisfy the following conditional data requirements:

A. Supporting storage stability (860.1380) data for the triazole metabolites are required to support the storage conditions (frozen) and intervals (up to 24.8 months) of raw agricultural and processed commodity samples collected for the studies reviewed. The U.S. Triazole Task Force (USTTF), whose members include Syngenta Crop Protection, Inc. among others, submitted a multi-year storage stability study for the triazole metabolites in various crop matrices and processed commodities (MRID 47606601) which is currently under review in HED (D363016). **Approval of the new uses herein are conditioned upon acceptance of this submitted study.**

B. The requirement for storage stability data for cattle commodities that was previously identified in DP# 340379 (8/9/07, W. Wassell and M. Sahafeyan) is a requirement to support this action. Data 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 is still needed, along with the studies cited by the petitioner (report numbers ABR-93012 and 202/99), which contain storage stability data for difenoconazole and CGA 205375.

Additionally, there are no poultry feedstuff associated with the uses being approved, but the requirement for storage stability data for poultry commodities that was previously identified in

DP# 340379 (8/9/07, W. Wassell and M. Sahafeyan) is still needed, as well as data 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 cited studies (report numbers ABR-93012 and 202/99), which contain storage stability data for difenoconazole and CGA 205375, are needed.

Syngenta submitted a response to these requirement on 1/18/10 under EPA Reg. No. 100-1262, via MRIDs 47957201; 47957202, and 47957203. **Approval of the new uses herein are conditioned upon acceptance of these submitted studies.**

C. Confined accumulation in rotational crops - **Submit by 4/7/2011.** The requirement for an additional confined rotational crop study (860.1850) that was previously identified in DP# 344680 (11/5/07, M. Sahafeyan) is still needed. Submit a confined rotational crop study which reflects phenyl-ring labeling at 1x the proposed maximum seasonal foliar application rate (0.46 lb ai/A).

D. Immunotoxicity study (870.7800) - **Submit by November 30, 2011.**

E. Freshwater Fish Toxicity Study (850.1075): **Submit by 4/7/2011.** Data that satisfy this requirement were provided for the bluegill sunfish and rainbow trout. However, the fathead minnow was the species used for the freshwater fish early-life stage study (850.1400) requirement. Because this test species is different from the two species used for the freshwater fish acute toxicity tests, a 96-hour LC50 for fathead minnow is needed.

F. Estuarine/Marine fish Early-Life Stage study (850.1400): **Submit by 4/7/2011.** No data were available to assess the chronic toxicity of difenoconazole to estuarine/marine fish. A study evaluating the chronic effects of difenoconazole on sheepshead minnow is needed to satisfy this data requirement. The LC50s for estuarine/marine fish were comparable to the LC50s for freshwater fish, suggesting similar acute sensitivity to difenoconazole. However, it was not possible to use the acute to chronic ratio (ACR) as the acute and chronic freshwater fish studies utilized two different species. Because of its expected use or mobility patterns, difenoconazole may enter estuarine/marine environments in significant concentrations. In the absence of acceptable data, potential chronic risks to estuarine/marine fish are unknown but RQs would be assumed to exceed LOCs for listed species.

G. Submitted data for freshwater fish were classified as supplemental; therefore, acceptable data for freshwater fish is also required. **Submit by 4/7/2011.** The test may be repeated with the fathead minnow or be conducted using a rainbow trout (preferred) or bluegill sunfish. The submitted fathead minnow early-life study was classified as supplemental. If the study is repeated with either a rainbow trout (preferred) or bluegill sunfish and found to be

acceptable, the data gap for the fathead minnow acute toxicity test would be eliminated. However, if the early-life stage study is repeated with the fathead minnow, then the data gap for the fathead minnow acute toxicity test remains.

H. Estuarine/Marine Invertebrate Life Cycle Study (850.1350): The submitted mysid shrimp study was classified as supplemental because reproductive effects were observed at all treatment levels. Acceptable estuarine/marine invertebrate data, which establishes a definitive NOAEC, is required. A new mysid study was submitted to EPA as a condition of registration on January 19, 2009, MRID No. 47648603. **Approval of the new uses herein are conditioned upon acceptance of this submitted study.**

I. Avian Acute Oral Toxicity Study (850.2100): **Submit by 4/7/2011.** Data that assess the effects of difenoconazole for one passerine species, AND either one waterfowl species or one upland game bird species for terrestrial, aquatic, forestry, and residential outdoor uses, are required. The current method of calculating a weight-adjusted LD50 using bobwhite quail or mallard duck data may over- or under-estimate risks to passerines because these birds may metabolize the chemical differently. Because the 850.2100 guideline has not yet been finalized, protocols for the study of passerine species should be submitted to EPA for approval prior to study initiation.

J. Terrestrial Plant Toxicity, Tier 1 (seeding emergence) (850.4100): **Submit by 4/7/2011.** Testing of a typical end-use product (TEP) is required for all pesticides having outdoor uses at the proposed maximum application rate. Tier II studies are not required unless Tier I studies indicate a $\geq 25\%$ effect to various growth parameters relative to the control. The submitted non-GLP study (MRID 469502-02; supplemental), which tested multiple concentrations, does not measure growth or other required endpoints. Currently, the lack of acceptable data caused habitat modification to be assumed as an indirect effect to all listed species.

K. Terrestrial Plant Toxicity, Tier I (vegetative vigor) (850.4150): **Submit by 4/7/2011.** Testing of a TEP is required for all pesticides having outdoor uses at the proposed maximum application rate. Tier II studies are not required unless Tier I studies indicate a $\geq 25\%$ effect to various growth parameters relative to the control. The submitted non-GLP study (MRID 469502-03; supplemental), which tested multiple concentrations, does not measure growth or other required endpoints. Currently, the lack of acceptable data causes habitat modification to be assumed as an indirect effect to all listed species.

L. Metabolite toxicity studies - **Submit by 4/7/2012.** Due to the degradation of difenoconazole to the major metabolites CGA-71019 (1,2,4-triazole) and CGA-142856 (triazolyl acetic acid), which are of toxicological concern, an ecological risk assessment is still required to determine the exposure and effects to non-target terrestrial and aquatic organisms. Therefore,

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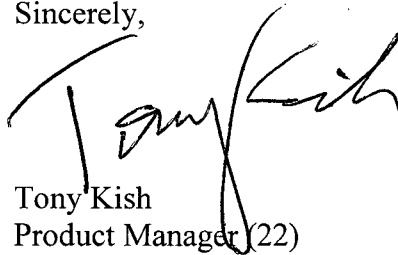
studies evaluating the acute effects of these two degradates on fish, birds, and daphnids are required. These data requirements can be satisfied by the following three guidelines: Avian Acute Oral Toxicity Study (850.2100); Acute Freshwater Fish Toxicity Study (850.1075); Acute Freshwater Invertebrate Toxicity Study (850.1010).

M. Sediment dwelling organisms - There is uncertainty associated with risk to sediment dwelling organisms. Pore water concentrations indicated that the concentrations of difenoconazole in the sediment are similar to that in the water column. Because difenoconazole is persistent, a study evaluating risk to sediment dwelling organisms was previously identified as a data gap. A sediment toxicity study determining the effects of difenoconazole residues to benthic organisms has been submitted and is currently under review to determine if it satisfies the data requirement. This sediment toxicity study was submitted as a condition of registration on January 18, 2009 via MRID No. 47648601. **Approval of the new uses herein are conditioned upon acceptance of this submitted study.**

Submit one copy of your final printed labeling before you release the product for shipment.

If you have any questions regarding this correspondence, contact Rose Kearns of my staff by phone at 703-305-5611 or via email at kearns.rosemary@epa.gov or myself at 703-308-9443 or via email at kish.tony@epa.gov.

Sincerely,



Tony Kish
Product Manager (22)
Fungicide Branch
Registration Division (7504P)

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.

SCP 739A

110.1 Pounds (50 kg)
Net Weight

**ACCEPTED
with COMMENTS
In EPA Letter Dated
APR 21 2010**
**Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, this 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: Brassica (Cole) leafy vegetables, bulb vegetables, citrus fruits, cucurbit vegetables, fruiting vegetables, grapes, pistachios, pome fruit, sugar beet, potatoes, tree nuts, 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

SCP 739A

DIF TEC 739 TOL AMEND - bb - 11-14-08

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