

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 15, 2022

Edwards Allen, Ph.D. Global Regulatory Manager Bayer U.S.- Crop Science 700 Chesterfield Pkwy West Chesterfield, MO 63017

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Updates to modify the company name and add the EPA registration number to the label Product Name: MON 89034 x MON 810 x MIR162 x MON 87411 EPA Registration Number: 524-656 Application Date: January 28, 2022 OPP Case Number: 00338525

Dear Dr. Allen:

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 registrant of this product has been changed from Monsanto Company to Bayer Crop Science, and our records and the product label have been updated accordingly. The registration number for the product has not changed and remains EPA Registration Number 524-656. 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. 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 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

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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.

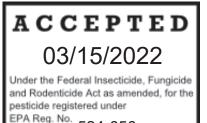
Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Leslie Paul by phone at (202) 566-1466 or via email at paul.leslie@epa.gov.

Sincerely,

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

Enclosure



524-656

# Plant-Incorporated Protectant Label

## MON 89034 × MON 810 × MIR162 × MON 87411

Insect-Protected, Herbicide-Tolerant Corn (OECD Unique Identifier: MON-89Ø34-3 × MON-ØØ81Ø-6 × SYN-IR162-4 × MON-87411-9)

## **Active Ingredients:**

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × MON 810 × MIR162 × MON 87411 corn (Unique Identifier MON-89Ø34-3 × MON- $\emptyset\emptyset$ 81 $\emptyset$ -6 × SYN-IR162-4 × MON-87411-9) .....≤0.0023%\*

*Bacillus thuringiensis* Cry1Ab protein and the genetic material (vector PV-ZMCT01) necessary for its production in MON 89034 × MON 810 × MIR162 × MON 87411 corn (Unique Identifier MON-89Ø34-3 × MON-ØØ81Ø-6 × SYN-IR162-4 × MON-87411-9)  $\leq 0.0011\%$ \*

*Bacillus thuringiensis* Vip3Aa20 protein and the genetic material (vector pNOV1300) necessary for its production in MON 89034 × MON 810 × MIR162 × MON 87411 corn (Unique Identifier MON-89Ø34-3 × MON- $\emptyset\emptyset$ 81 $\emptyset$ -6 × SYN-IR162-4 × MON-87411-9)  $\leq 0.0099\%$ \*

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × MON 810 × MIR162 × MON 87411 corn (Unique Identifier MON-89Ø34-3 × MON-ØØ81Ø-6 × SYN-IR162-4 × MON-87411-9)  $\leq 0.0051\%$ \*

dsRNA transcript comprising a *DvSnf7* inverted repeat sequence derived from *Diabrotica virgifera*, and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × MON 810 × MIR162 × MON 87411 corn (Unique Identifier MON-89Ø34-3 × MON-ØØ81Ø-6 × SYN-IR162-4 × MON-87411-9)  $\leq 0.00000049\%^*$ 

## **Other Ingredients:**

PMI (phosphomannose isomerase) protein and the genetic material necessary (vector pNOV1300) for its production in MON 89034  $\times$  MON 810  $\times$  MIR162  $\times$  MON 87411 corn (Unique Identifier MON-89Ø34-3  $\times$  MON-ØØ81Ø-6  $\times$  SYN-IR162-4  $\times$  MON-87411-9)..... $\leq 0.00068\%^*$ 

CP4 EPSPS (5-enolpyruvylshikimate-3-phosphate synthase) protein and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034  $\times$  MON 810  $\times$  MIR162  $\times$  MON 87411 corn (Unique Identifier MON-89Ø34-3  $\times$  MON-ØØ81Ø-6  $\times$  SYN-IR162-4  $\times$  MON-87411-9).... $\leq$  0.018%\*

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

### KEEP OUT OF REACH OF CHILDREN

# CAUTION

#### EPA Registration No. 524-656

#### EPA Establishment No. 524-MO-002

Bayer Crop Science 800 North Lindbergh Blvd. St Louis, MO 63167

NET CONTENTS

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

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.

This product may be used for breeding purposes, agronomic testing, increasing inbred seed stocks, and producing hybrid seed on up to a total of 20,000 acres per county and up to a combined United States (US) total of 250,000 acres per plant incorporated protectant (PIP) active ingredient per registrant per year. Commercial plantings of this product, for the purposes of grain production and controlling corn insect pests, are prohibited.

Harvested seed are not be allowed for sale as commercial seed in the U.S. under the current conditions of this registration but any non-treated seed containing MON  $89034 \times MON 810 \times MIR162 \times MON 87411$  may be sold as grain.

There are no refuge requirements for planting of MON 89034  $\times$  MON 810  $\times$  MIR162  $\times$  MON 87411 Corn.