



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 27, 2023

Ashley Young
U.S. Seeds Regulatory Specialist
Corteva Agriscience LLC
9330 Zionsville Road
Indianapolis, IN 46268

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –Revision to the Name of the Company
Product Name: SmartStax Enlist Refuge Advanced
EPA Registration Number: 68467-16
EPA Receipt Date: March 3, 2023
Action Case Number: 00439366

Dear Ms. Young:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

The primary company name of this product has been changed from Mycogen Seeds c/o Dow Agrosiences LLC to Corteva Agriscience LLC, and our records have been updated accordingly. 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. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new 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.

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 Leslie Paul via email at paul.leslie@epa.gov.

Sincerely,

 Digitally signed by
ALAN REYNOLDS
Date: 2023.04.27
10:13:41 -04'00'

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

Enclosure: Final Stamped Label

ACCEPTED

04/27/2023

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 68467-16

Plant-Incorporated Protectant Label

SmartStax[®] Enlist[™] Refuge Advanced

(Alternate Brand Name MON 89034 x TC1507 x MON 88017 x DAS-59122-7

Insect Protected Herbicide-Tolerant Corn With An Interspersed Refuge)

(Alternate Brand Name Refuge Advanced Powered by SmartStax[®])

(Alternate Brand Name SmartStax[®] Refuge Advanced)

(OECD Unique Identifier: MON-89034-3 x DAS- 01507-1 x
MON-88017-3 x DAS-59122-7)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3) ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3) ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- 01507-1) ≤ 0.0012%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88017-3) ≤ 0.0079%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0194%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ≤ 0.0042%*

Other Ingredients:

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ≤ 0.0052%*

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7 ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

‡ SmartStax[®] seed with this refuge configuration contains 95% MON 89034 x TC1507 x MON 88017 x DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA Registration No. 68467-16

EPA Establishment No. 62719-IN-001

Corteva Agriscience LLC

9330 Zionsville Road

Indianapolis, IN 46268

SmartStax[®] multi-event technology developed by Corteva Agriscience and Monsanto.

[®]SmartStax is a registered trademark of Bayer Group

Enlist[™] is a trademark of Corteva Agriscience and its affiliated companies

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. The plant-incorporated protectant (PIP) product must be used as specified in the terms and conditions of the registration.

This plant-incorporated protectant may be combined or produced 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.

SmartStax[®] Enlist[™] Refuge Advanced protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to SmartStax[®] Enlist[™] Refuge Advanced, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Product Use Guide for SmartStax[®] Enlist[™] Refuge Advanced or other applicable product use documents.

Sales of corn hybrids that contain Bt corn plant-incorporated pesticide(s) must be accompanied by a Product Use Guide which includes information on planting, production, and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing SmartStax[®] Enlist[™] Refuge Advanced must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on 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 refuge placement for commercial production must be included in the Product Use Guide.

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed. **The seed mix refuge option for SmartStax[®] Enlist[™] Refuge Advanced satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below.**

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed in the seed mixture receives the same treatment. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest

In cotton-growing regions where corn earworm is a significant pest, as defined below, the seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of SmartStax® Enlist™ Refuge Advanced planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the SmartStax® Enlist™ Refuge Advanced should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the SmartStax® Enlist™ Refuge Advanced. In-field refuge options include blocks, 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 refuge can be protected from lepidopteran damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of SmartStax® (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring this additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, 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 following language will be included on the seed bag tags for SmartStax® Enlist™ Refuge Advanced:

Management Guidelines

This product consists of a licensed seed-mixture/seed-blend containing 95% SmartStax® seed and a minimum of 5% seed that does not contain B.t. technologies for the control of corn borers or corn rootworms. When planted, the refuge will be interspersed within the field.

The interspersed refuge configuration in SmartStax® Enlist™ Refuge Advanced fulfills the grower's refuge requirements for this product in non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under SmartStax® registration 68467-7).

The interspersed refuge in SmartStax® Enlist™ Refuge Advanced corn is not sufficient to meet IRM requirements in regions that currently require a 20% structured refuge for SmartStax® (cotton growing regions and non-cotton growing regions where corn earworm is a significant pest). In these regions growers are required to plant a structured 20% corn refuge for corn earworm.

In the SmartStax 20% structured refuge areas, the structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block that is within ½ mile of the Refuge Advanced field. In-field refuge options include blocks, 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 four consecutive rows of corn wide.

Cotton Growing Region

The cotton-growing region requiring this additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, 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, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)

Corn Insects Controlled or Suppressed

| | |
|---------------------------------|---------------------------------------|
| European corn borer (ECB) | <i>Ostrinia nubilalis</i> |
| Southwestern corn borer (SWCB) | <i>Diatraea grandiosella</i> |
| Southern cornstalk borer (SCSB) | <i>Diatraea crambidoides</i> |
| Corn earworm (CEW) | <i>Helicoverpa zea</i> |
| Fall armyworm (FAW) | <i>Spodoptera frugiperda</i> |
| Stalk borer | <i>Papaipema nebris</i> |
| Lesser corn stalk borer | <i>Elasmopalpus lignosellus</i> |
| Sugarcane borer (SCB) | <i>Diatraea saccharalis</i> |
| Western bean cutworm (WBC) | <i>Richia albicosta</i> |
| Black cutworm | <i>Agrotis ipsilon</i> |
| Western corn rootworm (WCRW) | <i>Diabrotica virgifera virgifera</i> |
| Northern corn rootworm (NCRW) | <i>Diabrotica barberi</i> |
| Mexican corn rootworm (MCRW) | <i>Diabrotica virgifera zea</i> |

EPA Accepted:_____.