

264-669

4-7-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 7 2000

Dr. Sally Van Wert  
Director, Regulatory Affairs - Biotechnology North America  
Aventis CropScience USA LP  
2 T.W. Alexander Drive  
P.O. Box 12014  
Research Triangle Park, NC 27709

Dear Dr. Van Wert:

Subject: Amendment Application Dated February 4, 2000 Regarding Modification of Term 3 of the Terms and Conditions of this Registration and Revised Labeling/ StarLink™ Corn EPA Registration No. 264-669

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable, subject to the following.

- 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.
- 2) Term 3 of the terms and conditions of this registration is modified to read as follows.

Grower agreements (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. Specifically, growers must plant a minimum structured refuge of at least 20% non-Bt corn. Insecticide treatments for control of European corn borer, corn earworm and/or 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. Requirements for refuge deployment will be described in the Grower Guides/Product Use Guides. Growers must plant the refuge within 1/2 mile of their Bt corn acreage. In regions of the corn belt where conventional insecticides have historically been used to control ECB and SWCB, growers wanting the option to treat these pests must plant the refuge within 1/4 mile of their Bt corn. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field. When planting the refuge in strips across the field, growers must be instructed to plant multiple non-Bt rows whenever possible.

CONCURRENCES

|         |      | CONCURRENCES |  |  |  |  |  |
|---------|------|--------------|--|--|--|--|--|
| SYMBOL  | 1311 |              |  |  |  |  |  |
| SURNAME |      |              |  |  |  |  |  |
| DATE    |      |              |  |  |  |  |  |

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3) Make the following changes to the draft label submitted prior to releasing corn for shipment under the terms of this amendment.

a) Change the registration number referenced for Liberty to "264-660."

b) Replace the statement "However, harvesting of the corn planted after April 1, 2001 is permissible subject to the terms of this registration." with "However, harvesting of the corn planted prior to April 1, 2001 is permissible subject to the terms of this registration."

4) Submit five (5) copies of your final labeling.

Your release of Bt corn into commerce under these modified terms and conditions constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e).

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

Sincerely,

*Janet L. Andersen*

Janet L. Andersen, Ph.D.  
Director  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosure

| CONCURRENCES |  |  |  |  |  |  |
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# StarLink™ CORN

StarLink™ corn produces both an insecticidal protein, Cry9C from *Bacillus thuringiensis* subsp. *tolworthi*, for protection from European corn borer and Southwestern corn borer, suppression of Black cut worm and Common stalk borer, and a herbicide resistance protein, phosphinothricin acetyltransferase (PAT). PAT provides protection from the Liberty® herbicide (EPA Registration Number 264-669), a herbicide that has glufosinate-ammonium as its active ingredient.

StarLink™ corn are descended from corn plants transformed with vectors pRVA9909 and pDE110.

## KEEP OUT OF REACH OF CHILDREN CAUTION

Active Ingredient: *Bacillus thuringiensis* subsp. *tolworthi* Cry9C protein and the genetic material necessary for its production in corn .....0.9-4.7%\*<sup>†</sup>

Inert Ingredients: Substance produced by a marker gene and its controlling sequences in corn.....0.2-1.6%<sup>†</sup>

<sup>†</sup> The percentages list the ingredient as a percent of the total plant protein on a dry weight basis.  
\* US Patents pending.

EPA Registration No. 264-669  
EPA Establishment Number: 070218-BEL-001

## DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes. All field corn containing the plant-pesticide that is sold or distributed by Aventis CropScience USA LP or a cooperator or licensee of Aventis, must be accompanied by informational material that contains the following:

StarLink™ corn contain a *Bacillus thuringiensis* subsp. *tolworthi* insecticidal protein, Cry9C and may only be used according to the instructions below for the control of the following insects:

European corn borer ~~ACCEPTED~~ *Ostrinia nubilalis* (Huber)  
Southwestern corn borer ~~ACCEPTED~~ *Diatraea grandiosella* (Dyar)

In EPA Letter Dated

APR 7 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, the product is registered under EPA Reg. No. 264-669.

Aventis CropScience USA LP.  
2 T.W. Alexander Drive  
P.O. Box 12014  
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Revised label: 3 April 00

StarLink™ corn contain a *Bacillus thuringiensis* subsp. *tolworthi* insecticidal protein, Cry9C and may only be used according to the instructions below for the suppression of the following insects:

|                    |                                  |
|--------------------|----------------------------------|
| Black cut worm     | <i>Agrotis ipsion</i> (Hufnagel) |
| Common stalk borer | <i>Papaipema nebris</i> (Guen.)  |

Do not use this corn until you have read the Bag Tag and the Grower's Guide.

**Insect Resistant Management:** To protect this important technology, a structured non-*Bt* corn refuge must be planted in close proximity to your StarLink™ corn fields. Specifically, a structured refuge of non-*Bt* corn equal to at least 20% of the total corn acres must be planted. The refuge must be located within ½ mile of the StarLink™ field, unless you plan to use a foliar-applied insecticide for Corn borer control; then it must be planted within ¼ mile. Any insecticide treatment for Corn borer cannot include sprayable Bt products.

**Seed Production Uses:** Seeds expressing the Cry9C protein should be planted at a maximum of 40,000 seeds per acre on the site. Any seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field that is not used for seed production should be destroyed or used domestically for animal feed or non-food industrial purposes. None of the seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field, may be used for food uses or may enter international commerce.

**Feed or Non-food Industrial Uses:** Seeds expressing the Cry9C protein should be planted at a maximum of 40,000 seeds per acre on the site. Any seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field, should be used domestically for animal feed or non-food industrial purposes. None of the seeds, plants or plant materials in the StarLink™ plot, or within 660 feet of the field, may be used for food uses or may enter international commerce.

## STORAGE AND DISPOSAL

**Seed Storage:** Store in a cool dry place separate from conventional corn seed.

**Seed and Plant Disposal:** Any seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field, may be used domestically for animal feed or industrial purposes, or destroyed. None of the seeds, plants or plant materials in the StarLink™ field, or within 660 feet of the field, may be used for food uses or may enter international commerce.

**Container Disposal:** Do not reuse bag. Discard bag in trash. Ensure that the bag is completely empty of seed before disposal.

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For Product Inquiry Information,  
Call Toll Free: 1-877-STARLINK  
(1-877-782-7546)

The registration of this pesticide product for use in field corn will automatically expire on midnight April 1, 2001. After this registration has expired, no field corn seed that contain the pesticide product may be sold or planted. However, harvesting of the corn planted after April 1, 2001 is permissible subject to the terms of this registration.

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