UNITED STATES ENVIRONMENTAL PROTECTION

FEB 27 1998

Dr. Demetra Vlachos Senior Manager, Biotechnology Regulatory Affairs Novartis Seeds, Inc. - Field Crops - NAFTA P.O. Box 12257 Research Triangle Park, NC 27709-2257

Dear Dr. Vlachos:

Subject: Label Amendment Application to Amend the Term and Condition of the Subject Registration to Allow Unlimited Use Of Bt11 Bt Corn in Ten Counties of the Texas Panhandle EPA Registration No. 67979-1

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the following comments.

1) The term and condition restricting commercial sale listed in item 11 of our 1/24/97 letter approving limited use in the South is modified to read as follows:

Novartis will ensure that in the combined states of Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin, and Grady), 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 (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, Suffolk) and Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott, Stoddard) that the combined sale of this plantpesticide in all the above states will not exceed the amounts required to plant 100,000 acres per anum. Further, Novartis will ensure that for the states and counties listed above that the amount sold will result in no more than 5% of the corn planted in any county with more than 1000 acres of cotton. Per item 8 of the 1/24/97 letter Novartis will report all sales of this product by Novartis or its distributors annually to EPA no later than January 31st of the following year.

2) Correct the name and address of Novartis Seeds, Inc. on the label to reflect Novartis Seeds, Inc. - Field Crops - NAFTA.

CONCURRENCES								
SYMBOL 75/1W 75/16								
SURNAME MAYOUS HUTTON								
DATE 12/26/97 2/27/98								
EPA Form 1320-1A (1/90)	Printed on Recycled Paper	OFFICIAL FILE COPY						

\*U.S. Government Printing Office: 1992 - 920-956/40672

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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A stamped copy of the label is enclosed for your records. Submit five (5) copies of the final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of Bt corn into commerce with the amended grower guide constitutes acceptance of these conditions.

Sincerely,

Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution

Prevention Division (7511W)

CONCURRENCES								
SYMBOL								
SURNAME								
DATE						·		7-

EPA Form 1320-1A (1/90)

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\*U.S. Government Printing Office: 1992 — 820-858/AD672

## **INSECT RESISTANT CORN**

# Bt Protein Plant Pesticide Active Ingredient for the Control of European Corn Borer in Corn

(Pure form of the plant pesticide,

Bacillus thuringiensis subsp. kurstaki delta-endotoxin protein,
as expressed in corn cells)

## Active Ingredient:

### Inert Ingredient:

Keep Out of the Reach of Children

#### CAUTION

Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

ACCEPTED
with COMMENTS
In EPA Letter Dated

EPA Reg. No. 67979-1 EPA Est. No. 67979-IA-2

Tader the Federal Insecticide, Fungicide, and Redenticide Ast as amouded, for the posticide registered under EPA Reg. No.

Novartis Seeds, Inc. 7500 Olson Memorial Highway Golden Valley, MN 55427

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#### Directions for Use:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Novartis Seeds will ensure that in the combined states of Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Texas (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), Missouri (only the counties of Butler, Dunklin, Mississippi, New Madrid, Pemiscot, Scott and Stoddard), Oklahoma (only the counties of Bryan, Caddo, Canadian, Garvin and Grady) and 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), that the combined sale of corn seed containing this plant pesticide will not exceed the amounts required to plant 100,000 acres per annum. Further, Novartis Seeds will ensure that, for the states and counties listed above, the amounts sold will result in no more than 5% of the corn planted in any county having more than 1000 acres of cotton. Novartis Seeds will report all sales of this product by Novartis 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* CrylA(b) delta-endotoxin protein for control of:

European corn borer

(Ostrinia nubilalis)

In addition, some control or suppression of the following corn pests can be provided:

Southwestern corn borer Southern corn stalk borer

(Diatraea grandiosella) (Diatraea crambidoides)

Corn earworm

(Helicoverpa zea)

Fall armyworm

(Spodoptera frugiperda)

All com seed that contains the plant pesticide that is sold or distributed by Novartis Seeds or its distributors must be accompanied by informational material indicating the registration number (67979-1) and the active ingredient [Bacillus thuringiensis CrylA(b) delta-endotoxin and the genetic material (plasmid vector pZO1502) necessary for its production in corn], and stipulating that growers read the Grower Guide prior to planting the seed.

A Grower Guide must be distributed to all customers using seed containing the plant pesticide that will include instructions and recommendations regarding product use, insect resistance management, and integrated pest management.

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