

524-551

12/13/2005

119



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:

524-551

Date of Issuance:

12/13/05

Term of Issuance:

Conditional

Name of Pesticide Product:

MON 88017

## NOTICE OF PESTICIDE:

Registration  
 Reregistration  
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Monsanto Company  
1300 I Street, NW, Suite 450 East  
Washington, DC 20005

**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) The subject registration will automatically expire on midnight September 30, 2010.
- 3) The subject registration will be limited to *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in MON 88017 corn (OECD Unique Identifier: MON-88017-3 for use in field corn.

Signature of Approving Official:

(See Signature on Page 6)

Date:

12/13/05

4) Submit all data required to support the individual plant-incorporated protectant in Event MON863 (YieldGard Rootworm), 524-528. In the event that the Agency concludes MON 863 (YieldGard Rootworm) studies do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 corn must be submitted. These data may include a) laboratory toxicity testing with *Orius insidiosus* (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing.

5) You must commit to do the following Insect Resistance Management Program:

**a. Refuge Requirements**

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn.

1. Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.
2. Specifically, growers must plant a structured refuge of at least 20% non-corn rootworm protected Bt corn that may be treated with insecticides as needed to control corn rootworm larvae. Growers will not be permitted to apply CRW labeled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Cry3Bb1 field is treated in a similar manner.
3. Refuge planting options include: refuge acres should be planted as blocks adjacent to MON 88017 corn fields, perimeter strips, or as in-field strips.
4. External refuges must be planted adjacent (e.g., across the road) to Cry3Bb1 MON 88017 fields.
5. When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 consecutive rows wide.
6. Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labeled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Cry3Bb1 field is treated in a similar manner.
7. If the refuge is planted in a field that is in a crop rotation system, then MON 88017 must also be planted in a field that is in a crop rotation system.
8. If the refuge is planted on continuous corn, then the MON 88017 field may be planted on either continuous or in a field that is in a crop rotation system.

**b. Grower Agreements**

- 1] Persons purchasing the Bt corn 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] You must develop a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the Bt corn 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 within 90 days from the date of registration.
- 4] You must use grower agreements and submit to EPA within 90 days from the date of registration a copy

of that agreement and any specific stewardship documents referenced in the grower agreement. 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 of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, you must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.

5] You must establish a system (equivalent to what is already approved for MON 810, EPA Reg. No. 524-489) which is reasonably likely to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system.

6] You shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7] Beginning on January 31, 2007 and annually thereafter, you shall provide EPA with a report showing the number of units of its Bt MON 88017 corn seeds sold or 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 August through July.

8] You 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 Programs**

1] Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 88017 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 88017 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 88017 corn fields. 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 its records. The program shall involve at least one written communication annually to each Bt MON 88017 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, you shall revise, and expand as necessary, your 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] On January 31, 2007, you must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, you must provide EPA any substantive changes to your grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs 4]-15] below.

4] You must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 88017 Bt corn product 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 MON 88017 Bt corn product. You shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate the Cry3Bb1 CAP with the CAP already approved for

MON810, EPA Registration Number 524-489. You must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs 5] - 15] below.

5] You must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how you 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 MON 88017 Bt corn 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. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell MON 88017 Bt corn.

6] The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn 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. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] You shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year, beginning with 2007. You shall confer with EPA on the design and content of the survey prior to its implementation.

10] Annually, you shall revise, and expand as necessary, your compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. You must confer with the Agency prior to adopting any changes to a previously approved CAP.

11] You shall train its representatives who make on-farm visits with MON 88017 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, you shall take appropriate action, consistent with your "phased compliance approach," to promote compliance. This on-farm assessment program has no minimum acreage threshold for growers.

12] You shall carry out a program for investigating legitimate "tips and complaints" that its growers 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, you shall take appropriate action, consistent with your "phased compliance approach."

13] If a grower, who purchases MON 88017 Bt corn for planting, was specifically identified as not being in compliance during the previous year, You shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Beginning January 31, 2007 and annually thereafter, Monsanto shall provide a report to EPA

summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.

15] Monsanto and the seed corn dealers for Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

#### **9d. Insect Resistance Monitoring**

The Agency is imposing the following conditions for this product:

You must monitor for Cry3Bb1 resistance and/or trends in increased tolerance for corn rootworm. Sampling should be focused in those areas in which there is the highest risk of resistance development.

1. You must provide EPA its resistance monitoring plan for approval. A revised monitoring plan must be submitted to the Agency with 3 months of the date of registration consisting of a description of the steps to be taken to establish corn rootworm baseline sensitivity and damage guidelines. A detailed resistance monitoring plan must be submitted to the Agency for review by January 31, 2008. This plan must include: baseline sensitivity data, sampling (number of locations, samples per locations), sampling methodology and life-stage sampled, bioassay methodology, standardization procedures (including QA/QC provisions), detection technique and sensitivity, the statistical analysis of the probability of detecting resistance, and an interim description of rootworm damage guidelines.
2. You must develop and validate an appropriate discriminating or diagnostic dose assay by January 31, 2010.
3. You must finalize rootworm damage guidelines and submit these to BPPD by January 31, 2010.
4. You must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
5. You must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2007, reporting on populations collected the previous year.

#### **e. Remedial Action Plans**

Once a remedial action plan is approved for MON 863, it also must be used for corn rootworm suspected and confirmed resistance in MON 88017. If corn rootworm resistance is confirmed, all acres (MON 88017 and refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

The annual reporting requirements are as follows:


- 1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year;

- 2) Grower Agreement: number of units of *Bt* corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- 3) Grower Education: substantive changes to education program completed previous year, January 31st each year;
- 4) Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- 5) Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- 6) Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

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

# MON 88017

## Rootworm-Protected Corn Seed (OECD Unique Identifier: MON-88Ø17-3)

This product is effective in controlling damage caused by corn rootworm larval feeding on corn roots.

### Active Ingredient:

*Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3).....0.0075 - 0.013%

### Other Ingredients:

Substance produced by a marker gene and the genetic material necessary for its production (Vector ZMIR39) in event MON 88017 corn (OECD Unique Identifier: MON-88Ø17-3).....0.0042 - 0.0069%

Percentage (wt/wt) on a dry weight basis whole plant (forage).

## CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS \_\_\_\_\_

EPA Registration No. 524-~~XXXX~~ 551

EPA Establishment No. 524-MO-002

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

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
12-13-05**  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
524-551

## DIRECTIONS FOR USE

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

The following information regarding commercial production must be included in the MON 88017 corn Technology Use Guide (IRM Guide).

## INSECT RESISTANCE MANAGEMENT

Growers of MON 88017 must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% non-corn rootworm protected corn.

Refuge planting options include: adjacent blocks, perimeter strips or in-field strips. If blocks are implemented they must be adjacent (e.g., across the road) to the MON 88017 field. If perimeter strips are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide. If strips within a MON 88017 field are implemented, the strips must be at least 4, and preferably 6 consecutive rows wide.

The refuge and MON 88017 acres should be managed under comparable agronomic regimes. If the refuge is planted in a field that is in a crop rotation system, then MON 88017 must also be planted in a field that is in a crop rotation system. If the refuge is planted on continuous corn, then the MON 88017 field may be planted on either continuous or in a field that is in a crop rotation system.

Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae and other soil pests. The corn refuge can be treated with a non-*B.t.* insecticide to control late season pests such as corn borer or corn rootworm adults. However, if growers opt to treat the refuge while adult corn rootworm are present, then the MON 88017 acres must be treated in a like manner.

These refuge requirements will not apply to operations engaged in the propagation of inbred seed corn.

## CORN INSECTS CONTROLLED OR SUPPRESSED

This field corn has been transformed using biotechnology to produce the *B.t.* protein, Cry3Bb1, for control or suppression of the following coleopteran insects:

Western corn rootworm (*Diabrotica virgifera virgifera*)  
Northern corn rootworm (*Diabrotica barberi*)  
Mexican corn rootworm (*Diabrotica virgifera zea*)



MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. Patents: 4,940,835, 5,164,316, 5,188,642, 5,196,525, 5,322,938, 5,359,142, 5,633,435, 5,641,876, 5,717,084, 5,728,925, 5,804,425, and 6,501,009.