



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511M)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

524-663

Date of Issuance:

6/17/2024

NOTICE OF PESTICIDE:

☒ Registration

☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

MON 95379

Name and Address of Registrant (include ZIP Code):

Bayer CropScience
800 North Lindbergh Blvd.
St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency. In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

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.

Signature of Approving Official:

Mendelsohn, Mike

Digitally signed by Mendelsohn,
Mike

Date: 2024.06.17 22:18:52 -04'00'

Michael Mendelsohn, Chief
Emerging Technologies Branch
Biopesticides and Pollution Prevention Division (7511M)
Office of Pesticide Programs

Date:

6/17/2024

2. The subject registration is limited to *Bacillus thuringiensis* Cry1B.868 protein and the genetic material (Vector PV-ZMIR522223) necessary for its production in MON 95379 Maize (OECD Unique Identifier MON-95379-3) and *Bacillus thuringiensis* Cry1Da_7 protein and the genetic material (Vector PV-ZMIR522223) necessary for its production in MON 95379 Maize (OECD Unique Identifier MON-95379-3) for use in field corn.
3. The subject registration 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.
4. Planting seed containing this plant-incorporated protectant product 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. Commercial plantings of this product for the purposes of grain production and controlling insect pests are prohibited.
5. Plants that contain this plant-incorporated protectant product may be grown on up to a total of 100 acres per growing season, only in the states of Nebraska, Hawaii, and Iowa. Harvested seed cannot be allowed for sale as a commercial seed in the U.S. under the current terms of this registration but any non-treated seed grain containing MON 95379 may be sold as grain.
6. Bayer must provide reference material, appropriate control substances and technical support if requested by the Food and Drug Administration to support the analytical method for the Cry1Da_7 and Cry1B.868 proteins.
7. Make the following labeling change before you release this product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 524-663."

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 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 statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 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. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF):

- Basic CSF dated April 30, 2020

If you have any questions, please contact Matt Weiner by phone at (202) 566-1509 or via email at weiner.matthew@epa.gov.

Sincerely,

Mendelsohn,
Mike

Digitally signed by
Mendelsohn, Mike
Date: 2024.06.17 22:19:40
-04'00'

Michael Mendelsohn, Chief
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure: MON 95379 Stamped Label

Plant-Incorporated Protectant Label

MON 95379

(OECD Unique Identifier: MON-95379-3)

Active Ingredients:

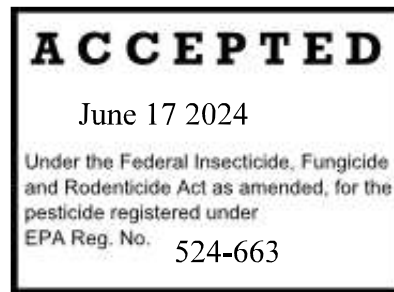
Bacillus thuringiensis Cry1B.868 protein and the genetic material (Vector PV-ZMIR522223) necessary for its production in MON 95379 corn (OECD Unique Identifier MON-95379-3) ≤0.036%*

Bacillus thuringiensis Cry1Da_7 protein and the genetic material (Vector PV-ZMIR522223) necessary for its production in MON 95379 corn (OECD Unique Identifier MON-95379-3) ≤0.01%*

*Percentage (wt/wt) on a dry weight basis for whole plant (forage) of MON 95379 plants

KEEP OUT OF REACH OF CHILDREN

CAUTION



EPA Registration No. 524-663

EPA Establishment No. 524-MO-002

Bayer CropScience LP
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 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.

Commercial plantings of this product for the purposes of grain production and controlling insect pests are prohibited. This product may be planted in the states of Nebraska, Hawaii and Iowa on a maximum total acreage of 100 acres per growing season for breeding operations, for example seed manufacturing, research, agronomic testing, small scale research trials, productions in breeding nurseries, increasing inbred seed stocks and producing hybrid seed. Harvested seed are 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 can be sold as grain). There are no refuge requirements for planting of this product.