


524-585

11/14/2013

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 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) Ariel Rios Building 1200 Pennsylvania Ave., NW Washington, D.C. 20460</p>	EPA Reg. Number:	Date of Issuance:
	524-585	NOV 14 2013
	Term of Issuance: Unconditional	
<p>NOTICE OF PESTICIDE:</p> <p><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Reregistration (under FIFRA, as amended)</p>	<p>Name of Pesticide Product:</p> <p>MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn</p>	
<p>Name and Address of Registrant (include ZIP Code):</p> <p>Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167</p>		
<p>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.</p>		
<p>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.</p> <p>This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.</p> <p>This product registration is unconditionally amended in accordance with FIFRA § 3(c)(5) provided that you comply with the following terms and conditions:</p> <p>1) Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.</p> <p>2) The subject registration will automatically expire at midnight on November 30, 2021.</p>		
<p>Signature of Approving Official:</p> <p><i>Robert McNally</i></p> <p>Robert McNally, Director Biopesticides and Pollution Prevention Division (7511P)</p>	<p>Date:</p> <p>11/14/13</p>	

3) The subject registration is limited to Cry1A.105 [*Bacillus thuringiensis* Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in corn event MON 89034 (OECD Unique Identifier MON-89034-3)] x Cry2Ab2 [*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in corn event MON 89034 (OECD Unique Identifier MON-89034-3)] x Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (vector PHP8999) in corn event TC1507 (OECD Unique Identifier DAS- 01507-1)] for use in field corn.

4) Submit or cite all data required to support MON 89034 x TC1507 plant-incorporated protectant products within the timeframes required by the terms and conditions of EPA Registration Number 524-575.

5) Implement the following Insect Resistance Management Program for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn

The required IRM program for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn must have the following elements:

- Requirements relating to creation of a non-Bt corn refuge in conjunction with the planting of any acreage of MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn;
- Requirements for Monsanto to prepare and require MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn users to sign "grower agreements," which impose binding contractual obligations on the grower to comply with the refuge requirements;
- Requirements regarding programs to educate growers about IRM requirements;
- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1 A.105, Cry2Ab2 and Cry1F proteins in the target insects;
- Requirements regarding a "remedial action plan," which contains measures Monsanto would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- Requirements for Monsanto to maintain and to make available to the Agency upon request the number of units of MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn sold by state and county, IRM grower agreements results, and substantive changes to educational programs, within three months of the request.

a) **Refuge Requirements for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn**

These refuge requirements do not apply to seed propagation of inbred and hybrid corn seed up to a total of 20,000 acres per county and up to a combined U.S. total of 250,000 acres per PIP active ingredient per registrant per year. Grower agreements (also known as stewardship agreements) will specify that growers must

adhere to the following refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

A structured refuge must be planted for lepidopteran pests. The structured refuge must be planted with corn hybrids that do not contain *Bt* technologies for the control of lepidopteran pests. The refuge and MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn should be sown on the same day, or with the shortest window possible between planting dates to ensure development is similar among varieties. If the refuge is planted on rotated ground, then the MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn must also be planted on rotated ground. If the refuge is planted on continuous corn, the MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn field may be planted on either continuous or rotated land. Refuge options are based on the planting of MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn in cotton or non-cotton growing regions and the insect pressure present in those locations. The refuge sizes for these regions are either 20% in cotton growing regions (i.e. 20 acres of non-*Bt* corn for every 80 acres MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn planted) or 5% in non-cotton growing regions (5 acres of non-*Bt* corn for every 95 acres of MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn planted). The refuge can be planted as a block within or adjacent (e.g., across the road) to the MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn, perimeter strips (i.e., strips around the field), or in-field strips. External refuges must be planted within 1/2 mile of the *Bt* field. If perimeter or infield strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-*Bt* insecticides if the population of one or more target lepidopteran pests of MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn in the refuge exceeds economic thresholds. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring a 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, 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 Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

b) Grower Agreement for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn

- 1) Monsanto must require that persons purchasing MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) Monsanto's grower agreement and/or any specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. Monsanto must write the grower agreement such that, by signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must implement a system (equivalent to that already approved for previously registered Monsanto *Bt* corn products), which is reasonably likely to assure that persons purchasing MON 89034 x

TC1507 Insect-Protected Herbicide-Tolerant Corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use a grower agreement for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability by Monsanto of the provisions of the agreement relating to the IRM program, Monsanto must submit to EPA 30 days prior to implementing a proposed change the text of such changes to ensure that it is consistent with the terms and conditions of this registration.

5) Monsanto shall maintain records of all MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

6) Monsanto shall make available to the Agency upon request records of the number of units of MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season, within three months of the request.

7) Monsanto 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 confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Program for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn users the importance of complying with the IRM program. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Within three months of EPA request, Monsanto shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of a report from the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC).

4) Monsanto will continue to conduct and support grower education (e.g. corn clinics, certified crop advisor training, etc.) that demonstrates the economic and technology-preserving value of crop rotation as a best agronomic practice. Monsanto will submit to EPA a report with evidence of the 2014 grower education program (specifically including the number of education sessions/trainings held, locations, number of attendees, examples of presentation materials and grower survey results if available) by July 31, 2014. For the following seasons, Monsanto will submit a similar report upon the request of the agency within three months of the request.

d) Insect Resistance Monitoring and Remedial Action Plans for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn

Existing programs for resistance monitoring and remedial action for lepidopteran target pests (e.g. European corn borer, corn earworm, southwestern corn borer) for MON 89034 and TC1507 are applicable and required for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31st each year, beginning in 2014, for the duration of the registration.

e) Annual Reporting Requirements for MON 89034 x TC1507 Insect-Protected Herbicide-Tolerant Corn

Monsanto must submit to the Agency by the dates specified below, beginning in 2014 (except where otherwise specified), the following information:

(1) Compliance Assurance Program: compliance assurance program activities, including IRM Grower Survey and on-farm assessment results, for the prior year and plans for the compliance assurance program for the current year on or before January 31st of each year;

2) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, by August 31st of each year, beginning in 2014.

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 the product constitutes acceptance of these conditions.

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

The basic confidential statement of formula (CSF) dated November 13, 2013 is acceptable and supersedes all previous basic CSFs. A copy has been placed in the file jacket for this registration.

Sincerely,



Robert McNally, Director
Biopesticides and Pollution
Prevention Division (7511P)

Enclosure

Plant-Incorporated Protectant Label

MON 89034 × TC1507

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1)

Alternate Brand Name: Genuity® PowerCore™

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in corn event MON 89034 (OECD Unique Identifier: MON-89034-3) ≤ 0.0026%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in corn event MON 89034 (OECD Unique Identifier: MON-89034-3) ≤ 0.0053%*

Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production (vector PHP8999) in corn event TC1507 (OECD Unique Identifier: DAS- 01507-1)..... ≤ 0.0012%*

Other Ingredients:

The marker protein, Phosphinothricin Acetyltransferase (PAT), and the genetic material necessary for its production (vector PHP8999) in corn event TC1507 (OECD Unique Identifier: DAS- 01507-1)..... ≤ 0.00045%*

*Maximum percent (wt/wt) of dry forage

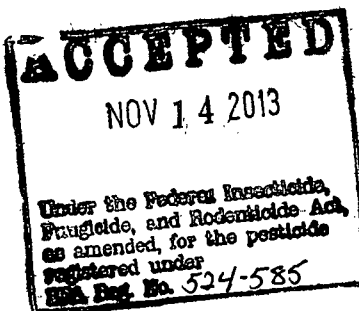
KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____
EPA Registration No. 524-XXX

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167



DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide and/or Insect Resistance Management (IRM) Grower Guide.

MON 89034 x TC1507 can be used to protect corn plants from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered PIPs that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

INSECT RESISTANCE MANAGEMENT

To help preserve the effectiveness of *B.t.* corn technologies, growers planting MON 89034 x TC1507 field corn, are required to follow an Insect Resistance Management (IRM) Plan.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per PIP active ingredient per registrant per year.

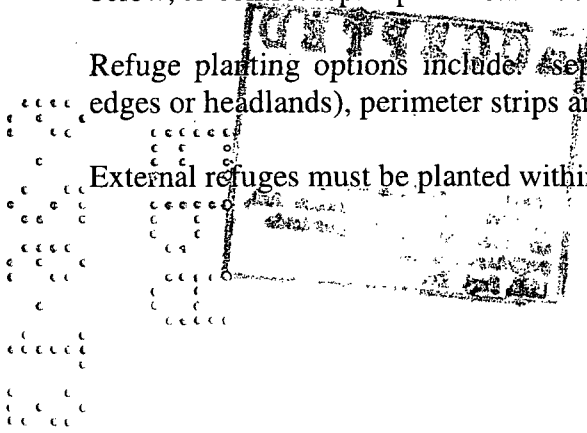
i) **Corn-Belt/Non-Cotton-Growing Area Refuge Requirements**

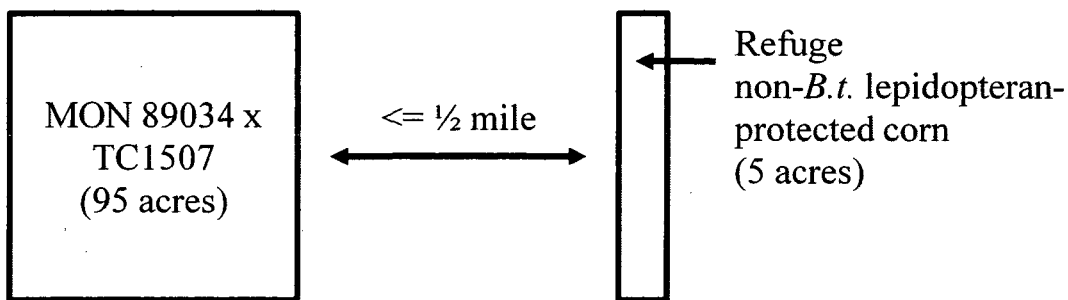
For MON 89034 x TC1507 field corn grown outside the cotton-growing areas (e.g., the Corn Belt), grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 5% corn, which is not a lepidopteran-protected *B.t.* corn hybrid. The refuge may be treated with insecticides, as described below, to control lepidopteran stalk-boring and other pests.

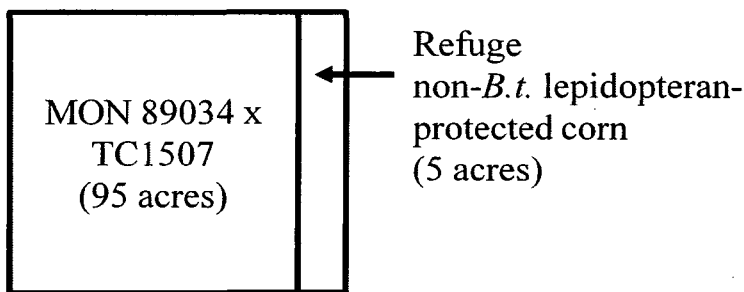
Refuge planting options include separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips and strips across the field.

External refuges must be planted within 1/2 mile.





When planting the refuge in strips across the field or as perimeter strips, refuges must be at least 4 consecutive rows wide.



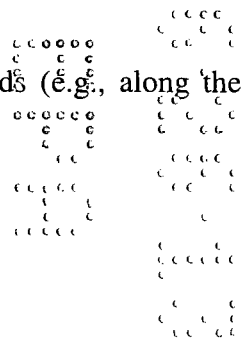
Insecticide treatments for control of insects included on this label may be applied only if economic thresholds are reached for one or more of these targeted pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *B.t.* insecticides must not be applied to non-*B.t.* corn refuges.

j) Cotton-Growing Area Refuge Requirements

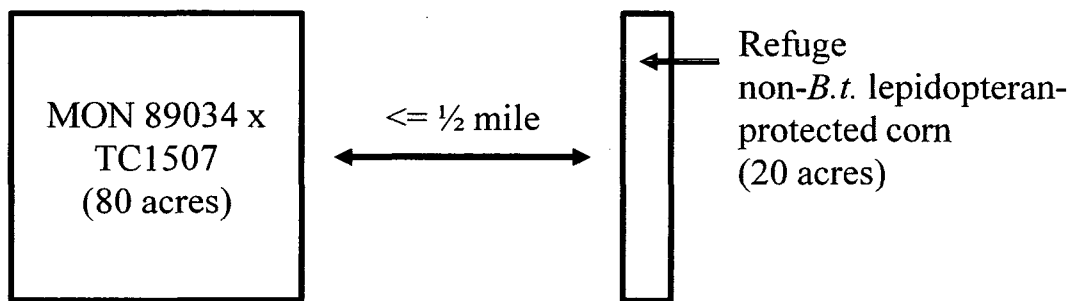
For MON 89034 x TC1507 field corn grown in cotton-growing areas, as defined below, grower guides must specify that growers must adhere to the following refuge requirements.

Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control insects included on this label.

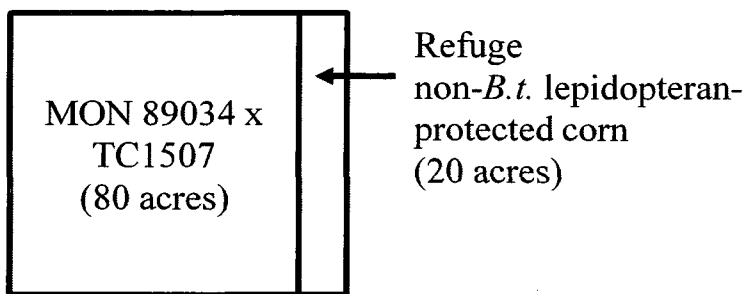
Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field.



External refuges must be planted within 1/2 mile.



When planting the refuge in strips across the field, refuges must be at least 4 consecutive rows wide.



Insecticide treatments for control of insects included on this label may be applied only if economic thresholds are reached for one or more of these targeted pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). Instructions to growers will specify that microbial *B.t.* insecticides must not be applied to non-*B.t.* corn refuges.

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, 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 Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed.

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Western bean cutworm (WBC)	<i>Richia albicosta</i>
Black cutworm	<i>Agrotis ipsilon</i>

Sales of corn hybrids that contain Monsanto's *B.t.* corn plant incorporated protectant must be accompanied by a grower guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* proteins is planted.

Genuity® PowerCore™ is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents:

Dow AgroSciences Patent Rights: 5510474, 6218188, and 6943282.

Monsanto Patent Rights: 5554798, 5593874, 5641876, 5717084, 5728925, 5859347, 6025545, 6051753, 6083878, 6489542, 6645497, 6713063, 6825400, 6962705, 7064249, 7070982, 7250501, 7304206, 7582434, 7618942, 7700830, 7927598, RE39247, and 8034997.

EPA Accepted: __/__/__/