



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 7, 2019

Heather Moore
Regulatory Affairs Manager
Syngenta Seeds, LLC- Field Crops- NAFTA
9 Davis Drive
Research Triangle Park, NC 27709

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Conversion of registration from commercial use to manufacturing use and removal of the expiration date.
Product Name: MIR604 Corn
EPA Registration Number: 67979-5
Submission Date: October 10, 2018
OPP Decision Number: 547092

Dear Ms. Moore:

On October 10, 2018, you submitted an application to amend the subject product registration. Your application requested to convert the product to a non-expiring, manufacturing use registration. This amendment request, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is 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.
2. The subject registration will be limited to *Bacillus thuringiensis* mCry3A protein and the genetic material (vector pZM26) necessary for its production in corn event MIR604 (OECD Unique Identifier: SYN-IR6Ø4-5) for use in field corn.
3. MIR604 Corn may only be used for breeding purposes, agronomic testing, increasing inbred seed and production hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant incorporated protectant active ingredient per registrant per year. Commercial plantings of this product for the purposes of grain production and controlling corn insect pests is prohibited.
4. This plant-incorporated protectant 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.

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 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. 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 9/29/2010

If you have any questions, please contact Matt Weiner by phone at (703) 347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a long horizontal flourish extending to the right.

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

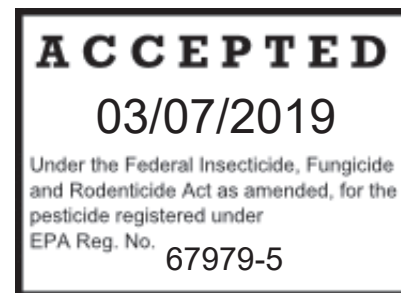
Enclosure

Plant-Incorporated Protectant Label
Manufacturing Use Product

MIR604 Corn
Alternate Brand Name:
Agrisure® GT/RW

Modified Cry3A Protein for Corn Rootworm Control

OECD Unique Identifier: SYN-IR604-5



This product is effective in controlling or suppressing damage caused by larvae of some corn rootworm species feeding on corn roots.

Active Ingredient:

Modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR604-5)..... ≤ 0.0029%*

Other Ingredients:

Phosphomannose isomerase and the genetic material necessary for its production (via elements of vector pZM26) in corn (SYN-IR604-5)..... ≤ 0.00025%*

*Percent dry weight in whole plant.

Keep Out of Reach of Children

CAUTION

NET CONTENTS _____

EPA Registration No. 67979-5
EPA Establishment No. 66736-NC-001

Syngenta Seeds, LLC - Field Crops – NAFTA
9 Davis Drive Research Triangle Park, NC
27709

DIRECTIONS FOR USE

Use of this plant-incorporated protectant in a manner inconsistent with the terms of this label is a violation of Federal law. MIR604 seed Corn may only be planted for research and breeding purposes, increasing inbred seed, or producing hybrid seed on up to 20,000 acres per county and up to a combined total 250,000 acres per year. Commercial plantings of this product for the purposes of grain production and controlling insect pests are prohibited.

MIR604 seed Corn 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.

There are no refuge requirements for planting of MIR604 Corn.

STORAGE AND DISPOSAL

Do not contaminate bodies of water by storage or disposal.