67979-8

10/10/2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/8

OCT 10 2008

Ms. Demetra Vlachos
Senior Regulatory Affairs Manager
Syngenta Seeds, Inc.
P.O. Box 12257
Research Triangle Park, NC 27709-2257

Dear Ms. Vlachos:

Subject: Your March 31, 2008; April 14, 2008; and May 15, 2008 Amendment Requests to Remove the Expiration Dates for Bt11 Insect Protected Field Corn with Yieldgard, Attribute Insect Protected Sweet Corn, and Bt11 x MIR604 Field Corn
EPA Registration No. 67979-1, 65268-1, and 67979-8

The amendments referred to above, submitted in connection with registration under section 3(c)(7)(A)of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable subject to the following comments.

1) For EPA Registration Numbers 67979-1, 65268-1, and 67979-1:

a) The subject 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 plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

b) The subject registration will automatically expire on midnight September 30, 2010.

We are currently unaware of any issues that would preclude a decision to remove the expiration date in the future. However, due to other statutory priorities, BPPD's review of the data and information submitted as conditions of registration is ongoing. Therefore, the expiration date is being extended to match that of corn rootworm resistant Bt corn as an interim measure.

c) Refuge requirements do not apply to seed propagation of inbred and hybrid corn seed corn up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year.

CONCURRENCES								
SYMBOL	7511P	7511P						
SURNAME								
DATE	10/9/08	10/10/08						

2) For EPA Registration Number 65268-1:

While MRID No. 458798-03 submitted by Syngenta Seeds provided data on the Cry1Ab protein levels in Bt11 field corn, it did not provide such data for sweet corn. Submit data and/or information regarding sweet corn Cry1Ab expression level within 12 months.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of Cry1Ab corn constitutes acceptance of these conditions.

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

Sincerely,

Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

	CONCURRENCES							
SYMBOL ▶								
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DATE ▶								

* U.S. Government Printing Office: 2005 206-899 (mac)

Bt11 x MIR604 Corn

[Alternate brand name: *Agrisure® CB/LL/RW* Corn]

Plant-incorporated protectant:
Cry1Ab and mCry3A proteins for control of corn borers and corn rootworms

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and root feeding damage caused by corn rootworms.

Active Ingredients:

Bacillus thuringiensis Cry1Ab delta-endotoxin protein and the genetic material necessary for its production (via elements of pZO1502) in corn (SYN-BTØ11-1)....	≤0.0029%*
Modified Cry3A protein and the genetic material necessary for its production (via elements of pZM26) in corn (SYN-IR604-5)	≤0.0069%*

Inert Ingredients:

Phosphinothricin acetyltransferase marker protein and the genetic material necessary for its production (via elements of pZO1502) in corn (SYN-BTØ11-1)...	≤0.00002%*
Phosphomannose isomerase protein and the genetic material necessary for its production (via elements of pZM26) in corn (SYN-IR604-5).....	≤0.0002%*

*Percent (wt/wt) of whole plant on a dry weight basis

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-8
EPA Establishment No. 66736-NC-01

Syngenta Seeds, Inc. - Field Crops - NAFTA
P.O. Box 12257
3054 East Cornwallis Rd.
Research Triangle Park, NC 27709

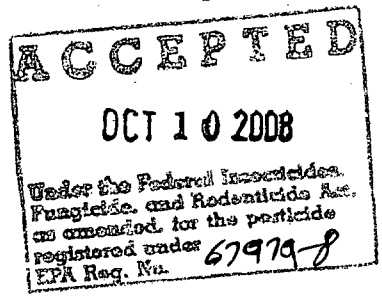
DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with this labeling. All corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds or its distributors must be accompanied by informational material (e.g., a bag tag) indicating the registration number (67979-8) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins Cry1Ab and mCry3A for control or suppression of the following lepidopteran and coleopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Corn earworm (*Helicoverpa zea*)



Fall armyworm (*Spodoptera frugiperda*)
Sugarcane borer *(Diatraea saccharalis)*
Common stalk borer *(Papaipema nebris)*
Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zeae*)

Insect Resistance Management

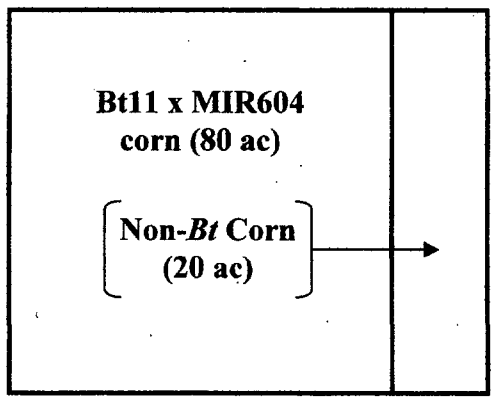
The following information regarding commercial production of Bt11 x MIR604 corn must be included in the Grower Guide (or equivalent).

Corn Belt / Non-Cotton Growing Region Refuge Requirements

For corn grown in the US Corn Belt two options for deployment of the refuge are available to growers.

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and refuge acres). It can be planted as a block adjacent to the Bt11 x MIR604 field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4, and preferably 6, consecutive rows wide. If strips within the Bt11 x MIR604 field are implemented, then at least 4, and preferably 6, consecutive rows should be planted. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late-season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the Bt11 x MIR604 field must be treated in a similar manner. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants, etc.). The following is a schematic of one common refuge deployment option:

Common Refuge

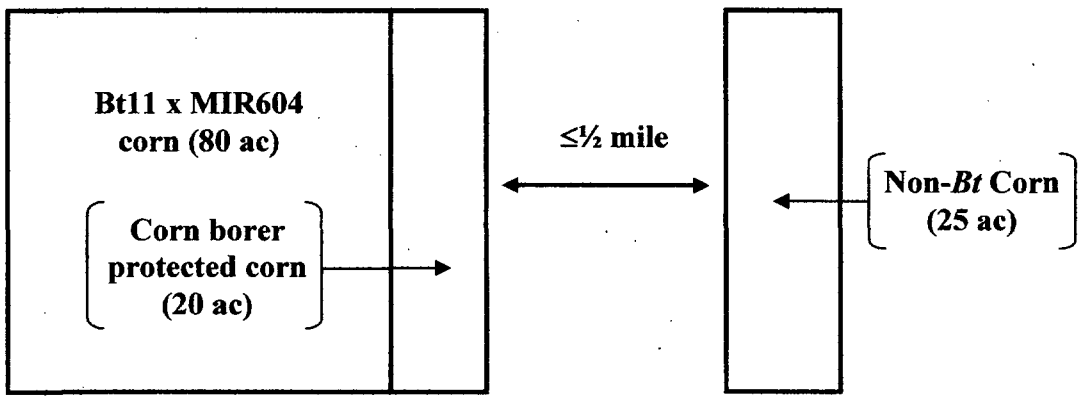


The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-*Bt*/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR604 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. The corn rootworm refuge must be planted with a non-*Bt*/corn rootworm-protected hybrid, but can be planted with Bt corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn rootworm refuge acres) and can be planted as an adjacent block, perimeter strips, or in-field strips. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the Bt11 x MIR604 field must be treated in a similar manner. Growers who fail to comply with the IRM requirements risk losing access to the product.

The following is a schematic of one separate refuge option with the corn rootworm refuge planted as a block within the field and the corn borer refuge planted within ½ mile of the Bt11 x MIR604 field:

Separate-Refuge Option

{Two-Refuge Option, Double-Refuge Option, Paired-Refuge Option}



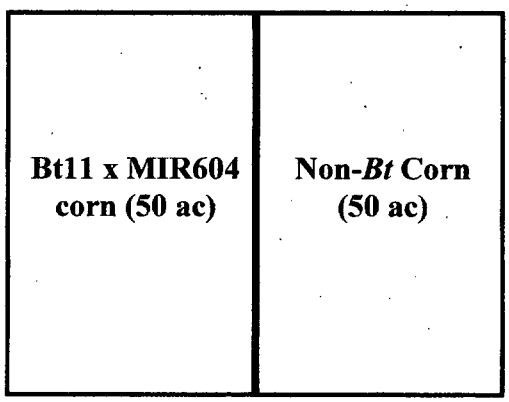
Corn/Cotton Growing Area {Cotton Growing Area} Refuge Requirements

For Bt11 x MIR604 corn grown in cotton-growing areas the common refuge and separate refuge options are also available, however, the refuge area is larger. Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, 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, Ochiltree, 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 Dunkin, New Madrid, Pemiscot, Scott, and Stoddard).

The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and refuge acres). It can be planted as a block adjacent to the Bt11 x MIR604 field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4, and preferably 6, consecutive rows wide. If strips within the Bt11 x MIR604 field are implemented, then at least 4, and preferably 6, consecutive rows should be planted. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the Bt11 x MIR604 field must be treated in a similar manner.

The following is a schematic of one common refuge deployment option:

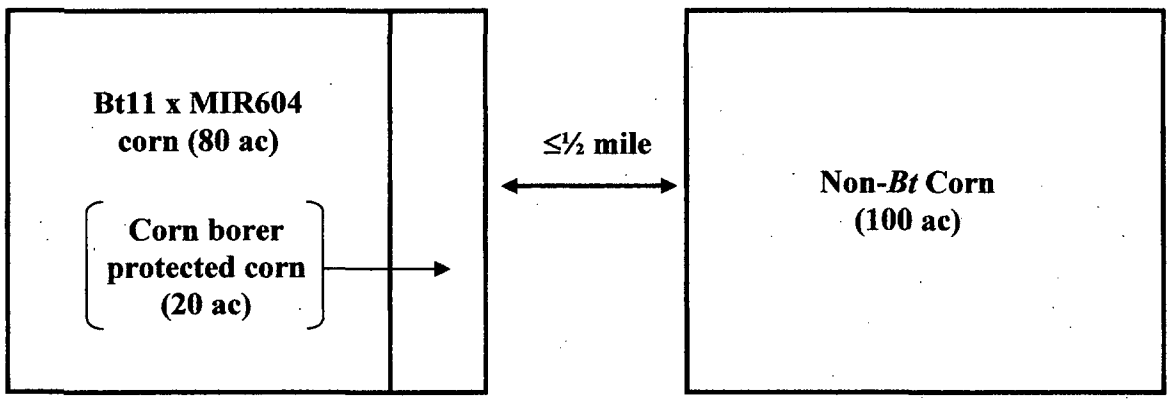
Common Refuge



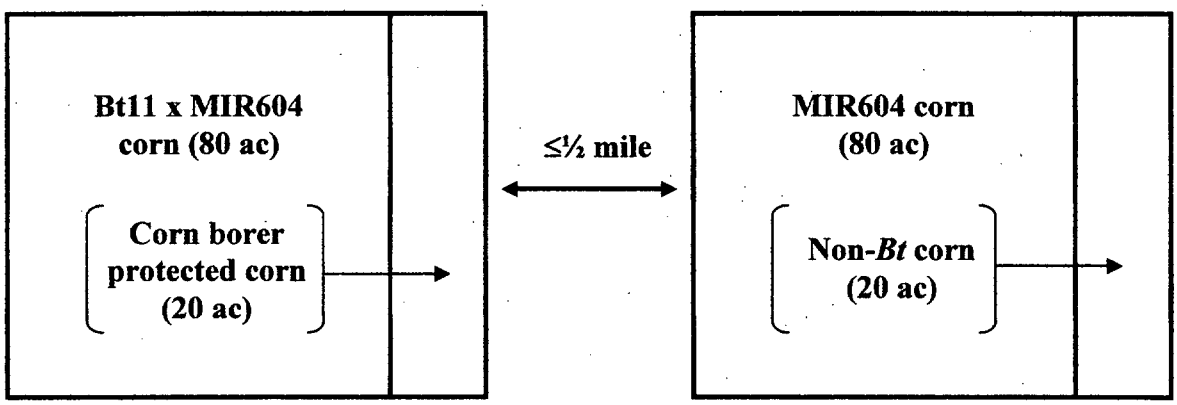
The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-*Bt*/lepidopteran-protected hybrid, must represent at least 50% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR604 field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-*Bt* foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. The corn rootworm refuge must be planted with a non-*Bt* corn/rootworm-protected hybrid, but can be planted with *Bt* corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR604 acres and corn rootworm refuge acres) and be planted as an adjacent block, perimeter strips, or in-field strips. The corn rootworm refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-*Bt* foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the Bt11 x MIR604 field must be treated in a similar manner. Growers who fail to comply with the IRM requirements risk losing access to the product.

The following are schematics for two separate-refuge options with the corn rootworm refuge planted as a block within the Bt11 x MIR604 field and the corn borer refuge planted as a block within ½ mile of the Bt11 x MIR604 field:

Separate -Refuge Options
{Two-Refuge Options, Double-Refuge Options, Paired Refuge Options}



- or -



Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the Grower Guide {IRM Guide} for Bt11 x MIR604 corn or other applicable product use documents. Growers who fail to comply with the IRM requirements risk losing access to the product.

The subject registration will automatically expire at midnight September 30, 2010.