



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 28, 2015

Stephanie L. Burton
U.S. Regulatory Manager
Mycogen Seeds, c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation
Amendment – To extend the expiration date, update the CSF and label to include the
OECD unique identifiers and make other minor label revisions
Product Name: Herculex[®] XTRA Insect Protection
EPA Registration Number: 68467-6
Application Date: June 16, 2015
OPP Decision Number: 509443

Dear Ms. Burton:

The amended labeling and confidential statement of formula (CSF) 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, are 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.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 09/25/2015

Any CSFs other than that listed above is superseded/no longer valid.

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 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 stylized flourish at the end.

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

Enclosure

Plant-Incorporated Protectant Label

Herculex® XTRA Insect Protection

OECD Unique Identifier: DAS-Ø15Ø7-1 x DAS-59122-7

Active Ingredients:

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS-Ø15Ø7-1)≤ 0.00174%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.01684%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.00676%*

Other Ingredient:

PAT protein (phosphinothricin acetyl transferase) and the genetic material genetic material (vectors PHP8999 and PHP17662) necessary for its production in corn events DAS-Ø15Ø7-1 and DAS-59122-7 (OECD Unique Identifiers: DAS-Ø15Ø7-1 and DAS-59122-7) ≤ 0.00151%*

* Maximum Percent (%) dry weight of whole plant

KEEP OUT OF REACH OF CHILDREN

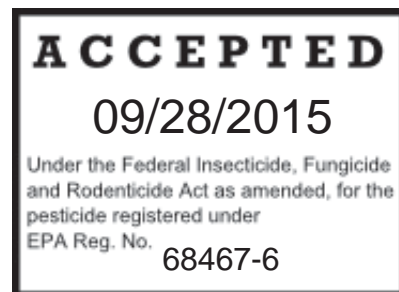
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CAUTION

EPA Registration Number 68467-6

EPA Establishment Number 62719-IN-1

Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268



® Registered Trademark of Dow AgroSciences LLC

DIRECTIONS FOR USE

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

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

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.

Herculex® XTRA Insect Protection corn (Herculex® XTRA) combines the insect protection features of Herculex® I and Herculex® RW in the same corn hybrid (inbred). Herculex® 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 Herculex® XTRA corn, an insect resistance management plan must be implemented.

Routine applications of insecticides to control western corn rootworm, northern corn rootworm, or Mexican corn rootworm are unnecessary for corn containing the *B.t.* Cry34/35Ab1 insecticidal crystal proteins.

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 (PIP) active ingredient per registrant per year.

Seed bags or bag tags will prominently display the refuge size requirement using color graphics accompanied by text. For seed distributed outside cotton-growing areas the information will indicate that the product requires a 20% structured refuge for lepidopteran pests, and for seed distributed within cotton-growing areas the information will indicate that the product requires a 50% structured refuge for lepidopteran pests. For all seed, the information will indicate that the product requires a 20% structured refuge for corn rootworm.

Growers are instructed to read information on insect resistance management. Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Product Use Guide for Herculex® XTRA corn or other applicable product use documents.

The following information regarding refuge placement for commercial production must be included in the Growing Guide.

The use of Herculex® XTRA Insect Protection corn requires accompanying refuge corn for both the Cry1F and Cry34/35Ab1 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, corn rootworm-resistant *Bt* corn (e.g., Herculex® RW Insect Protection) may be planted in the lepidopteran refuge for the Cry1F component and lepidopteran-resistant *Bt* corn (e.g., Herculex® I Insect Protection) 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. 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 Insect Protection corn can serve as an in-field lepidopteran refuge for one field planted to Herculex® XTRA and an external lepidopteran refuge for separate fields planted to Herculex® XTRA, while the rootworm refuge is planted as Herculex® I Insect Protection corn 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.

A. Lepidopteran refuge for the Cry1F component.

1. *Refuge size*, Corn-Growing Areas (Corn Belt and other non-corn/cotton-growing regions). The use of Herculex® XTRA corn 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 of Herculex® XTRA corn 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 not more than ½ mile from the Herculex® XTRA corn field.
 - The lepidopteran refuge can be planted within the Herculex® XTRA corn field as blocks (e.g., along the edges or headlands)
 - The lepidopteran refuge can be planted within the Herculex® XTRA corn field as strips across the field at least four consecutive rows wide.
4. *Refuge management*.
 - Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer 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). 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, and 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, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

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

1. *Refuge size*. The use of Herculex® XTRA corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a rootworm-protected *Bt* hybrid.
2. *Refuge location*. The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex® XTRA corn 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 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 Herculex® XTRA corn and rootworm refuge corn are not permitted.
 - If the rootworm refuge is planted on rotated ground, then Herculex® XTRA corn must also be planted on rotated ground.

- If the rootworm refuge is planted in continuous corn, the Herculex® XTRA corn 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 Herculex® XTRA corn.
- Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Herculex® XTRA corn 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 Herculex® XTRA corn 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 Herculex® XTRA 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.
- 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 two individual traits, as follows:

1. *Refuge size* shall be 20% in corn-growing areas and 50% in cotton-growing areas (see list of states 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 Herculex® XTRA 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 Herculex® XTRA and refuge corn are not permitted.
 - If the combined refuge is planted on rotated ground, then the Herculex® XTRA corn must also be planted on rotated ground.
 - If the combined refuge is planted on continuous corn, the Herculex® XTRA corn 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 Herculex® XTRA corn.
 - Insecticide treatments in the combined refuge for control of European corn borer, corn earworm, southwestern corn borer, and other lepidopteran 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). These pests can be treated with CRW-labeled insecticide on the combined refuge acres without treating the Herculex® XTRA Insect Protection corn 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 Herculex® XTRA corn acres only if treatment occurs when adults corn rootworms are not present. Pests on the Herculex® XTRA corn 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 Herculex® XTRA 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 Mexican corn rootworm northern corn rootworm southwestern corn borer western bean cutworm western corn rootworm lesser corn stalk borer southern corn stalk borer sugarcane borer

EPA Accepted: _____