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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 26, 2022

Paul Miles
Regulatory Manager
Syngenta Crop Protection, LLC
9 Davis Drive
Research Triangle Park
North Carolina 27709 USA

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Addition and Removal of Target Pests
Product Name: Bt11 x MIR604 Corn
EPA Registration Number: 67979-8
EPA Receipt Date: 07/07/2022
Action Case Number: 00377245

Dear Mr. Miles:

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 statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 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 by phone at (202) 566-1461 or via email at glikes.michael@epa.gov.

Sincerely,

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

Enclosure

NOTIFICATION
67979-8
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:
08/26/2022

Plant-incorporated Protectant Label

Bt11 × MIR604 Corn
Alternate Brand Names:
Agrisure® CB/LL/RW
Agrisure® 3000GT
Agrisure Artesian® 3011A

OECD Unique Identifier: SYN-BTØ11-1 × SYN-IR6Ø4-5

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and root feeding damage caused by corn rootworms.

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn (SYN-BTØ11-1).....	≤ 0.0029%*
Modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR6Ø4-5)	≤ 0.0069%*

Inert Ingredients:

Phosphinothricin acetyltransferase and the genetic material necessary for its production (via elements of vector pZO1502) in corn (SYN-BTØ11-1)	≤ 0.00002%*
Phosphomannose isomerase and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR6Ø4-5)	≤ 0.0013%*

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-8
EPA Establishment No. 66736-NC-001

Syngenta Seeds, LLC - Field Crops – NAFTA
P.O. Box 12257
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. All commercial corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds or its distributors must be accompanied by informational material stipulating that growers read the IRM Stewardship Guide (or equivalent guidance) prior to planting the seed. The refuge size and requirement must be displayed on the seed bag or bag tag in both text and graphic format as shown below.

Important grower information.
This hybrid requires you to plant:

For more information please refer to the Syngenta Stewardship Guide.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins Cry1Ab and mCry3A for control or suppression of the following lepidopteran and coleopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
~~True armyworm (*Pseudelatia unipuncta*)~~
Sugarcane borer *(Diatraea saccharalis)*
Common stalk borer *(Papaipema nebris)*
Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zeae*)
Beet armyworm *(Spodoptera exigua)*

Insect Resistance Management

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

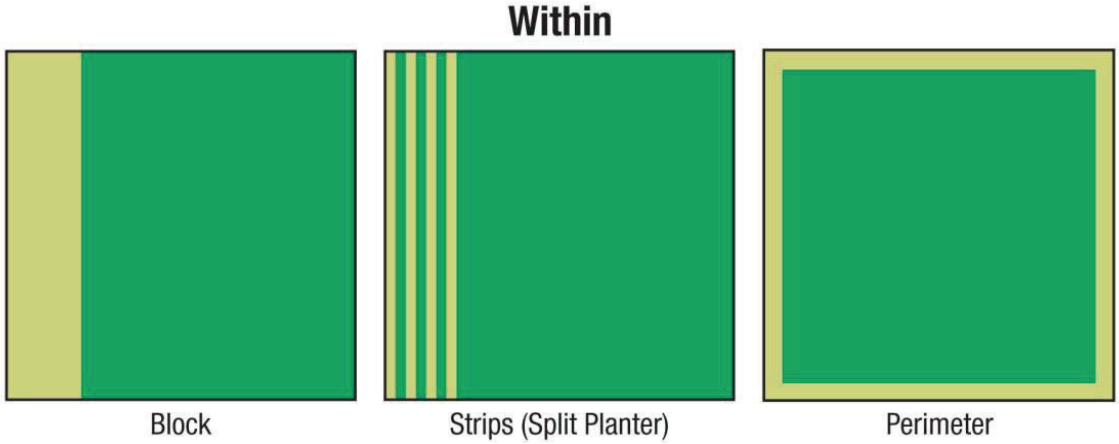
The following information regarding commercial production of Bt11 × MIR604 corn must be included in the Grower Guide (or equivalent).

Corn Belt / Non-Cotton Growing Region Refuge Requirements

For Bt11 × MIR604 corn (expressing Cry1Ab and mCry3A proteins) grown in non-cotton-growing areas of the United States, two options for deployment of the refuge are available to growers.

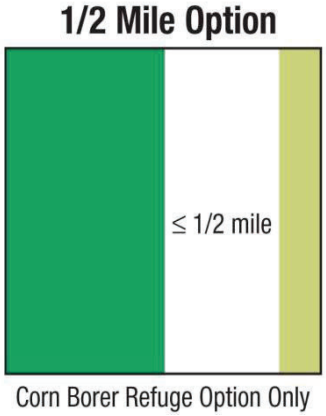
The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 × MIR604 corn acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 × MIR604 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late-season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the Bt11 × MIR604 corn field must be treated in a similar manner.

Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants, etc.). The following is a schematic of common refuge-deployment options:



The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 × MIR604 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 × MIR604 corn field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar-applied insecticide for corn borer control, if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 × MIR604 corn acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g., across the road) to the Bt11 × MIR604 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late-season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11×MIR604 corn field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The following is a schematic of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within a ½ mile of the Bt11 × MIR604 corn field:



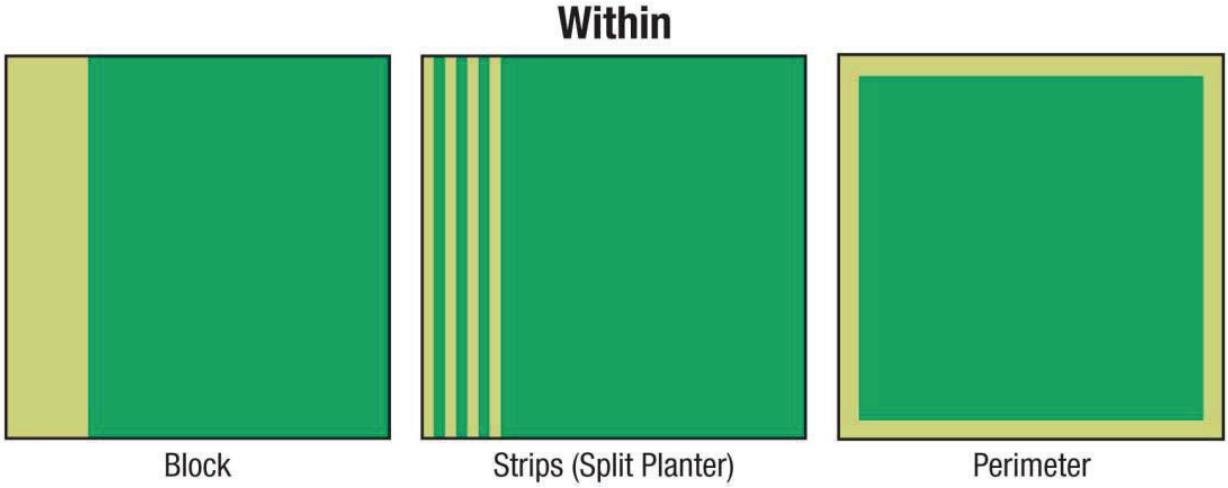
Cotton-Growing Area Refuge Requirements

For Bt11 × MIR604 corn grown in cotton-growing areas the common refuge and separate refuge options are also available, however, the refuge area is larger. Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer,

Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman) Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 × MIR604 corn acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11×MIR604 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter strips or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late-season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the Bt11 × MIR604 corn field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The following is a schematic of common refuge-deployment options:

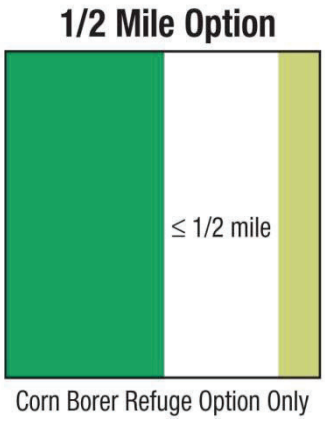


The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with corn that is not a lepidopteran-protected *Bt* hybrid, must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 × MIR604 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 × MIR604 corn field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm

larval control, or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). The corn rootworm refuge must be planted with corn that is not a corn rootworm-protected *Bt* hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 × MIR604 corn acres and corn rootworm refuge acres), and must be planted as a block within or adjacent (e.g., across the road) to the Bt11 × MIR604 corn field, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late-season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications, then the Bt11 × MIR604 corn field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants).

The following is a schematic for a separate-refuge option with the corn borer refuge planted as a block within a ½ mile of the Bt11 × MIR604 corn field:

Separate -Refuge Option



Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the IRM Stewardship Guide for Bt11 ×MIR604 corn or other applicable product use documents.