

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs

Biopesticides and Pollution Prevention Division (7511M)

1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

**NOTICE OF PESTICIDE:** 

X Registration

\_\_\_\_ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

96144-3

9/30/2025

Term of Issuance:

Unconditional

Name of Pesticide Product:

Insect-Resistant TC1507 x MON810

Corn

Name and Address of Registrant (include ZIP Code):

Inari Agriculture, Inc. One Kendall Square Building 600/700 Suite 7-501

Cambridge, MA 02139

**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 EPA requires all registrants of similar products to submit such data.

Signature of Approving Official:

Digitally signed by ALAN REYNOLDS

Date: 2025.09.30

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Date:

9/30/2025

Alan Reynolds, Product Manager 94 Emerging Technologies Branch

Biopesticides and Pollution Prevention Division (7511M)

Office of Pesticide Programs

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- 2. The subject registration will be limited to *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (vector PHP8999) in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø71-1) and *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (vector PV-ZMBK07) in corn event MON 810 (OECD Unique Identifier: MON-ØØ81Ø-6), and 5% non-Bt seed that when planted creates an interspersed refuge within the field, for use in field corn.
- 3. This plant-incorporated protectant product 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. Insect-Resistant TC1507 x MON810 Corn may only be planted in the following states: Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri (except for the following counties: Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin.
- 5. **Insect Resistance Management (IRM) Program.** The required IRM program for Insect-Resistant TC1507 x MON810 Corn must have the following elements:
  - a. Requirements regarding programs to educate growers about IRM requirements.
  - b. Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to the Cry1F or Cry1Ab proteins in the target insects.
  - c. Requirements regarding a "remedial action plan" that contains measures Inari would take in the event that any field relevant insect resistance was detected as well as to report on activity under the plan to EPA.
  - d. Requirements for Inari to maintain, and provide the Agency upon request, the number of units sold by state and county and substantive changes to educational programs. Inari is required to submit reports within three months of the Agency's request.
  - e. Bag Tag Requirements for Insect-Resistant TC1507 x MON810 Corn: Seed bags and/or bag tags for corn hybrids that contain the plant-incorporated protectant produced in Insect-Resistant TC1507 x MON810 Corn must display the active ingredient, registration number, and the states permitted for use of the product. The bag tag must also stipulate that growers read the Inari Stewardship Guide (or equivalent guidance) prior to planting this product.
  - f. Requirements for annual reports on or before the time frames specified in the Annual Reports section below.

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g. The monitoring and reporting obligations shall be in effect only if units of Insect-Resistant TC1507 x MON810 Corn have been sold and are being actively grown in a commercial setting within the reporting period. In lieu of an annual report for periods in which the product is not sold, Inari must submit a letter stating that no sales of Insect-Resistant TC1507 x MON810 Corn have occurred and thus no annual report is required.

## 6. Refuge Requirements for Insect-Resistant TC1507 x MON810 Corn

- Each seed bag of Insect-Resistant TC1507 × MON810 Corn contains a lepidopteran refuge that is blended in the same bag (5% non-*Bt* seed) and is automatically implemented when the grower plants the product. No additional refuge is required when planting this product.
- Insecticide treatments for control of European Corn Borer (ECB), Southwestern corn borer (SWCB), and other lepidopteran target pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

## 7. IRM Education Program for Insect-Resistant TC1507 x MON810 Corn

- Inari must implement a comprehensive IRM education program designed to provide guidance to growers on actions to take when unexpected damage occurs. Specifically, the IRM education program will include:
  - i. Inari will create a Technical Use Guide (TUG) for Insect-Resistant TC1507 x MON810 Corn, which clearly outlines the importance of proper stewardship and best management practices when planting the product. Inari will make the TUG available via a portal on an Inari-hosted website.
  - ii. Inari must submit a copy of the TUG to EPA by November 30th of the year prior to commercialization of Insect-Resistant TC1507 x MON810 Corn.
- Upon EPA request, Inari shall provide copies of grower education materials and information
  on grower education activities including any substantive changes to these materials and
  activities within three months of the Agency's request. Inari must implement a "bag tag"
  that will be attached to all bags of Insect-Resistant TC1507 x MON810 Corn sold and
  delivered. The product label accepted by EPA must include how this information will be
  conveyed to growers via text and graphics.

#### 8. Insect Resistance Monitoring and Mitigation Plan for Insect-Resistant TC1507 x MON810 Corn

Inari must monitor for resistance to Cry1F and Cry1Ab expressed in Insect-Resistant TC1507

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x MON810 Corn. Monitoring must be conducted for the key target pests: *Ostrinia nubilalis* (European corn borer; ECB) and *Diatraea grandiosella* (southwestern corn borer; SWCB).

- The monitoring program shall be focused on investigating reports of unexpected levels of damage by ECB and/or SWCB that meet the criteria below. Inari will instruct its customers to contact them if such incidents occur. Inari must investigate all legitimate reports submitted to the company or the company's representatives.
- If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB and SWCB), Inari will implement the actions described below, based on the following definitions of suspected and confirmed resistance.
- **Suspected resistance:** EPA defines suspected resistance to mean field reports of unexpected levels of insect-feeding damage for which:
  - i. The corn in question has been confirmed to express Cry1F and Cry1Ab;
  - ii. It has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage;
  - iii. For ECB, at least one of the following criteria are met:
    - Leaf feeding damage that includes elongated lesions in addition to the pin-holeand shot-hole-sized feeding scars characteristic of ECB. This is equivalent to an ECB damage rating of 4 on the Guthrie 1–9 rating scale (Guthrie et al. 1960);
    - In a 30-plant sample from the affected area of field, more than 2 places with more than 2 inches of tunneling (stalk, ears, ear shanks);
    - The presence of entrance holes in the plant stalk, with the accumulation of frass near and behind leaf axils;
    - The presence of live ECB larvae.
  - iv. For SWCB, at least one of the following criteria are met:
    - Leaf feeding damage includes small lesions and a few small, elongated lesions characteristic of SWCB. This is equivalent to a damage rating of 3 on the modified Davis 1–9 scale (Davis et al. 1992);
    - In a 30-plant sample from the affected area of the field, more than two PIPexpressing plants each with more than four inches of tunneling and/or girdling by overwintering SWCB larvae;
    - The presence of live SWCB larvae.

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- v. If ECB or SWCB resistance is suspected, Inari will do the following:
  - Report any cases of suspected ECB or SWCB resistance to EPA within 30 days;
  - Attempt to collect the respective insect from the field with unexpected damage levels;
  - Neonate ECB or SWCB generated from the populations collected from UXI fields will be tested in diet overlay assays similar to those described by Marçon et al. (1999).
     Assays will be conducted using lyophilized leaf tissue from Inari Insect-Resistant TC1507 x MON 810 plants. LC<sub>50</sub> and EC<sub>50</sub> values from the collected population will be compared to results from a susceptible population.
- Confirmed resistance: EPA defines confirmed resistance to mean, in the case of field reports of unexpected levels of damage from the key target pests, that the following criterion is met:
  - i. In a standardized laboratory bioassay, the  $LC_{50}$  or  $EC_{50}$  of the collected population exceeds the upper limit of the 95% confidence interval of the baseline  $LC_{50}$  or  $EC_{50}$  for susceptible populations.
- Response to suspected or confirmed resistance in a key target pest as the cause of unexpected levels of damage in the field:
  - Report any cases of suspected or confirmed ECB or SWCB resistance to EPA within 30 days. As part of this consultation, Inari will propose a resistance mitigation plan for Agency review for cases of confirmed resistance.
  - ii. Actions to be taken by Inari during the year the unexpected damage event was recorded (i.e., suspected resistance):
    - Reinforce educational materials with the affected grower(s), specifically reviewing ECB and/or SWCB pest management practices;
    - Provide Integrated Pest Management (IPM) recommendations to the affected grower(s), including assessment of fields adjacent to the affected field(s) with similar traits;
    - Inform regional extension/local crop consultants of the unexpected damage event in the county where damage occurred as well as the surrounding counties. These communications will be coordinated between Inari's local sales team and seeds dealers, growers, consultants, county extension agents, seed distributors, in-state university cooperators and state/federal authorities.
    - Where in-season management tactics are possible, Inari will recommend to affected grower(s) to:

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- Destroy stalk tissue and apply appropriate tillage. Shred the corn stubble shortly after harvest using a flail mower in order to assist in the prevention of ECB or SWCB from overwintering and then emerging in following spring.
- Consider applying appropriate foliar chemical insecticides if the damage is from first-generation ECB or SWCB (i.e., leaf-feeding larvae) to control any second-generation moths that emerge.

## iii. Actions to be taken by Inari following resistance confirmation:

- Continued reinforcement of educational material with the affected grower(s), including a review of lepidopteran (ECB or SWCB) pest management practices and IPM recommendations. These recommendations include assessments of fields adjacent to the affected field(s) with similar traits.
- Continued communication with regional extension/local crop consultants of the
  unexpected damage event in the county where damage occurred as well as the
  surrounding counties. These communications will be coordinated between Inari's
  local sales team and seeds dealers, growers, consultants, county extension agents,
  seed distributors, in-state university cooperators and state/federal authorities.
- Recommended management options include:
  - Rotation to a non-ECB or SWCB host crop;
  - Switching to a Bt corn product with a different mode of insecticidal action or planting non-Bt corn;
  - Applying appropriate foliar chemical insecticides if ECB or SWCB populations reach an established economic threshold.
- iv. Unless otherwise agreed with EPA, stop sale and distribution of the Insect-Resistant TC1507 x MON810 Corn product in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;
- v. In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the Insect-Resistant TC1507 x MON810 Corn product affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

#### 9. Refuge Assurance Program for Insect Resistant TC1507 x MON810 Corn

Inari must implement a Blended Seed Refuge Assurance Program designed to ensure that Insect-Resistant TC1507 x MON810 Corn products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

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- 1. Trait purity check on seed lots prior to blending;
- 2. Standard Operating Procedures for the blending process;
- 3. Calibration of blending equipment; and
- 4. Records and data retention records for seed blend products.
  - a. Calibration records Inari will retain documentation for one year on the equipment calibration including the procedure, when it was conducted and the results.
  - b. Blend proportion records (weight and kernel based) Inari will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an Insect-Resistant TC1507 x MON810 Corn product by seed lot.

All records must be maintained at the Inari blending facility and must be available for EPA review upon request. All blending records must be maintained at the Inari blending facilities, third party contractors, and Inari licensees and must be available for EPA review upon request.

Should Inari or Inari's Licensees be notified by USDA/AMS or State Seed Control Officials that your seed blend products have been found to have a lower percentage of the refuge component than is represented on the label, they must notify EPA within 30 days. This would constitute information reportable under FIFRA section 6(a)(2).

#### 10. Annual Reporting Requirements for Insect-Resistant TC1507 x MON810 Corn

- The following annual report must be submitted:
  - a. Insect resistance monitoring results: results of monitoring and investigations of damage reports on or before September 30<sup>th</sup> each year.

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 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 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 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 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.

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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 12/05/2024

If you have any questions, please contact Matt Weiner by email at <a href="weiner.matthew@epa.gov">weiner.matthew@epa.gov</a> or by phone at (202) 566-1509.

Sincerely,

Digitally signed by ALAN REYNOLDS Date: 2025.09.30

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Alan Reynolds, Product Manager 94
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure: Stamped Label for Insect-Resistant TC1507 × MON810 Corn

## **Plant-Incorporated Protectant Label**

#### **Insect-Resistant TC1507 × MON810 Corn**

(OECD Unique Identifiers: DAS-Ø15Ø7-1 × MON-ØØ81Ø-6)

This product is effective in limiting corn leaf, stalk, and ear damage caused by European corn borers and certain other lepidopteran pests.

## **Active Ingredients:**

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (PHP8999) in TC1507 corn (DAS-Ø15Ø7-1) .....≤ 0.00305%\*

Bacillus thuringiensis subsp. kurstaki Cry1Ab protein and the genetic material necessary for its production (PV-ZMCT01) in corn event MON810 (MON-ØØ81Ø-6) .....≤ 0.0695%\*

## **Inert Ingredient:**

Phosphinothricin acetyltransferase (PAT) protein and the genetic material necessary for its production (PHP8999) in TC1507 corn (DAS-Ø15Ø7-1) .....≤0.000642%\*

\*Percentage on a dry weight basis from the highest concentration measured in individual whole plant tissues.

## **Keep Out of the Reach of Children**

#### **CAUTION**

EPA Reg. No. 96144-x EPA Est. No. 96144-IN-001

#### Inari Agriculture, Inc.

One Kendall Square Building 600/700 Suite 7-501 Cambridge, MA 02139

# ACCEPTED

09/30/2025

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

96144-3

#### **Directions for Use**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. The plant-incorporated protectants (PIPs) must be used in accordance with the conditions of registration.

Insect-Resistant TC1507  $\times$  MON810 Corn consists of up to 95% TC1507  $\times$  MON810 corn seed and a minimum of 5% non-Bt corn seed blended in a single lot of seed. This product controls certain above-ground lepidopteran corn pests. The blended non-Bt seed provides a refuge for susceptible pests to avoid selection for resistance.

Insect-Resistant TC1507 × MON810 Corn can be planted for commercial production purposes as well as for research, agronomic evaluation, seed increase, and production in breeding nurseries as specified in the terms and conditions of this registration and on the labeling.

These PIPs may be combined through conventional breeding with other registered PIPs that are similarly approved for use in combination, through conventional breeding, with other PIPs to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

Commercial cultivation may not occur in cotton-growing regions but is permitted in the following states, designated as primary corn-growing areas: Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri (excluding Dunklin, New Madrid, Pemiscot, Scott, and Stoddard counties), Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin.

All commercial Insect-Resistant TC1507 × MON810 Corn seed that is sold by Inari Agriculture, Inc., or its distributors must be accompanied by informational material (e.g., a bag tag) indicating the EPA registration number and the active ingredients, and stipulating that growers read the product Insect Resistance Management (IRM) Stewardship Guide (or equivalent guidance) prior to planting the seed.

#### IMPORTANT GROWER INFORMATION:

Insect-Resistant TC1507 × MON810 Corn

EPA Reg. No. 96144-x

This product may only be used in the states of Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri (excluding Dunklin, New Madrid, Pemiscot, Scott, and Stoddard counties), Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin.

Cultivation in cotton-growing regions is prohibited.

For more information refer to the Stewardship Guide

## **Insects Controlled or Suppressed**

Insect-Resistant TC1507 × MON810 Corn has been genetically modified to produce *Bacillus thuringiensis* (Bt) Cry1F and Cry1Ab delta-endotoxin proteins for control or suppression of:

- Black cutworm (*Agrotis ipsilon*)
- Corn earworm (*Helicoverpa zea*)
- European corn borer (Ostrinia nubilalis)
- Fall armyworm (*Spodoptera frugiperda*)
- Western bean cutworm (*Striacosta albicosta*)
- Lesser corn stalk borer (*Elasmopalpus lignosellus*)
- Southern corn stalk borer (*Diatraea crambidoides*)
- Southwestern corn borer (Diatraea grandiosella)
- Stalk borer (*Papaipema nebris*)
- Sugarcane borer (*Diatraea saccharalis*)

Foliar insecticide treatments for control of the listed pests may be applied only if economic thresholds are reached for one or more of these pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

## **Insect Resistance Management**

Each seed bag of Insect-Resistant TC1507 × MON810 Corn contains a lepidopteran refuge that is blended in the same bag and is automatically implemented when the grower plants the product. No additional refuge is required when planting this product, which may only be used in non-cotton growing areas of the United States.

An Insect Resistance Management (IRM) Stewardship Guide (or equivalent guidance) must be distributed to all customers using seed containing the PIPs. The IRM Stewardship Guide will include instructions and recommendations regarding product use, insect resistance management, and integrated pest management.