

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 4, 2015

Heidi Reistad U.S. Regulatory Manager Mycogen Seeds, c/o Dow AgroSciences LLC 9330 Zionsville Road Indianapolis, IN 46268

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –To extend

the expiration date, revise the CSF and label to include the primary brand name and

revise the label to clarify cotton region refuge requirements.

Product Name: PowerCore[™] Enlist[™] Refuge Advanced

EPA Registration Number: 68467-21 Application Date: May 11, 2015 OPP Decision Number: 505088

Dear Ms. Reistad:

The amended labeling and confidential statement of formula (CSF) referred to above, submitted in connection with registration under Sec. 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable and the expiration date of the registration has been hereby extended to Nov. 30, 2018.

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 it.

Please note that the record for this product currently contains the following acceptable CSF:

• Basic CSF dated 05/11/2015

Any CSFs other than that listed above are superseded/no longer valid.

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

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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, these registrations 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

PowerCore™ Enlist™ Refuge Advanced

(Alternate Brand Name PowerCore™ Refuge Advanced)
(Alternate Brand Name Refuge Advanced Powered by PowerCore®)
(Alternate Brand Name MON 89034 x TC1507 Insect-Protected, Herbicide Tolerant Corn with an Interspersed Refuge)

(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1)

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-89Ø34-3) ≤ 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-89Ø34-3) ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- \emptyset 15 \emptyset 7-1) $\leq 0.00122\%$ *

Other Ingredients:

The marker protein, PAT (phosphinothricin acetyl transferase), and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 $\leq 0.00045\%^*$

*Maximum percent (wt/wt) of dry forage

 \ddagger PowerCore[®] seed with this refuge configuration contains 95% MON 89034 \times TC1507 mixed with at least 5% non-Bt corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS

CAUTION

EPA Registration No. 68467-21

EPA Establishment No. 62719-IN-1

Mycogen Seeds c/o Dow AgroSciences LLC 9330 Zionsville Rd. Indianapolis, IN 46268 ACCEPTED

11/04/2015

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

68467-21

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 (PIP) 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.

PowerCore[™] Enlist[™] Refuge Advanced protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label. In order to minimize the risk of these pests developing resistance to PowerCore[™] 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 PowerCore™ 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 PowerCore™ 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 and minimum of 5% non-PIP seed. The seed mix refuge option for PowerCore™ Enlist™ Refuge Advanced satisfies the refuge requirements in all regions other than in the cotton growing region 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 x TC1507 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.

Additional refuge requirements in the cotton growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, the seed-mixture containing MON 89034 × TC1507 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 PowerCore™ 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 PowerCore™ 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 PowerCore™ 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 MON 89034×TC1507 in the refuge exceeds economic thresholds. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region where corn earworm is a significant pest, which requires 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 PowerCore™ Enlist™ Refuge Advanced.

Management Guidelines

This product consists of a licensed seed-mixture/seed-blend containing 95% PowerCore® 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 PowerCore™ 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.

The interspersed refuge in PowerCore™ Enlist™ Refuge Advanced is not sufficient to meet IRM requirements in the cotton growing region 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 cotton-growing region where corn earworm is a significant pest, the structured refuge may be planted as an infield or adjacent (e.g., across the road) refuge or as a separate block that is within ½ mile of the PowerCore™ Enlist™ 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 where corn earworm is a significant pest, which requires 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)

Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Diatraea grandiosella Diatraea crambidoides Helicoverpa zea Spodoptera frugiperda Papaipema nebris Elasmopalpus lignosellus Diatraea saccharalis Richia albicosta Agrotis ipsilon

Ostrinia nubilalis