67979-24 1/30/2014 1/9

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JAN 30 2014

Sydney Jarrett
Syngenta Biotechnology, Ind.
3054 E. Cornwallis Road
P.O. Box 12257
Research Triangle Park
North Carolina, 27709

Subject: Alternate Brand Names and Refuge Graphics
EPA Reg. No: 67979-24
Notification Completed, Dated January 29, 2014

Dear Ms. Jarrett:

The Biopesticides and Pollution Prevention Division has completed and accepted your revised labeling for Notification under PRN 98-10 dated above. A review of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. The label submitted with this application has been stamped "Notification accepted" and will be placed in our records.

Questions concerning this action should be directed to Kenneth Haymes, Ph.D. at 703 347-0398 or email at haymes.kenneth@epa.gov.

Sincerely,

Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division

ONCURRENCES								
SYMBOL ▶	[illegible]	7511P	7511P					
SURNAME ▶	Haymes	Reynolds	[illegible]					
DATE ▶	1/30/14	1/30/14	1/30/14					

EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

EPA	United States Environmental Protection Agency Washington, DC 20460	☐ Registration ☐ Amendment ☒ Other	OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67979-24	Kimberly Nesci	☒ None ☐ Restricted
Company/Product (Name) Bt11×MIR604×TC1507×5307 corn	PM # Team 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops - NAFTA
P.O. Box 12257, 3054 East Cornwallis Road
Research Triangle Park, NC 27709
☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☒ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Label notification pursuant to PR Notice 98-10: addition of alternate brand names; addition of refuge graphic requested by EPA. Not a PRIA action-no fee.

Section – III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper w/ polyurethane liner ☐ Other
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	*(Specify)*

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other: _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Sydney Jarrett	Regulatory Affairs Specialist	(919) 226-7505

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	3. Title	4. Typed Name	5. Date
Sydney Jarrett	Regulatory Affairs Specialist	Sydney Jarrett	October 23, 2013

EPA Form 8570-1

3/9

Sydney Jarrett
Tel. 1.919.226.7505
Fax 1.919.226.7462
sydney.jarrett@syngenta.com

Syngenta Biotechnology, Inc.
3054 E. Cornwallis Road
P.O. Box 12257
Research Triangle Park
North Carolina 27709 USA

syngenta

October 23, 2013

U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Attn: Kimberly Nesci, Branch Chief
Biopesticides and Pollution Prevention Division

Subject: Label notification for Insect-resistant corn
EPA Reg. No. 67979-24

Dear Ms. Nesci,

Please find enclosed revised labeling for Bt11×MIR604×TC1507×5307 Corn. Pursuant to the provisions of PR Notice 98-10, Syngenta is notifying the Agency of the following changes being made to the Bt11×MIR604×TC1507×5307 Corn label:

1. Addition of alternate brand names

2. Inclusion of the refuge graphic requested by the Agency for plant-incorporated protectant (PIP) products

This letter is accompanied by EPA form 8570-1, a redline copy of the revised label, and four copies of the final revised label text. Label notifications are not subject to a PRIA fee.

If you require further information, please feel free to contact me directly.

Sincerely,

Sydney Jarrett

Sydney Jarrett
US Regulatory Affairs Specialist

Notification Accepted

Date: 01/30/2014

Reviewer: Haynes

Plant-incorporated Protectant Label

Bt11×MIR604×TC1507×5307 Corn

Alternate brand name: *Agrisure® Duracade™ 5122 Corn*
Agrisure® Duracade™ 5122A Corn
Agrisure® Duracade™ Refuge Renew 5122 Corn
Agrisure® Duracade™ Refuge Renew 5122A Corn

OECD Unique Identifier: SYN-BTØ11-1×SYN-IR6Ø4-5×DAS-15Ø7-1×SYN-Ø53Ø7-1

This product is effective in controlling corn leaf, stalk, ear, and root feeding damage caused by lepidopteran and corn rootworm pests.

Active Ingredients:

Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1) ..... ≤0. 00460%*

Bacillus thuringiensis mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR6Ø4-8) ..... ≤0.00041%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (via elements of vector PHI8999) in TC1507 corn (DAS-Ø15Ø7-1) ..... ≤0.00103%*

Bacillus thuringiensis eCry3.1Ab protein and the genetic material necessary for its production (via elements of vector pSYN12274) in 5307 corn (SYN- Ø53Ø7-1) ..... ≤0.00335%*

Other Ingredients:

A marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in Bt11corn (SYN-BTØ11-1) and (via elements of vector PHI8999) in TC1507 corn (DAS-Ø15Ø7-1) ..... ≤0.00022%*

A marker protein and the genetic material necessary for its production (via elements of vector pZM26) in MIR604 corn (SYN-IR6Ø4-8) and (via elements of vector pSYN12274) in 5307 corn (SYN- Ø53Ø7-1) ..... ≤0.00132%*

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

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Registration No. 67979-24
EPA Establishment No. 66736-NC-01

Syngenta Seeds, Inc. – Field Crops – NAFTA
P.O. Box 12257
3054 East Cornwallis Road
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.

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 registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

All seed corn that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds, Inc. or its distributors must be accompanied by informational material (*e.g.* a bag tag) indicating the registration number and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting the seed. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

Insects Controlled or Suppressed

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab, mCry3A, Cry1F, and eCry3.1Ab for control or suppression of the following coleopteran and lepidopteran insects:

European corn borer (*Ostrinia nubilalis*)
Southwestern corn borer (*Diatraea grandiosella*)
Southern cornstalk borer (*Diatraea crambidoides*)
Corn earworm (*Helicoverpa zea*)
Fall armyworm (*Spodoptera frugiperda*)
Black cutworm (*Agrotis ipsilon*)
Western bean cutworm (*Striacosta albicosta*)
Sugarcane borer (*Diatraea saccharalis*)
Lesser cornstalk borer (*Elasmopalpus lignosellus*)
Common stalk borer (*Papaipema nebris*)
Western corn rootworm (*Diabrotica virgifera virgifera*)
Northern corn rootworm (*Diabrotica barberi*)
Mexican corn rootworm (*Diabrotica virgifera zea*)

Insect Resistance Management

The following information regarding commercial production of Bt11×MIR604× TC1507×5307 corn must be included in the Syngenta Stewardship Guide (or equivalent). Growers must plant a refuge when using this product. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the Syngenta Stewardship guide/product use guide and/or in supplements to the Stewardship guide. Growers have two options for deployment of the refuge:

Refuge Option 1

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 pests. The refuge area must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11×MIR604×TC1507×5307 corn acres and refuge acres). It must be planted as a block adjacent to the Bt11×MIR604×TC1507×5307 corn field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide. If the common refuge is planted on rotated ground, then Bt11×MIR604×TC1507×5307 corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11×MIR604×TC1507×5307 corn field may be planted on either continuous or rotated land.

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×MIR604×TC1507×5307 corn 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 or crop consultants). Pests other than adult corn rootworms can be treated with an appropriate pest-labeled insecticide on the common refuge acres without treating the Bt11×MIR604×TC1507×5307 corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11×MIR604×TC1507×5307 corn acres can be treated as needed without having to treat the common refuge.

Refuge Option 2

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 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum of Bt11×MIR604×TC1507×5307 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11×MIR604×TC1507×5307 corn field. Refuge planting options include separate fields, blocks within fields (*e.g.*, along the edges or headlands), perimeter strips, or in-field strips. If perimeter or in- field strips are implemented, the strips must be at least four consecutive rows wide. 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. Economic thresholds will be determined using methods recommended by local or regional professionals (*e.g.*, Extension Service agents or crop consultants).

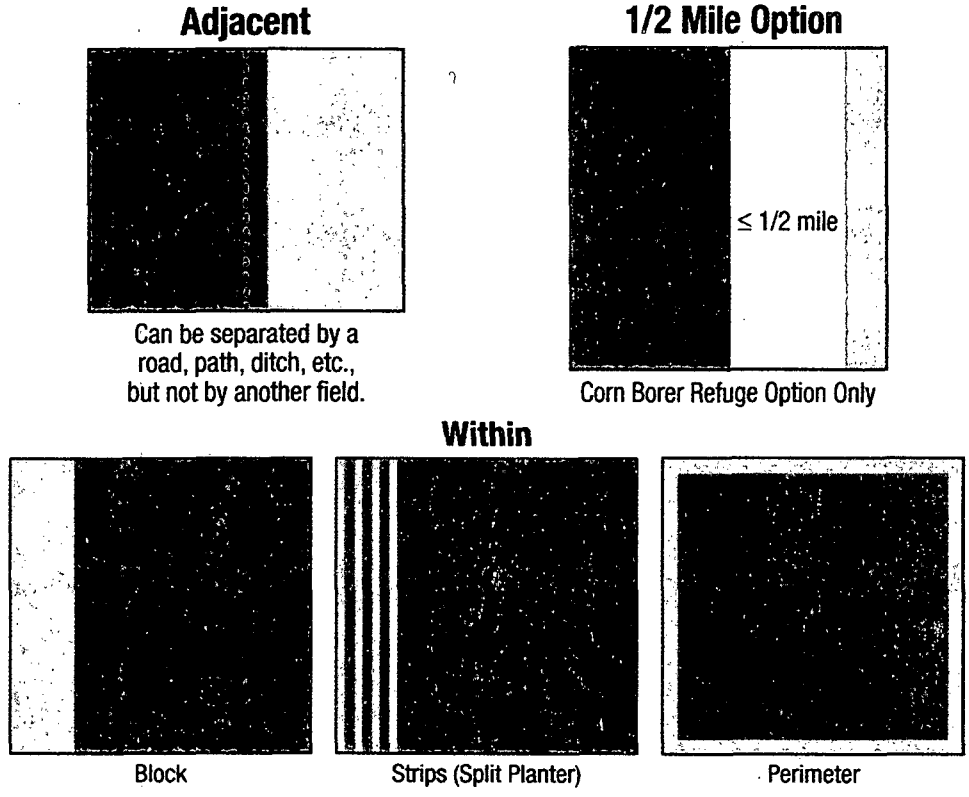
The corn rootworm refuge cannot be planted with a corn rootworm-protected Bt hybrid, but can be planted with a non-Bt hybrid or a Bt corn hybrid that controls corn borers. The corn rootworm refuge must represent at least 5% (or 20% in cotton growing regions) of the grower's corn acres (*i.e.*, sum Bt11×MIR604×TC1507×5307 corn acres and rootworm refuge acres) and must be planted as an adjacent block, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four consecutive rows wide. If the rootworm refuge is planted on rotated ground, then Bt11×MIR604×TC1507×5307 corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the Bt11×MIR604×

TC1507×5307 cornfield may be planted on either continuous or rotated land. More generally, the corn rootworm refuge should utilize comparable agronomic practices as the Bt11×MIR604× TC1507×5307 corn acres. 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×MIR604×TC1507×5307 corn field must be treated in a similar manner. Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the Bt11×MIR604×TC1507×5307 corn acres only if treatment occurs when adult corn rootworms are not present or if a pesticide without activity against adult corn rootworms is used. Pests on the Bt11×MIR604×TC1507×5307 corn acres can be treated as needed without having to treat the rootworm refuge.

Cotton-Growing Areas Requiring 20% Refuge Corn

State	Counties Identified by EPA as Cotton-Growing Areas				
Alabama	All Counties				
Arkansas	All Counties				
Florida	All Counties				
Georgia	All Counties				
Louisiana	All Counties				
Mississippi	All Counties				
Missouri	Dunklin	New Madrid	Pemiscot	Scott	Stoddard
North Carolina	All Counties				
Oklahoma	Beckham Harmon Washita	Caddo Jackson	Comanche Kay	Custer Kiowa	Greer Tillman
South Carolina	All Counties				
Tennessee	Carroll Franklin Lake Rutherford	Chester Gibson Lauderdale Shelby	Crockett Hardeman Lincoln Tipton	Dyer Hardin Madison	Fayette Haywood Obion
Texas	All counties with the exception of the following: Carson Lipscomb	Dallam Moore	Hansford Ochiltree	Hartley Roberts	Hutchinson Sherman
Virginia	Dinwiddie Southampton	Franklin City Suffock City	Greensville Surrey	Isle of Wright Sussex	Northampton

The following are schematics of the various refuge deployment options:



The following text and graphic indicating the refuge size requirement will appear on Bt11×MIR604×TC1507×5307 seed corn bags or bag tags.

Important grower information.
This hybrid requires you to plant:

For more information please refer to the Syngenta Stewardship Guide.