

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 8, 2017

Patrick McCain Regulatory Affairs Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, NC 27419

Subject: PRIA Label Amendment – Adding the new uses of sedaxane on cereal grains crop

group 15; forage, fodder and straw of cereal grains crop group 16; and peanut

Product Name: Sedaxane Technical EPA Registration Number: 100-1381

Application Date: 2/23/2016 Decision Number: 515102

Dear Patrick McCain:

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/registration/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 submit to the Agency the honey bee adult and larvae acute and chronic oral toxicity studies. The deadline for you to submit these required data to the Agency is 12/8/2019. Your failure to provide these data in a timely or adequate manner may result in initiation of a cancellation action against your registration.

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,

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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.

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 Nathan Mellor by phone at 703-347-8562, or via email at mellor.nathan@epa.gov.

Enclosure

Rachel C. Holloman, Chief Fungicide and Herbicide Branch,

Rachel C. Holloman

Registration Division,

Office of Pesticide Programs

[Master Label]

Sedaxane Technical

Active Ingredient:

Other Ingredients: 2.0%

Total: _____ 100.0%

*CAS No. 874967-67-6

ACCEPTED

12/08/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 100-1381

KEEP OUT OF REACH OF CHILDREN.

CAUTION

See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1381

EPA Est.

Product of

882 pounds (400 kg) Net Weight

FIRST AID	
If swallowed	Call a poison control center or doctor immediately for treatment advice.
	Have a 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 to an unconscious person.
If in eyes	 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	Take off contaminated clothing.
clothing	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
If inhaled	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.
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

Harmful if swallowed, causes moderate eye irritation, harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

Environmental Hazards

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.

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 into an end-use fungicide.

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).

Only for formulation into a fungicide for the following seed treatment uses: cereal grains crop group 15; cotton; dried shelled pea and bean crop subgroup 6C; foliage of legume vegetables (except soybean) crop subgroup 7A; forage, fodder and straw of cereal grains crop group 16; peanut; potato; rapeseed (including canola) crop subgroup 20A; soybean; and sugarbeet.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place. Store in original containers only. Keep container closed when not in use. Do not store near food or feed.

Pesticide Disposal

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

Container Handling

Bags: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available or dispose of empty

bag in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities.

Fiber Drums with Liners: Nonrefillable 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 by other procedures approved by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in a manner required by its liner.

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.

CONTAINER IS NOT SAFE FOR FOOD, FEED OR DRINKING WATER.

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, 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 Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

Manufactured for: Syngenta Crop Protection, LLC P.O. Box 18300 Greensboro, North Carolina 27419-8300

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