

67979-13

117

JAN 22 2010

Mr. Scott A. Huber  
Regulatory Affairs Manager  
Syngenta Seeds, Incorporated – Field Crops – NAFTA  
P.O. Box 12257  
Research Triangle Park, NC 27709-2257

Re: Syngenta Seeds, Inc. – Field Crops – NAFTA; Bt11 x MIR162 x MIR604 Corn  
EPA Registration No. 67979-13  
Minor Label (“Fast Track”) Amendment  
Submission dated 11/25/2009  
Decision #424139

Dear Mr. Huber:

The Agency has reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Addition of the secondary lepidopteran corn pest, Dingy cutworm (*Feltia jaculifera*).
- 2) Modification of the Ingredient Statement in accordance with commonly accepted Agency practices utilized specifically for plant-incorporated protectants.
- 3) Correction of minor typographical errors.

In addition to the label amendment specified above, the confidential statement of formula (CSF) was updated. The new CSF dated January 11, 2010 supersedes the previous CSF dated January 16, 2009 and will be filed in the Agency’s records as the official CSF.

The changes referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), are acceptable provided that you:

- 1) Submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

CONCURRENCES							
SYMBOL	7511P	7511P	7511P				
SURNAME	KAUSCH	Reynolds	Relf				
DATE	01/12/2010	1/21/10	1/22/10				

Mr. Scott A. Huber  
EPA Reg. No. 67979-13

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If the above condition is not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment constitutes acceptance of this condition. If you have any questions, contact Jeannine Kausch at 703-347-8920 or by email at [kausch.jeannine@epa.gov](mailto:kausch.jeannine@epa.gov).

Stamped copies of the label and confidential statement of formula are enclosed for your records.

Sincerely,



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

Enclosures (2):  
-Accepted Label  
-Confidential Statement of Formula dated January 11, 2010

JAN 22 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 67979-13

**Bt11 x MIR162 X MIR604 Corn**

[Alternate brand name: *Agrisure*<sup>™</sup> 3100]

OECD Unique Identifier: SYN-BT011-1 x SYN-IR162-4 x SYN-IR604-5

**Plant-incorporated protectant:**

**Cry1Ab, Vip3Aa20 and mCry3A proteins for control of corn borers, other lepidopteran pests and corn rootworms**

This product is effective in controlling corn leaf, stalk, and ear damage caused by certain lepidopteran pests 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 vector pZO1502) in corn event Bt11 (SYN-BT011-1)..... ≤ 0.0017%\*

*Bacillus thuringiensis* Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (SYN-IR162-4)..... ≤ 0.0088%\*

*Bacillus thuringiensis* mCry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn event MIR604 (SYN-IR604-5)..... ≤ 0.0021%\*

**Other Ingredients:**

A marker protein and the genetic material necessary for its production (via elements of vector pZO1502) in corn event Bt11 (SYN-BT011-1)..... ≤ 0.0001%\*

A marker protein and the genetic material necessary for its production (via elements of vectors pNOV1300 and pZM26) in corn events MIR162 and MIR604 (SYN-IR162-4 and SYN-IR604-5)..... ≤ 0.00095%\*

\*Percent in whole plants on a dry weight basis

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

EPA Registration No. 67979-13  
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

<sup>™</sup> Agrisure is a trademark of a Syngenta Group company

**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 (67979-13) 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, Vip3Aa20 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*)
- Beet armyworm (*Spodoptera exigua*)
- Black cutworm (*Agrotis ipsilon*)
- Western bean cutworm (*Striacosta albicosta*)
- Sugarcane borer (*Diatraea saccharalis*)
- Western corn rootworm (*Diabrotica virgifera virgifera*)
- Northern corn rootworm (*Diabrotica barberi*)
- Mexican corn rootworm (*Diabrotica virgifera zea*)
- Common stalk borer (*Papaipema nebris*)
- Dingy Cutworm (*Feltia jaculifera*)

**Insect Resistance Management**

The following information regarding commercial production of Bt11 x MIR162 x MIR604 corn must be included in the Grower Guide (or equivalent).

*Refuge Requirements for Bt11 x MIR162 x MIR604 Corn*

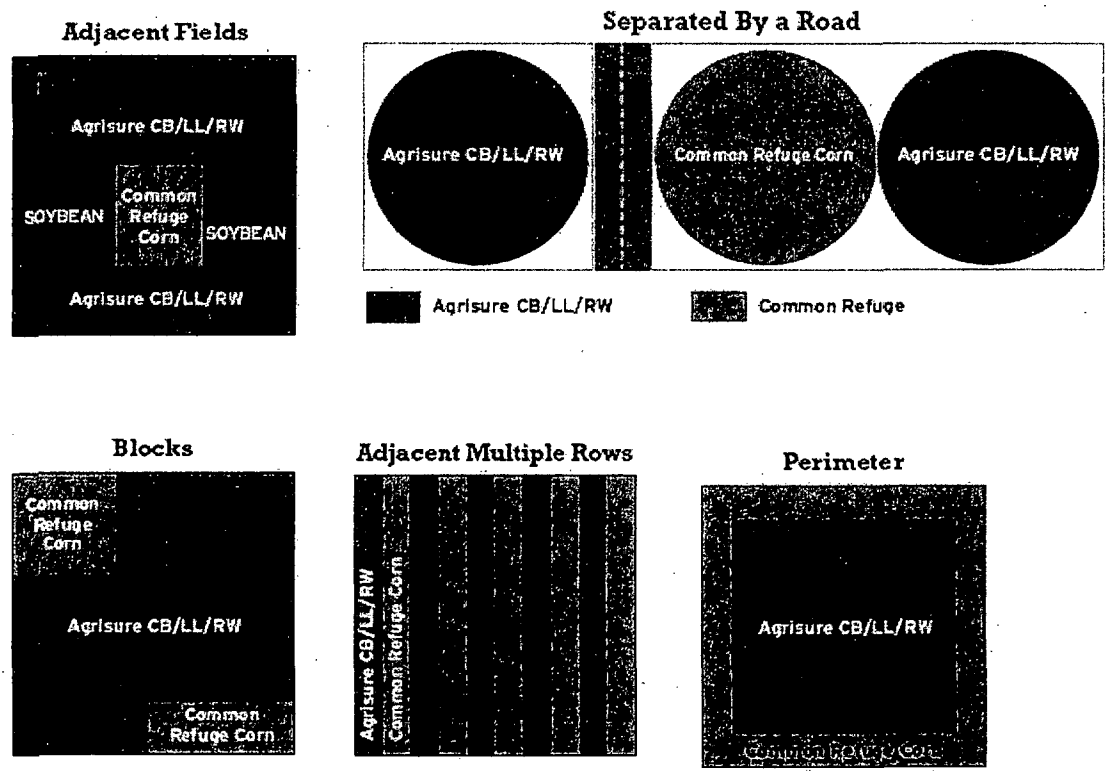
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

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 MIR162 x MIR604 corn acres and refuge acres). It must be planted as a block adjacent to the Bt11 x MIR162 x MIR604 corn field, perimeter strips, or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. If the common refuge is planted on rotated ground, then Bt11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the common refuge is planted in continuous corn, the Bt11 x MIR162 x MIR604 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 x MIR162 x MIR604 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 x MIR162 x MIR604 corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Bt11 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the common refuge.

The following is a schematic of common refuge deployment options:



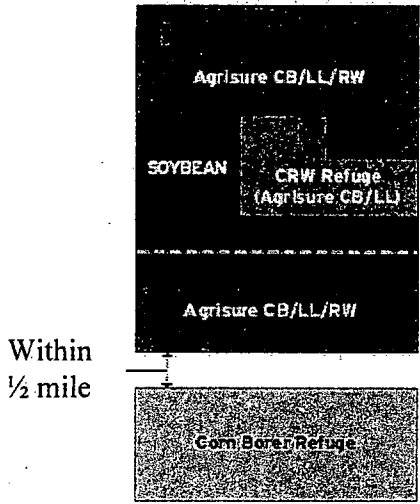
The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e., sum of Bt11 x MIR162 x MIR604 corn acres and corn borer refuge acres), and must be planted within ½ mile of the Bt11 x MIR162 x MIR604 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 4 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 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 MIR162 x MIR604 corn acres and corn 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 4 consecutive rows wide. If the rootworm refuge is planted on rotated ground, then Bt11 x MIR162 x MIR604 corn must also be planted on rotated ground. If the rootworm refuge is planted in continuous corn, the Bt11 x MIR162 x MIR604 corn field may be planted on either continuous or rotated land. More generally, the rootworm refuge should utilize comparable agronomic practices as the Bt11 x MIR162 x MIR604 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 x MIR162 x MIR604 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 x MIR162 x MIR604 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 x MIR162 x MIR604 corn acres can be treated as needed without having to treat the rootworm refuge.

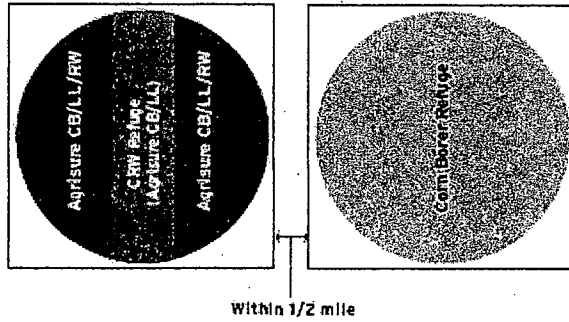
Growers who fail to comply with the IRM requirements risk losing access to Bt11 x MIR162 x MIR604 corn.




The following is a schematic of separate refuge deployment options:

### Adjacent Fields

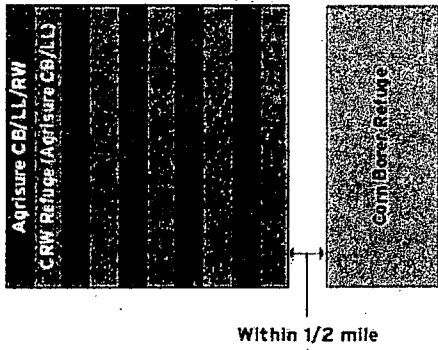


### Block

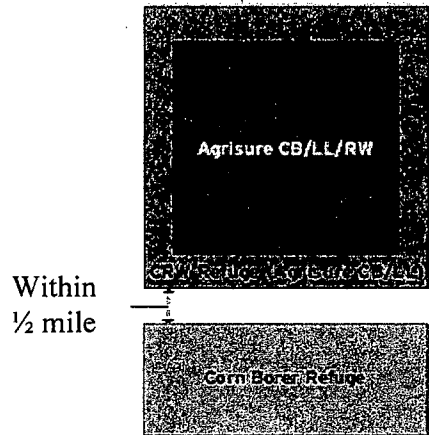





-  Agrisure CB/LL/RW
-  Corn Rootworm Refuge (Agrisure CB/LL)
-  Corn Borer Refuge

### Adjacent Multiple Rows



### Perimeter



-  Agrisure CB/LL/RW
-  Corn Rootworm Refuge (Agrisure CB/LL)
-  Corn Borer Refuge