

45639-221

2-1-1999

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 1 1999

Dr. Sally Van Wert
Manager, Regulatory Affairs - Biotechnology
AgrEvo USA Company
Little Falls Centre One
2711 Centerville Road
Wilmington, DE 19808

Dear Dr. Van Wert:

Subject: Amendment Application Dated January 25, 1999 Regarding Modification of Terms 1, 2, and 3 of the Terms and Conditions of this Registration / StarLink™ Corn
EPA Registration No. 45639-221

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 1 of the terms and conditions of this registration is modified to read as follows.

This registration will automatically expire on midnight May 30, 2000. After this registration has expired, no field corn seed that contain the pesticide product may be sold or planted. However, harvesting of such corn planted prior to May 30, 2000 is permissible subject to the terms of this registration. AgrEvo USA Company is liable for the actions of its customers in regard to meeting the terms and limitations of this registration.

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

This registration is for field corn to be used only in animal feed, industrial non-food uses such as ethanol production, and seed increase. In addition, any corn grown within 660 feet of Cry9C corn must also be limited to use in animal feed and industrial non-food uses such as ethanol production. The acreage for corn planted may not exceed 2.5 million acres for the duration of this registration. AgrEvo must implement their plan (proposed in letter to EPA dated 1/22/99) to direct the use of all grain not harvested for seed increase to animal feed or industrial non-food use.

CONCURRENCES

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SYMBOL	7511C	7511C				
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4) Term 3 of the terms and conditions of this registration is modified to read as follows.

AgrEvo USA Company must require that growers follow the USDA NC-205 guidelines for refuge are followed for all Cry9C corn. These guidelines reflect the current knowledge base among USDA, academic, industry, and EPA scientists. Specifically, a 20-30% unsprayed or 40% sprayed non-Bt corn structured refuge in close proximity to the Bt crop is required. The refuge must be established within 1500-2000 feet of the Bt crop. Any insecticide treatment cannot include sprayable Bt products.

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

a) Delete "(formerly 70218-1)".

b) In the **Insect Resistance Management** section, replace "...to at least 20% of the total corn acres..." with "...to at least 20 -30% of the total corn acres..." and add "Any insecticide treatment cannot include sprayable Bt products."

c) Insert the **Seed Production Uses, Feed or Industrial Uses, and Seed and Plant Disposal** sections exactly as they appear on the PGS labeling approved May 12, 1998 along with the notice of registration for this product.

6) Submit five (5) copies of your final printed 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

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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 45639-199), a selective 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:	<i>Bacillus thuringiensis</i> subsp. <i>tolworthi</i> Cry9C protein and the genetic material necessary for its production in corn	0.9-4.7% ^{†*}
Inert Ingredients:	Substance produced by a marker gene and its controlling sequences in corn	0.2-1.6% [†]

[†] The percentages list the ingredient as a percent of the total plant protein on a dry weight basis.

* US Patents pending.

EPA Registration No. 45639-221 (formerly 70218-1)

EPA Establishment Number: 70218-BEL-001

ACCEPTED
with COMMENTS
in EPA Letter Dated
FEB 1 1999
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
45639-221

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 AgrEvo USA Company or a cooperator or licensee of AgrEvo, 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 | <i>Ostrinia nubilalis</i> (Huber) |
| Southwestern corn borer | <i>Diatraea grandiosella</i> (Dyar) |

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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
Common stalk borer

Agrotis ipsion (Hufnagel)
Papaipema nebris (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 (1500-2000 feet) to your StarLink™ corn fields. Specifically, a refuge of non-*Bt* corn equal to at least 20% of the total corn acres must be left unsprayed for control of European corn borer. If foliar sprays are applied for ECB control then at least 40% of the total corn acres must be planted to non-*Bt* corn.

STORAGE AND DISPOSAL

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

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

**For Product Inquiry Information,
Call Toll Free: 1-888-GO-LIB-LINK
(1-888-465-4254)**