

68467-3

9-30-2004

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg. Number:

68467-3

Date of Issuance:

SEP 30 2004

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

WideStrike

Name and Address of Registrant (include ZIP Code):

Dow AgroSciences
9330 Zionsville Road
Indianapolis, IN 46268-1054

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit production information for this product to Mr. Owen Beeder of Registration Division (7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.
3. This registration is registered under FIFRA § 3(c)(7)(C) because of the outstanding Insect Resistance Management data. Submit the following data within the specified timeframes:
4. This registration will automatically expire on September 30, 2009.

Signature of Approving Official:

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(See second page for signature)

Date:

9/30/04

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5. Change your identifying symbol to read 68467-3.
6. Submit five (5) copies of the revised final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

The following terms and conditions apply:

Data

- a) By July 31, 2005, Dow AgroSciences must provide the Agency with additional empirical data or published literature (other than Gould et al., 2002) that support the use of CBW alternate hosts as natural refugia. Data would include larval and adult production of CBW on each alternate host for each generation relative to cotton and WideStrike® cotton and the spatial scale and source of moth production.
- b) Should Dow AgroSciences wish to use their CBW resistance management model to support changes to the insect resistance management strategy, then this model must be revised per the recommendations of the June 8-10, 2004 SAP report dated August 19, 2004 and submitted to the Agency for review.

Gene Flow

The following information regarding commercial production must be included in the grower guide for WideStrike® Cotton and is a term of this amendment:

- 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.

The following information regarding test plots and seed production must occur on bags of WideStrike cotton intended for these purposes and is a term of this amendment.

- 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.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

Insect Resistance Management

The required IRM program for *Bt* cotton must have the following elements:

- Requirements relating to creation of a non-*Bt* cotton refuge in conjunction with the planting of any acreage of *Bt* cotton;
- Requirements for Dow AgroSciences to prepare and require *Bt* cotton users to sign “grower agreements” which impose binding contractual obligations on the grower to comply with the refuge requirements;
- Requirements for Dow AgroSciences to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- Requirements for Dow AgroSciences to develop, implement, and report to EPA on programs to evaluate and promote growers’ compliance with IRM requirements;
- Requirements for Dow AgroSciences to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ac and Cry1F proteins in the target insects;
- Requirements for Dow AgroSciences to develop, and if triggered, to implement a “remedial action plan” which would contain measures Dow AgroSciences would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- Annual reports on or before January 31st each year.

a. Refuge Requirements

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. 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 lbs 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 ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the *Bt* cotton fields.

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 ½ 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).

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. The community refuge pilot must consist of the following:

There will be a community refuge coordinator for each pilot site. Each community refuge coordinator must submit a signed community refuge form listing all of the participants at the pilot site to Dow AgroSciences by July 1st annually. Dow AgroSciences must provide EPA, if requested, with a copy of the signed community refuge form. The community refuge coordinator will maintain a copy of the field map (to scale) or suitable scalar representation of the community refuge for review by Dow AgroSciences or EPA as part of the compliance program.

On an annual basis, Dow AgroSciences must conduct at least one telephone audit of a statistically representative sample of community refuge coordinators from communities in all states participating in the community refuge. EPA shall review the questions annually prior to the start

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of the growing season.

The community refuge program users must be included in the telephone compliance survey and the on-farm visits to be conducted by Dow AgroSciences under section 3.c. below.

Beginning January 31, 2006 and annually each January 31st, Dow AgroSciences must provide a written report to EPA annually on community refuge use and compliance. The community refuge report may be combined in a single report with other compliance activities.

On an annual basis, Dow AgroSciences must conduct a review of the community refuge program and submit that review to the Agency as to any proposed changes by January 31st. An appropriate amendment for any proposed changes must be submitted to the Agency.

b. Grower Agreements

While Dow AgroSciences will have flexibility to design its program to fit its own business practices, the registration is specifically conditioned on meeting the following requirements.

- 1) Persons purchasing the *Bt* cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Dow AgroSciences must establish by the 2005 growing season, a system which is reasonably likely to assure that persons purchasing the *Bt* cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. The proposed system will be submitted to EPA on or before December 1, 2004.
- 4) Dow AgroSciences must submit a copy of its grower agreement to EPA by December 1, 2004. If Dow AgroSciences wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Dow AgroSciences must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this amendment.
- 5) Dow AgroSciences must establish a system which is reasonably likely to assure that persons purchasing the *Bt* cotton sign grower agreement(s), and must provide by December 1, 2004 a written description of that system.
- 6) Monsanto shall maintain records of all *Bt* cotton grower agreements for a period of three years from December 31 of the year in which the agreement was signed.
- 7) Beginning on January 31, 2006 and annually thereafter, Dow AgroSciences shall provide EPA with a report on the number of units of the *Bt* cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior October through September. Note: the first report shall contain the specified information for the time frame starting with the date of registration and ending

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September 30, 2005.

8) Dow AgroSciences must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

c. IRM Education and IRM Compliance Monitoring Programs

Dow AgroSciences must implement the following IRM education and compliance monitoring programs:

- 1) Dow AgroSciences must design and implement a comprehensive, ongoing IRM education program designed to convey to *Bt* cotton users the importance of complying with the IRM program. The program shall include information encouraging *Bt* cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to *Bt* cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. Copies of the materials, including the Grower Guide or other technical bulletins, must be submitted to EPA for their records. The program shall involve at least one written communication annually to each WideStrike® cotton grower separate from the grower agreement. Dow AgroSciences shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.
- 2) Annually, Dow AgroSciences shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- 3) Beginning January 31, 2006 and annually thereafter, Dow AgroSciences shall provide a report to EPA summarizing the activities it carried out under its education program for the prior year and its plans for its education program during the current year.
- 4) Dow AgroSciences shall design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the *Bt* cotton product. Dow AgroSciences shall prepare and submit by January 31, 2005 a written description of its compliance assurance program. Other required features of the program are described in paragraphs 5 - 12 below.
- 5) Dow AgroSciences shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Dow AgroSciences will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase WideStrike® cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.
- 6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of WideStrike® cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Dow AgroSciences shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year. Dow AgroSciences shall confer with EPA on the design and content of the survey prior to its implementation for the 2005 growing

season and annually, thereafter.

7) Annually, Dow AgroSciences shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Dow AgroSciences will confer with the Agency prior to adopting any changes.

8) Dow AgroSciences shall train its representatives who make on-farm visits with WideStrike® cotton growers to perform assessments of compliance with IRM requirements. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Dow AgroSciences shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

9) Dow AgroSciences shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Dow AgroSciences shall take appropriate action, consistent with its "phased compliance approach."

10) If a grower, who purchases WideStrike® cotton for planting, was specifically identified as not being in compliance during the previous year, Dow AgroSciences shall visit the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

11) Beginning January 31, 2006 and annually thereafter, Dow AgroSciences shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Dow AgroSciences and the results of these visits the number of tips investigated, the percent of growers not in compliance with each refuge option (both size and distance), and the follow-up actions taken.

12) Dow AgroSciences must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

d. Insect Resistance Monitoring.

The registration of Cry1Ac and Cry 1F PIPs expressed in cotton is conditioned on Dow AgroSciences carrying out appropriate programs to detect the emergence of insect resistance as early as possible. Resistance monitoring programs include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. Dow AgroSciences should coordinate its monitoring efforts for WideStrike® with the current resistance monitoring programs for other *Bt* ICPs. The Agency is imposing the following conditions:

1) Dow AgroSciences will develop and ensure the implementation of a plan for resistance monitoring for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of tobacco budworm and cotton bollworm population to Cry1Ac and Cry1F proteins. Sites must be focused in areas with high risk of resistance (e.g. where adoption is at least 75% of the cotton planted in that county or parish) while overall being distributed throughout the areas where tobacco budworm and cotton bollworm

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are important pests. The sampling program should be segregated into different sampling regions rather than sampling within each state in which these insects are economic pests. At least 20 specific collection sites will be established in time for the 2005 growing season. Discriminating doses for each toxin must be developed for tobacco budworm and cotton bollworm. Dow AgroSciences must provide EPA with the baseline susceptibility data for the Cry1F and Cry1Ac proteins and establish diagnostic/discriminating dose concentrations for both the Cry1F and Cry1Ac proteins by September 1, 2005.

2) Dow AgroSciences will develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm population to Cry1Ac and Cry1F proteins. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest. Dow AgroSciences must provide EPA with the baseline susceptibility data for the Cry1Ac protein and establish a diagnostic/discriminating dose concentration for both the Cry1Ac proteins by September 1, 2005.

3) Dow AgroSciences shall provide a detailed description to EPA of its resistance monitoring plan by January 31, 2005. The description shall include: sampling (number of locations and samples per locations), sampling methodology, bioassay methodology, standardization procedures, detection technique and sensitivity, and the statistical analysis of the probability of detecting resistance.

4) Dow AgroSciences must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, black cutworm, fall armyworm, southern armyworm, and European corn borer. Dow AgroSciences will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Dow AgroSciences will investigate all damage reports. See Remedial Action Plans section below.

5) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by September 1st each year for the duration of the conditional registration.

e. Remedial Action Plans

Specific remedial action plans are required for WideStrike® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Dow AgroSciences must implement the Arizona *Bt* Cotton Working Group's Remedial Action Plan. Dow AgroSciences must obtain approval from EPA before modifying the Arizona *Bt* Cotton Working Group's Remedial Action Strategy. The Arizona *Bt* Cotton Working Group's Remedial Action Plan can be found in Enclosure 1.

2) Remedial Action Plan for Tobacco Budworm and Cotton Bollworm

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Based upon the Arizona model, a Remedial Action Plan for cotton bollworm and tobacco budworm must be developed and implemented by Dow AgroSciences if suspected or confirmed resistance is found. Dow AgroSciences must submit a remedial action plan (or plans) for tobacco budworm and cotton bollworm to the Agency by January 31, 2006 for approval prior to its implementation. An Interim Remedial Action Plan for Cotton Bollworm and Tobacco Budworm is contained in Enclosure 2. Dow AgroSciences must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

Annual Reports

Dow AgroSciences will provide an annual report to EPA on its Cry1Ac and Cry1F PIPs expressed in cotton. This report must include, but is not limited to, annual sales (both units sold and estimated acres planted) by county and by state (sales data must be summed individually for each state), research status for any outstanding data requirements as covered in 3 above, grower education completed last year and planned for the following year with any changes highlighted, the description of grower agreements in place, grower compliance with IRM requirements including compliance with the community refuge option, and insect resistance monitoring results.

SUPPLEMENTAL STUDIES

- Dow AgroSciences must submit an avian chronic exposure study by September 30, 2008.
- Dow AgroSciences must submit a non-target insect more appropriate for cotton fields, i.e., a maximum hazard dose laboratory toxicity study using the organism, *Orius insidiosus* (minute pirate bug) by September 30, 2008.
- Dow AgroSciences must submit soil fate/terrestrial expression studies for long range soil persistence.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely,



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

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Mycogen Brand Cry1F (synpro)/Cry1Ac (synpro) Construct 281/3006 Cotton Insect Resistant Cotton Seed

Pure form of the plant-pesticide, *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 and Cabbage Looper.

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*

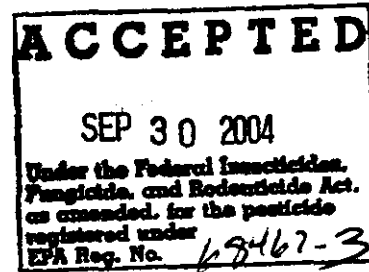
*ng/mg seed tissue on a wet weight basis

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

EPA REG. NUMBER: 68467-__

EPA ESTABLISHMENT NUMBER: 62719-IN-1.

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



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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-pesticide 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 and Cabbage Looper.

Growers are instructed to read information on insect resistance management.

USE PATTERN

CROP	PESTS
cotton	Cotton Bollworm Tobacco Budworm Pink Bollworm Beet Armyworm Fall Armyworm Southern Armyworm Soybean Looper Cabbage Looper

EPA Accepted: __/__/__