

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 21, 2020

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

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Primary

brand name change to MON 88702 x MON 15985 x COT102 SI

Product Name: MON 88702 x MON 15985 x COT102 SI

EPA Registration Number: 524-657 Application Date: 03/26/2020 OPP Decision Number: 561683

Dear Mr. Chi:

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 primary brand name of this product has been changed from MON 88702 x MON 15985 x COT102 to MON 88702 x MON 15985 x COT102 SI, 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 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

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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: Stamped label for MON 88702 x MON 15985 x COT102 SI

ACCEPTED 04/21/2020

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

524-657

Plant-Incorporated Protectant Label

MON 88702 × MON 15985 × COT102 SI

(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)
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-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7)≤ 0.0012%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-GHBK11) necessary for its production in MON $88702 \times MON 15985 \times COT102$ cotton (OECD Unique Identifier MON- $887\emptyset2-4 \times MON-15985-7 \times SYN-IR1\emptyset2-7$) $\leq 0.041\%$ *
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-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7)≤ 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)≤ 0.00066%*
β -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-887Ø2-4 × MON-15985-7 × SYN-IR1Ø2-7) $\leq 0.0068\%$ *
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)

KEEP OUT OF REACH OF CHILDREN

^{*} Percentage (wt/wt) on a dry weight basis.

CAUTION

EPA Registration No. 524-657

EPA Establishment No. 524-MO-002

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

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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.