

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 13, 2020

David J. Chi Regulatory Affairs Manager Bayer U.S. – Crop Science Monsanto Company 700 Chesterfield Parkway West Chesterfield, MO 63017

Subject: Non-PRIA (Pesticide Registration Improvement Act) Amendment to amend the terms of registration and product label Product Name: MON 88702 x MON 15985 x COT102 EPA Registration Number: 524-657 Application Date: September 23, 2019 OPP Decision Number: 556072

Dear Mr. Chi:

The amendment referred to above, submitted in connection with registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you comply with the following terms and conditions.

- The subject registration will be limited to the following *Bacillus thuringiensis* proteins: Cry51Aa2.834\_16 (vector PV-GHIR508523), Cry1Ac (vector PV-GHBK04), Cry2Ab2 (vector PV-GHBK11), Vip3Aa19 (vector pCOT1) and the genetic material necessary for their production in cotton (OECD Unique Identifier: MON-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2- 7).
- 2. The subject registration will automatically expire at midnight on January 31, 2021.
- 3. Submit and/or cite all data required for registration or registration review of MON 88702 × MON 15985 × COT102 cotton when the EPA requires all registrants of similar products to submit such data.
- 4. MON 88702 × MON 15985 × COT102 cotton seed may only be planted for the purposes of agronomic evaluation, seed increase, and production in breeding nurseries as specified in the terms of this registration and on the labeling.
- 5. Commercial plantings of this product for the purposes of commodity production and controlling insect pests are prohibited.
- 6. Plants that contain the pesticide product may be grown on a total of 40,000 acres or less per year in the

Page 2 of 2 EPA Reg. No. 524-657 OPP Decision No. 556072

U.S. and the territory of Puerto Rico, with a limit of 2,000 acres per county, subject to the restrictions below.

The following restrictions apply to this product:

a) No planting of MON 88702 × MON 15985 × COT102 cotton is permitted south of Route 60 (near Tampa) in Florida.

b) Experimental plots and breeding nurseries of MON  $88702 \times MON 15985 \times COT102$  cotton are prohibited on the U.S. Virgin Islands and Hawaii.

c) Test plots or breeding nurseries, regardless of plot size, may be established on the island of Puerto Rico without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within three miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop, and

d) Harvested seed are not allowed for sale as commercial seed in the U.S. under the current terms of this registration, but any seed containing MON  $88702 \times MON 15985 \times COT102$  may be handled in accordance with legal and regulatory requirements.

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.

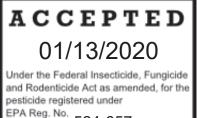
A revised label reflecting the changes in terms and conditions above is attached to this amendment approval letter.

If you have any questions, please contact Michael Glikes of my team by phone at (703) 305-6231 or via email at glikes.michael@epa.gov.

Sincerely,

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

Attachment



524-657

## **Plant-Incorporated Protectant Label**

# MON 88702 × MON 15985 × COT102

(OECD Unique Identifier MON-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7)

#### **Active Ingredients:**

Bacillus thuringiensis Cry51Aa2.834\_16 protein and the genetic material (vector PV-GHIR508523) necessary for its production in MON 88702 × MON 15985 × COT102 cotton (OECD Unique Identifier MON-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7) ...... $\leq 0.027\%^*$ 

*Bacillus thuringiensis* Cry1Ac protein and the genetic material (vector PV-GHBK04) necessary for its production in MON 88702 × MON 15985 × COT102 cotton (OECD Unique Identifier MON-887 $\emptyset$ 2-4 × MON-15985-7 × SYN-IR1 $\emptyset$ 2-7)......  $\leq 0.0012\%$ \*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material (vector PV-GHBK11) necessary for its production in MON 88702 × MON 15985 × COT102 cotton (OECD Unique Identifier MON-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7)...... $\leq 0.041\%$ \*

*Bacillus thuringiensis* Vip3Aa19 protein and the genetic material (vector pCOT1) necessary for its production in MON 88702 × MON 15985 × COT102 cotton (OECD Unique Identifier MON-887 $\emptyset$ 2-4 × MON-15985-7 × SYN-IR1 $\emptyset$ 2-7).......  $\leq$  0.000432%\*

#### **Inactive Ingredients:**

Neomycin phosphotransferase II (NPTII) protein and the genetic material (vector PV-GHBK04) necessary for its production in MON 88702 × MON 15985 × COT102 cotton (OECD Unique Identifier MON-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7) ....... $\leq 0.00066\%*$ 

 $\beta$ -glucuronidase (GUS) protein and the genetic material (vector PV-GHBK11) necessary for its production in MON 88702 × MON 15985 × COT102 cotton (OECD Unique Identifier MON-88702-4 × MON-15985-7 × SYN-IR102-7) .....  $\leq 0.0068\%^*$ 

Hygromycin B phosphotransferase (APH4) protein and the genetic material (vector pCOT1) necessary for its production in MON 88702 × MON 15985 × COT102 cotton (OECD Unique Identifier MON-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7) ...... $\leq 0.000076\%$ \*

\* Percentage (wt/wt) on a dry weight basis.

## KEEP OUT OF REACH OF CHILDREN

# CAUTION

## EPA Registration No. 524-657

## EPA Establishment No. 524-MO-002

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

NET CONTENTS\_\_\_\_\_

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be planted for breeding purposes, for example, seed manufacturing, research, agronomic testing, small scale research trials, and productions in breeding nurseries, on a total of 40,000 acres or less per year in the U.S.A., and the territory of Puerto Rico, with a limit of 2,000 acres per county, (subject to the restrictions detailed below).

The following restrictions apply to this product:

a) Experimental plots and breeding nurseries of this product are prohibited on the U.S. Virgin Islands, South of Route 60 (near Tampa) in Florida, and Hawaii.

b) Test plots or breeding nurseries, regardless of plot size, may be established on the island of Puerto Rico without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within three miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

c) Harvested seed is not allowed for sale as commercial seed in the U.S. under the current conditions of this registration, but any harvested material containing this product may be handled in accordance with legal and regulatory requirements (e.g., non-treated seed may be sold as grain).

Commercial plantings of this product are prohibited.

There are no refuge requirements for planting of this product.