

68467-3

09/26/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 26 2005

OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

Dr. Irene Gatti
Regulatory Leader-Biotech
Regulatory Success-Americas
Dow AgroSciences LLC
9220 Zionsville Road
Indianapolis, IN 46268

Subject: Label Amendment Application Dated June 14, 2005
Proposed Monitoring Program
Product Name: WideStrike® Cotton
EPA Registration Number: 68467-3

Dear Dr. Gatti:

The amendment referred to above, submitted in connection with your registration under FIFRA section 3(c)(7)(C), is acceptable. The label is amended as follows:

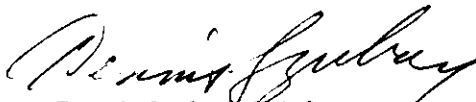
- 1) Added item c) to the "Directions for Use" section regarding commercial production: "c) Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson."
- 2) Added pests: black cutworm, citrus peelminer, cotton leafperforator, European corn borer, omnivorous leafroller, and saltmarsh in first paragraph of label under "Directions for Use" and in table entitled "Use Patterns."

All amended changes to the label must be put into the 2006 Grower Guide. A copy of the stamped, approved label is enclosed for your records.

BPPD's review of the WideStrike® cotton monitoring program is enclosed. The submitted pink bollworm monitoring program is "acceptable." The tobacco budworm and cotton bollworm monitoring program is "supplemental." Dow must address the particular recommendations for the tobacco budworm and cotton bollworm monitoring programs and resubmit this plan to EPA for approval.

If you have any questions, please contact Sharlene Matten, at 703-605-0514, or by e-mail at matten.sharlene@epa.gov.

Sincerely,



Dennis Szuhay, Chief
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511C)

Enclosure

WideStrike™

EPA Reg. No. 68467-3

Registration Notes:

Proposed changes by amendment:

1. As a condition of acceptance from previous label amendment, added item c) to the "Directions for Use" section regarding commercial production: 'c) Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.' under the use directions.
2. Added pests Black Cutworm, Citrus Peelminer, Cotton Leafperforator, European Corn Borer, Omnivorous Leafroller, and Saltmarsh Caterpillar in first paragraph of label, under 'Directions for Use' and in table entitled 'Use Patterns'.

™ Trademark of Mycogen Seeds

THIS LABEL IS NOT FOR DISTRIBUTION

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WideStrike™ Insect Resistant Cotton Seed

Pure form of the plant-incorporated protectant, *Bacillus thuringiensis* var. *aizawai* strain PS811 and *Bacillus thuringiensis* var. *kurstaki* strain HD73 delta endotoxin protein as produced in cotton cells. For control of Cotton Bollworm, Tobacco Budworm, Pink Bollworm, Beet Armyworm, Fall Armyworm, Southern Armyworm, Soybean Looper, Cabbage Looper, Black Cutworm, Citrus Peelminer, Cotton Leafperforator, European Corn Borer, Omnivorous Leafroller, and Saltmarsh Caterpillar.

Active Ingredient:

Bacillus thuringiensis var. *aizawai* Cry1F and the genetic material (from the insert of plasmid pGMA281) necessary for its production in cotton and *Bacillus thuringiensis* var. *kurstaki* Cry1Ac and the genetic material (from the insert of plasmid pMYC3006)

necessary for its production in cotton.....	Cry1F Event 281	1.4 – 6.6 ng/mg*
	Cry1Ac Event 3006	0.44 – 0.70 ng/mg*

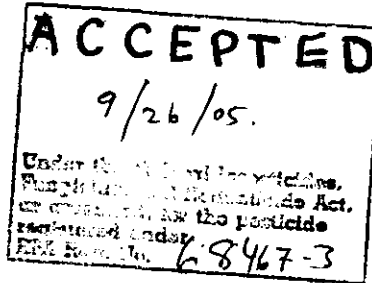
*ng/mg seed tissue on a wet weight basis

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA REG. NUMBER: 68467-3

EPA ESTABLISHMENT NUMBER: 62719-IN-1.

Mycogen Seeds
c/o Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis IN 46268



™Trademark of Mycogen Seeds

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DIRECTIONS FOR USE

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

The plant-incorporated protectant product should be used as specified in the terms and conditions of the registration.

Cotton has been transformed to express *Bacillus thuringiensis* var. *aizawai* strain PS811 and *Bacillus thuringiensis* var. *kurstaki* strain HD73 delta endotoxin protein for control of the Cotton Bollworm, Tobacco Budworm, Pink Bollworm, Beet Armyworm, Fall Armyworm, Southern Armyworm, Soybean Looper, Cabbage Looper, Black Cutworm, Citrus Peelminer, Cotton Leafperforator, European Corn Borer, Omnivorous Leafroller, and Saltmarsh Caterpillar.

The following information regarding commercial production must be included in the grower guide for WideStrike cotton:

- a) No planting of WideStrike cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of WideStrike cotton is prohibited in Hawaii, Puerto Rico, and the US Virgin Islands.
- c) Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding test plots and seed production must occur on bags of WideStrike cotton intended for the following purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bt.-cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

All growers of WideStrike cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-Bt cotton (refuge cotton) is planted for every 95 acres of WideStrike cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lb active ingredient per acre). The variety of cotton planted in the refuge must be comparable to WideStrike cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to WideStrike cotton. Ensure that a non-Bt cotton refuge is maintained within at least 1/2 linear mile (preferably adjacent to or within 1/4 mile or closer) from the Bt cotton fields.

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2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of WideStrike cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to *Bt* cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to WideStrike cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Btk* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* refuge is maintained within at least 1 linear mile (preferably within 1/2 mile or closer) from the *Bt* cotton fields

3) Embedded Refuge

Plant at least 5 acres of non-*Bt* cotton (refuge cotton) for every 95 acres of WideStrike cotton. The refuge cotton must be embedded as a contiguous block within the *Bt* cotton field, but not at one edge of the field (i.e., refuge block(s) surrounded by WideStrike cotton). For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the WideStrike cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*Bt* cotton may be utilized as the embedded refuge. The variety of cotton planted in the refuge must be comparable to WideStrike cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to WideStrike cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding WideStrike cotton field in which it is embedded (or fields within a field unit) except only at the pre-squaring cotton stage when the refuge may be treated with any lepidopteran insecticide to control foliage feed caterpillars.

4) Embedded Refuge for Pink Bollworm Only

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of WideStrike cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding *Bt* cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the WideStrike cotton. There is no field unit option.

5) Community Refuge

This option allows multiple growers to manage refuge for external, unsprayed and external, sprayed refuge options or both. This option is not allowed for the embedded/in-field options. The community refuge for insect resistance management must meet the requirements of either the 5% external unsprayed refuge and/or the 20% sprayed option, or an appropriate combination of the two options.

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USE PATTERN

CROP	PESTS
cotton	Cotton Bollworm Tobacco Budworm Pink Bollworm Beet Armyworm Fall Armyworm Southern Armyworm Soybean Looper Cabbage Looper Black Cutworm Citrus Peelminer Cotton Leafperforator European Corn Borer Omnivorous Leafroller Saltmarsh Caterpillar

EPA Accepted: 9/16/05

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Cry1F Event 281 1.4 – 6.6 ng/mg*
Cry1Ac Event 3006 0.44 – 0.70 ng/mg*

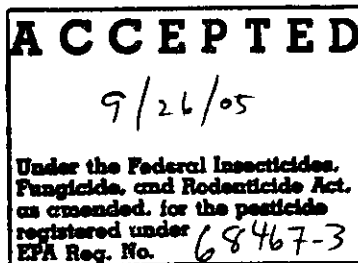
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11/11

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EPA Accepted: 9/26/05