



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

September 28, 2015

Jamie Staley  
U.S. Registration Manager  
Pioneer Hi-Bred International, Inc.  
7100 NW 62<sup>nd</sup> Avenue  
Johnston, IA 50131

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –To extend the expiration date and make other minor label revisions  
Product Name: Optimum<sup>®</sup> Trisect<sup>®</sup>  
EPA Registration Number: 29964-13  
Application Date: June 26, 2015  
OPP Decision Number: 509339

Dear Mr. Staley:

The amended labeling referred to above, submitted in connection with registration under Sec. 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable and the expiration date of the registration has been hereby extended to January 31, 2016.

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 it.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling.

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 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

Page 2 of 2

EPA Reg. No. 29964-13

OPP Decision No. 509339

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 Ann Sibold of my team by phone at (703) 305-6502 or via email at [sibold.ann@epa.gov](mailto:sibold.ann@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a stylized flourish at the end.

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

Enclosure

# Optimum<sup>®</sup> TRIsect<sup>®</sup>

(OECD Unique Identifier: DAS-Ø15Ø7-1xSYN-IR6Ø4-5)

## Active Ingredients:

*Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 ..... <0.0016%\*

*Bacillus thuringiensis* mCry3A protein and the genetic material (via elements of pZM26) necessary for its production in corn event SYN-IR6Ø4-5 ..... <0.0018%\*

## Other Ingredients:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 ..... <0.00046%\*

Phosphomannose isomerase (PMI) protein and the genetic material (via elements of pZM26) necessary for its production in corn event SYN-IR6Ø4-5 ..... <0.0010%\*

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\* % total protein on a on a dry wt. basis as expressed in corn plant cells (whole plant)

**KEEP OUT OF REACH OF CHILDREN**

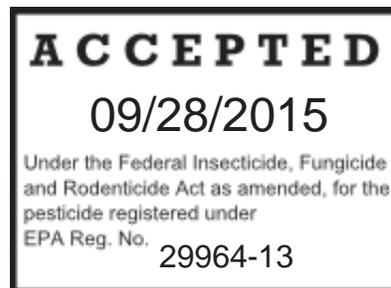
**CAUTION**

NET CONTENTS \_\_\_\_\_

EPA REGISTRATION NUMBER: 29964-13

EPA ESTABLISHMENT NUMBER: 029964-IA-001

Pioneer Hi-Bred International, Inc.  
7300 NW 62<sup>nd</sup> Avenue  
Johnston, IA 50131



## DIRECTIONS FOR USE

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

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 to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

The plant-incorporated protectant must be used as specified in the terms and conditions of the registration.

Optimum<sup>®</sup> TRIssect<sup>®</sup> combines the insect protection features of Herculex<sup>®1</sup> I and Agrisure<sup>®2</sup> RW in the same corn hybrid (inbred). Optimum TRIssect corn hybrids protect corn crops from leaf, stalk and ear damage caused by lepidopteran corn pests such as the European corn borer and root damage caused by corn rootworm (CRW) larvae. In order to minimize the risk of the corn pests developing resistance to Optimum TRIssect, an insect resistance management plan must be implemented.

## INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

These refuge requirements do not apply to seed increase/propagation of inbred and 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.

Corn seed bags or bag tags for products containing Optimum TRIssect must include the refuge size requirement in text and graphical format.

The following information regarding refuge placement for commercial production must be included in the Grower Guide:

The use of Optimum TRIssect requires accompanying refuge corn for the Cry1F and mCry3A components that meets the requirements of the individual traits, described below. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge (see C. below), or the refuge for each trait may be planted separately (see A. and B. below).

For the separate refuges, CRW-resistant *Bt* corn (e.g., Herculex<sup>®</sup> Rootworm) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran-resistant *Bt* corn (e.g., Herculex<sup>®</sup> I) may be planted in the CRW refuge for the mCry3A component. Depending on cropping practices, pest problems, and pest management options employed on any given farm, growers may need to choose different refuge arrangements for different fields. Two refuge blocks (one for CRW, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of CRW-resistant *Bt* corn (e.g. Herculex<sup>®</sup> Rootworm) can serve as an in-field lepidopteran refuge for one field planted to Optimum TRIssect and an external lepidopteran refuge for separate fields planted to Optimum TRIssect, while the CRW refuge is planted as lepidopteran-resistant *Bt* corn (e.g., Herculex<sup>®</sup>) in an external adjacent field. In all options, size and management of each individual refuge must be followed as described in A. and B below.

Other refuge designs and combinations are permissible as long as in all cases the size and management of each refuge are described in A., B., and C. below.

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<sup>1</sup> Herculex Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. Herculex is a registered trademark of Dow AgroSciences LLC.

<sup>2</sup> Agrisure<sup>®</sup> is a trademark of, and used under license from, a Syngenta Group Company. Agrisure<sup>®</sup> technology incorporated into these seeds is commercialized under a license from Syngenta Crop protection AG

## **A. Lepidopteran refuge for the Cry1F and mCry3A components.**

1. *Refuge size*, Corn-Growing Areas (= Corn Belt and other non corn/cotton-growing regions). The use of Optimum TRIsect requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
2. *Refuge size* (Corn/Cotton-growing areas). \*\* The use Optimum TRIsect requires an accompanying 50% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
3. *Refuge location*.
  - The lepidopteran refuge can be planted in a separate field within a ½ mile of the Optimum TRIsect field.
  - The lepidopteran refuge can be planted within the Optimum TRIsect field as blocks (e.g. along the edges or headlands).
  - The lepidopteran refuge can be planted within the Optimum TRIsect field as strips across the field at least four (4) consecutive crop rows wide.
4. *Refuge management*.
  - Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, sugarcane borer, and southern corn stalk borer 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). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

\*\* Cotton growing areas consist of the following states Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

## **B. Corn rootworm refuge for the mCry3A component.**

1. *Refuge size*. The use of Optimum TRIsect requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a CRW-protected *Bt* hybrid.
2. *Refuge location*. The CRW refuge is required to be planted within or adjacent (e.g. across the road) to the Optimum TRIsect field.
3. *Refuge management options*. The CRW refuge can be managed in such a way that there is little or no yield loss to CRW, but must be managed in a way that it is sufficiently productive of susceptible CRW adults.
  - The in-field CRW refuge options may be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
  - Seed mixtures of Optimum TRIsect and CRW refuge corn are not permitted.
  - If the CRW refuge is planted on rotated ground, then Optimum TRIsect must also be planted on rotated ground.

- If the CRW refuge is planted in continuous corn, the Optimum TRIssect field may be planted on either continuous or rotated land (option encouraged where WCRW rotation-resistant biotype may be present).
- Application of soil insecticide is permitted in the CRW refuge.
- Seed treatment is permitted in the CRW refuge, either at a rate for CRW protection or at a rate for controlling secondary soil pests.
- If aerial insecticides are applied to the CRW refuge for control of CRW adults, the same treatment must also be applied in the same time-frame to the Optimum TRIssect field.
- Pests other than adult CRW can be treated on the CRW refuge acres without treating the Optimum TRIssect acres only if treatment occurs when adult CRW are not present or if a pesticide without activity against adult CRW is used. Pests on the Optimum TRIssect acres can be treated as needed without having to treat the CRW refuge.
- The CRW refuge can be planted to any corn hybrid that does not express PIPs for CRW control (e.g. lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).
- The CRW refuge and Optimum TRIssect should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.
- Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the CRW population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn. However, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

**C. For the combined refuge option (i.e. the lepidopteran refuge combined with the rootworm refuge by planting non-*Bt* corn), the refuge must be planted and managed such that it is consistent with the requirements of the two individual traits, as follows:**

1. *Refuge size* shall be 20% in corn-growing areas and 50% in cotton-growing areas (see list labeled with " \*\* " under A).
2. *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g. across the road) to the Optimum TRIssect corn field.
3. *Refuge management options*
  - The in-field refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.
  - Seed mixtures of Optimum TRIssect and refuge corn are not permitted.
  - If the combined refuge is planted on rotated ground, then the Optimum TRIssect corn must also be planted on rotated ground.
  - If the combined refuge is planted on continuous corn, the Optimum TRIssect field may be planted on either continuous or rotated land (option encouraged where WCRW rotation-resistant biotype may be present).
  - Application of soil insecticide for CRW control is permitted in the combined refuge.
  - Seed treatment is permitted in the combined refuge, either at a rate for CRW protection or at a rate for controlling secondary soil pests.
  - If aerial insecticides are applied to the combined refuge for control of CRW adults, the same treatment must also be applied in the same timeframe to Optimum TRIssect corn.
  - Insecticide treatments in the combined refuge for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, sugarcane borer, lesser corn stalk borer, and southern corn stalk borer 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). These pests can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Optimum TRIssect acres only if

treatment occurs when adult CRW are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.

- Pests other than adult CRW can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Optimum TRIsect acres only if treatment occurs when adult CRW are not present. Pests on the Optimum TRIsect acres can be treated as needed without having to treat the refuge.
- The combined refuge can be planted to any corn hybrid that does not express PIPs for lepidopteran or CRW control (i.e. herbicide tolerant corn or conventional corn).
- The combined refuge and Optimum TRIsect corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.

### Use Pattern

Crop	Pests
Field corn	black cutworm corn earworm European corn borer fall armyworm lesser corn stalk borer southern corn stalk borer southwestern corn borer sugarcane borer western bean cutworm  western corn rootworm northern corn rootworm Mexican corn rootworm