



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 23, 2021

Andrea Burns
Regulatory Manager
Syngenta Seeds, LLC – Field Crops – NAFTA
9 Davis Drive
Research Triangle Park, NC 27709

Subject: Labeling Notifications per Pesticide Registration Notice (PRN) 98-10– Addition of alternate brand name

Product Name: Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn
EPA Registration Number: 67979-35
OPP Case Number: 00329831
Application Date: October 14, 2021

Dear Ms. Burns:

The U.S. Environmental Protection Agency (EPA) is in receipt of your applications for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced products. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of these requests for applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10.

The labeling submitted with the applications have been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications for each product.

Should you wish to add/retain a reference to your company’s website on your labels, 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.

If you have any questions, please contact Michael Glikes of my team by phone at (202) 566-1461 or via email at glikes.michael@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Reynolds". The signature is fluid and cursive, with a long horizontal stroke at the end.

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

Enclosure

Plant-incorporated Protectant Label

Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn

Alternate Brand Names:

Agrisure Duracade[®] 5332 E-Z Refuge[®]
Agrisure Duracade[®] 5332A E-Z Refuge[®]
DuracadeViptera[®] Z3

OECD Unique Identifier:

SYN-BT011-1 × SYN-IR162-4 × SYN-IR604-5 × MON-89034-3 × SYN- 05307-1

Plant-incorporated protectants:

Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2 and eCry3.1Ab insecticidal proteins

This product is effective in limiting corn leaf, stalk, ear, and root feeding damage caused by lepidopteran and coleopteran pests

Active Ingredients:

Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BT011-1).....≤0.0209%*

Bacillus thuringiensis Vip3Aa20 protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4).....≤0.0192%*

Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5)≤0.00168%*

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (via elements of vector PV-ZMIR245) in MON 89034 corn (MON-89034-3)≤0.00448%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (via elements of vector PV-ZMIR245) in MON 89034 corn (MON-89034-3).....≤0.0104%*

Bacillus thuringiensis eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN12274) in 5307 Corn (SYN-05307-1).....≤0.0239%*

Other Ingredients:

Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BT011-1)≤0.000140%*

Phosphomannose isomerase marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4) (via elements of vector pZM26) in MIR604 corn (SYN-IR604-5), and (via elements of vector pSYN12274) in 5307 corn (SYN- 05307-1)≤0.00493%*

*Percent (wt/wt) of whole plant on a dry weight basis

CAUTION
KEEP OUT OF REACH OF CHILDREN

EPA Registration No. 67979-35
EPA Establishment No. 66736-NC-01

Syngenta Seeds, LLC– Field Crops – NAFTA
9 Davis Drive
Research Triangle Park, NC 27709

DIRECTIONS FOR USE

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

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered PIPs that are similarly approved for use in combination to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits. All seed corn containing this PIP 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 equivalent guidance) prior to planting their 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

Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn has been genetically transformed to produce the insecticidal proteins Cry1Ab, Vip3Aa20, mCry3A, Cry1A.105, Cry2Ab2, eCry3.1Ab for control or suppression of the following coleopteran and lepidopteran insects:

Northern corn rootworm (*Diabrotica barberi*)
Western corn rootworm (*Diabrotica virgifera virgifera*)
Mexican corn rootworm (*Diabrotica virgifera zea*)
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

Each bag of Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn contains a blend of 95% Bt11 × MIR162 × MIR604 × MON 89034 × 5307 seed and 5% non-Bt refuge seed. The following information regarding commercial production of Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn must be included in the Syngenta Stewardship Guide (or equivalent).

IRM Requirements for Corn-Growing Areas of the U.S.

Refuge seed is blended into each bag of Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn. There is no requirement for growers to plant a separate structured refuge for managing resistance risk in corn-growing areas of the U.S. Corn-growing areas are those counties and states not defined below as comprising the cotton-growing areas of the U.S. Read the Syngenta Stewardship Guide or refer to the Table below

IRM Requirements for Cotton-Growing Areas of the U.S.

In cotton-growing areas growers who plant Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn must plant a supplemental 20% structured refuge. The following table lists those states and counties identified by the Environmental Protection Agency (EPA) as cotton-growing areas.

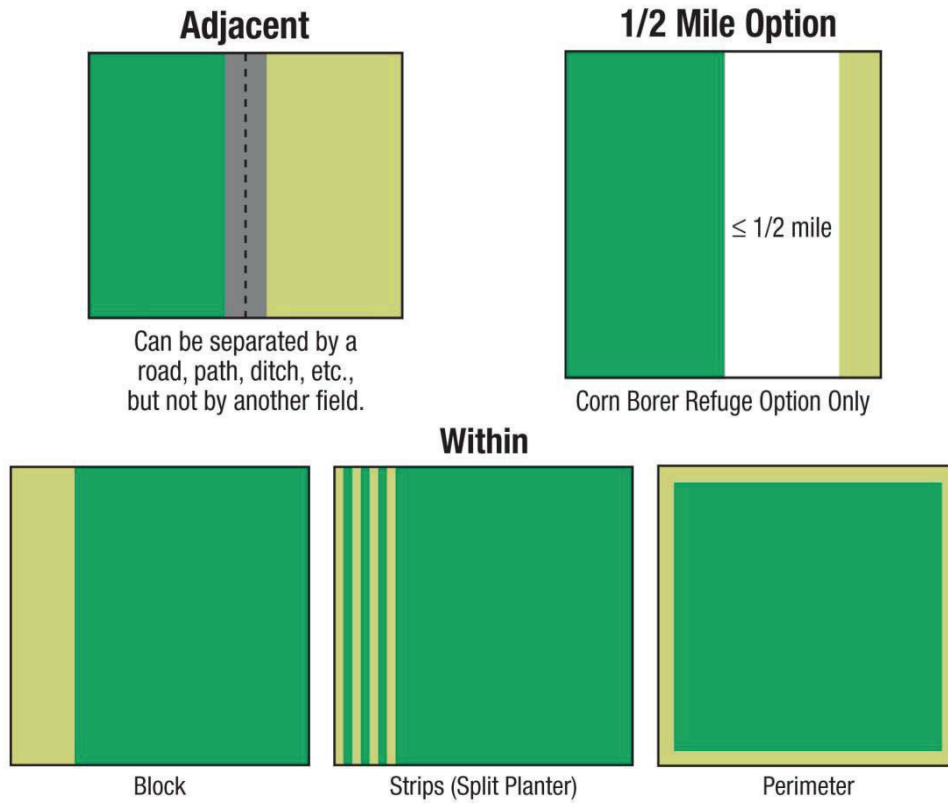
| State | Counties Identified by EPA as Cotton-Growing Areas | | | |
|----------------|--|---|-------------------------------------|--|
| Alabama | All Counties | | | |
| Arkansas | All Counties | | | |
| Florida | All Counties | | | |
| Georgia | All Counties | | | |
| Louisiana | All Counties | | | |
| Mississippi | All Counties | | | |
| Missouri | Dunklin Stoddard | New Madrid | Pemiscot | Scott |
| North Carolina | All Counties | | | |
| Oklahoma | Beckham Greer Kiowa | Caddo Harmon Tillman | Comanche Jackson Washita | Custer Kay |
| South Carolina | All Counties | | | |
| Tennessee | Carroll Fayette Hardin Lincoln Shelby | Chester Franklin Haywood Madison Tipton | Crockett Gibson Lake Obion | Dyer Hardeman Lauderdale Rutherford |
| Texas | All counties with the exception of the following: | | | |
| | Carson Hutchinson Roberts | Dallam Lipscomb Sherman | Hansford Moore | Hartley Ochiltree |
| Virginia | Dinwiddie Northampton Sussex | Franklin City Southampton | Greensville Suffolk City | Isle of Wight Surrey |

The 20% supplemental refuge must be planted with hybrids that do not contain Bt technologies. The supplemental refuge can be planted as strips within the field, perimeter strips, a block within the field, a block adjacent to the field, or a separate block within ½ mile of the Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn field. If in-field or perimeter strips are planted, the strips must be at least four consecutive rows wide.

The supplemental refuge in cotton-growing areas can be protected from feeding damage by application of non-Bt microbial insecticides if the population of one or more lepidopteran pests exceeds economic thresholds. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). In addition, the supplemental refuge can be protected from corn rootworm feeding damage by use of an appropriate seed treatment or conventional

insecticide.

The following are schematics of the various refuge deployment options:



The following text and graphic indicating the refuge size requirement will appear on Bt11 × MIR162 × MIR604 × MON 89034 × 5307 Refuge Seed Blend Corn bags or bag tags.

**Important grower information.
Supplemental refuge planting requirement.**



**For more information, please refer
to Syngenta Stewardship Guide.**