

67979-1

10/10/2008

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/6

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	▶ [Signature]	[Signature]					
DATE	▶ 10/9/08	10/10/08					

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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

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YIELDGARD® INSECT RESISTANT CORN
[Alternate Brand Name: *Agrisure®CB/LL* Corn]

***Bt* Protein**
Plant-Incorporated Protectant Active Ingredient
for the Control of European Corn Borer in Field Corn

**(Pure form of the plant-incorporated protectant
Bacillus thuringiensis Cry1Ab delta-endotoxin protein
as expressed in corn cells)**

Active Ingredient:

Bacillus thuringiensis Cry1Ab delta-endotoxin
and the genetic material (as contained in plasmid
vector pZO1502) necessary for its production
in corn (SYN-BTØ11-1) 0.0002 - 0.0006%
by seed weight

Inert Ingredient:

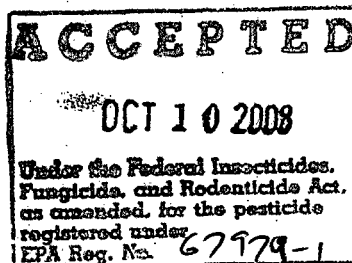
Substance produced by a marker gene and its
controlling sequences in corn (SYN-BTØ11-1)... < 0.0000001%
by seed weight

Keep Out of the Reach of Children

CAUTION

EPA Reg. No. 67979-1
EPA Est. No. 67979-IA-2

Syngenta Seeds, Inc. – Field Crops – NAFTA
3054 East Cornwallis Road
P. O. Box 12257
Research Triangle Park, NC, USA 27709-2257



Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. The subject registration will automatically expire at midnight September 30, 2010.

A Grower Guide (or equivalent guidance) must be distributed to all customers using seed containing the plant incorporated-protectant. The Grower Guide will include instructions and recommendations regarding product use, insect resistance management, and integrated pest management. The following information regarding commercial production must be included in the Grower Guide for cotton and non-cotton growing areas.

Corn Belt/Non-Cotton Growing Areas

For Cry1Ab field corn grown outside cotton-growing areas (e.g., the Corn Belt), the Grower Guide must specify that growers must adhere to the following refuge requirements:

- Growers must plant a structured refuge of at least 20% non-*Bt* corn which may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile (¼ mile or closer preferred).
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 rows wide.
- Insecticide treatments for control of European corn borer, Corn earworm, and Southwestern corn 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). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn refuges.

Cotton Growing Areas

For *Bt* field corn grown in cotton growing areas, the Grower Guide must specify that growers must adhere to the following refuge requirements:

- Growers must plant a structured refuge of at least 50% non-*Bt* corn which may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within ½ mile (¼ mile or closer preferred).
- When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, and southwestern corn 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). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to non-*Bt* corn refuges.

Cotton growing areas consist of the following:

- Alabama: all counties
- Arkansas: all counties
- Florida: all counties
- Georgia: all counties
- Louisiana: all counties
- Mississippi: all counties
- Missouri: only the counties of Dunkin, New Madrid, Pemiscot, Scott and Stoddard
- North Carolina: all counties
- Oklahoma: only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita
- South Carolina: all counties
- 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: all 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

Syngenta Seeds will report all sales of this product by Syngenta Seeds or its distributors annually to the EPA no later than January 31 of the following year.

Corn has been genetically modified to produce a *Bacillus thuringiensis* Cry1Ab delta-endotoxin protein for control or suppression of:

- | | |
|--------------------------|----------------------------------|
| 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>) |
| Sugarcane borer | (<i>Diatraea saccharalis</i>) |
| Common stalk borer | (<i>Papaipema nebris</i>) |

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All corn seed that contains the plant pesticide that is sold or distributed by Syngenta Seeds or its distributors must be accompanied by informational material indicating the registration number (67979-1) and the active ingredient [*Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material (as contained in plasmid vector pZO1502) necessary for its production in corn], and stipulating that growers read the Grower Guide prior to planting the seed.

This 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.