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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 30, 2021

Andrea Burns
Regulatory Manager
Syngenta Crop Protection, LLC
9 Davis Drive
Research Triangle Park, NC 27709

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10– Addition of alternate brand names
Product Name: Bt11×DAS-59122-7×MIR604×TC1507 Corn
EPA Registration Number: 67979-17
OPP Case Number: 00304858
Application Dated: June 1, 2021

Dear Ms. Burns:

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 applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with the 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 for this product.

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.

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
67979-17
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:
06/30/2021

Plant-Incorporated Protectant Label

Bt11×DAS-59122-7×MIR604×TC1507 Corn

Alternate brand name: Agrisure™ 3122
Agrisure® 3122 Refuge Renew™
Agrisure® 3122A Refuge Renew™

OECD Unique Identifier: SYN-BTØ11-1×DAS-59122-7×SYN-IR6Ø4-5×DAS-Ø15Ø7-1

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

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BTØ11-1) ..... ≤0.006392%*

Bacillus thuringiensis Cry34Ab1 delta-endotoxin protein and the genetic material necessary for its production (via elements of vector PHP17662) in corn event DAS 59122-7 (DAS-59122-7)... ..... ≤0.02162%*

Bacillus thuringiensis Cry35Ab1 delta-endotoxin protein and the genetic material necessary for its production (via elements of vector PHP17662) in corn event DAS 59122-7 (DAS-59122-7)... ..... ≤0.004242%*

Bacillus thuringiensis mCry3A insecticidal protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR6Ø4-5) ..... ≤0.0004888%*

Bacillus thuringiensis Cry1F delta-endotoxin protein and the genetic material necessary for its production (via elements of vector PHP8999) in TC1507 corn (DAS-Ø15Ø7-1) ..... ≤0.001071%*

Other Ingredients:

A marker protein and the genetic material necessary for its production (via elements of vector PHP8999 and elements of vector pZO1502) in corn events TC1507 (DAS-Ø15Ø7-1) and Bt11 (SYN-BTØ11-1) ..... ≤0.000837%*

A marker protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR604 (SYN-IR6Ø4-8) ..... ≤0.000444%*

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-17
EPA Establishment No. 66736-NC-01
®/™ - Trademarks of Syngenta

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 its labeling.

This plant-incorporated protectant may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, 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 or distributed by Syngenta Seeds, Inc. or its distributors must be accompanied by informational material (*e.g.* a bag tag) indicating the registration number (67979-17) and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting the seed.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, Cry34Ab1, Cry35Ab1, mCry3A, and Cry1F for control or suppression of the following coleopteran and lepidopteran insects:

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

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.

Refuge Requirements for Bt11×DAS-59122-7×MIR604×TC1507 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/product use guide and/or in supplements to the Stewardship guide.

The following information regarding commercial production of Bt11×DAS-59122-7×MIR604×TC1507 Corn must be included in the Grower Guide (or equivalent). Growers must plant a refuge when using this product.

Two options for deployment of the refuge are allowed:

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 pests. The refuge area must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum Bt11×DAS-59122-7×MIR604×TC1507 Corn acres and refuge acres). It must be planted as a block adjacent to the Bt11×DAS-59122-7×MIR604×TC1507 Corn field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide. If the common refuge is planted on rotated ground, then Bt11×DAS-59122-7×MIR604×TC1507 Corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11×DAS-59122-7×MIR604×TC1507 Corn field may be planted on either continuous or rotated land. 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×DAS-59122-7×MIR604×TC1507 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). Pests other than adult corn rootworms can be treated with an appropriate pest-labeled insecticide on the common refuge acres without treating Bt11×DAS-59122-7×MIR604×TC1507 Corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11×DAS-59122-7×MIR604×TC1507 Corn acres can be treated as needed without having to treat the common refuge.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11×DAS-59122-7×MIR604×TC1507 Corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11×DAS-59122-7×MIR604×TC1507 cornfield. Refuge planting options include separate fields, blocks within fields (*e.g.*, along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in- field strips are implemented, the strips must be at least four consecutive rows wide. 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).

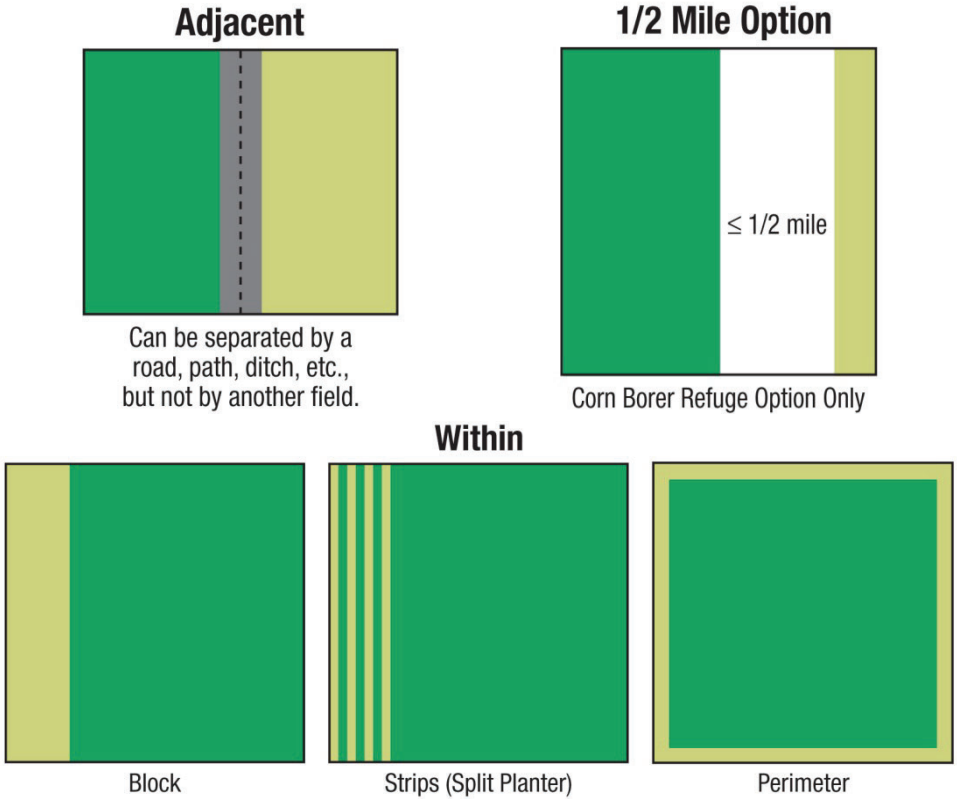
The corn rootworm refuge must be planted with a non-Bt/corn rootworm-protected Bt hybrid, but can be planted with a Bt corn hybrid that controls corn borers. The corn rootworm refuge must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11×DAS-59122-7×MIR604×TC1507 corn acres and rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide. If the rootworm refuge is planted on rotated ground, then Bt11×DAS-59122-7×MIR604×TC1507 corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the Bt11×DAS-59122-7×MIR604×TC1507 cornfield may be planted on either continuous or rotated land.

More generally, the corn rootworm refuge should utilize comparable agronomic practices as the Bt11×DAS-59122-7×MIR604×TC1507 corn acres. 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; however, if rootworm adults are present at the time of foliar applications, then the Bt11×DAS-59122-7×MIR604×TC1507 corn field must be treated in a similar manner. Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Bt11×DAS-59122-7×MIR604×TC1507 corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on Bt11×DAS-59122-7×MIR604×TC1507 corn acres can be treated as needed without having to treat the rootworm refuge.

Cotton-Growing* Areas Requiring 20% Refuge Corn

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	New Madrid	Pemiscot	Scott	Stoddard
North Carolina	All Counties				
Oklahoma	Beckham Harmon Washita	Caddo Jackson	Comanche Kay	Custer Kiowa	Greer Tillman
South Carolina	All Counties				
Tennessee	Carroll Franklin Lake Rutherford	Chester Gibson Lauderdale Shelby	Crockett Hardeman Lincoln Tipton	Dyer Hardin Madison	Fayette Haywood Obion
Texas	All counties with the exception of the following: Carson Lipscomb	Dallam Moore	Hansford Ochiltree	Hartley Roberts	Hutchinson Sherman
Virginia	Dinwiddie Southampton	Franklin City Suffolk City	Greensville Surrey	Isle of Wright Sussex	Northampton

The following are schematics of the various refuge deployment options:



The following text and graphic indicating the refuge size requirement will appear on Bt11×DAS-59122-7×MIR604×TC1507 seed corn bags or bag tags.

Important grower information.
Supplemental refuge planting requirement.

5% refuge
Corn-growing areas

or

20% refuge
Cotton-growing areas

For more information, please refer to Syngenta Stewardship Guide.