

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 8, 2019

Ellen Lentz Regulatory Affairs Manager Syngenta Seeds, LLC 9 Davis Drive Research Triangle Park, NC 27709

 Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10- Addition of Alternative brand name
Product Name: Bt11 x MIR162 Corn
EPA Registration Number: 67979-12
Application Date: September 18, 2019
OPP Decision Number: 555469

Dear Ms. Lentz:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA 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 Assurance.

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If you have any questions, please contact Michael Glikes of my team by phone at (703) 231-6499 or via email at glikes.michael@epa.gov.

Sincerely,

Alan Reynolds, Team Leader Emerging Technologies Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

Enclosure

NOTIFICATION

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The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

10/08/2019

Plant-incorporated Protectant Label

Bt11 × MIR162 Corn

Alternate brand names: Agrisure Viptera[®] 3110 Corn Agrisure Viptera[®] 3110A Corn Attribute[®] II Sweet Corn <u>Attribute[®] Plus Sweet Corn</u>

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OECD Unique Identifier: SYN-BTØ11-1×SYN-IR162-4

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and certain lepidopteran pests in both field corn and sweet corn.

Active Ingredients:	
<i>Bacillus thuringiensis</i> Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1)	≤0.00233%*
<i>Bacillus thuringiensis</i> Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)	≤0.0087%*
Other Ingredients:	
Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1)	≤0.000101%*
Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)	≤0.00057%*
*Percent dry weight in whole plant	

KEEP OUT OF REACH OF CHILDREN CAUTION NET CONTENTS: ____

EPA Reg. No. 67979-12 EPA Est. No. 66736-NC-01 Syngenta Seeds, LLC – Field Crops – NAFTA 9 Davis Drive Research Triangle Park, NC 27709

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DIRECTIONS FOR USE

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

The subject registration will automatically expire at midnight on December 31, 2023.

This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination,

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through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

All seed corn that contains the plant-incorporated protectant sold by Syngenta Seeds, LLC or its distributors must be accompanied by informational material (*e.g.* a bag tag) indicating the EPA registration number and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalence guidance) prior to planting the seed. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

Insects Controlled or Suppressed

Field and sweet corn have been genetically transformed to produce the insecticidal proteins, Cry1Ab and Vip3Aa20, for control or suppression of the following lepidopteran insects:

Black cutworm (Agrotis ipsilon) Southern cornstalk borer (Diatraea crambidoides) Southwestern corn borer (Diatraea grandiosella) Sugarcane borer (Diatraea saccharalis) Lesser cornstalk borer (Elasmopalpus lignosellus) Dingy Cutworm (Feltia jaculifera) Corn earworm (Helicoverpa zea) European corn borer (Ostrinia nubilalis) Common stalk borer (Papaipema nebris) True armyworm (Pseudaletia unipuncta) Beet armyworm (Spodoptera exigua) Fall armyworm (Spodoptera frugiperda) Western bean cutworm (Striacosta albicosta)

INSECT RESISTANCE MANAGEMENT

These insect resistance management requirements do not apply to breeding, research, or increase/propagation of inbred and hybrid Bt11 \times MIR162 seed corn up to a total of 20,000 acres per county and up to a combined United States (US) total of 250,000 acres per registrant per year.

An IRM Stewardship Guide or equivalent guidance must be distributed to all customers planting this seed, with the exception of sweet corn home garden users. The guide will include instructions and recommendations regarding product use and insect resistance management. The following information regarding commercial production must be included in the IRM Stewardship Guide or equivalent guidance.

Bt11 × MIR162 Field Corn

- Growers must plant a structured refuge when using Bt11 × MIR162 Field Corn. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the Syngenta Stewardship Guide and/or in supplements to the Stewardship Guide.
- Growers must plant a refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides, as detailed below, to control

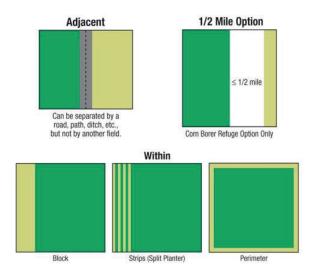
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lepidopteran stalk-boring and other pests.

- Refuge planting options include separate fields, blocks within fields (*e.g.* along the edges or headlands), perimeter strips, and strips across the field.
- External refuges must be planted within $\frac{1}{2}$ mile of the Bt11 × MIR162 corn field.
- If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide.
- The refuge can be treated with an insecticide for control of European corn borer, corn earworm, Southwestern corn borer, and other lepidopteran pests listed on the label, if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

The following are schematics of the various refuge deployment options:



The following text and graphic indicating the refuge size requirement must appear on $Bt11 \times MIR162$ seed bags or bag tags for field corn varieties.



For more information, please refer to the Syngenta Stewardship Guide

Bt11 × MIR162 Sweet Corn

- A refuge is not required for planting of sweet corn varieties. However, the crop must be destroyed within 30 days of harvest, preferably within 14 days of harvest.
- The allowed crop destruction methods for commercial plantings are: rotary mowing, discing, or plow-down. Crop destruction methods should destroy any surviving insects.

For home garden or educational use of Bt11 \times MIR162 sweet corn, the following informational material will appear on individual seed packets:

- This seed is for home garden and/or educational use only (total Bt11 × MIR162 sweet corn planted must be less than 20 acres).
- Within 30 days of harvesting ears of corn, but preferably 14 days, corn plants must be chopped with a hoe or other garden tool to ensure that sweet corn insect pests do not develop resistance to this product.

In addition, IRM educational information will be available in seed catalogues and on websites offering Bt11 \times MIR162 sweet corn hybrids for sale to home gardeners.