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 to:

- Correct the common name of *P. nebris* as a target pest;
- Remove "Trecepta™ corn" as an alternate brand name;
- Modify the designations for the active and inactive ingredients;
- Replace the registration number "524-AEL" with "524-625;"
- Make minor changes to the Directions for Use.

Product Name: MON 89034 x MIR162
EPA Registration Number: 524-625
Application Dates: March 29, 2018
OPP Decision Numbers: 542188

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, remove "Trecepta™ corn" as an alternate brand name, replace the registration number "524-AEL" with "524-625," 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 542188). 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 alternate brand name "Tricepta™ Corn" has been removed from the registration, 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 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 × MIR162

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4)

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

Active Ingredients:

Bacillus thuringiensis Cry1A.105 and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4) ..... ≤0.0059%*

Bacillus thuringiensis Cry2Ab2 and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4) ..... ≤0.0043*

Bacillus thuringiensis Vip3Aa20 and the genetic material (vector pNOV1300) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4) ..... ≤0.015%*

Other Ingredients:

Phosphomannose isomerase (PMI) marker protein and the genetic material (vector pNOV1300) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4) ..... ≤0.00068%*

*Percentage (wt/wt) on a dry weight basis for whole plant (forage) of MON 89034 × MIR162 plants.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS_____

EPA Registration No. 524-625

EPA Establishment No. 524-MO-002

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

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 × MIR162 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers and corn earworm.

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.

Refuge Requirements for MON 89034 × MIR162 Field Corn

In order to minimize the risk of corn borers and corn earworm developing resistance to MON 89034 × MIR162 field corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

For the sole purpose of manufacturing and small scale research trials for observation, 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.

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

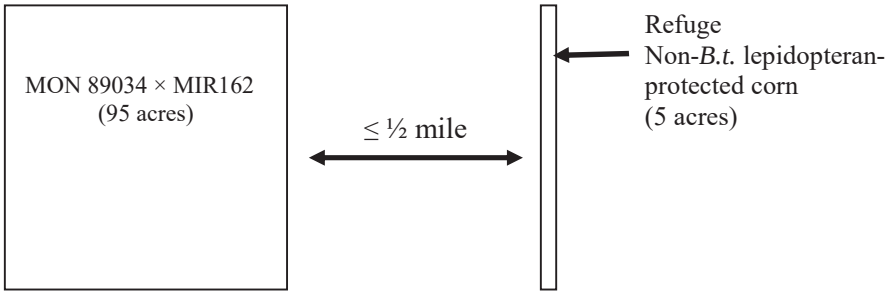
For MON 89034 × MIR162 field corn grown outside cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements.

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.

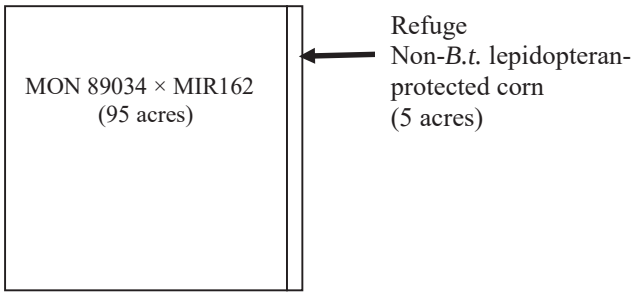
Insecticide treatments for pests listed on this label may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). 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), 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.



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, 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, Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

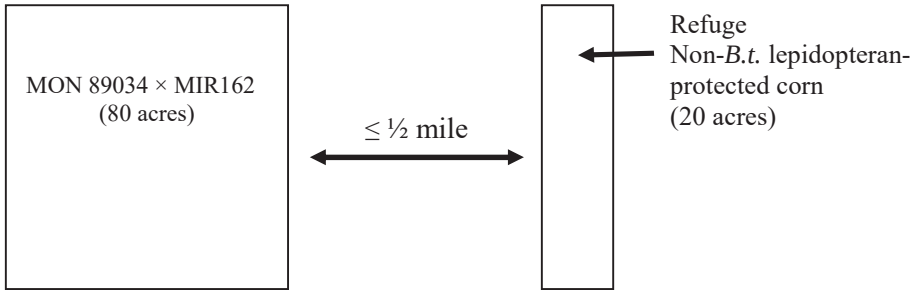
For MON 89034 × MIR162 field corn grown in cotton-growing areas, grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 20% corn, which is not a lepidopteran-protected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests.

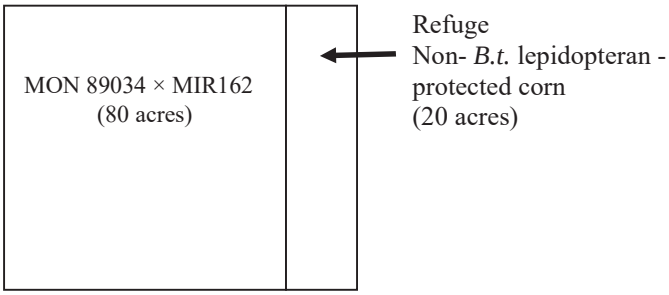
Insecticide treatments for pests listed on this label may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions 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), 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.



Corn Insects Controlled or Suppressed

European corn borer	*Ostrinia nubilalis*
Southwestern corn borer	*Diatraea grandiosella*
Southern cornstalk borer	*Diatraea crambidoides*
Corn earworm	*Helicoverpa zea*
Fall armyworm	*Spodoptera frugiperda*
Stalk borer	*Papaipema nebris*
Sugarcane borer	*Diatraea saccharalis*
Beet armyworm	*Spodoptera exigua*
True armyworm	*Pseudelatia unipuncta*
Black cutworm	*Agrotis ipsilon*
Western bean cutworm	*Striacosta albicosta*
Lesser cornstalk borer	*Elasmopalpus lignosellus*
Dingy Cutworm	*Feltia jaculifera*

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 × MIR162 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