



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<sup>®</sup> RW Insect Protection  
EPA Registration Number: 68467-5  
Application Date: June 12, 2015  
OPP Decision Number: 509369

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Any CSFs other than that listed above is superseded/no longer valid.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](mailto: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<sup>®</sup> RW Insect Protection**

OECD Unique Identifier: DAS-59122-7

**Active Ingredients:**

*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) .....≤ 0.0088%\*

*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) .....≤ 0.00181%\*

**Other Ingredient:**

PAT protein (phosphinothricin acetyl transferase) and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7) ..... ≤ 0.000058%\*

\* Maximum Percent (%) dry weight whole plant

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KEEP OUT OF REACH OF CHILDREN

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

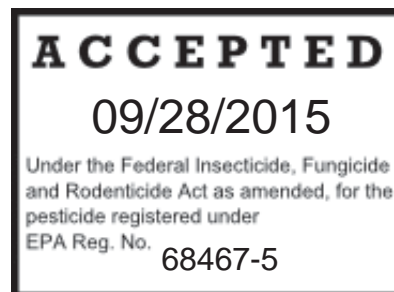
**CAUTION**

**EPA REGISTRATION NUMBER: 68467-5**

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

Mycogen Seeds  
c/o Dow AgroSciences LLC  
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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.

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

Herculex<sup>®</sup> RW Insect Protection corn has been transformed to express the *Bacillus thuringiensis* (*B.t.*) strain PS149B1 Cry34/35Ab1 insecticidal crystal proteins (ICPs) for the control of western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*Diabrotica barberi*), and Mexican corn rootworm (*Diabrotica virgifera zea*) pests.

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 ICPs.

### **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.

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> RW corn or other applicable product use documents.

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

1. *Refuge size.* The use of Herculex<sup>®</sup> RW Insect Protection corn from event DAS-59122-7 requires an accompanying 20% refuge.
2. *Refuge location.* The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Herculex<sup>®</sup> RW Insect Protection corn field.
3. *Refuge management options.* The rootworm refuge may 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 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<sup>®</sup> RW Insect Protection and refuge corn are not permitted.
  - If the refuge is planted on rotated ground, then Herculex<sup>®</sup> RW Insect Protection corn must also be planted on rotated ground.
  - If the refuge is planted in continuous corn, the Herculex<sup>®</sup> RW Insect Protection 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 refuge.
  - Seed treatment is permitted in the refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.

- If aerial insecticides are applied to the refuge for control of CRW adults, the same treatment must also be applied in the same time-frame to Herculex<sup>®</sup> RW Insect Protection corn.
- Pests other than adult corn rootworms can only be treated with CRW-labeled insecticide on the refuge acres without treating the Herculex<sup>®</sup> RW Insect Protection corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Herculex<sup>®</sup> RW Insect Protection corn acres can be treated as needed without having to treat the refuge.
- The rootworm refuge can be planted to any corn hybrid that does not express PIPs for rootworm control (e.g., lepidopteran-protected *B.t.* corn, herbicide-tolerant corn, or conventional corn).
- The refuge and Herculex<sup>®</sup> RW Insect Protection 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.

**USE PATTERN**

<b>CROP</b>	<b>PESTS</b>
field corn	western corn rootworm northern corn rootworm Mexican corn rootworm

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