

524-597

11/16/2012

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

NOV 16 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63137

Subject: MON 89034 Seed Blend
EPA Registration No. 524-597
May 14, 2012 Application to (1) Amend the Registration to Extend the Expiration Date and (2) Amend the Label

Dear Dr. Ruezinsky:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable and includes the following changes:

1. The expiration date for this product registration set forth in the Registration Notice dated Nov. 16, 2011 is extended to November 30, 2017.

2. The registration notice dated Nov. 16, 2011 is amended to add the following term of registration:

In conjunction with EPA Reg. No. 524-606, submit a report providing the following data and information by August 30, 2014:

To address the potential for resistance development in European Corn Borer (ECB) and Southwestern Corn Borer (SWCB)

- Submit revised modeling incorporating the structural elements recommended by the SAP (explicit larval movement, switch from a frequency-based model to one including density dependent larval mortality, epistatic mechanisms for resistance in target pests), with separate analyses for SWCB and ECB. Monsanto must include non-uniform oviposition in the modeling for both ECB and SWCB, especially (but not only) for the second generation of adults, which will more likely lay eggs on *Bt* rather than on damaged (or crowded out) *non-Bt* refuge plants in seed blends.
- Submit biological research on adult movement (related to mating and movement from refuges), larval movement, larval feeding (i.e., selective feeding within corn ears or on pollen), survival of heterozygote genotypes on MON 89034 (markers may need to be determined for heterozygotes), and the potential for epistatic mechanisms of resistance (particularly with older instars).

To address the potential for resistance development in Corn Earworm (CEW)

• CEW can have up to six generations per year in the southern U.S. and may be at greater risk for resistance in a seed blend environment. Submit CEW modeling for product durability that addresses the following concerns:

a. CEW will encounter a mosaic of *Bt* expression in kernels of refuge corn ear as well as in *Bt* corn ear. Seed blends containing *Bt* and non-*Bt* seeds may actually accelerate resistance in ear-feeding Lepidoptera including corn earworm and fall armyworm. *Bt* ingestion has shown to promote wandering in larvae, and individuals that receive a sublethal dose may move to another kernel. Horner et al. 2003 evaluated feeding patterns of CEW in MON810 and non-*Bt* maize and determined that larvae had greater movement on *Bt* ears and essentially sampled kernels at greater frequency than their counterparts who fed exclusively and in a more compact fashion on non-*Bt* corn ears. This ability to move to another source of kernel in this mosaic of toxins (lethal vs. sublethal) and also to a nontoxin environment will give heterozygous individuals a great fitness advantage: the functional dominance of the resistance allele will increase. (Porter 2011, personal communication)

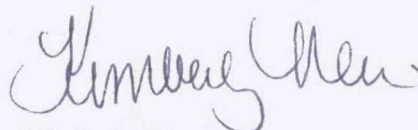
b. Horner and Dively (2003) found that CEW exposed to Cry1Ab had reduced cannibalistic behavior which, they hypothesize, could serve as a mechanism to increase the selective differential between susceptible and resistant CEW and essentially lead to greater resistance evolution. (Cannibalistic behavior results " in partially resistant larvae feeding on nontoxic food [their fellow intoxicated larvae], thus temporarily providing escape from exposure to the *Bt* endotoxin.")

c. CEW development on *Bt* corn is delayed (Sims et al. 1996, Storer et al. 2001). This could enable a fraction of adult CEW to mate with CEW emerging from *Bt* cotton. Discretely breeding populations could become continuously breeding for part of the year in this scenario. This may be an important aspect to incorporate into IRM models of the south where corn and cotton are host plants of the same pest. Theoretical explorations are needed to assess effects of this delayed development on corn on the resistance evolution in CEW.

3. Should material and field-relevant concerns regarding the durability of any of the constituent toxins of MON 89034 Seed Blend arise, EPA reserves the right to reassess this registration's expiration date. In no event, however, will EPA shorten the expiration date to impact the immediate growing season.

The label is acceptable. A copy of the stamped label is enclosed for your records.

Sincerely,



Kimberly Nesci,
Acting Chief, Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

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Plant-Incorporated Protectant Label

MON 89034 Seed Blend

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89034-3)

Alternate Brand Names: Genuity® VT Double PRO® RIB Complete®‡

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0020-0.0056%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn.....0.0015-0.0055%*

*Percentage (wt/wt) on a dry weight basis whole plant (forage) of MON 89034 plants

The MON 89034 seed with this refuge configuration contains 95% MON 89034 mixed with 5% non-Bt corn within a single lot of seed

‡ Genuity® VT Double PRO® RIB Complete® seed with this refuge configuration contains 95% MON 89034 × NK603 mixed with 5% non-Bt corn within a single lot of seed.

KEEP OUT OF REACH OF CHILDREN

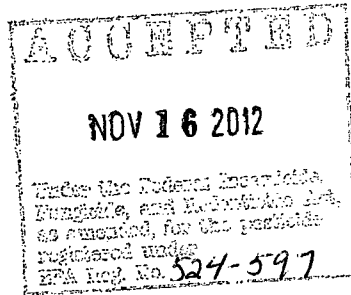
Caution

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EPA Registration No. 524-597

EPA Establishment No. 524-MO-002

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



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DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the grower guide. MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

Refuge Requirements

A refuge must consist of corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product achieves the required refuge as the refuge is interspersed within the field and occurs only by planting a licensed seed-mixture containing MON 89034 or MON 89034 stacked with other non-PIP technologies, with a minimum of 5% non-PIP seed. This refuge configuration complies with refuge requirements only in the U.S. Corn Belt.

The sufficiency of this refuge configuration is defined by geography, and ultimately is based on insect presence and species. **The seed mix refuge option for MON 89034 complies with refuge requirements only in the U.S. Corn Belt.**

The 95/5% MON 89034 seed mix product may be planted in cotton growing areas; however, planting the 95/5% MON 89034 seed mix in cotton growing areas still requires planting an additional 20% structured refuge (block, strips, or border) as defined for MON 89034 EPA registration 524-575. **The interspersed refuge option for MON 89034 does not alone comply with refuge requirements in cotton growing areas.**

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, 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, Ochiltrie, 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).

The seed mix (interspersed) refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 and MON 89034 stacks with non-PIP corn.

With this option, the field containing an interspersed refuge may be treated with labeled insecticides to control additional corn pests, including larval or adult lepidopteran pests, because both the MON 89034 and refuge are treated in the same manner. Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, southern cornstalk borer, sugarcane borer, fall armyworm, and corn stalk 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 the field containing a seed mix interspersed refuge.

Corn Insects Controlled

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Corn stalk borer	<i>Papaipema nebris</i>
Sugarcane borer	<i>Diatraea saccharalis</i>

Sales of corn hybrids that contain Monsanto's Bt corn plant incorporated protectant must be accompanied by a grower guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

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.

Genuity[®] VT Double PRO[®] RIB Complete[®] is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5554798, 5593874, 5641876, 5717084, 5728925, 5859347, 6025545, 6051753, 6083878, 6489542, 6645497, 6713063, 6825400, 6962705, 7064249, 7070982, 7250501, 7304206, 7582434, 7618942, 7700830, 7927598, RE39247, and 8034997.