

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 5, 2018

David Chi Regulatory Affairs Manager Monsanto Company 800 North Lindbergh Blvd. St. Louis, Missouri 63167

Subject:

Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –

- Modify the designations for the active and inactive ingredients;
- Removal of Genuity® PowerCoreTM as an Alternate Brand Name;
- Make minor changes to the Directions for Use;
- Remove Western bean cutworm (*R. albicosta*) as a target pest;
- Replace "524-XXX" with "524-585."

Product Name: MON 89034 x TC1507 EPA Registration Number: 524-585 Application Dates: 3/29/2018 OPP Decision Numbers: 542191

Dear Mr. Chi:

In an application dated March 29, 2018, you notified the U.S. Environmental Protection Agency (EPA) that you requested to modify the designations for the active and inactive ingredients, to remove Genuity® PowerCoreTM as an Alternate Brand Name, to remove Western bean cutworm (*R. albicosta*) as a target pest, to replace "524-XXX" with "524-585", and to make minor changes to the Directions for Use. Subsequently, the EPA determined that the actions requested do not fall under the scope of Pesticide Registration Notice (PRN) 98-10 and therefore converted the notification to a non-PRIA amendment (OPP Decision No. 542191). The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Additionally, Genuity® PowerCoreTM has been removed from the registration. 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

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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 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.

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 Matt Weiner by phone at 703-347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

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

Enclosure

Plant-Incorporated Protectant Label

MON 89034 × TC1507

Insect-Protected, Herbicide-Tolerant Corn (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507 \leq 0.0012%*
Other Ingredients:
PAT protein (Phosphinothricin Acetyl transferase) and the genetic material necessary (vector PHP8999) for its production in corn event TC1507 \leq 0.00045%*
*Maximum percent (wt/wt) of dry forage

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS____

EPA Registration No. 524-585

EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

ACCEPTED

07/05/2018

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

524-585

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Information regarding commercial production as specified in the terms and conditions of this registration must be included in the Technology Use Guide and/or Insect Resistance Management (IRM) Grower Guide.

MON 89034 x TC1507 can be used to protect corn plants from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on 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, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

INSECT RESISTANCE MANAGEMENT

To help preserve the effectiveness of *B.t.* corn technologies, growers planting MON 89034 x TC1507 field corn are required to follow an Insect Resistance Management (IRM) Plan.

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 PIP active ingredient per registrant per year.

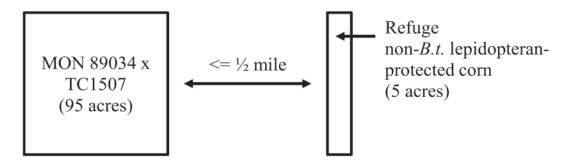
a) Corn-Belt/Non-Cotton-Growing Area Refuge Requirements

For MON 89034 x TC1507 field corn grown outside the cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements.

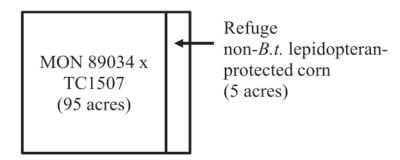
Growers must plant a structured refuge of at least 5% corn, which is not a lepidopteranprotected *B.t.* corn hybrid. The refuge may be treated with insecticides, as described below, to control lepidopteran stalk-boring and other pests.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field or as perimeter strips, refuges must be at least four (4) consecutive rows wide.



Insecticide treatments for control of insects included on this label may be applied only if economic thresholds are reached for one or more of these targeted pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *B.t.* insecticides must not be applied to non-*B.t.* corn refuges.

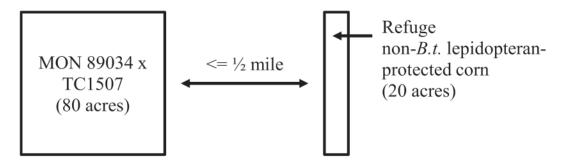
b) Cotton-Growing Area Refuge Requirements

For MON 89034 x TC1507 field corn grown in cotton-growing areas, as defined below, grower guides must specify that growers must adhere to the following refuge requirements.

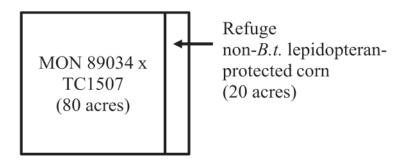
Growers must plant a structured refuge of at least 20% corn which is not a lepidopteranprotected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control insects included on this label.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least four (4) consecutive rows wide.



Insecticide treatments for control of insects included on this label may be applied only if economic thresholds are reached for one or more of these targeted pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *B.t.* insecticides must not be applied to non-*B.t.* corn refuges.

Cotton-growing areas include 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)

Black cutworm

Ostrinia nubilalis Diatraea grandiosella Diatraea crambidoides

Helicoverpa zea

Spodoptera frugiperda Papaipema nebris

Elasmopalpus lignosellus Diatraea saccharalis

Agrotis ipsilon

Sales of corn hybrids that contain Monsanto's *B.t.* corn plant-incorporated protectant must be accompanied by a grower 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 *B.t.* proteins is planted.

MON 89034 × TC1507 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents that can be found at http://www.monsantotechnology.com