

67979-1

03/28/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

MAR 28 2007

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Sherri Gray
Exponent
1730 Rhode Island Ave., NW
Suite 1000
Washington, DC 20036

Subject: Notification to add alternate brand name
Agrisure™ CB/LL with YieldGard®
EPA Reg. No: 67979-1
Dated February 28, 2007

Dear Ms. Gray:

The Biopesticides and Pollution Prevention Division is in receipt of the above dated applications. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action requested falls within the scope of PR 98-10. Our records have been duly noted, and the label submitted with this application has been stamped Notification received, but not reviewed and will be placed accordingly in our records.

Questions concerning this action should be directed to me at 703-308-8269 or email at reilly.sheryl@epa.gov.

Sincerely,

Sheryl K. Reilly

Sheryl K. Reilly, PhD, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division

CONCURRENCES

SYMBOL	▶ 7511P						
SURNAME	▶ Pollard						
DATE	▶ 3/28/07						



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 67979-1	2. EPA Product Manager Michael Mendelsohn	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Syngenta Seeds, Inc.-Field Crops-NAFTA / YieldGard	PM# 92	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Seeds, Inc.-Field Crops-NAFTA 3054 Cornwallis Road Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar to <u>NOTIFICATION</u> in composition and labeling to: EPA Reg. No. <u>3128/07</u> Product Name <u>ate</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final product is in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

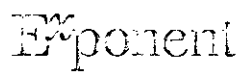
Submission of an alternate brand name "Agrisure CB/LL with YieldGard" pursuant to PR Notice 98-10.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sheri Gray	Title Authorized Representative	Telephone No. (Include Area Code) 202-772-4964
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Sheri Gray</i>	3. Title Authorized Representative	
4. Typed Name Sheri Gray	5. Date 2-28-07	



Exponent
1730 Rhode Island Ave., NW
Suite 1100
Washington, DC 20036

telephone 202-772-4900
facsimile 202-772-4979
www.exponent.com

February 28, 2007

Michael Mendelsohn
Product Manager 92
Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: YieldGard®
EPA Registration Number 67979-1
Project No. WD000457.000 LOT0

Dear Mr. Mendelsohn:

On behalf of our client, Syngenta Seeds, Inc. (3054 Cornwallis Road, Research Triangle Park, North Carolina 27709), Exponent, Inc. is submitting a label notification pursuant to PR Notice 98-10 for the EPA registered product YieldGard® (EPA registration number 67979-1). Please find enclosed the following documents in support of this notification:

- EPA 8570-1 Form
- Product Label (5 copies)

The purpose of this notification is to add the alternate brand name (ABN):
Agrisure™ CB/LL with YieldGard®.

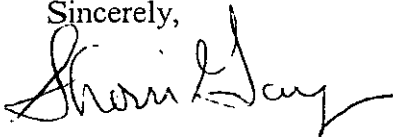
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions, please contact me at (202) 772-4964.

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Mr. Mendelsohn
February 28, 2007
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Sincerely,



Sherri Gray
Authorized Representative of
Syngenta Seeds, Inc.

Enclosures

cc: Larry Zeph, Syngenta Seeds Inc.
Kevin Tucker, Exponent

Ex

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Syngenta Seeds, Inc. – Field Crops - NAFTA
P. O. Box 12257 (mail)
3054 East Cornwallis Road (shipping)
Research Triangle Park, North Carolina 27709-2257

March 23, 2007

Ms. Carol Pollard
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

VIA FAX

Re: EPA Registration Number 67979-1; YieldGard® Alternate Brand Name Notification

Dear Ms. Pollard:

This is to inform you that Syngenta Seeds, Inc. – Field Crops – NAFTA authorizes Sherry Gray of Exponent, Inc. to represent our company with regard to the label notification pursuant to PR Notice 98-10 for the EPA registered PIP active ingredient in Syngenta's YieldGard® corn (EPA registration number 67979-1).

If you have any questions, please contact me at 919 541 8572.

Sincerely,

A handwritten signature in black ink that reads "Demetra Vlachos". The signature is written in a cursive, flowing style.

Demetra Vlachos
Senior Manager, Regulatory Affairs
Syngenta Seeds, Inc. – Field Crops - NAFTA

cc: Sherry Gray, Exponent, Inc.
Larry Zeph, Syngenta

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YIELDGARD® INSECT RESISTANT CORN
[Alternate Brand Name: AGRISURE™ CB/LL with YIELDGARD®]

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)

NOTIFICATION
Received But Not Reviewed
Date: 3/28/07
Initial: CP

Active Ingredient:

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

Inert Ingredient:

Substance produced by a marker gene and its
controlling sequences in corn < 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 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 October 15, 2008.

A Grower Guide 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.

For the 2002 growing season, 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 Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott and Stoddard
- North Carolina: all counties
- Oklahoma: only the counties of Bryan, Caddo, Canadian, Garvin and Grady
- South Carolina: all counties
- Tennessee: only the counties of Carroll, Chester, Crockett, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Henderson, Lake, Lauderdale, Lawrence, Lincoln, McNairy, 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 Greensville, Isle of Wight, Northampton, Southampton, Sussex and Suffolk

The list of states and counties identified below for 2003 and beyond may optionally be applied for the 2002 growing season.

For the 2003 and subsequent growing seasons, 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 of:

European corn borer	(<i>Ostrinia nubilalis</i>)
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In addition, some control or suppression of the following corn pests can be provided:

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>)

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.