

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 –

- Correct the common name of *P. nebris* as a target pest;
- Add lesser corn stalk borer (*E. lignosellus*) as a target pest;
- Modify the designations for the active and inactive ingredients;
- Make minor changes to the Directions for Use.

Product Name: MON 89034

EPA Registration Number: 524-575 Application Date: March 29, 2018 OPP Decision Number: 542189

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, correct the common name of *P. nebris* as a target pest, add lesser corn stalk borer (*E. lignosellus*) as a target pest, and make minor changes to the Directions for Use section. Subsequently, the EPA determined that the actions requested do not fall under the scope of Pesticide Registration Notice 98-10 and therefore converted the notification to a non-PRIA amendment (OPP Decision Number 542189). The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

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.

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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

Lepidopteran-Protected Corn (OECD Unique Identifier: MON-89Ø34-3)

This product is effective in controlling leaf, stalk, and ear damage caused by corn borers.

Active Ingredients: **Bacillus thuringiensis** Cry1A.105 protein and the genetic material (Vector PV-ZMIR245) necessary for its production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)... **Second Second Second

*Percentage (wt/wt) on a dry weight basis for whole plant (forage)

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS

EPA Registration No. 524-575

EPA Establishment No. 524-MO-002

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

ACCEPTED

07/05/2018

524-575

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.

The subject registration will automatically expire on midnight September 30, 2022.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

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.

1) Refuge Requirements for MON 89034 Field Corn

In order to minimize the risk of corn borers developing resistance to MON 89034 field corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

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. Furthermore, these refuge requirements do not apply to commercial hybrid sweet corn.

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

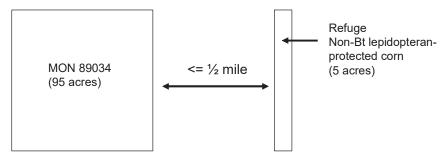
For MON 89034 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements.

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

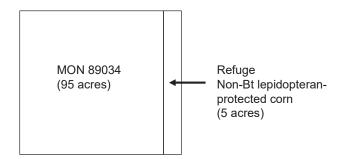
Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm, lesser corn stalk borer, and stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds 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.

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, refuges must be at least 4 consecutive rows wide.



b) Cotton-Growing Area Refuge Requirements

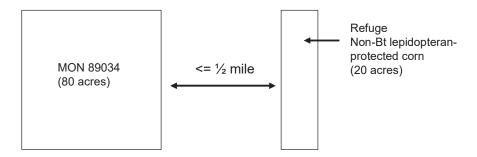
Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, 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, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

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

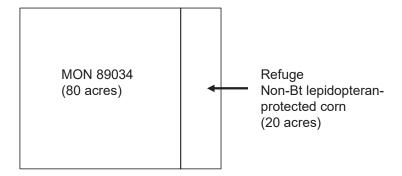
Growers must plant a structured refuge of at least 20% corn which is not a lepidopteranprotected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests. Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm, lesser corn stalk borer, and stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial *B.t.* insecticides must not be applied to non-*B.t.* corn refuges.

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, refuges must be at least four (4) consecutive rows wide.



2) Post-Harvest Requirements for MON 89034 Sweet Corn

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

Corn Insects Controlled or Suppressed

European corn borer Ostrinia nubilalis
Southwestern corn borer Diatraea grandiosella
Southern cornstalk borer Diatraea crambidoides

Corn earwormHelicoverpa zeaFall armywormSpodoptera frugiperdaStalk borerPapaipema nebrisLesser corn stalk borerElasmopalpus lignosellusSugarcane borerDiatraea saccharalis

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 is a product of Monsanto's research program 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