



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: Correction to approval letter dated September 16, 2015 to approve revised label submitted 9/11/2015 in connection with the Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – To extend registration expiration date to September 30, 2020, correct the label active ingredient statement, make other minor revisions to the label and revise the confidential statement of formula
Product Name: Herculex[®] I Insect Protection
EPA Registration Number: 68467-2
Application Date: June 12, 2015 and subsequent label revision dated 9/11/2015
OPP Decision Number: 506228

Dear Ms. Burton:

The subject letter is revised as follows:

The amended labeling (submitted 9/11/2015) and Confidential Statement of Formula (CSF) dated September 9, 2015, referred to above, submitted in connection with registration under Sec. 3(c)(5) 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 September 30, 2020.

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 them.

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

- Basic CSF dated 09/09/2015

Any CSFs other than those listed above are superseded/no longer valid.

A stamped copy of your revised label 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 Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-Incorporated Protectant Label

Herculex® I Insect Protection
OECD Unique Identifier: DAS-Ø15Ø7-1

Active Ingredient:

Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event DAS-Ø15Ø7-1(OECD Unique Identifier: DAS-Ø15Ø7-1) ≤ 0.00027%*

Other Ingredient:

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vector PHP8999) necessary for its production in corn event DAS-Ø15Ø7-1 (OECD Unique Identifier: DAS-Ø15Ø7-1) ≤0.002%*

*Maximum % total protein on a dry weight basis in plant cells (whole plant).

KEEP OUT OF REACH OF CHILDREN

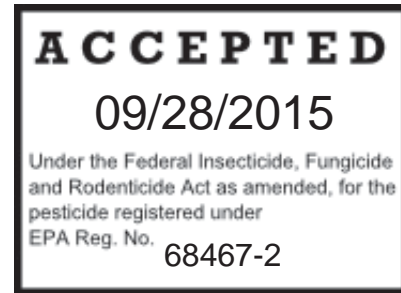
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CAUTION

EPA REGISTRATION NUMBER: 68467-2

EPA ESTABLISHMENT NUMBER: 62719-IN-1

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



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DIRECTIONS FOR USE

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

Herculex® I Insect Protection corn 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® I Insect Protection corn has been transformed to express a *Bacillus thuringiensis* subsp. *aizawai* (*B.t.a.*) delta-endotoxin Cry1F protein for control of the European corn borer (*Ostrinia nubilalis*) and other lepidopteran pests.

Routine applications of insecticides to control European corn borer are unnecessary when corn expressing the *B.t.a.* Cry1F ICP is planted.

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, and for seed distributed within cotton-growing areas the information will indicate that the product requires a 50% structured refuge.

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® I corn or other applicable product use documents.

The following information regarding commercial production must be included in the grower guides for cotton and non-cotton growing areas.

1. *Refuge size, Corn-Growing Areas (Corn Belt and other non-corn/cotton-growing regions).* The use of Herculex® I Insect Protection corn requires an accompanying 20% refuge consisting of non-*Bacillus thuringiensis* (*Bt*) corn or corn that is not a lepidopteran-protected *Bt* hybrid.
2. *Refuge size, (Corn/Cotton-growing areas).** The use of Herculex® I Insect Protection 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® I Insect Protection corn field.
 - The lepidopteran refuge can be planted within the Herculex® I Insect Protection corn field as blocks (e.g., along the edges or headlands)
 - The lepidopteran refuge can be planted within the Herculex® I Insect Protection 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).

USE PATTERN

CROP	PESTS
Field corn	Black cutworm Corn earworm European corn borer Fall armyworm Southwestern corn borer Western bean cutworm Lesser Corn Stalk Borer Southern Corn Stalk Borer Sugarcane Borer

EPA Accepted: _____