

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 22, 2023

Ashley Young U.S. Seeds Regulatory Specialist Corteva Agriscience LLC 7100 NW 62 Avenue PO Box 1000 Johnston, IA 50131-1000

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Revision to

the Name of the Company

Product Name: Herculex® I Insect Protection

EPA Registration Number: 68467-2 EPA Receipt Date: 02/15/2023 Action Case Number: 00432987

Dear Ms. Young:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

The primary company name of this product has been changed from Mycogen Seeds c/o Dow AgroSciences LLC to Corteva Agriscience LLC, and our records have been updated accordingly. 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.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

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 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

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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. If you have any questions, please contact Mary Beth Claude by phone at (202) 566-1460 or via email at Claude.MaryBeth@epa.gov.

Sincerely,

Digitally signed by ALAN REYNOLDS Date: 2023.05.22 17:42:24 -04'00'

Alan Reynolds, Team Leader Emerging Technologies Branch Biopesticides and Pollution Prevention Division (7511M) Office of Pesticide Programs

Enclosure: Final Stamped Label

### **Plant-Incorporated Protectant Label**

## **Herculex**<sup>®</sup> **I Insect Protection** OECD Unique Identifier: DAS-Ø15Ø7-1

# ACCEPTED

05/22/2023

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 204077

68467-2

### 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

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

CAUTION

**EPA REGISTRATION NUMBER: 68467-2** 

**EPA ESTABLISHMENT NUMBER: 62719-IN-1** 

Corteva Agriscience LLC 9330 Zionsville Road Indianapolis, IN 46268

### 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<sup>®</sup> 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 Acce	pted: