



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 62nd Avenue
Johnston, IA 50131

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –To extend the expiration date, update the primary brand name to Optimum[®] Intrasect[®] Xtra, add to the label language specifying bag tags with refuge size requirements and make other minor label revisions
Product Name: Optimum[®] Intrasect[®] Xtra
EPA Registration Number: 29964-8
Application Date: June 26, 2015
OPP Decision Number: 509327

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

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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.

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
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Optimum[®] Intrasect[®] Xtra

(OECD Unique Identifier: DAS-Ø15Ø7-1xDAS-59122-7xMON-ØØ81Ø-6)

Active Ingredients:

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1 ≤0.0011%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ≤0.0054%

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (PHP17662 T-DNA) necessary for its production in corn event DAS-59122-7 ≤0.0042%*

Bacillus thuringiensis Cry1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON-ØØ81Ø-6 ≤0.0015%*

Other Ingredient:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A and PHP17662 T-DNA) necessary for its production in corn events DAS-Ø15Ø7-1 and DAS-59122-7 ≤0.0013%*

* Percentage (wt/wt) on a dry wt. basis for whole plant (forage).

KEEP OUT OF REACH OF CHILDREN

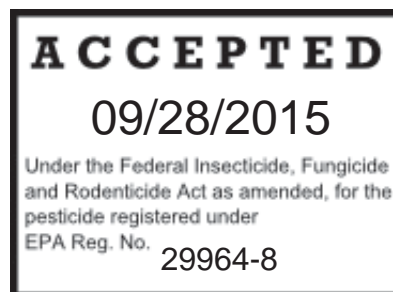
CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-8

EPA ESTABLISHMENT NUMBER: 029964-IA-001

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



DIRECTIONS FOR USE

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

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

Optimum[®] Intrasect[®] Xtra combines the insect protection features of Herculex^{®1} XTRA (EPA Reg. No.: 29964-5) and Yieldgard² Corn Borer (EPA Reg. No.: 524-489) in the same corn hybrid or inbred. Optimum Intrasect Xtra 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 larvae. In order to minimize the risk of the corn pests developing resistance to Optimum Intrasect Xtra, an insect resistance management plan must be implemented.

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 Intrasect Xtra must include the refuge size requirement in text and graphical format.

Growers are instructed to read information on insect resistance management. The following information regarding refuge placement for commercial production must be included in the Grower Guide:

The use of Optimum Intrasect Xtra requires accompanying refuge corn for the Cry1F, Cry1Ab and Cry34/35Ab1 components that meets the requirements of the individual traits, described below. The refuge(s) for these 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, corn rootworm-resistant *Bt* corn (e.g., Herculex[®] RW; EPA Reg. No.: 29964-4) may be planted in the lepidopteran refuge for the Cry1F and Cry1Ab components and lepidopteran-resistant *Bt* corn (e.g., Herculex[®] I; EPA Reg. No.: 29964-3) may be planted in the corn rootworm refuge for the Cry34/35Ab1 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. Possible options include: two refuge blocks (one for rootworm, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of Herculex[®] RW (EPA Reg. No.: 29964-4) can serve as an in-field lepidopteran refuge for one field planted to Optimum Intrasect Xtra and an external lepidopteran refuge for separate fields planted to Optimum Intrasect Xtra, while the rootworm refuge is planted as lepidopteran-resistant *Bt* corn (e.g., Herculex[®] I; EPA Reg. No.: 29964-3) 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.

¹ Herculex[®] Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. [®]Herculex is a registered trademark of Dow AgroSciences LLC.

² Yieldgard is a registered trademark used under the license from Monsanto Company.

A. Lepidopteran refuge for the Cry1F and Cry1Ab components.

1. *Refuge size*, In all Corn-growing Areas the use of Optimum Intrasect Xtra requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.
2. *Refuge location*.
 - The lepidopteran refuge can be planted in a separate field within a ½ mile of the Optimum Intrasect Xtra field.
 - The lepidopteran refuge can be planted within the Optimum Intrasect Xtra field as blocks (e.g. along the edges or headlands).
 - The lepidopteran refuge can be planted within the Optimum Intrasect Xtra field as strips across the field at least four (4) consecutive crop rows wide.
3. *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, 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). Microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

B. Corn rootworm refuge for the Cry34/35Ab1 component.

1. *Refuge size*. The use of Optimum Intrasect Xtra requires an accompanying 20% refuge consisting of non-*Bt* corn or non-corn rootworm-resistant *Bt* corn.
2. *Refuge location*. The rootworm refuge is required to be planted within or adjacent (e.g. across the road) to the Optimum Intrasect Xtra field.
3. *Refuge management options*. The rootworm refuge can be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.
 - The in-field rootworm 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 Intrasect Xtra and rootworm refuge corn are not permitted.
 - If the rootworm refuge is planted on rotated ground, then Optimum Intrasect Xtra must also be planted on rotated ground.
 - If the rootworm refuge is planted in continuous corn, the Optimum Intrasect Xtra 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 rootworm refuge.
 - Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.
 - If aerial insecticides are applied to the rootworm refuge for control of CRW adults, the same treatment must also be applied in the same time-frame to Optimum Intrasect Xtra
 - Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Optimum Intrasect Xtra acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Optimum Intrasect Xtra acres can be treated as needed without having to treat the rootworm refuge.
 - The rootworm refuge can be planted to any corn hybrid that does not express PIPs for rootworm control (e.g. lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).

- The rootworm refuge and Optimum Intrasect Xtra 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 rootworm 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 individual traits, as follows:

1. *Refuge size* shall be 20% in all corn-growing areas.
2. *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g. across the road) to the Optimum Intrasect Xtra 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 Intrasect Xtra and refuge corn are not permitted.
 - If the combined refuge is planted on rotated ground, then the Optimum Intrasect Xtra must also be planted on rotated ground.
 - If the combined refuge is planted on continuous corn, the Optimum Intrasect Xtra 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 corn rootworm control is permitted in the combined refuge.
 - Seed treatment is permitted in the combined refuge, either at a rate for rootworm 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 Intrasect Xtra.
 - 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, stalk borer or 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 Intrasect Xtra acres only if treatment occurs when adult corn rootworms are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.
 - Pests other than adult corn rootworms can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Optimum Intrasect Xtra acres only if treatment occurs when adult corn rootworms are not present. Pests on the Optimum Intrasect Xtra 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 rootworm control (i.e. herbicide tolerant corn or conventional corn).
 - The combined refuge and Optimum Intrasect Xtra 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 stalk borer sugarcane borer western bean cutworm western corn rootworm northern corn rootworm Mexican corn rootworm