

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 20, 2022

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

Subject: Non-PRIA (Pesticide Registration Improvement Act) Amendment – Extension of

Registration Expiration Date and Revised Product Label

Product Name: Bt11 Insect-Resistant Corn

EPA Registration Number: 67979-1 EPA Receipt Date: June 15, 2022 OPP Case Number: 00371955

Dear Ms. Burns:

The amendment referenced above, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

The subject registration will automatically expire at midnight on September 30, 2023. 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. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

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 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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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.

A previously approved Confidential Statement of Formula, dated May 5, 2014, is on file for this product.

If you have any questions, please contact Matt Weiner by email at <u>weiner.matthew@epa.gov</u> or by phone at (202) 566-1509.

Sincerely,

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

Enclosure

ACCEPTED

09/20/2022

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

67979-1

Plant-incorporated Protectant Label

Bt11 Insect-Resistant Corn

Alternate Brand Names:
Agrisure® CB/LL
Agrisure® GT/CB/LL
Bt11 Field Corn
Agrisure® 3010
Agrisure Artesian® 3010A

OECD Unique Identifier: SYN-BTØ11-1

This product is effective in limiting corn leaf, stalk, and ear damage caused by corn borers and certain other lepidopteran pests.

Active Ingredient:

Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1)....≤0.0028%*

Inert Ingredient:

Phosphinothricin acetyltransferase protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1)..... \leq 0.00002%*

Keep Out of the Reach of Children CAUTION

NET CONTENTS:

EPA Reg. No. 67979-1 EPA Est. No. 67979-IA-002 Syngenta Seeds, LLC. – Field Crops - NAFTA 9 Davis Drive Research Triangle Park, NC 27709

Agrisure® is a trademark of a Syngenta Group company

Directions for Use

It is a violation of Federal law to use this product in a 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 plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

^{*}Percentage on a dry weight basis from the highest concentration measured in individual plant tissues.

All commercial corn seed that contains Bt11 Insect-Resistant Corn that is sold by Syngenta Seeds or its distributors must be accompanied by informational material (e.g. bag tag) indicating the EPA registration number and the active ingredients, and stipulating that growers read the product Insect Resistance Management (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:



50%
refuge
Cotton-growing areas

For more information please refer to the Syngenta Stewardship Guide.

Insects Controlled or Suppressed

Corn has been genetically modified to produce a *Bacillus thuringiensis* Cry1Ab delta-endotoxin protein for control or suppression of:

Southern cornstalk borer (Diatraea crambidoides)
Southwestern corn borer (Diatraea grandiosella)
Sugarcane borer (Diatraea grandiosella)
Lesser cornstalk borer (Elasmopalpus lignosellus)

Corn earworm (Helicoverpa zea)
European corn borer (Ostrinia nubilalis)
Common stalk borer (Papaipema nebris)
Fall armyworm (Spodoptera frugiperda)
Beet armyworm (Spodoptera exigua)

Insect Resistance Management

An IRM Stewardship Guide (or equivalent guidance) must be distributed to all customers using seed containing the plant incorporated-protectant. The IRM Stewardship Guide will include instructions and recommendations regarding product use, insect resistance management, and integrated pest management. The following information regarding refuge requirements for commercial production must be included in the IRM Stewardship Guide for the corn belt and cotton-growing areas.

These IRM requirements do not apply to breeding, research, propagation of inbred seed, or production of hybrid seed corn on up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per plant-incorporated protectant active ingredient per registrant per year.

Corn Belt (Non cotton-Growing Areas)

For Bt11 Insect-Resistant Corn grown in the Corn Belt (non cotton-growing areas), growers must adhere to the following refuge requirements:

- Growers must plant a refuge of at least 20% non-Bt corn and/or non-lepidopteran-resistant Bt corn.
- The refuge can be planted as a block, strips within the field, perimeter around the field, adjacent or a separate block planted within ½ mile.
- A neighbor's field does not meet the refuge requirements.
- Strips, blocks, or perimeter refuges must be a minimum of 4 contiguous rows wide.
- Non-Bt foliar insecticide treatments may be applied only if economic thresholds are reached for one or more pests. Economic thresholds will be determined using methods recommended by local or regional professionals (*e.g.* Extension service agents, crop consultants).
- The refuge should be planted with a hybrid that is agronomically similar to and managed similarly to the Bt11 Insect-Resistant Corn.

Cotton-Growing Areas

For Bt field corn grown in cotton-growing areas (defined below) growers must adhere to the following refuge requirements.

- Growers must plant a refuge of at least 50% non-Bt corn and/or non-lepidopteran-resistant Bt corn.
- The refuge can be planted as a block, strips within the field, perimeter around the field, adjacent or a separate block planted within ½ mile.
- A neighbor's field does not meet the refuge requirements.
- Strips, blocks, or perimeter refuges must be a minimum of 4 contiguous rows wide.
- Non-Bt foliar insecticide treatments may be applied only if economic thresholds are reached for one or more pests. Economic thresholds will be determined using methods recommended by local or regional professionals (*e.g.* Extension service agents, crop consultants).
- The refuge should be planted with a hybrid that is agronomically similar to and managed similarly to the Bt11 Insect-Resistant Corn.

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	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 Dallam Hansford Hartley Hutchinson Lipscomb Moore Ochiltree Roberts Sherman				
Virginia	Dinwiddie Southampton	Franklin City Suffolk City	Greensville Surrey	Isle of Wright Sussex	Northampton

Schematics showing refuge deployment options:

