

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 27, 2016

David Chi Regulatory Affairs Manager Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment – to update terms and conditions of registration, update CSF and labels with OECD unique identifiers and make other minor changes Product Name: MON 89034 x DAS-59122-7 EPA Registration Number: 524-584 Application Date: November 23, 2015 and subsequent resubmissions OPP Decision Number: 513483

Dear Mr. Chi:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

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 12/14/2016

Any CSFs other than those listed above are superseded/no longer valid.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

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Should you wish to add 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 me by phone at (703) 605-0515 or via email at reynolds.alan@epa.gov.

Sincerely,

Alan Reynolds, Team Leader

Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs

Enclosure

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

## MON 89034 × DAS-59122-7

ACCEPTED 12/27/2016 Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 524-584

Insect-Protected, Herbicide-Tolerant Corn (OECD Unique Identifier: MON-89Ø34-3 × DAS-59122-7)

#### **Active Ingredients:**

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in MON 89034 × DAS-59122-7 Corn (OECD Unique Identifier MON-89Ø34-3 × DAS-59122-7).....<0.0026%\*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in MON 89034 × DAS-59122-7 Corn (OECD Unique Identifier MON-89Ø34-3 × DAS-59122-7) .....  $\leq 0.0053\%^*$ 

Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in MON 89034 × DAS-59122-7 Corn (OECD Unique Identifier MON-89Ø34-3 × DAS-59122-7).....  $\leq 0.0194\%^*$ 

Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in MON 89034 × DAS-59122-7 Corn (OECD Unique Identifier MON-89Ø34-3 × DAS-59122-7).....≤0.0042%\*

#### **Other Ingredients:**

PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vector PHP17662) for its production in MON 89034 × DAS-59122-7 Corn (OECD 

\*Maximum percent (wt/wt) of dry forage

KEEP OUT OF REACH OF CHILDREN

# **CAUTION**

NET CONTENTS

**EPA Registration No. 524-584** 

EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

#### **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. Commercial plantings of this product, for the purposes of grain production and controlling corn insect pests, are prohibited.

Harvested seed are not allowed for sale as commercial seed in the U.S. under the current conditions of this registration, but any non-treated seed containing MON 89034  $\times$  DAS-59122-7 may be sold as grain.

There are no refuge requirements for planting MON 89034 × DAS-59122-7 Corn.