

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 15, 2021

David J. Chi Global Regulatory Manager Bayer – Crop Science Monsanto Company 700 Chesterfield Parkway West Chesterfield, Missouri 63017 USA

 Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – Include OECD Unique Identifiers, correct typographical errors, and update label directions
Product Name: TC1507 × MON 88017 Insect-Protected, Herbicide-Tolerant Corn EPA Registration Number: 524-583
Application Dates: 12/14/2016 and 1/5/2017
OPP Case Number: 00074904

Dear Mr. Chi:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable provided that you comply with the updated terms and conditions as described in this letter.

- 1. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.
- The subject registration will be limited to *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (vector PHP8999) in event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-1) and *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR39) in event MON 88017 (OECD Unique Identifier: MON-88Ø17-3) for use in field corn.
- 3. 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.
- 4. 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.

5. Harvested seed are not allowed for sale as commercial seed in the U.S. under the current conditions of this registration, but any non-treated seed containing TC1507 x MON 88017 may be sold as grain.

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

• Basic CSF dated 01/05/2017

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. 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 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 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



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

524-583

# **Plant-Incorporated Protectant Label**

# TC1507 × MON 88017

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: DAS- Ø15Ø7-1 × MON-88Ø17-3)

#### **Active Ingredients:**

*Bacillus thuringiensis* Cry1F protein and the genetic material necessary (vector PHP8999) for its production in TC1507 × MON 88017 Corn (OECD Unique Identifier: DAS- $01507-1 \times MON-88017-3$ )..... $\leq 0.0012\%^*$ 

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in TC1507 × MON 88017 Corn (OECD Unique Identifier: DAS- $01507-1 \times MON-88017-3$ )..... $\leq 0.0079\%^*$ 

#### **Other Ingredients:**

CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in TC1507 × MON 88017 Corn (OECD Unique Identifier: DAS- $\emptyset$ 15 $\emptyset$ 7-1 × MON-88 $\emptyset$ 17-3).....  $\leq 0.0052\%$ \*

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vector PHP8999) for its production in TC1507 × MON 88017 Corn (OECD Unique Identifier: DAS- $\emptyset$ 15 $\emptyset$ 7-1 × MON-88 $\emptyset$ 17-3)..... $\leq$  0.00045%\*

\*Maximum percent (wt/wt) of dry forage

### KEEP OUT OF REACH OF CHILDREN

# CAUTION

NET CONTENTS

EPA Registration No. 524-583 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.

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 allowed for sale as commercial seed in the U.S. under the current conditions of this registration, but any non-treated seed containing TC1507  $\times$  MON 88017 may be sold as grain.

There are no refuge requirements for planting TC1507  $\times$  MON 88017 Corn.