



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

December 18, 2020

Jamie Staley  
U.S. Seeds Regulatory Affairs Leader  
Mycogen Seeds  
c/o Dow AgroSciences LLC  
7100 NW 62 Avenue  
PO Box 1000  
Johnston, IA 50131-1000

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – To convert the registration from commercial use to manufacturing use (seed increase) and to make minor revisions to the label  
Product Name: Herculex® XTRA Insect Protection  
Registration Number: 68467-6  
Application Date: December 9, 2020  
OPP Case Number: 00146640

Dear Mr. Staley:

On December 9, 2020, you submitted a request to amend the subject product to convert it to a non-expiring manufacturing use (seed increase) registration and make minor label changes. This amendment request, submitted in connection with registration under Sec. 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided that you comply with the updated terms as described in this letter.

1. Submit and/or cite all data required for registration or registration review of Herculex® XTRA Insect Protection when the EPA requires all registrants of similar products to submit such data.
2. The subject registration is limited to *Bacillus thuringiensis* Cry1F protein and the genetic material (vector PHP899) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS-01507-1) and *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 (Cry34/35Ab1) proteins and the genetic material (vector PHP17662) necessary for their production in corn event DAS 59122-7 (OECD Unique Identifier: DAS-5922-7) for use in field corn.
3. This product may be used for breeding purposes, research, agronomic testing, increasing inbred seed stocks and producing hybrid seed on 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. Commercial plantings of this product for the purposes of grain production and controlling corn insect pests are prohibited. Harvested seeds are not allowed for sale as commercial seed in the U.S. under the terms of this registration, but any non-treated seed (i.e., seed without a seed treatment applied) containing Herculex® XTRA Insect Protection may be sold commercially as grain.

4. Herculex® XTRA Insect Protection 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 soybean varieties with combined pesticidal traits.

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.

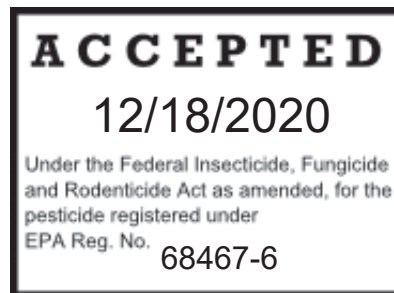
If you have any questions, please contact Matt Weiner by phone at (703) 347-0333 or via email at [weiner.matthew@epa.gov](mailto:weiner.matthew@epa.gov).

Sincerely,



Alan Reynolds, Team Leader  
Emerging Technologies 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

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

**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

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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.

This plant-incorporated protectant (PIP) 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.

This product may be used for breeding purposes, agronomic testing, increasing inbred seed stocks, and producing hybrid seed on up to a total of 20,000 acres per county and up to a combined United States (US) total of 250,000 acres per plant incorporated protectant (PIP) active ingredient per registrant per year. Harvested seed is not allowed for sale as commercial seed in the U.S. under the conditions of this registration, but any non-treated seed (*i.e.* seed without a seed treatment applied) may be sold commercially as grain. Commercial plantings of this product, for the purposes of grain production and controlling corn insect pests, are prohibited.

EPA Accepted: \_\_\_\_\_