



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

May 6, 2015

Dr. Ruhi Rezaaiyan, Ph.D.  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419

Subject: Label Amendment – New Uses: Dried shelled pea and bean Subgroup 6C;  
Bushberry Subgroup 13-07B; Petition #4F8231 With Rule Published 4/2/2015  
Product Name: Difenoconazole Technical  
EPA Registration Number: 100-739  
Application Date: December 26, 2013  
Decision Number: 486674

Dear Dr. Rezaaiyan:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(c)(7)(B), subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. You are required to comply with the data requirements and due dates listed below:

a. **850.4100 (Terrestrial plant toxicity, seedling emergence) – TEP**

This requirement was originally listed in the EPA letter dated 4/21/2010 for EPA Reg. No. 100-739 (D403560) and was required by 4/7/2011. A Tier I study was submitted (MRID 48453203) but was found Supplemental. The available Tier I study is Supplemental because there were biologically significant effects observed in dicots at the limit test concentration which is below the maximum labeled single application rate (turf; 0.26 lb ai/A). Our understanding is that 0.26 lb ai/A is the highest current single application rate but Syngenta must verify this is correct and conduct the study at the highest possible single application rate on any difenoconazole label. The current risk assessment is impacted by the lack of a NOAEC for dicots. Tier II testing is required for the dicot species that showed effects in the available study (lettuce, soybean, and sugar beet). Furthermore, a NOAEC must be established at the maximum single application rate (Tier 1 test) for the other seven test species (those showing no effects in the available study) to meet the data requirement; alternatively, Tier II testing may be conducted for those species. Syngenta recently requested a one year extension and therefore this study is now **due one year from the date of this letter.**

**b. 850.4150 (Terrestrial plant toxicity, vegetative vigor) – TEP**

This requirement was originally listed in the EPA letter dated 4/21/2010 for EPA Reg. No. 100-739 (D403560) and was required by 4/7/2011. A Tier I study was submitted (MRID 48453204) but was found Supplemental. The available Tier I study is Supplemental because the limit test concentration is below the maximum labeled single application rate (turf; 0.26 lb ai/A). Our understanding is that 0.26 lb ai/A is the highest current single application rate but Syngenta must verify this is correct and conduct the study at the highest possible single application rate on any difenoconazole label. The current risk assessment is not impacted. To satisfy the data requirement, a NOAEC must be established for all ten test species at the maximum single application rate (Tier I test). Alternatively, Tier II testing may be conducted. Syngenta recently requested a one year extension and therefore this study is now **due one year from the date of this letter.**

**c. Chronic toxicity to benthic invertebrates (whole sediment: freshwater and estuarine/marine) – difenoconazole (TGAI)**

This freshwater invertebrate requirement was originally listed in the Agency letter dated 1/16/2008 for EPA Reg No. 100-739 and a study was submitted (MRID 47648601) but found Supplemental. There is uncertainty associated with chronic risk to benthic invertebrates given that pore water EECs are similar to water column EECs and a lack of acceptable toxicity data for benthic invertebrates. Although this sediment toxicity study (range finding with a freshwater midge) is available, the numerous deviations in the study limit its use for quantitative purposes. Data are recommended because the chronic LOC (1.0) is exceeded for aquatic invertebrates based on comparison of water column species toxicity data to pore water EECs. Sediment chronic toxicity testing with three species is required: freshwater midge, freshwater amphipod, and marine/estuarine amphipod.

Three studies are required, each tests a different species (one with a freshwater midge, one with a freshwater amphipod, and one with a marine/estuarine amphipod).

There is not a guideline number because the 850 guidelines for chronic testing are in the process of being finalized. However, in the meantime, the Agency recommends Syngenta consider the available Agency-wide guidelines for chronic testing of freshwater and estuarine/marine organisms (see below). As indicated in 40 CFR Part 158, protocols must be submitted for review prior to initiating the studies, and in enough time to meet the submission due date.

USEPA 2000. Methods for Measuring the Toxicity and Bioaccumulation of Sediment-associated Contaminants with Freshwater Invertebrates. EPA 600/R-99/064

USEPA 2001. Methods for Assessing the Chronic Toxicity of Marine and Estuarine Sediment-associated Contaminants with the Amphipod *Leptocheirus plumulosus*. EPA 600/R-01/020

**The protocols for the three studies must be submitted with enough time for the Agency to review and approve them, and for the three actual studies to be submitted within two years of the date of this letter.**

- d. **850.4550 (Cyanobacteria toxicity) – difenoconazole (TGAI).** There is some uncertainty about risk to aquatic plants because an acceptable study with blue green algae (cyanobacteria) is not available. There are not currently any listed non-vascular plants so the uncertainty is for non-listed species. Blue-green algae would need to be about 6-9 times more sensitive than *Navicula pelliculosa* to exceed the LOC (non-listed species) for the proposed uses, assuming that the degradates (1,2,4-triazole, triazole acetic acid, and CGA-205375) and difenoconazole are equal in toxicity. **This study must be submitted within one year from the date of this letter.**

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Karen Samek by phone at (703) 347-8825, or via email at [samek.karen@epa.gov](mailto:samek.karen@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Tony Kish". The signature is written in a cursive style with a large, looping initial "T".

Tony Kish, Product Manager 22  
Fungicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

**Difenoconazole Technical**

For Formulation into End-Use Fungicide Products

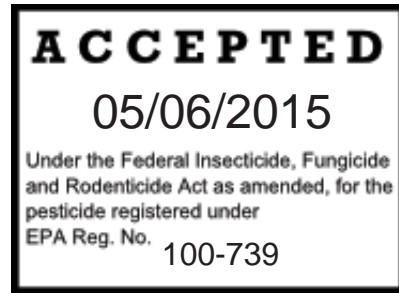
Active Ingredient:	
Difenoconazole* .....	95.0%
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Other Ingredients:	5.0%
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Total:	100.0%

\*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. 70992-CHE-003

Product of Switzerland

Product ID 22578

SCP 739A-L5P 0812

110.23 pounds (50 kg)  
Net Weight

<b>FIRST AID</b>	
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Call 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 do so by the poison control center or doctor.</li><li>• Do not give anything 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 eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If inhaled</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>NOTE TO PHYSICIAN</b>	
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.	
<b>HOT LINE NUMBER</b>	
For 24-Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call <b>1-800-888-8372</b>	

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## **PRECAUTIONARY STATEMENTS**

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### **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 and before eating, drinking, chewing gum, using tobacco, or using the toilet. 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 areas. For terrestrial uses: Do not apply directly to water, or to 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.

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## CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

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**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, LLC 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, oats, rye), cotton, sweet corn, and canola.

This product is intended for formulation into fungicides for the following foliar uses: brassica (cole) (subgroup 5A and 5B), bulb vegetables (subgroup 3-07A and 3-07B), bushberry (subgroup 13-07B); carrots, chickpea, citrus fruits (crop group 10-10), cucurbit vegetables (crop group 9), dried beans and peas (subgroup 6C); fruiting vegetables (crop group 8-10), grapes, pome fruit (crop group 11-10), Rapeseed Subgroup 20A, soybean, stone fruit (crop group 12), strawberries and other low-growing berries (subgroup 13-07G except cranberry), sugar beet, tree nuts (crop group 14), all vegetables in tuberous and corm subgroup crops (subgroup 1C) and golf course turf. Also for formulation into fungicide for outdoor application to established ornamentals in landscaped areas, to include recreational parks, institutional sites, golf courses and residential properties by commercial and non-professional (e.g., homeowner) applicators. Also for ornamental plants, brassica (cole) leafy vegetables, bulb vegetables, fruiting vegetables and tomatoes, for sale to residential consumers, commercially grown in benches, flats, plugs, liners, and beds indoors in greenhouses and outdoors in shade houses, lath houses, other outdoor growing structures and nurseries, and ornamental plants in interior landscapes, and outdoor landscapes and commercial and residential structures.



## **STORAGE AND DISPOSAL**

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

### **Pesticide Storage**

Store in a cool, dry, secure 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 Handling**

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of it in a manner required by its liner.

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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, LLC  
P.O. Box 18300  
Greensboro, North Carolina 27419-8300

DIFENOCONAZOLE TECHNICAL 739 MAS 0812 AMEND B&B NOV2013-C-CLEAN – sw – 4-27-15  
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