

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 21, 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 and Formulation Amendment – To extend registration expiration date to September 30, 2020, correct the label active ingredient statement, revise the confidential statement of formula and make other minor revisions to the label Product Name: Herculex[®] I EPA Registration Number: 29964-3 Application Date: June 26, 2015 OPP Decision Number: 506628

Dear Mr. Staley:

The amended labeling and Confidential Statement of Formula (CSF) dated June 26, 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 06/26/2015

Any CSFs other than those listed above are superseded/no longer valid.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

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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,

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

Enclosure

HERCULEX^{®*} I INSECT PROTECTION

(OECD Unique Identifier: DAS-Ø15Ø7-1)

Active Ingredients:

Bacillus thuringiensis Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1......<u><</u>0.00027%**

Other Ingredients:

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1......<u><</u>0.0020%**

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-3

EPA ESTABLISHMENT NUMBER: 029964-IA-001.

Pioneer Hi-Bred International, Inc. 7300 NW 62nd Avenue Johnston, IA 50131 ACCEPTED 09/21/2015 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 29964-3

^{*} Herculex[®] I Insect Protection technology by Dow AgroSciences and Pioneer Hi-Bred. Herculex[®] is a registered trademark of Dow AgroSciences LLC.

DIRECTIONS FOR USE

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

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

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

Herculex[®] I has been transformed to express a *Bacillus thuringiensis* subsp. *aizawai* (*B.t.a.*) deltaendotoxin 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 for corn containing the *B.t.a.* delta-endotoxin Cry1F protein.

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 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.

Growers are instructed to read information on insect resistance management. The following information regarding commercial production must be included in the grower guides for cotton and non-cotton growing areas:

Corn-Belt/Non-Cotton Growing Areas

Herculex[®] I grown outside cotton-growing areas (e.g., the Corn Belt), growers must adhere to the following refuge requirements.

- Growers must plant a structured refuge of at least 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn which may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within 1/2 mile.
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall
 armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer,
 and sugarcane 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 non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.

Cotton-Growing Area Refuge Requirements

Herculex[®] I grown in cotton-growing areas, growers must adhere to the following refuge requirements:

- Growers must plant a structured refuge of 50% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within 1/2 mile.
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall
 armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer,
 and sugarcane 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 non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include 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).

Сгор	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