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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 28, 2015

Sydney Jarrett
Regulatory Affairs Manager
Syngenta Seeds, Inc. – Field Crops – NAFTA
P.O. Box 12257, 3054 East Cornwallis Road
Research Triangle Park, NC 27709

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – To extend the registration expiration date and amend the label to add refuge graphics, delete the alternate brand names from the label, and make other minor label revisions
Product Name: Bt11 x MIR604 Corn
EPA Registration Number: 67979-8
Application Date: July 17, 2015
OPP Decision Number: 509368

Dear Ms. Jarrett:

The amended labeling, referred to above, submitted in connection with registration under Sec. 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable and the expiration date of the registration has been hereby extended to January 31, 2016.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling.

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 FIFRA and is subject to review by the U.S. Environmental Protection Agency (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.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Ann Sibold of my team by phone at (703) 305-6502 or via email at sibold.ann@epa.gov.

Sincerely,

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

Enclosure

Plant-incorporated Protectant Label

Bt11 × MIR604 Corn

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-01

Syngenta Seeds, Inc. - Field Crops - NAFTA
P.O. Box 12257
3054 East Cornwallis Rd.
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*)

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).

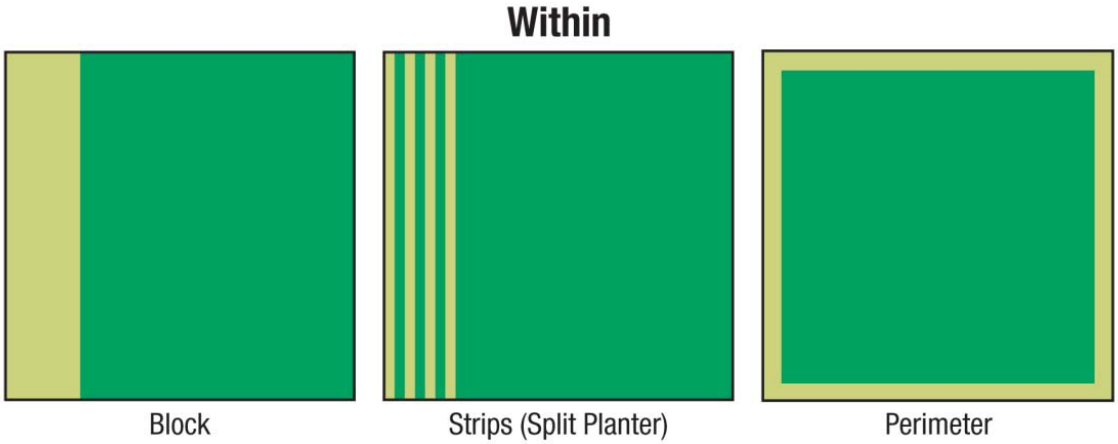
Corn Belt / Non-Cotton Growing Region Refuge Requirements

For Bt11 × MIR604 field 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

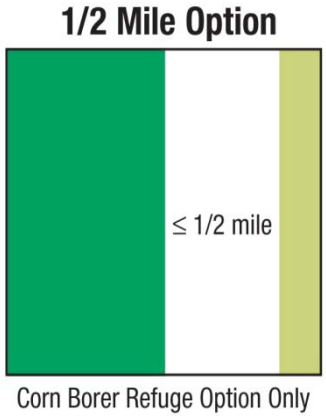
control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 × MIR604 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11 × MIR604 field, perimeter strips (i.e., strips around 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 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 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 × MIR604 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 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 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 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 field:

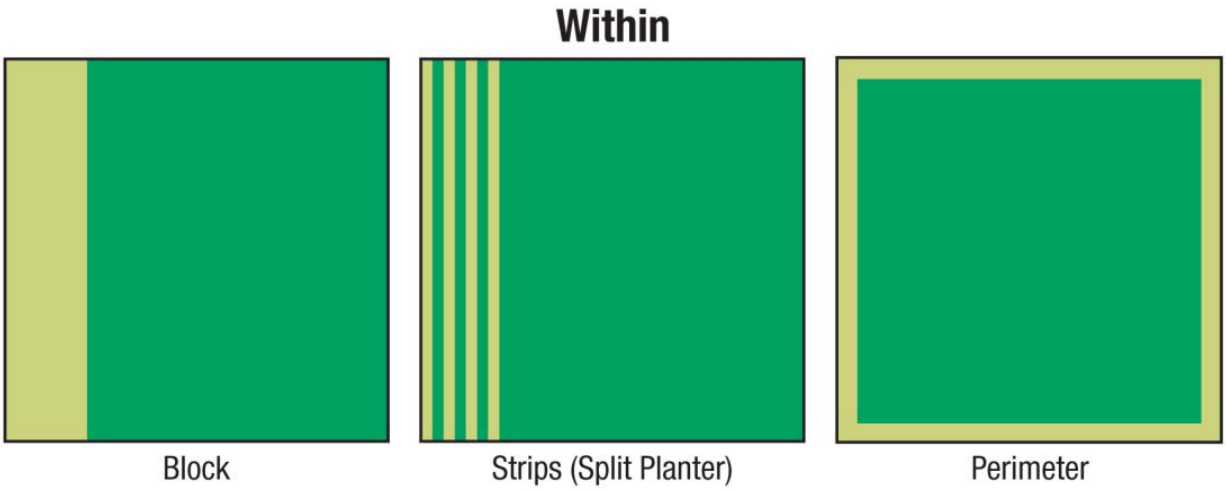


Cotton-Growing Area Refuge Requirements

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 acres and refuge acres). It must be planted as a block within or adjacent (e.g., across the road) to the Bt11×MIR604 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 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).

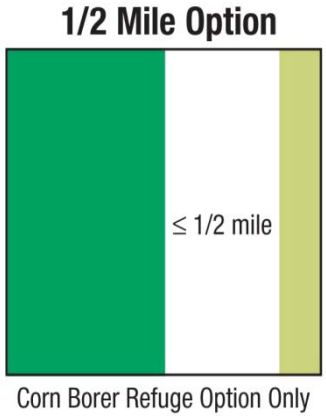
The following is a schematic of common refuge-deployment options:



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 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 × MIR604 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 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 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 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 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.