



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

EPA Reg. Number
67979-5

Date of Issuance
10/3/06

Term of Issuance: Conditional

Name of Pesticide Product:
Agrisure™ RW Rootworm-
Protected Corn

NOTICE OF PESTICIDE:

[x] Registration
[] Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Syngenta Seeds, Inc. - Field Crops - NAFTA
P.O. Box 12257, 3054 East Cornwallis Road
Research Triangle Park, NC 27709-2257

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) The subject registration will automatically expire on midnight September 30, 2010.
2) The subject registration will be limited to mCry3A corn, modified Cry3A protein and the genetic material necessary for its production (via elements of pZM26) in Event MIR604 corn SYN-IR604-8.
3) 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.
4) Provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of a mCry3A analytical method within 6 months from the date that the Agency requests them.

Signature of Approving Official: [Handwritten Signature]

Date: 10/3/06

Table with columns for SYMBOL, SURNAME, DATE, and CONCURRENCES. Includes handwritten entries for 7511P, Rios, and 10/3/06.

5) Submit field degradation studies evaluating accumulation and persistence of mCry3A in several different soils in various strata. Representative fields must have been planted with mCry3A corn and include both conventional tillage and no-till samples and be harvested under typical agronomic conditions. Sampling must continue until the limit of detection is reached. Studies should include soils with high levels of a variety of clays. Both ELISA and insect bioassays need to be conducted and compared to determine if mCry3A is accumulating or persisting in soil samples. A protocol is due within 90 days of the date of registration. Should the registration expiration date be extended, a final report regarding data from fields that have had three continuous years of cultivation of Event MIR604 corn is due by January 31, 2011.

6) Three (3) year full-scale field or semi-field studies for evaluation of mCry3A Event MIR604 corn exposure on non-target invertebrates must be conducted. Full-scale field experiments must be appropriately designed to provide a measure of ecological impacts (larger fields, more replicates, more samples per plot based on recommendations of the August, 2002 SAP and subsequent relevant research on appropriate study design). A protocol is due within 90 days of the date of registration. Should the registration expiration date be extended, a final report is due January 31, 2011.

7) Submit the following data to augment the mCry3A amino acid sequence analysis to known toxins and allergens within six months of the date of registration: specification of which version of NCBI database was utilized; descriptions of parameters utilized; and dates accessed for the BLAST search.

8) Submit the following insect resistant management data by January 31, 2010.

a) Initiate establishment of CRW strains that are resistant to mCry3A and investigate the nature, inheritance, and fitness costs of specific mechanisms of resistance to the mCry3A protein expressed in MIR604 maize.

b) Study the behavioral deterrence (avoidance) mechanism further and submit appropriate results.

c) Continue studies on the biological impact of adults surviving on MIR604 maize and submit these results.

9) You must 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 mCry3A field is treated in a similar manner.

3] Refuge planting options include: refuge acres should be planted as blocks adjacent to mCry3A MIR604 corn fields, perimeter strips, or as in-field strips.

4] External refuges must be planted adjacent (e.g., across the road) to mCry3A MIR604 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 mCry3A field is treated in a similar manner.

7] If the refuge is planted in a field that is in a crop rotation system, then MIR604 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 MIR604 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] The registrant must develop a system (equivalent to what is already approved for Bt11 field corn, EPA Reg. No. 67979-1) 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] The registrant 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 Syngenta 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, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and

5] The registrant must establish a system (equivalent to what is already approved for Bt11, EPA Reg. No. 67979-1) 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] The registrant 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, 2008 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MIR604 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] Beginning in January 31, 2008, and annually thereafter, the registrant shall submit annual reports on units sold by State (units sold by county level will be made available to the Agency upon request), IRM grower agreement results, and the compliance assurance program, including the education program on or before January 31st each year.

9] The registrant 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] Syngenta must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MIR604 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MIR604 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MIR604 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 MIR604 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Syngenta 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, the registrant 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] *On January 31, 2008, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its 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] *The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MIR604 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 MIR604 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate the mCry3A CAP with the CAP already approved for Bt11, EPA Registration Number 67979-1. The registrant 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] *The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant 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 MIR604 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 MIR604 Bt corn.*

6] *The IRM compliance assurance program shall include an annual survey conducted by an independent third party of a statistically representative sample of growers of Bt corn products who plant the vast majority of all corn in the U.S. and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn-Belt and who plant 100 or more acres of corn in corn-cotton areas.. 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.*

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] *The registrant 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 2008. The registrant shall confer with other Bt*

corn registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, the registrant shall revise, and expand as necessary, its 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. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.

11] The registrant shall conduct an annual on-farm assessment program. The registrant shall train its representatives who make on-farm visits with growers of their Bt corn products to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

12] The registrant 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, the registrant shall take appropriate action, consistent with its "phased compliance approach."

13] If a grower, who purchases MIR604 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant 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, 2008 and annually thereafter, Syngenta 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] The registrant and the seed corn dealers for the registrant 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.

d. Insect Resistance Monitoring

The Agency is imposing the following conditions for this product:

The registrant must monitor for mCry3A 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] The registrant 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] The registrant 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] The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.

5] The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2008, reporting on populations collected the previous year.

e. Remedial Action Plans

The following program summary describes, in order of events, the steps that must be taken to implement a remedial action plan if resistance to target pests is confirmed (this general process has been implemented for other lepidopteron and CRW Bt corn products).

1. Definition of Suspected Resistance: Resistance will be suspected if investigations of unexpected damage reports show that:

- a. implicated maize plant roots were expressing the mCry3A protein at the expected level;
- b. alternative causes of damage or lodging, such as non-target pest insect species, weather, physical damage, larval movement from alternate hosts, planting errors, and other reasonable causes for the observations, have been ruled out;
- c. the level of damage exceeds guidelines for expected damage.

If resistance is "suspected", the registrants will instruct affected growers to use alternate pest control measures such as adulticide treatment, crop rotation the following year, or use of soil or seed insecticides the following year. These measures are intended to reduce the possibility of potentially resistant insects contributing to the following year's pest population.

2. Confirmation of Resistance: Resistance will be confirmed if all of the following criteria are met by progeny from the target pest species sampled from the area of "suspected resistance":

- a. the proportion of larvae that can feed and survive on mCry3A roots from neonate to adult is significantly higher than the baseline proportion (currently being established);
- b. the LC₅₀ of the test population exceeds the upper limit of the 95% confidence interval for the LC₅₀ of a standard unselected population and/or survival in the diagnostic assay is significantly greater than that of a standard unselected population, as established by the ongoing baseline monitoring program;
- c. the ability to survive is heritable;
- d. mCry3A plant assays determine that damage caused by surviving insects would exceed economic thresholds;
- e. the identified frequency of field resistance could lead to widespread product failure if

subsequent collections in the affected field area(s) demonstrated similar bioassay results.

3. Response to Confirmed Resistance: When resistance is "confirmed", the following steps will be taken:

- a. EPA will receive notification within 30 days of resistance confirmation;
- b. affected customers and extension agents will be notified about confirmed resistance;
- c. affected customers and extension agents will be encouraged to employ alternative CRW control measures;
- d. sale and distribution of mCry3A maize in the affected area will cease immediately;
- e. a long-term resistance management action plan will be devised according to the characteristics of the resistance event and local agronomic needs. [The details of such a plan should be approved by EPA and all appropriate stakeholders.]

f. Annual Reporting Requirements

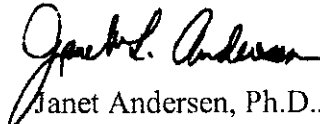
- 1) Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- 2) Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 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, beginning in 2008.

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.

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

Sincerely,



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

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Agrisure™ RW Rootworm-Protected Corn
Plant-Incorporated Protectant:
Modified Cry3A Protein for Corn Rootworm Control

This product is effective in controlling or suppressing damage caused by larvae of some corn rootworm species feeding on corn roots.

Active Ingredient:

Modified Cry3A protein, and the genetic material necessary for its production (via elements of pZM26) in corn (SYN-IR604-8) ≤ 0.029%*

Other Ingredients:

Phosphomannose isomerase protein, and the genetic material necessary for its production (via elements of pZM26) in corn (SYN-IR604-8) ≤ 0.002%*

*Percentage in whole plants on a dry weight basis.

Keep Out of Reach of Children

CAUTION

EPA Registration No. 67979-5

EPA Establishment No. 66736-NC-001

Syngenta Seeds, Inc. - Field Crops – NAFTA
P.O. Box 12257
3054 East Cornwallis Rd.
Research Triangle Park, NC 27709

ACCEPTED
with COMMENTS
to EPA Letter 10/2/06
OCT 03 2006

67979-5

DIRECTIONS FOR USE

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

The following information regarding commercial planting of Agrisure™ RW hybrid field corn must be included in the Grower Guide for Agrisure™ RW Rootworm-Protected Corn.

Insect Resistance Management

Growers of Agrisure™ RW 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 labelled insecticides to the refuge for control of insect pests while adult corn rootworm are present unless the Agrisure™ RW field is treated in a similar manner.

Refuge planting options include: refuge acres should be planted as blocks adjacent to Agrisure™ RW corn fields, perimeter strips, or as in-field strips.

External refuges must be planted adjacent (e.g., across the road) to Agrisure™ RW fields.

When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 consecutive rows wide.

Insecticide treatments for control of corn rootworm larvae may be applied. Instructions to growers will specify that insecticides labelled for control of corn rootworm adults cannot be applied while adults are present in the refuge unless the Agrisure™ RW field is treated in a similar manner.

If the refuge is planted in a field that is in a crop rotation system, then Agrisure™ RW must also be planted in a field that is in a crop rotation system.

If the refuge is planted on continuous corn, then the Agrisure™ RW field may be planted on either continuous or in a field that is in a crop rotation system.

These refuge requirements do not apply to operations related to the seed increase/propagation of Agrisure™ RW inbred and hybrid seed.

Corn Insects Controlled or Suppressed

Corn has been genetically transformed to produce a modified Cry3A protein for control or suppression of the following coleopteran insects:

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