



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 8, 2021

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

Subject: Non-PRIA (Pesticide Registration Improvement Act) Amendment – Modification of terms regarding planting restrictions in Florida and changing the company name on the label to Bayer CropScience LP.
Product Name: MON 531
EPA Registration Number: 524-555
Application Date: August 25, 2021
OPP Case Number: 00318494

Dear Mr. Chi:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided you comply with the updated terms and conditions as described in this letter.

1. The subject of this registration will be limited to *Bacillus thuringiensis* Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 531 (OECD unique identifier: MON-ØØ531-6) for use in cotton.
2. Submit and/or cite all data required for registration or registration review of MON 531 when the EPA requires all registrants of similar products to submit such data.
3. Seed containing *Bacillus thuringiensis* Cry1Ac protein and the genetic material necessary for its production in MON 531 cotton 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.
4. Commercial plantings of this product for the purposes of commodity production and controlling insect pests are prohibited.
5. Plants that contain MON 531 may be grown at a total of 40,000 acres or less per year in the U.S. and territory of Puerto Rico, with a limit of 2,000 acres per county, subject to the restrictions below.

6. The following restrictions apply to this product:
- a. No planting of MON 531 cotton is permitted in the Florida counties of Pinellas, Hillsborough, Hardee, Highlands, Okeechobee, and St. Lucie and all counties south thereof.
 - b. Experimental plots and breeding nurseries of MON 531 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 531 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 stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling.

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

Sincerely,



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

Enclosure

MON 531

(OECD unique identifier: MON-ØØ531-6)

Active Ingredients:

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 531 cotton.....≤0.00052%*

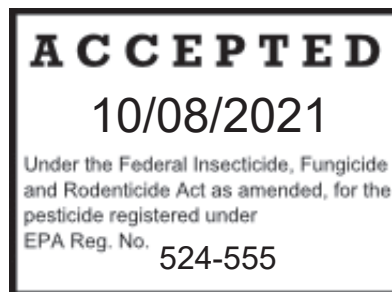
Other Ingredients:

Substance produced by the marker gene and the genetic material necessary for its production [PV-GHBK04] in event MON 531 cotton.....≤0.0014%*

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

KEEP OUT OF REACH OF CHILDREN

CAUTION



EPA Registration Number 524-555
EPA Establishment Number 524-MO-002

Bayer CropScience LP
800 North Lindbergh Blvd.
Saint Louis, Missouri 63167

NET CONTENTS _____

DIRECTIONS FOR USE

1. It is a violation of federal law to use this product in a manner inconsistent with its labeling.

2. Commercial plantings of this product for the purposes of commodity production and controlling insect pests are prohibited.

3. This product may be used for breeding, and small scale research trials on up to a total of 2,000 acres per county and up to a combined United States total of 40,000 acres, subject to the following restrictions:

a) In Florida, planting or sale for commercial planting of this product is prohibited in Pinellas, Hillsborough, Hardee, Highlands, Okeechobee, and St. Lucie and all counties south thereof.

b) Experimental plots and breeding nurseries of this product are prohibited in Hawaii and the U.S. Virgin Islands.

c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may only be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established 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 this product may be handled in accordance with legal and regulatory requirements.