

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

April 22, 2025

Jenel Richard
Regulatory Specialist
Syngenta Seeds, LLC – Field Crops NAFTA
9 Davis Drive
Durham, NC 27713

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Addition of

Alternate Brand Name and Update to Company Address Product Name: Bt11 x MIR162 x MZIR098 x DP4114 Corn

EPA Registration Number: 67979-41 EPA Receipt Date: 02/18/2025 Action Case Number: 00645478

Dear Ms. Richard:

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

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. The revised company address and alternate brand name: DurastakViptera™ Refuge Renew™ have been added to the product's 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 and is subject to review by 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 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 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 EPA's Office of Enforcement and Compliance Assurance.

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If you have any questions, please contact Stephanie Kelly by phone at (202) 566-0890 or via email at kelly.stephanie@epa.gov.

Sincerely,

Digitally signed by ALAN REYNOLDS Date: 2025.04.22 15:52:51 -04'00'

Alan Reynolds, Product Manager 94 Emerging Technologies Branch Biopesticides and Pollution Prevention Division (7511M) Office of Pesticide Programs

Enclosure: Copy of the Product Label Stamped "Notification"

Plant-incorporated Protectant Label

Bt11 × MIR162 × MZIR098 × DP4114 Corn

Alternate Brand Name:

DurastakVipteraTM Refuge RenewTM

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:

04/22/2025

OECD Unique Identifier:

SYN-BTØ11-1 × SYN-IR-162-4 × SYN-ØØØ98-3 × DP-ØØ4114-3

Plant-incorporated protectants:

Cry1Ab, Vip3Aa20, mCry3A, eCry3.1Ab, Cry34Ab1, Cry35Ab1, and Cry1F insecticidal proteins

| Active Ingredients: |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1)≤0.00187* |
| <i>Bacillus thuringiensis</i> Vip3Aa20 protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR-162-4)≤0.0106%* |
| Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pSYN17629) in MZIR098 corn (SYN-ØØØ98-3)≤0.00212%* |
| Bacillus thuringiensis eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN17629) in MZIR098 corn (SYN-ØØØ98-3)≤0.00148%* |
| Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary for its production (via elements of vector PHP27118) in DP4114 corn (DP-ØØ4114-3)≤0.00795%* |
| Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary for its production (via elements of vector PHP27118) in DP4114 corn (DP-ØØ4114-3)≤0.00201%* |
| Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (via elements of vector PHP27118) in DP4114 corn (DP-ØØ4114-3)≤0.00057%* |
| Other Ingredients: |
| Phosphinothricin acetyltransferase protein and the genetic material necessary for its production (via elements of vectors pZO1502, PHP27118, and pSYN17629) in Bt11 Corn (SYN-BTØ11-1), DP4114 corn (DP-ØØ4114-3), and MZIR098 corn (SYN-ØØØ98-3), respectively≤0.000365%* |
| Phosphomannose isomerase protein and the genetic material necessary for its production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4)≤0.000878%* |

^{*} Max percent (wt/wt) of dried forage at R4

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CAUTION KEEP OUT OF REACH OF CHILDREN

EPA Registration No. 67979-41 EPA Establishment No. 66736-NC-01 Syngenta Seeds, LLC. - Field Crops NAFTA 9 Davis Drive Research Triangle Park Durham, NC 27709-27713

DIRECTIONS FOR USE

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

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 seeds. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

STORAGE AND DISPOSAL

Do not contaminate bodies of water by storage or disposal.

INSECTS CONTROLLED OR SUPPRESSED

Bt11×MIR162×MZIR098 × DP4114 Corn has been genetically transformed to produce the insecticidal proteins Cry1Ab, Vip3Aa20, Cry1F, mCry3A, eCry3.1Ab, Cry34Ab1, and Cry35Ab1 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*)

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*)

Common stalk borer (*Papaipema nebris*)

Dingy cutworm (Feltia jaculifera)

Western corn rootworm (*Diabrotica virgifera virgifera*)

Northern corn rootworm (*Diabrotica barberi*)

Mexican corn rootworm (*Diabrotica virgifera zea*)

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Insect Resistance Management

Each bag of Bt11 \times MIR162 \times MZIR098 \times DP4114 Corn contains 100% Bt11 \times MIR162 \times MZIR098 \times DP4114 Corn seeds. The following information regarding commercial production of Bt11 \times MIR162 \times MZIR098 \times DP4114 Corn must be included in the Syngenta Stewardship Guide (or equivalent).

IRM Requirements for Corn-Growing Areas of the US

Corn growers in corn-growing areas who plant $Bt11 \times MIR162 \times MZIR098 \times DP4114$ Corn must plant a supplemental 5% structured refuge. Corn-growing areas exclude counties and states defined as cotton-growing areas. For more information, refer to the Syngenta Stewardship Guide or the table below.

IRM Requirements for Cotton-Growing Areas of the US

In cotton-growing areas, growers who plant $Bt11 \times MIR162 \times MZIR098 \times DP4114$ 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.

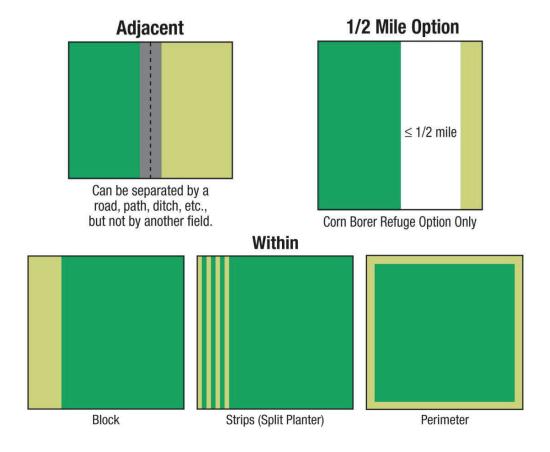
| State | Counties Identified by EPA as Cotton-Growing Areas | | | |
|----------------|----------------------------------------------------|-----------------------------------------------------|-------------------------------------|----------------------------------------------|
| Alabama | All Counties | | | |
| 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 |
| | All counties with the following exceptions: | | | |
| Texas | Carson Hutchinson Roberts | Dallam Lipscomb Sherman | Hansford Moore | Hartley Ochiltree |
| Virginia | Dinwiddie Northampton Sussex | Franklin City Southampton | Greensville Suffolk City | Isle of Wight Surrey |

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The refuge must be planted with hybrids that do not contain Bt technologies. The 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 within½ mile of the Bt11 × MIR162 × MZIR098 × DP4114 Corn field. If in-field or perimeter strips are planted, the strips must be at least four consecutive rows wide.

The 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 refuge can be protected from corn rootworm feeding damage by use of an appropriate seed treatment or conventional insecticide.

The followings are schematics of the various refuge deployment options:



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The following text and graphic indicating the supplemental refuge size requirement will appear on Bt11 × MIR162 × MZIR098 × DP4114 Corn bags or bag tags.

Important grower information. Supplemental refuge planting requirement.



For more information, please refer to Syngenta Stewardship Guide.

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