**Volume 1 of 1 of Submission**

**Administrative Materials:**

# Application to Extend/Amend Experimental Use Permit 67979-EUP-4

**for**

# Modified Cry3A *Bacillus thuringiensis* Insect Control Protein as Expressed in Event MIR604 Corn Plants

**and**

# Breeding Stack of Event MIR604 Corn with Event Bt11 Corn Expressing a Cry1Ab *Bacillus thuringiensis* Insect Control Protein (MIR604 X Bt11)

**August 15, 2005**

**Submitted By:**

**Syngenta Seeds, Inc. – Field Crops - NAFTA**
**P. O. Box 12257**
**3054 East Cornwallis Road**
**Research Triangle Park**
**North Carolina, USA 27709-2257**

**STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS**

No claim of confidentiality is made for any information contained in this volume on the basis of its falling within the scope of FIFRA 10(d), (1) (A), (B), or (C).

Company: Syngenta Seeds, Inc. – Field Crops – NAFTA

Company Agent: Demetra Vlachos

Demetra Vlachos
Senior Manager, Regulatory Affairs

Date: August 15, 2005

## GOOD LABORATORY PRACTICE STATEMENT

Information in this document represents administrative materials and is not subject to Good Laboratory Practice requirements.

Author/Submitter: Demetra Vlachos

Demetra Vlachos
Senior Manager, Regulatory Affairs
Syngenta Seeds, Inc. – Field Crops – NAFTA

Date: August 15, 2005

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**Syngenta Seeds, Inc.**
P. O. Box 12257 (mail)
3054 East Cornwallis Road (shipping)
Research Triangle Park, North Carolina 27709-2257

August 15, 2005

Mr. Michael Mendelsohn
Biopesticides and Pollution Prevention Division
Document Processing Desk (EUP)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell St.
Arlington, VA 22202-4501

***Via Express Courier Delivery***

**Re: Application to Amend/Extend Experimental Use Permit No. 67979-EUP-4 for Modified Cry3A Protein as Expressed in Event MIR604 Corn Plants and a Breeding Stack of Event MIR604 Corn with Event Bt11 Corn Expressing a Cry1Ab Protein**

Dear Mr. Mendelsohn:

Syngenta Seeds, Inc. – Field Crops – NAFTA (Syngenta Seeds) is submitting the accompanying application to amend and extend Experimental Use Permit No. 67979-EUP-4 to allow (1) continued field testing of the modified Cry3A (mCry3A) *Bacillus thuringiensis* insect control protein and the genetic material necessary for its production in Event MIR604-derived field corn plants, and (2) the first large-scale field testing of a conventional breeding 'stack' of Event MIR604 corn with Event Bt11 corn expressing a Cry1Ab *Bacillus thuringiensis* insect control protein (MIR604 X Bt11 corn). MIR604 plants are currently being field tested under EUP No. 67979-EUP-4, which was approved March 23, 2005 and allows plantings through February 28, 2006. The Cry1Ab plant-incorporated protectant (PIP) in Bt11 field corn has been registered since 1996 under EPA Reg. No. 67979-1. By combining the MIR604 and Bt11 traits *via* conventional breeding, corn hybrids produce both the mCry3A protein for control of key coleopteran pests and Cry1Ab protein for control of key lepidopteran pests.

**The proposed PRIA fee category for this EUP amendment/extension application is B86 ("PIP, EUP Amendment, Food Use")**. To meet critical product development timelines, Syngenta Seeds requests that 67979-EUP-4 be amended and extended for the period of March 2006 through February 28, 2007. We also request that all field activities (*e.g.,* data collection, harvesting and processing of seed) associated with these plantings be authorized through October 15, 2007. Depending on local weather conditions, corn planting often begins in the southern regions of the US in mid-March. Therefore, taking into consideration the time that will be required to obtain State approvals upon renewal of the EUP, **we kindly ask that this EUP amendment/extension be approved no later than February 28, 2006.**

Concurrently with the issuance of permit 67979-EUP-4, a temporary exemption from the requirement of a tolerance was granted for the mCry3A protein and the genetic material necessary for its production in corn, under 40 CFR Part 174.456. This exemption expires on October 15, 2006. The present EUP amendment/extension application is accompanied by a **petition to extend the expiration date on the current mCry3A temporary tolerance exemption by one year, to October 15, 2007.**

In addition to the mCry3A PIP, MIR604 plants produce phosphomannose isomerase (PMI), a marker protein that is inert with respect to pesticidal activity. PMI, and the genetic material necessary for its production in all plants, is permanently exempt from the requirement of a tolerance, under 40 CFR Part 180.1252. The Cry1Ab PIP in Bt11 corn is permanently exempt from the requirement of a tolerance under 40 CFR Part 180.1173. The marker protein in Bt11 corn is phosphinothricin acetyltransferase (PAT), which is permanently exempt from the requirement of a tolerance under 40 CFR Part 180.1151.

Syngenta Seeds' application for FIFRA Section 3 registration of the mCry3A PIP in MIR604 corn is currently under Agency review (EPA File Symbol 67979-L). Also under review is Syngenta Seeds' Petition for a permanent exemption from the requirement of a tolerance for the mCry3A protein and the genetic material necessary for its production in all corn (Petition File Symbol PP 4F6838). These regulatory submissions, together with the EUP applications for the mCry3A PIP in MIR604 corn, are supported by an extensive data package that includes product characterization data and studies demonstrating the safety of mCry3A and MIR604 corn for humans, animals and the environment.

Expression of the mCry3A protein within MIR604 corn plants provides resistance to two important coleopteran corn pests, western corn rootworm (*Diabrotica virgifera virgifera*) and northern corn rootworm (*D. longicornis barberi*). The damage and yield loss attributed to rootworms result in an annual cost to U.S. growers exceeding one billion dollars. To date, MIR604 corn plants have shown excellent economic control of both western and northern corn rootworms, and evaluations of additional related pest species are underway. Bt11 field corn expressing a Cry1Ab PIP has been commercially grown in the US since 1997, and has provided growers with excellent control of European corn borer (*Ostrinia nubilalis*), as well as control or suppression of other important lepidopteran pests including southwestern corn borer (*Diatraea grandiosella*), corn earworm (*Helicoverpa zea*), fall armyworm (*Spodoptera frugiperda*), and southern cornstalk borer (*D. crambidoides*). Upon commercial approval, corn hybrids derived from Event MIR604 and the breeding stack of events MIR604 X Bt11 are expected to offer US growers highly effective and important new options in pest control. In particular, stacked MIR604 X Bt11 hybrids are expected to provide US growers with effective control of the most economically damaging insect pests of field corn, packaged in a single product. Growers will be able to minimize their use of conventional insecticide products to control these pests and will realize substantial benefits in yield, crop/grain quality, convenience, efficiency, and safety to workers and the environment.

The proposed amended/extended EUP program will require the planting of up to **4640 acres of MIR604 corn among a total of 29 states and Puerto Rico.** Of this acreage, 2066 acres represent plantings of MIR604 corn (not stacked with Bt11), 2259 acres represent plantings of stacked MIR604 X Bt11 corn, and 315 acres represent parent MIR604 inbreds planted for the purpose of producing MIR604 X Bt11 hybrid corn seed for future evaluations. Correspondingly, 315 additional acres of Bt11 parent inbred plantings will also be needed for the same purpose. Additionally, up to 14,332 associated corn acres will be planted to non-MIR604 genotypes that are part of an EUP protocol, including control/check plants and border rows.

The amended/extended EUP program will consist of five field trial protocols:

- Breeding and Observation
- Efficacy Evaluation
- Agronomic Observation
- Inbred and Hybrid Production
- Regulatory Studies

Complete details, including justification for the requested acreage, are provided in Section G of the accompanying application materials. Syngenta Seeds will submit a confidential list of the cooperators and test locations prior to planting of the approved trials.

Syngenta Seeds considers this letter and the accompanying administrative materials, listed in Attachment 1, as Category "A" documents. Accordingly, Syngenta Seeds makes no specific claims of confidentiality regarding this information. Under separate cover, I am sending you a CD-ROM containing a copy of the administrative materials volume in PDF format, to facilitate public access to this information.

My colleagues at Syngenta and I look forward to working with the Agency to achieve the regulatory approvals that will allow our current product development plans for MIR604 corn and MIR604 X Bt11 corn to proceed without delay. Please contact me if you have any questions regarding the proposed EUP program or the accompanying materials. Many thanks, in advance, for facilitating the timely review of this submission.

Sincerely,

Demetra Vlachos
Senior Manager, Regulatory Affairs
Syngenta Seeds, Inc.
Tel. (919) 541-8572; Fax: (919) 541-8535; demetra.vlachos@syngenta.com

Attachment: List of Accompanying Documents and Volumes in Submission

Enclosures: Petition for Extension of the Temporary Exemption from the Requirement of a Tolerance for Modified Cry3A *Bacillus thuringiensis* Insect Control Protein and the Genetic Material Necessary for its Production in All Corn (in duplicate)

Diskette Containing Notice of Filing of Petition for Temporary Tolerance Exemption (in electronic format)

cc: Dennis Szuhay, BPPD/OPP/EPA
Diana Felner, Syngenta America
Robert Joseph, Syngenta Seeds
John Steffens, Syngenta Seeds
Jeffrey Stein, Syngenta Seeds
Henry-York Steiner, Syngenta Seeds

## ATTACHMENT 1: LIST OF ACCOMPANYING DOCUMENTS AND VOLUMES IN SUBMISSION

**Name and Address of Submitter:** Syngenta Seeds, Inc. Field Crops – NAFTA
P. O. Box 12257, 3054 East Cornwallis Rd.
Research Triangle Park, NC 27709-2257

**Regulatory Action in Support of Which This Package is Submitted:**

Extension/amendment of Experimental Use Permit 67979-EUP-4 to allow the field testing of the following plant-incorporated protectants (PIPs): modified Cry3A *Bacillus thuringiensis* insect control protein as expressed in Event MIR604 field corn plants and a breeding stack of Event MIR604 corn with Event Bt11 field corn expressing a Cry1Ab *Bacillus thuringiensis* insect control protein

**Transmittal Date:** August 15, 2005

| Vol. No. | Category | Study Title/Contents | Guideline No. | MRID No. |
|---|---|---|---|---|
| N/A | A | Cover Letter/Transmittal Document | N/A | ADMIN |
| N/A | A | Attachment 1: List of Accompanying Documents and Volumes in Submission | N/A | |
| N/A | A | Enclosure (in duplicate): Petition for Extension of the Temporary Exemption from the Requirement of a Tolerance for Modified Cry3A *Bacillus thuringiensis* Insect Control Protein and the Genetic Material Necessary for its Production in All Corn | N/A | |
| N/A | A | Diskette Containing Notice of Filing of Petition for Temporary Tolerance Exemption (in electronic format) | N/A | |
| 1 | A | Administrative Materials<br>1. Cover Letter/Transmittal Document<br>2. Application for EUP to Ship and Use a Pesticide for Experimental Purposes Only (EPA Form 8570-17)<br>3. Statement of Formula (EPA Form 8570-4)<br>4. Sections A through G of EUP Request | N/A | ADMIN |

**EPA FORM 8570-17:**

**APPLICATION FOR EXPERIMENTAL USE PERMIT TO SHIP AND USE A PESTICIDE FOR EXPERIMENTAL PURPOSES ONLY**

☆ U.S. GOVERNMENT PRINTING OFFICE: 1999 – 452-584/25008

Form Approved. OMB No. 2070-0040.

EPA

United States
ENVIRONMENTAL PROTECTION AGENCY
Washington, DC 20460

OPP Identifier Number

Office of Pesticides Programs (7505C)

# Application for Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only

**1. Type of Application**

☐ New ☒ Amendment (See No. 2)

☒ Extension *(Give Permit Number below)*

**Permit Number** 67979-EUP-4

**2. Briefly explain (attach a separate sheet if necessary)**

Proposed PRIA fee category is "B86" for a PIP EUP Amendment, Food Use. The proposed EUP program will evaluate corn plants derived from Event MIR604, which produces a modified Cry3A protein for control of corn rootworm pests. 'Stacked' MIR604 X Bt11 corn plants will also be evaluated. The details of the program are explained in Section G of the accompanying EUP application. Plantings are proposed in 29 states & Puerto Rico during the period of March 15, 2006 - Feb. 28, 2007, with associated field and shipping activities continuing until no later than Oct. 15, 2007.

**3. Name and Address of Firm/Person to Whom the Experimental Use Permit is to be Issued (include Zip Code)** *(Type or Print)*

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

**4. Name and Address of Shipper only if shipment is intended or if different from applicant's name and address (include Zip Code)** *(Type or Print)*

Detailed information will be provided prior to the effective date of the permit.

**EPA Company Number** 67979

**5. Name of Product**

Event MIR604 Rootworm-Protected Corn
and
MIR604 X Bt11 Rootworm- and Corn Borer-Protected Corn

**6. Is Product Registered with EPA?**

☒ No

☐ Yes (Give Registration Number or File Symbol below)

Registration Number _____

File Symbol _____

**7. Total Quantity of Product Proposed for Shipment/Use**

Pounds of formulated product 92,800 lb seed

Pounds of active ingredient 0.26 lb. (=117 grams)

**8. Acreage or Area to be Treated**

4640 total acres of MIR604 corn or stacked MIR604 X Bt11 corn, plus 315 acres of associated Bt11 parent seed

**9. Proposed Period of Shipment/Use**

February 28, 2006 - October 15, 2007

**10. Places from which Shipped**

Shipments may occur to/from locations in AR, CA, CO, FL, HI, IA, IL, ID, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, NM, NE, ND, NY, OH, PA, SD, TN, TX, VA, WI and Puerto Rico

**11. Crop/Site to be Treated**

Field corn

**12. Specify the name and number of the contact person most familiar with this application.**

Demetra Vlachos tel. 919-541-8572

email: demetra.vlachos@syngenta.com

**13. Signature of Applicant or Authorized Firm Representative**

Demetra Vlachos

**14. Title**
Senior Manager, Regulatory Affairs

**15. Date Signed**
Aug. 15, 2005

## Certification

This is to certify that food or feed derived from the experimental program will not be used or offered for consumption or sale for consumption, except by laboratory or experimental animals, if illegal residues are present in or on such food or feed.

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment, or both, under applicable law.

**Below for EPA Use Only**

In any correspondence on this application, refer to this number

Normal review time indicates that processing of this application should be completed by (date)

Name of EPA Contact Person

Telephone Number

Received by:
EPA-OPP Registration Division,
Washington, DC 20460

EPA Form 8570-17 (Rev. 1-94) Previous Editions are Obsolete

**EPA FORM 8570-4**

**STATEMENT OF FORMULA**

*Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)*

Form Approved. OMB No. 2070-0060 Approval expires 5-31-98

**EPA** United States Environmental Protection Agency Washington, DC 20460

A. [✓] Basic Formulation [ ] Alternative Formulation

B. Page 1 of 2

See Instructions on Back

## Office of Pesticide Programs (7505C) - Confidential Statement of Formula

**1. Name and Address of Applicant/Registrant** *(Include ZIP Code)*

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

**2. Name and Address of Producer** *(Include ZIP Code)*

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

**3. Product Name**

Event MIR604 Rootworm-Protected Corn

**4. Registration No./File Symbol**
67979-EUP-4

**5. EPA Product Mgr/Team No.**
Mike Mendelsohn/BPPD

**6. Country Where Formulated**
USA

**7. Pounds/Gal or Bulk Density**
N/A

**8. pH**
N/A

**9. Flash Point/Flame Extension**
N/A

| EPA USE ONLY | 10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)* | 11. Supplier Name & Address | 12. EPA Reg. No. | 13. Each Component in Formulation a. Amount | 13. b. % by Weight | 14. Certified Limits % by Weight a. Upper Limit | 14. b. Lower Limit | 15. Purpose in Formulation |
|---|---|---|---|---|---|---|---|---|
| | Modified Cry3A Bacillus thuringiensis protein & the genetic material necessary for its production (via elements of pZM26) in Event MIR604 corn (SYN-IR604-5) | Syngenta Seeds, Inc.<br>P. O. Box 12257, 3054 Cornwallis Rd.<br>Research Triangle Park, NC 27709-2257 | N/A | 5 - 26 ug/g leaf* | 5-26E-4 | 0.013 | 0.0001 | Active ingredient |
| | same as above | same as above | N/A | 7 - 26 ug/g root* | 7-26E-4 | 0.013 | 0.0001 | Active ingredient |
| | same as above | same as above | N/A | 0.8 - 2 ug/g seed* | 8-20E-5 | 0.001 | 0.00002 | Active ingredient |
| | same as above | same as above | N/A | 0 ug/g pollen** | N/A | N/A | N/A | Active ingredient |
| | same as above | same as above | N/A | 7 - 24 ug/g plant* | 7-24E-4 | 0.012 | 0.0001 | Active ingredient |
| | (CONTINUED) | (CONTINUED) | | | | | | |
| | *Range of avg. ELISA values for modified Cry3A/g dry wt. tissue of hybrid plants sampled across a growing season (or when tissue is present). | | | | | | | |
| | ** No modified Cry3A detected in pollen. | | | | | | | |

**16. Typed Name of Approving Official** Demetra Vlachos

**17. Total Weight** 100%

**18. Signature of Approving Official** Demetra Vlachos

**19. Title** Senior Manager, Regulatory Affairs

**20. Phone No.** (Include Area Code) 919-541-8572

**21. Date** 3/11/05

EPA Form 8570-4 (Rev. 8-94)

White - EPA File Copy (original) Pink - Applicant

*Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)*

Form Approved. OMB No. 2070-0060 Approval expires 5-31-98

**EPA** United States Environmental Protection Agency Washington, DC 20460

A. ☑ Basic Formulation ☐ Alternative Formulation

B. Page 2 of 2

See Instructions on Back

## Office of Pesticide Programs (7505C) - Confidential Statement of Formula

| 1. Name and Address of Applicant/Registrant *(Include ZIP Code)* | 2. Name and Address of Producer *(Include ZIP Code)* |
|---|---|
| Syngenta Seeds, Inc. - Field Crops - NAFTA<br>P. O. Box 12257, 3054 East Cornwallis Rd.<br>Research Triangle Park, NC 27709-2257 | Syngenta Seeds, Inc. - Field Crops - NAFTA<br>P. O. Box 12257, 3054 East Cornwallis Rd.<br>Research Triangle Park, NC 27709-2257 |

| 3. Product Name | 4. Registration No./File Symbol | 5. EPA Product Mgr/Team No. | 6. Country Where Formulated |
|---|---|---|---|
| Event MIR604 Rootworm-Protected Corn | 67979-EUP-4 | Mike Mendelsohn/BPPD | USA |
| | 7. Pounds/Gal or Bulk Density: N/A | 8. pH: N/A | 9. Flash Point/Flame Extension: N/A |

| EPA USE ONLY | 10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)* | 11. Supplier Name & Address | 12. EPA Reg. No. | 13. Each Component in Formulation a. Amount | 13. b. % by Weight | 14. Certified Limits % by Weight a. Upper Limit | 14. b. Lower Limit | 15. Purpose in Formulation |
|---|---|---|---|---|---|---|---|---|
| | (CONTINUED FR. PAGE 1) | | | | | | | |
| | Phosphomannose isomerase, a marker protein, & the genetic material necessary for its production (via elements of pZM26) in Event MIR604 corn (SYN-IR6Ø4-5) | Syngenta Seeds, Inc.<br>P. O. Box 12257, 3054 East Cornwallis Rd.<br>Research Triangle Park, NC 27709-2257 | N/A | <0.1 - 2 ug/g leaf* | <1-20E-5 | 0.001 | ND** | Marker gene product |
| | same as above | same as above | N/A | <0.2 - 1 ug/g root* | <2-10E-5 | 0.0005 | ND | Marker gene product |
| | same as above | same as above | N/A | <0.1-.5 ug/g seed* | <1-5E-5 | 0.00025 | ND | Marker gene product |
| | same as above | same as above | N/A | 4 - 5 ug/g pollen* | 4 - 5E-4 | 0.0025 | 0.00008 | Marker gene product |
| | same as above | same as above | N/A | <0.1-2 ug/g plant* | <1-20E-5 | 0.001 | ND | Marker gene product |
| | *Range of avg. ELISA values for phosphomannose isomerase/g dry wt. tissue of hybrid plants sampled across a growing season (or when tissue is present). | | | | | | | |
| | **Not Detectable | | | | | | | |

16. Typed Name of Approving Official: Demetra Vlachos

17. Total Weight: 100%

18. Signature of Approving Official: Demetra Vlachos

19. Title: Senior Manager, Regulatory Affairs

20. Phone No. (Include Area Code): 919-541-8572

21. Date: 3/11/05

EPA Form 8570-4 (Rev. 8-94)

White - EPA File Copy (original) Pink - Applicant

*Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)*

Form Approved. OMB No. 2070-0060 Approval expires 5-31-98

**EPA** United States Environmental Protection Agency Washington, DC 20460

A. ☑ Basic Formulation ☐ Alternative Formulation

B. Page 1 of 3

See Instructions on Back

## Office of Pesticide Programs (7505C) - Confidential Statement of Formula

**1. Name and Address of Applicant/Registrant** *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops - NAFTA
P. O. Box 12257, 3054 East Cornwallis Rd.
Research Triangle Park, NC 27709-2257

**2. Name and Address of Producer** *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops - NAFTA
P. O. Box 12257, 3054 East Cornwallis Rd.
Research Triangle Park, NC 27709-2257

**3. Product Name**
MIR604 X Bt11 Rootworm- and Corn Borer-Protected Corn

**4. Registration No./File Symbol**
67979-EUP-4

**5. EPA Product Mgr/Team No.**
Mike Mendelsohn/BPPD

**6. Country Where Formulated**
USA

**7. Pounds/Gal or Bulk Density**
N/A

**8. pH**
N/A

**9. Flash Point/Flame Extension**
N/A

| EPA USE ONLY | 10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)* | 11. Supplier Name & Address | 12. EPA Reg. No. | 13. Each Component in Formulation a. Amount | 13. b. % by Weight | 14. Certified Limits % by Weight a. Upper Limit | 14. b. Lower Limit | 15. Purpose in Formulation |
|---|---|---|---|---|---|---|---|---|
| | Modified Cry3A Bacillus thuringiensis protein & the genetic material necessary for its production (via elements of pZM26) in Event MIR604 corn (SYN-IR6Ø4-5) | Syngenta Seeds, Inc. P. O. Box 12257, 3054 East Cornwallis Rd. Research Triangle Park, NC 27709-2257 | N/A | 5 - 26 ug/g leaf* | 5-26E-4 | 0.013 | 0.0001 | Active ingredient |
| | same as above | same as above | N/A | 7 - 26 ug/g root* | 7-26E-4 | 0.013 | 0.0001 | Active ingredient |
| | same as above | same as above | N/A | 0.8 - 2 ug/g seed* | 8-20E-5 | 0.001 | 0.00002 | Active ingredient |
| | same as above | same as above | N/A | 0 ug/g pollen** | N/A | N/A | N/A | Active ingredient |
| | same as above | same as above | N/A | 7 - 24 ug/g plant* | 7-24E-4 | 0.012 | 0.0001 | Active ingredient |
| | (CONTINUED) | (CONTINUED) | | | | | | |
| | *Range of avg. ELISA values for modified Cry3A/g dry wt. tissue of hybrid plants sampled across a growing season (or when tissue is present). | | | | | | | |
| | ** No modified Cry3A detected in pollen. | | | | | | | |

**16. Typed Name of Approving Official** Demetra Vlachos

**17. Total Weight** 100%

**18. Signature of Approving Official** Demetra Vlachos

**19. Title** Senior Manager, Regulatory Affairs

**20. Phone No. (Include Area Code)** 919-541-8572

**21. Date** 8/15/05

**EPA Form 8570-4 (Rev. 8-94)** White - EPA File Copy (original) Pink - Applicant

★ U.S. GPO: 1995-386-820/20414

*Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)*

Form Approved. OMB No. 2070-0060 Approval expires 5-31-98

EPA United States Environmental Protection Agency Washington, DC 20460

A. ☑ Basic Formulation ☐ Alternative Formulation

B. Page 2 of 3

See Instructions on Back

**Office of Pesticide Programs (7505C) - Confidential Statement of Formula**

**1. Name and Address of Applicant/Registrant** *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops - NAFTA
P. O. Box 12257, 3054 East Cornwallis Rd.
Research Triangle Park, NC 27709-2257

**2. Name and Address of Producer** *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops - NAFTA
P. O. Box 12257, 3054 East Cornwallis Rd.
Research Triangle Park, NC 27709-2257

**3. Product Name**
MIR604 X Bt11 Rootworm- and Corn Borer-Protected Corn

**4. Registration No./File Symbol**
67979-EUP-4

**5. EPA Product Mgr/Team No.**
Mike Mendelsohn/BPPD

**6. Country Where Formulated**
USA

**7. Pounds/Gal or Bulk Density**
N/A

**8. pH**
N/A

**9. Flash Point/Flame Extension**
N/A

| EPA USE ONLY | 10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)* | 11. Supplier Name & Address | 12. EPA Reg. No. | 13. Each Component in Formulation a. Amount | 13. b. % by Weight | 14. Certified Limits % by Weight a. Upper Limit | 14. b. Lower Limit | 15. Purpose in Formulation |
|---|---|---|---|---|---|---|---|---|
| | (CONTINUED FR. PAGE 1) | | | | | | | |
| | Phosphomannose isomerase, a marker protein, & the genetic material necessary for its production (via elements of pZM26) in Event MIR604 corn (SYN-IR6Ø4-5) | Syngenta Seeds, Inc. P. O. Box 12257, 3054 East Cornwallis Rd. Research Triangle Park, NC 27709-2257 | N/A | <0.1 - 2 ug/g leaf* | 1-20E-5 | 0.001 | ND** | Marker gene product |
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| | same as above | same as above | N/A | <0.1-.5 ug/g seed* | <1-5E-5 | 0.00025 | ND | Marker gene product |
| | same as above | same as above | N/A | 4 - 5 ug/g pollen* | 4 - 5E-4 | 0.0025 | 0.00008 | Marker gene product |
| | same as above | same as above | N/A | <0.1-2 ug/g plant* | 1-20E-5 | 0.001 | ND | Marker gene product |
| | *Range of avg. ELISA values for phosphomannose isomerase/g dry wt. tissue of hybrid plants sampled across a growing season (or when tissue is present). | | | | | | | |
| | **Not Detectable | | | | | | | |

**16. Typed Name of Approving Official** Demetra Vlachos

**17. Total Weight** 100%

**18. Signature of Approving Official** Demetra Vlachos

**19. Title** Senior Manager, Regulatory Affairs

**20. Phone No. (Include Area Code)** 919-541-8572

**21. Date** 8/15/05

**EPA Form 8570-4 (Rev. 8-94)** White - EPA File Copy (original) Pink - Applicant

★ U.S. GPO: 1995-386-820/20414

*Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)*

Form Approved. OMB No. 2070-0060 Approval expires 5-31-98

United States Environmental Protection Agency
Washington, DC 20460

A. [✓] Basic Formulation [ ] Alternative Formulation

B. Page 3 of 3

See Instructions on Back

**Office of Pesticide Programs (7505C) - Confidential Statement of Formula**

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops - NAFTA
P. O. Box 12257, 3054 East Cornwallis Rd.
Research Triangle Park, NC 27709-2257

2. Name and Address of Producer *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops - NAFTA
P. O. Box 12257, 3054 East Cornwallis Rd.
Research Triangle Park, NC 27709-2257

3. Product Name
MIR604 X Bt11 Rootworm- and Corn Borer-Protected Corn

4. Registration No./File Symbol
67979-EUP-4

5. EPA Product Mgr/Team No.
Mike Mendelsohn/BPPD

6. Country Where Formulated
USA

7. Pounds/Gal or Bulk Density
N/A

8. pH
N/A

9. Flash Point/Flame Extension
N/A

| EPA USE ONLY | 10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)* | 11. Supplier Name & Address | 12. EPA Reg. No. | 13. Each Component in Formulation a. Amount | 13. b. % by Weight | 14. Certified Limits % by Weight a. Upper Limit | 14. b. Lower Limit | 15. Purpose in Formulation |
|---|---|---|---|---|---|---|---|---|
| | Bacillus thuringiensis Cry1Ab delta-endotoxin and the genetic material (as contained in pZO1502) necessary for its production in Bt11 corn (SYN-BTØ11-1) | Syngenta Seeds, Inc. P. O. Box 12257, 3054 East Cornwallis Rd. Research Triangle Park, NC 27709-2257 | 67979-1 | 14 - 131 ug/g leaf* | 1-13E-3 | 0.066 | 0.0003 | Active ingredient |
| | same as above | same as above | 67979-1 | 10 - 19 ug/g root* | 1-2 E-3 | 0.010 | 0.0002 | Active ingredient |
| | same as above | same as above | 67979-1 | 1.8 - 2 ug/g seed* | ~2E-5 | 0.001 | 0.00004 | Active ingredient |
| | same as above | same as above | 67979-1 | <0.15 ug/g pollen | <15E-6 | 0.00008 | 0.00001 | Active ingredient |
| | same as above | same as above | 67979-1 | 7 - 68 ug/g plant | 7-68E-4 | 0.034 | 0.0001 | Active ingredient |
| | Phosphinothricin acetyltransferase marker protein and the genetic material (as contained in pZO1502) necessary for its production in Bt11 corn (SYN-BTØ11-1) | same as above | N/A | <0.001ug/g seed** | <1 E-7 | 0.00000 | 0.00000 | Marker gene product |
| | *Range of avg. ELISA values for Cry1Ab/g dry wt. tissue of hybrid plants sampled across a growing season (or when tissue is present). | | | | | | | |
| | **Trace quantities of phosphinothricin acetyltransferase are present in other plant tissues. | | | | | | | |

16. Typed Name of Approving Official: Demetra Vlachos

17. Total Weight: 100%

18. Signature of Approving Official: Demetra Vlachos

19. Title: Senior Manager, Regulatory Affairs

20. Phone No. (Include Area Code): 919-541-8572

21. Date: 8/15/05

EPA Form 8570-4 (Rev. 8-94)

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★ U.S. GPO: 1995-386-820/20414

**SECTIONS A - G OF EUP REQUEST**

**SECTION A**

**PRODUCT CHEMISTRY**

## SECTION A

## PRODUCT CHEMISTRY

Event MIR604-derived corn plants express the plant-incorporated protectant (PIP) active ingredient modified Cry3A (mCry3A) *Bacillus thuringiensis* insect control protein and the genetic material necessary for its production. Evaluations of MIR604 field corn are currently in progress under EUP permit 67979-EUP-4, which became effective on March 23, 2005. The present application seeks approval to amend and extend the activities under the present EUP for the 2006 growing season. Additionally, 'stacks' resulting from breeding crosses between Event MIR604 field corn and Event Bt11 field corn (MIR604 X Bt11) will also be tested under the amended/extended EUP program. Event Bt11 plants express a Cry1Ab PIP that has been registered for use in field corn since 1996 under EPA Reg. No. 67979-1. Syngenta Seeds has applied for Section 3 commercial registration of the PIP active ingredient in MIR604 corn; this application (EPA File Symbol 67979-L) is currently pending.

The combination of MIR604 and Bt11 traits in MIR604 X Bt11 plants was achieved entirely *via* conventional breeding, *i.e.*, no retransformation was required. MIR604 X Bt11 plants produce both the mCry3A protein for control of key coleopteran pests and Cry1Ab protein for control of key lepidopteran pests.

Detailed information regarding the product chemistry of the mCry3A PIP active ingredient in Event MIR604 corn plants is contained in the previously submitted data volumes listed below.

| STUDY TITLE | MRID NO. |
|---|---|
| Characterization and Safety of Modified Cry3A *Bacillus thuringiensis* Protein and Maize (Corn) Plants Derived from Event MIR604 | 46155601 |
| Molecular Characterization of Event MIR604 Maize (Corn) Expressing a Modified Cry3A *Bacillus thuringiensis* Protein | 46155602 |
| Full-Text of Selected Literature References Describing Methods Cited in MRID No. 46155602, 'Molecular Characterization of Event MIR604 Maize (Corn) Expressing a Modified Cry3A *Bacillus thuringiensis* Protein' | 46466702 |
| Responses to Questions Raised During EPA Review of Data Submitted in Support of Pending Experimental Use Permit and Temporary Tolerance Exemption for Modified Cry3A Protein as Expressed in Event MIR604 Maize (Corn)(67979-EUP-4; Petition File Symbol 4G6808); Supplements to MRID Nos. 46155602, 46155603, 46155604, 46155605, 46155606, 46155607, 46155609 & 46425202 | 46466701 |

Event MIR604 plants also express the selectable marker phosphomannose isomerase (PMI), which is inert with regard to pesticidal activity. Detailed information regarding the characteristics of PMI is contained in the data volumes listed above, and in the additional data volume listed below.

| STUDY TITLE | MRID NO. |
|---|---|
| Characterization and Safety of Phosphomannose Isomerase (PMI), a Selectable Marker Expressed in Event 3243M-Derived Maize (Corn) Plants. | 45934402 |

Product characterization data describing Event Bt11 plants, including descriptions of the Cry1Ab PIP, the phosphinothricin acetyltransferase (PAT) marker protein, and the genetic material necessary for production of these proteins in Event Bt11 plants, are contained in data volumes previously reviewed by the Agency in support of the current registration of the Cry1Ab PIP in Bt11 corn. The reviews of these data are summarized in the Agency's Biopesticides Registration Action Document dated Oct. 15, 2001 (http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad2/2-id_health.pdf.)

**SECTION B**

**PROPOSED LABELING**

**PROPOSED**
**MASTER LABEL**

**67979-EUP-4**

## Subparts:

1. Event MIR604 Corn Seed
2. Stacked Event MIR604 X Event Bt11 (MIR604 X Bt11) Corn Seed
3. Event Bt11 Corn Seed

# Modified Cry3A Protein for Corn Rootworm Control:

# Event MIR604 Corn Seed

## EPA EXPERIMENTAL USE PERMIT NUMBER: 67979-EUP-4

This package contains seed for transgenic insect-resistant corn that produces a modified Cry3A protein with activity against some rootworm pests. The seed is derived from Event MIR604, which contains the gene encoding the insecticidal protein *via* elements of plasmid vector pZM26.

## For Experimental Use Only

**For use only at an application site of a Cooperator and in accordance with the terms and conditions of the Experimental Use Permit (EUP). This labeling must be in the possession of the user at the time the corn seed is planted. Not for sale to any person other than a Participant or Cooperator of the EPA-approved Experimental Use Program.**

**Active Ingredient:**

Modified Cry3A *Bacillus thuringiensis* protein and the genetic material necessary for its production (*via* elements of pZM26) in Event MIR604 corn (SYN-IR6Ø4-5): …..…….……. ≤ 0.001%*

**Inert Ingredient:**

A marker protein and the genetic material necessary for its production (*via* elements of pZM26) in Event MIR604 corn (SYN-IR6Ø4-5): ……..... ≤ 0.0003%*

*Percent dry weight of seed

EPA ESTABLISHMENT NUMBER 66736-NC-01

NET CONTENTS: _____ pounds of corn seed

Syngenta Seeds, Inc.
P. O. Box 12257
3054 East Cornwallis Rd.
Research Triangle Park, NC 27709

### DIRECTIONS FOR USE

Use of this seed in a manner inconsistent with the terms of the Experimental Use Permit (EUP) is a violation of Federal law. This seed containing a modified Cry3A protein pesticide (plant-incorporated protectant) may only be used according to the field protocols as specified in the approved EUP program. Cooperators must have a copy of each applicable protocol prior to initiating any research with these seeds.

### STORAGE AND DISPOSAL

**Storage:** Store in a cool dry place inaccessible to children. Do not contaminate water, food, or feed by storage or disposal.

**Pesticide disposal:** Any seed not used in these experiments must be returned to the seed provider or disposed of as specified in the field protocols.

**Container disposal:** Do not reuse bag. Insure that the bag is completely empty of seeds before destroying.

# Modified Cry3A Protein for Corn Rootworm Control and Cry1Ab Protein for European Corn Borer Control:

# Stacked Event MIR604 X Event Bt11 (MIR604 X Bt11) Corn Seed

## EPA EXPERIMENTAL USE PERMIT NUMBER: 67979-EUP-4

This package contains seed for transgenic insect-resistant corn that produces a modified Cry3A protein with activity against some rootworm pests and a Cry1Ab protein with activity against some lepidopteran pests. The seed is derived by a breeding stack of Event MIR604 (which contains the gene encoding the modified Cry3A protein *via* elements of plasmid vector pZM26) and Event Bt11 (which contains the gene encoding the Cry1Ab protein *via* elements of plasmid vector pZO1502).

## For Experimental Use Only

**For use only at an application site of a Cooperator and in accordance with the terms and conditions of the Experimental Use Permit (EUP). This labeling must be in the possession of the user at the time the corn seed is planted. Not for sale to any person other than a Participant or Cooperator of the EPA-approved Experimental Use Program.**

**Active Ingredients:**

Modified Cry3A *Bacillus thuringiensis* protein and the genetic material necessary for its production (*via* elements of pZM26) in MIR604 X Bt11 corn (SYN-IR6Ø4-5; SYN-BTØ11-1): ..…..…..…….. ≤ 0.001%*

*Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material (as contained in plasmid vector pZO1502) necessary for its production in MIR604 X Bt11 corn (SYN-IR6Ø4-5; SYN-BTØ11-1): …… 0.0002 - 0.0006%*

**Inert Ingredients:**

A marker protein and the genetic material necessary for its production (*via* elements of pZM26) in MIR604 X Bt11 corn (SYN-IR6Ø4-5; SYN-BTØ11-1): …..……..……..…..…… ≤ 0.0003%*

A marker protein and the genetic material necessary for its production (*via* elements of pZO1502) in MIR604 X Bt11 corn (SYN-IR6Ø4-5; SYN-BTØ11-1): ……..……..……..…….. .≤ 0.0000001%*

*Percent dry weight of seed

EPA ESTABLISHMENT NUMBER 66736-NC-01

NET CONTENTS: _____ pounds of corn seed

Syngenta Seeds, Inc.
P. O. Box 12257
3054 East Cornwallis Rd.
Research Triangle Park, NC 27709

### DIRECTIONS FOR USE

Use of this seed in a manner inconsistent with the terms of the Experimental Use Permit (EUP) is a violation of Federal law. This seed containing a modified Cry3A and Cry1Ab protein pesticides (plant-incorporated protectants) may only be used according to the field protocols as specified in the approved EUP program. Cooperators must have a copy of each applicable protocol prior to initiating any research with these seeds.

### STORAGE AND DISPOSAL

**Storage:** Store in a cool dry place inaccessible to children. Do not contaminate water, food, or feed by storage or disposal.

**Pesticide disposal:** Any seed not used in these experiments must be returned to the seed provider or disposed of as specified in the field protocols.

**Container disposal:** Do not reuse bag. Insure that the bag is completely empty of seeds before destroying.

# Cry1Ab Protein for European Corn Borer Control:

# Event Bt11 Corn Seed

## EPA EXPERIMENTAL USE PERMIT NUMBER: 67979-EUP-4

This package contains seed for transgenic insect-resistant corn that produces a Cry1Ab protein with activity against some lepidopteran pests.

## For Experimental Use Only

**For use only at an application site of a Cooperator and in accordance with the terms and conditions of the Experimental Use Permit (EUP). This labeling must be in the possession of the user at the time the corn seed is planted. Not for sale to any person other than a Participant or Cooperator of the EPA-approved Experimental Use Program.**

**Active Ingredient:**

*Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material (as contained in plasmid vector pZO1502) necessary for its production in Bt11 corn (SYN-BTØ11-1): ……..…….…… 0.0002 - 0.0006%*

**Inert Ingredient:**

A marker protein and the genetic material necessary for its production (*via* elements of pZO1502) in Bt11 corn (SYN-BTØ11-1): ……..……..…….... ≤ 0.0000001%*

*Percent dry weight of seed

EPA ESTABLISHMENT NUMBER 66736-NC-01

NET CONTENTS: _____ pounds of corn seed

Syngenta Seeds, Inc.
P. O. Box 12257
3054 East Cornwallis Rd.
Research Triangle Park, NC 27709

### DIRECTIONS FOR USE

Use of this seed in a manner inconsistent with the terms of the Experimental Use Permit (EUP) is a violation of Federal law. This seed containing modified Cry3A and Cry1Ab protein pesticides (plant-incorporated protectants) may only be used according to the field protocols as specified in the approved EUP program. Cooperators must have a copy of each applicable protocol prior to initiating any research with these seeds.

### STORAGE AND DISPOSAL

**Storage:** Store in a cool dry place inaccessible to children. Do not contaminate water, food, or feed by storage or disposal.

**Pesticide disposal:** Any seed not used in these experiments must be returned to the seed provider or disposed of as specified in the field protocols.

**Container disposal:** Do not reuse bag. Insure that the bag is completely empty of seeds before destroying.

# SECTION C

# TOXICOLOGY DATA

# SECTION C

# TOXICOLOGY DATA

## TOXICITY TO MAMMALS

### Modified Cry3A and PMI Proteins Expressed in MIR604 Corn

Detailed information regarding the mammalian safety of the modified Cry3A *Bacillus thuringiensis* insect control protein is contained in the data volumes listed below.

| STUDY TITLE | MRID NO. |
|---|---|
| Characterization and Safety of Modified Cry3A *Bacillus thuringiensis* Insect Control Protein and Maize (Corn) Plants Derived from Event MIR604 | 46155601 |
| Characterization of Modified Cry3A Protein Produced in Event MIR604-Derived Maize (Corn) and Comparison with Modified Cry3A Protein Expressed in Recombinant *Escherichia coli* | 46155603 |
| Characterization of Modified Cry3A Test Substance MCRY3A-0102 and Certificate of Analysis | 46155605 |
| Further Characterization of Modified Cry3A Test Substance MCRY3A-0102 | 46155606 |
| *In vitro* Digestibility of Modified Cry3A Protein (MCRY3A-0102 and IAPMIR604-0103) Under Simulated Gastric Conditions | 46155607 |
| Effect of Temperature on the Stability of Modified Cry3A Protein (MCRY3A-0102) | 46155608 |
| Analysis for the Presence of Modified Cry3A Protein in Wet and Dry Milled Fractions, Corn Oil and Corn Chips from Corn (Maize) Event MIR604 | 46155609 |
| Acute Oral Toxicity Study of Modified Cry3A Protein (MCRY3A-0102) in the Mouse | 46155610 |
| Modified Cry3A *Bacillus thuringiensis* Protein as Expressed in Transgenic Maize Event MIR604: Assessment of Amino Acid Homology with Known Toxins | 46155613 |
| Modified Cry3A *Bacillus thuringiensis* Protein as Expressed in Transgenic Maize Event MIR604: Assessment of Amino Acid Homology with Known Allergens | 46155612 |
| Responses to Questions Raised During EPA Review of Data Submitted in Support of Pending Experimental Use Permit and Temporary Tolerance Exemption for Modified Cry3A Protein as Expressed in Event MIR604 Maize (Corn)(67979-EUP-4; Petition File Symbol 4G6808); Supplements to MRID Nos. 46155602, 46155603, 46155604, 46155605, 46155606, 46155607, 46155609 & 46425202 | 46466701 |

Detailed information regarding the mammalian safety of the 'inert' PMI (phosphomannose isomerase) marker protein is contained in the data volumes listed below. PMI, together with the genetic material necessary for its production, accompanies the mCry3A PIP active ingredient in Event MIR604 corn.

| STUDY TITLE | MRID NO. |
|---|---|
| Characterization and Safety of Phosphomannose Isomerase (PMI), a Selectable Marker Expressed in Event 3243M-Derived Maize (Corn) Plants | 45934402 |
| Phosphomannose Isomerase (Sample PMI-0198): Acute Oral Toxicity Study in Mice | 45934407 |
| *In vitro* Digestibility of PMI Protein Under Simulated Mammalian Gastric and Intestinal Conditions | 45934408 |
| Effects of Temperature on the Stability of Phosphomannose Isomerase | 45934409 |
| Phosphomannose Isomerase Protein as Expressed in Transgenic Maize Event MIR604: Assessment of Amino Acid Homology with Known Toxins | 45934405 |
| Descriptions of Phosphomannose Isomerase Protein Homologues Identified in Syngenta Seeds Biotechnology Report No. SSB-016-03. Supplement to Final Report, EPA MRID No. 45934405, titled 'Phosphomannose Isomerase Protein as Expressed in Transgenic Maize Event MIR604: Assessment of Amino Acid Homology with Known Toxins' | 46205201 |
| Phosphomannose Isomerase Protein as Expressed in Transgenic Maize Event MIR604: Assessment of Amino Acid Homology with Known Allergens | 46425202 |
| Responses to Questions Raised During EPA Review of Data Submitted in Support of Pending Experimental Use Permit and Temporary Tolerance Exemption for Modified Cry3A Protein as Expressed in Event MIR604 Maize (Corn)(67979-EUP-4; Petition File Symbol 4G6808); Supplements to MRID Nos. 46155602, 46155603, 46155604, 46155605, 46155606, 46155607, 46155609 & 46425202 | 46466701 |

**Cry1Ab Protein and PAT Proteins Expressed in Bt11 Corn**

Data supporting the mammalian safety of the Cry1Ab and PAT proteins expressed in Bt11 corn are contained in data volumes previously reviewed by the Agency in support of the current Bt11 field corn registration (EPA Reg. No. 67979-1). The reviews of these data are summarized in the Oct. 15, 2001 EPA Biopesticides Registration Action Document (http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad2/2-id_health.pdf).

Subsequent to the 2001 re-registration of the Cry1Ab PIP active ingredient in Bt11 corn, the following studies relevant to the mammalian safety of this PIP were additionally submitted by Syngenta Seeds.

| STUDY TITLE | MRID NO. |
|---|---|
| Cry1Ab Protein as Expressed in Transgenic Maize Event Bt11: Assessment of Amino Acid Homology with Known Toxins | 45879801 |
| Cry1Ab Protein as Expressed in Transgenic Maize Event Bt11: Assessment of Amino Acid Homology with Known Allergens | 45879802 |

## SECTION C (CONT'D)

## TOXICITY TO NON-TARGET ORGANISMS

### Modified Cry3A Protein Expressed in MIR604 Corn

Data and information supporting the lack of toxicity of the modified Cry3A (mCry3A) protein to non-target organisms, including wildlife and beneficial invertebrates, are provided in the following previously submitted study volumes. Lack of exposure to endangered Coleoptera is described in MRID Nos. 46155615 and 46265601, listed below.

| STUDY TITLE | MRID NO. |
|---|---|
| Summary of Data Demonstrating the Environmental Safety of Modified Cry3A *Bacillus thuringiensis* Insect Control Protein and Event MIR604-Derived Corn (Maize) to Non-Target Organisms<br>[This data summary and assessment has been superseded by the data summary and assessment that follows below.] | 46155615 |
| Environmental Safety Assessment of Modified Cry3A Protein and Event MIR604 Corn to Non-Target Organisms | 46265601 |
| An Acute Oral Toxicity Study of Modified Cry3A Protein (MCRY3A-0102) in the Northern Bobwhite | 46155616 |
| Evaluation of Transgenic Corn (Maize) MIR604 in Broiler Chickens | 46265615 |
| A 28-Day Laboratory Study to Evaluate the Effects of Modified Cry3A Maize Fish Feed (FFMIR604-0103) on the Growth of Juvenile Rainbow Trout (*Oncorhynchus mykiss*) | 46155617 |
| Characterization of Fish Feed Test Substance (FFMIR604-0103) Prepared from Event MIR604-Derived Maize Grain: Supplement to Final Report – US EPA MRID No. 46155617 – Titled: 'A 28-Day Laboratory Study to Evaluate the Effects of Modified Cry3A Maize Fish Feed (FFMIR604-0103) on the Growth of Juvenile Rainbow Trout (*Oncorhynchus mykiss*)' | 46265602 |
| A semi-field test to evaluate the effects of the modified Cry3A protein (MCRY3A-0102) on brood development of the honeybee, *Apis mellifera* (Hymenoptera: Apidae) | 46155618 |
| A Laboratory Test of the Toxicity of Modified Cry3A Protein (MCRY3A-0102) to Larvae and Adults of the Ladybird Beetle, *Coccinella septempunctata* (Coleoptera: Coccinellidae) | 46265603 |
| Analysis of Test Diet Used to Expose *Coccinella septempunctata* to Modified Cry3A Protein: Supplement to Report Titled "A Laboratory Test of the Toxicity of Modified Cry3A Protein (MCRY3A-0102) to Larvae and Adults of the Ladybird Beetle, *Coccinella septempunctata* (Coleoptera: Coccinellidae)" | 46265604 |

| | |
|---|---|
| A Laboratory Toxicity Test of the Modified Cry3A Protein (MCRY3A-0102) to Larvae of the Ground-Dwelling Beetle, *Poecilus cupreus* (Coleoptera: Carabidae) | 46265605 |
| Analysis of Test Diet Used to Expose *Poecilus cupreus* To Modified Cry3A Protein: Supplement to Report Titled "A Laboratory Toxicity Test of the Modified Cry3A Protein (MCRY3A-0102) to Larvae of the Ground-Dwelling Beetle, *Poecilus cupreus* (Coleoptera: Carabidae)" | 46265606 |
| A Laboratory Toxicity Test of Modified Cry3A Protein (MCRY3A-0102) to the Rove Beetle, *Aleochara bilineata* (Coleoptera: Staphylinidae) | 46265607 |
| Analysis of Test Diet Used to Expose *Aleochara bilineata* to Modified Cry3A Protein: Supplement to Report Titled "A Laboratory Toxicity Test of Modified Cry3A Protein (MCRY3A-0102) to the Rove Beetle, *Aleochara bilineata* (Coleoptera: Staphylinidae)" | 46265608 |
| A Laboratory Toxicity Test of Modified Cry3A Protein (MCRY3A-0102) to the Predatory Bug, *Orius insidiosus* (Heteroptera: Anthocoridae) | 46265609 |
| Analysis of Test Diet Used to Expose *Orius insidiosus* to Modified Cry3A Protein: Supplement to Report Titled "A Laboratory Toxicity Test of Modified Cry3A Protein (MCRY3A-0102) to the Predatory Bug, *Orius insidiosus* (Heteroptera: Anthocoridae)" | 46265610 |
| Determination of Acute Toxicity of Modified Cry3A Protein (MCRY3A-0102) to the Earthworm *Eisenia fetida* in an Artificial Soil Substrate | 46265611 |
| Analysis of Artificial Soil Used to Expose *Eisenia fetida* to Modified Cry3A Protein: Supplement to Report Titled "Determination of Acute Toxicity of Modified Cry3A Protein (MCRY3A-0102) to the Earthworm *Eisenia fetida* in an Artificial Soil Substrate" | 46265612 |
| Modified Cry3A Protein as Expressed in Event MIR604 Corn (Maize): Request to Waive Freshwater Aquatic Invertebrate Testing, Tier I | Not Applicable |

**Cry1Ab Protein Expressed in Bt11 Corn**

Data and information supporting the lack of toxicity of the Cry1Ab protein in Bt11 corn to non-target organisms, including wildlife and beneficial invertebrates, are contained in data volumes previously reviewed by the Agency in support of the current Bt11 field corn registration (EPA Reg. No. 67979-1). The reviews of these data are summarized in the Agency's Biopesticides Registration Action Document (BRAD) (http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad2/3-ecological.pdf.) dated Oct. 15, 2001. The BRAD also summarizes information supporting the conclusions that: (1) monarch butterfly (*Danaus plexippus*) populations will not be adversely affected by pollen from Bt11 plants, and (2) endangered Lepidoptera will not be exposed to pollen or Cry1Ab protein from Bt11 plants.

Subsequent to the 2001 re-registration of the Cry1Ab PIP active ingredient in Bt11 corn, the following studies relevant to the environmental safety of this PIP were additionally submitted on behalf of Syngenta Seeds.

| STUDY TITLE | MRID NO. |
|---|---|
| Field Surveys of Non-Target Invertebrate Populations in Bt Corn | 45652001 |
| Evaluation of Transgenic Corn Event Bt11 in Broiler Chickens[1] | 45652101 |
| Impact of VIP3A and Cry1Ab Transgenic Maize (Corn) Leaf Tissue (Samples LLPACHA-0100, LLBt11-0100, and LLPACHABt11-0100) on 28-Day Survival and Reproduction of Collembola (*Folsomia candida*) | 45835810 |
| Effects on Monarch Butterfly Larvae after Continuous Exposure to Cry1Ab-Expressing Corn Pollen During Anthesis | 46162001 |

[1] This study described in this data volume was subsequently published in a peer-reviewed journal. The citation is: Brake, J., Faust, M. and Stein, J. (2003) Evaluation of Transgenic Event Bt11 Hybrid Corn in Broiler Chickens. *Poultry Science* 82: 551-559.

**SECTION D**

**RESIDUE AND ENVIRONMENTAL DATA**

## SECTION D

## RESIDUE AND ENVIRONMENTAL DATA

### Modified Cry3A Protein Expressed in MIR604 Corn

Detailed information describing the levels of modified Cry3A protein (the insecticidal principle) and PMI protein (the selectable marker) in Event MIR604-derived corn plants is summarized in the following previously submitted data volume.

| STUDY TITLE | MRID NO. |
|---|---|
| Quantification of Modified Cry3A and PMI Proteins in Transgenic Maize (Corn) Tissues, Whole Plants, and Silage Derived from Transformation Event MIR604 | 46155604 |

Detailed information describing the fate of modified Cry3A protein from Event MIR604-derived plants in the environment is summarized in the following previously submitted data volumes.

| STUDY TITLE | MRID NO. |
|---|---|
| Summary of Data on Modified Cry3A Protein Levels in Event MIR604 Corn Plants and the Environmental Fate of Modified Cry3A Protein<br>[This data summary and assessment has been superseded by the data summary and assessment that follows below.] | 46155619 |
| Environmental Fate Assessment of Modified Cry3A Protein in Event MIR604 Corn | 46265613 |
| Laboratory Soil Degradation of Modified Cry3A Protein (MCRY3A-0102) | 46265614 |

### Cry1Ab Protein Expressed in Bt11 Corn

Data relevant to the environmental fate of the Cry1Ab protein in Event Bt11 corn are summarized and reviewed in the October 15, 2001 EPA Biopesticides Registration Action Document (BRAD) for the *Bacillus thuringiensis* (*Bt*) Plant-Incorporated Protectants (http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad2/3-ecological.pdf). Also included in that assessment are evaluations of the potential for weediness in Bt corn,

the potential for gene flow from Bt corn to other plants or horizontal gene transfer to soil microbes, and the fate of Bt Cry proteins in soil.

Subsequent to EPA's publication of the 2001 BRAD, the following additional data volumes relevant to tissue-specific concentrations of Cry1Ab in Bt11 field corn and the environmental fate of the Cry1Ab protein in Bt11 corn have been submitted on behalf of Syngenta Seeds.

| STUDY TITLE | MRID NO. |
|---|---|
| Quantification of Cry1Ab Protein in Maize (Corn) Tissues And Whole Plants Derived from Transformation Event Bt11 | 45879803 |
| Assessment of the Potential Persistence and Accumulation of Cry1Ab Protein in Soil as a Result of Sustained Bt Corn Use[2] | 46022401 |

[2] The study described in this data volume has recently been published in a peer-reviewed journal. The citation is: Dubelman, S., Ayden, B., Bader, B., Brown, C., Jiang, C. and Vlachos, D. (2005) Cry1Ab protein does not persist in soil after 3 years of sustained Bt corn use. *Environ. Entomol.* 34 (4): 915-921.

**SECTION E**

**EFFECTIVENESS DATA**

## SECTION E

## EFFECTIVENESS DATA

### Event MIR604 Corn Expressing Modified Cry3A Protein for Control of Coleoptera

Event MIR604-derived field corn plants produce a modified Cry3A protein for control of larvae of certain chrysomelid beetle species. To date, evaluations of Event MIR604-derived field corn indicate that the plants provide substantial control against feeding damage by natural infestations of western corn rootworm *(Diabrotica virgifera virgifera* LeConte*)* and northern corn rootworm *(Diabrotica barberi* Smith and Lawrence). Additional efficacy evaluations are in progress under the 2005 program for 67979-EUP-4. One objective of the proposed amended EUP program for 2006 is to continue gathering additional efficacy data from plantings of multiple MIR604 corn hybrids at multiple locations. These studies will evaluate product performance under different levels of pest pressure and environmental conditions in a variety of corn-growing areas. Efficacy against additional coleopteran corn pests will also be evaluated.

### Event Bt11 Corn Expressing Cry1Ab Protein for Control of Lepidoptera

Event Bt11-derived field corn plants produce a Cry1Ab protein for control of larvae of certain lepidopteran species. Event Bt11 field corn plants provide a high level of control of European corn borer (*Ostrinia nubilalis* Hübner), and additionally provide some control or suppression of Southwestern corn borer (*Diatraea grandiosella* Dyar), Southern cornstalk borer [*Diatraea crambidoides* (Grote)], corn earworm [*Helicoverpa zea* (Boddie)] and fall armyworm [*Spodoptera frugiperda* (JE Smith)]. Event Bt11 has been commercially planted in the U.S. for lepidopteran control since 1997. Syngenta Seeds is the sole registrant of the active ingredient in Event Bt11, under EPA Reg. No. 67979-1.

### Stacked MIR604 X Bt11 Corn Expressing Modified Cry3A and Cry1Ab Proteins

Through conventional plant breeding, corn plants have been developed that express the traits of both Event MIR604 and Event Bt11 corn in 'stacked' combination (MIR604 X Bt11). Field corn hybrids expressing both the modified Cry3A protein and the Cry1Ab protein are predicted to have comparable efficacy to plants from the parent MIR604 and Bt11 events, and thus provide a combined spectrum of effective coleopteran and lepidopteran control or suppression. One objective of the proposed 2006 EUP field program is to broadly examine the efficacy of multiple MIR604 X Bt11 field corn hybrids under different levels of pest pressure and environmental conditions in a variety of corn-growing areas.

# SECTION F

# TOLERANCE EXEMPTION PROPOSAL

# SECTION F

# TOLERANCE EXEMPTION PROPOSAL

## Modified Cry3A Protein Expressed in Event MIR604 Corn Plants

Concurrently with the issuance of permit 67979-EUP-4 in March 2005, a temporary exemption from the requirement of a tolerance was granted for the modified Cry3A (mCry3A) protein and the genetic material necessary for its production in corn, under 40 CFR Part 174.456. This exemption expires October 15, 2006. The present EUP amendment/extension application is accompanied by a petition to extend the expiration date on the current mCry3A temporary tolerance exemption by one year, to October 15, 2007.

On April 30, 2004, Syngenta Seeds submitted an application for FIFRA Section 3 registration of the mCry3A PIP in MIR604 corn (EPA File Symbol 67979-L). Accompanying the Section 3 application was Syngenta Seeds' Petition for a permanent exemption from the requirement of a tolerance for the mCry3A protein and the genetic material necessary for its production in all corn (Petition File Symbol PP 4F6838). These submissions are currently under Agency review

## PMI Protein Expressed in Event MIR604 Corn Plants

In addition to the mCry3A PIP, Event MIR604 plants produce phosphomannose isomerase (PMI), a marker protein that is inert with respect to pesticidal activity. PMI, and the genetic material necessary for its production in all plants, is permanently exempt from the requirement of a tolerance, under 40 CFR Part 180.1252.

## Cry1Ab Protein Expressed in Event Bt11 Corn Plants

The Cry1Ab PIP in Bt11 corn is permanently exempt from the requirement of a tolerance under 40 CFR Part 180.1173.

## PAT Protein Expressed in Event Bt11 Corn Plants

The marker protein in Bt11 corn is phosphinothricin acetyltransferase (PAT), which is permanently exempt from the requirement of a tolerance under 40 CFR Part 180.1151.

# SECTION G

## Proposed Experimental Program

## for the Plant-Incorporated Protectant

## Modified Cry3A Protein as Expressed in Event MIR604 Corn and Breeding Stacks of Event MIR604 X Bt11 Corn

**August 15, 2005**

**Submitted By:**

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

## SECTION G

## PROPOSED EXPERIMENTAL PROGRAM

The proposed experimental use program will be under the overall management of the following scientist:

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Regulatory Specialist
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Participants managing the scientific aspects of the various field trial protocols are listed within each specific protocol. Cooperators and specific trial locations for each field protocol will be provided to the Environmental Protection Agency prior to planting time.

### Overview of Experimental Program

Syngenta Seeds, Inc. is requesting an extension and amendment of its current Experimental Use Permit (67979-EUP-4) for modified Cry3A (mCry3A) protein as expressed in Event MIR604 field corn. Under the amended/extended EUP program, Syngenta Seeds also intends to evaluate stacks of Event MIR604 field corn with Event Bt11 field corn expressing a Cry1Ab protein that is a registered plant-incorporated protectant (EPA Reg. No. 67979-1). Stacking of events MIR604 and Bt11 is achieved entirely by conventional plant breeding methods, i.e., not by re-transformation of either parent event. The resulting MIR604 X Bt11 plants express both mCry3A protein to control key coleopteran pests and Cry1Ab protein to control key lepidopteran pests.

The proposed amended/extended EUP program will require the planting of up to **4640 acres of MIR604 corn among a total of 29 states and Puerto Rico.** Of this acreage, 2066 acres represent plantings of MIR604 corn (not stacked with Bt11), 2259 acres represent plantings of stacked MIR604 X Bt11 corn, and 315 acres represent parent MIR604 inbreds planted for the purpose of producing MIR604 X Bt11 hybrid corn seed for future evaluations. Correspondingly, 315 additional acres of Bt11 parent inbred plantings will also be needed for the same purpose. Additionally, up to 14,332 associated corn acres will be planted to non-MIR604 genotypes that are part of an EUP protocol, including control/check plants and border rows.

Authorization is requested for plantings **beginning in mid-March 2006 and continuing through February 2007, with associated field activities (e.g., data collection, harvesting and processing of seed) continuing through October 15, 2007.** (The current EUP allows plantings through February 28, 2006 and associated field activities through October 15, 2006.)

The acreage requested under the amended/extended EUP program is required to meet Syngenta Seeds' current testing and product development needs, which have significantly expanded since our initial EUP application for MIR604 corn. Higher acreage is required to: (1) evaluate MIR604 corn in an expanded number of locations, under various environmental conditions, and varying degrees of pest pressure; (2) evaluate stacked MIR604 X Bt11 corn under a similar variety of conditions in multiple locations; (3) evaluate the performance of MIR604 in combination with other traits; and (4) introgress and evaluate the MIR604 trait in a greatly expanded base of corn germplasm in different maturity groups. This expanded germplasm base is, in part, attributable to Syngenta Seeds' 2004 acquisitions of the Garst Seed Co. and a majority stake in Golden Harvest, two well-established seed companies. These acquisitions have greatly expanded the number of corn breeding lines into which Syngenta traits must be introgressed. In turn, acreage requirements for field evaluations of new trait/germplasm/environment combinations have also increased significantly.

The amended/extended EUP program will consist of five field trial protocols, which are described in detail in this Section G document.

- Breeding and Observation
- Efficacy Evaluation
- Agronomic Observation
- Inbred and Hybrid Production
- Regulatory Studies

For each state and Puerto Rico, the maximum acreage per protocol, numbers of locations per protocol, and numbers of MIR604, MIR604 X Bt11 or associated Bt11 plants are given in Tables 1 and 2. Table 1 summarizes information relevant to plantings and evaluations of Event MIR604 corn *per se*. Table 2 summarizes similar information for breeding stacks of Event MIR604 X Event Bt11.

The total seed required for all proposed MIR604 and MIR604 X Bt11 plantings will contain a maximum of 117 grams of mCry3A protein, based on 0.9 µg mCry3A/g seed. As indicated by "Pounds of formulated product" on the accompanying EPA Form 8570-17, the total weight of seed required for these MIR604 and MIR604 X Bt11 plantings will be 92,800 lbs. (This is calculated using an average planting density of 30,000 plants per acre, requiring an average of 20 lbs of seed per acre.)

The EPA has indicated that information describing the average numbers of hybrids, inbreds and isolines to be tested per location and the acreage for each experiment per location is useful to the Agency when reviewing proposed EUP programs. However, Syngenta Seeds will not have such detailed information available until just prior to planting the proposed experimental plots, pending the outcome of winter nursery plantings, seed quality testing and final planning activities. Where general information is currently available, it has been included in the relevant field trial protocols described herein.

## Abbreviations Used in Table 1 and/or Table 2

| | |
|---|---|
| **ST** | State (or Puerto Rico) |
| **Tot.** | Total |
| **MIR604 Ac.** | Maximum acres of MIR604 corn |
| **Bt11 Ac.** | Maximum acres of Bt11 corn |
| **Oth. Ac.** | Maximum "other" acres of non-MIR604 corn that are part of the EUP protocol, incl. control/check plots and border rows |
| **No. Loc.** | Maximum number of locations |
| **Max. No. MIR604 Plants** | Maximum number of MIR604 plants, assuming 30,000 plants/acre |

**Table 1. Proposed Experimental Use Program for MIR604 Field Corn Plantings from March 2006 through February 2007**

| ST | Tot. MIR 604 Ac. | Tot. Oth. Ac. | Tot. No. Loc | Breeding & Obs. | | | Efficacy Evaluat'n. | | | Agronomic Observ'n | | | Inbred/Hybrid Prod. | | | Regulatory Studies | | | Max. No. MIR604 Plants |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | MIR 604 Ac. | Oth. Ac. | No. Loc. | MIR 604 Ac. | Oth. Ac. | No. Loc. | MIR 604 Ac. | Oth. Ac. | No. Loc. | MIR 604 Ac. | Oth. Ac. | No. Loc. | MIR 604 Ac. | Oth. Ac. | No. Loc. | |
| AR | 5 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | 150,000 |
| CA | 5 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | 150,000 |
| CO | 54 | 134 | 11 | 1 | 3 | 1 | 1 | 19 | 2 | 52 | 112 | 8 | | | | | | | 1,620,000 |
| FL | 5 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | 150,000 |
| HI | 240 | 62 | 24 | 30 | 18 | 12 | | | | | | | 210 | 44 | 12 | | | | 7,200,000 |
| IA | 436 | 963 | 120 | 14 | 14 | 12 | 13 | 167 | 30 | 192 | 632 | 42 | 210 | 130 | 34 | 7 | 20 | 2 | 13,080,000 |
| ID | 0 | 0 | 0 | | | | | | | | | | | | | | | | 0 |
| IL | 255 | 1319 | 117 | 14 | 14 | 15 | 13 | 367 | 30 | 208 | 648 | 42 | 10 | 270 | 28 | 10 | 20 | 2 | 7,650,000 |
| IN | 107 | 547 | 51 | 5 | 15 | 5 | 10 | 112 | 17 | 86 | 306 | 17 | 6 | 114 | 12 | | | | 3,210,000 |
| KS | 50 | 178 | 16 | 1 | 3 | 1 | 3 | 49 | 7 | 46 | 126 | 8 | | | | | | | 1,500,000 |
| KY | 7 | 9 | 3 | 1 | 3 | 1 | | | | 6 | 6 | 2 | | | | | | | 210,000 |
| LA | 5 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | 150,000 |
| MD | 10 | 20 | 2 | | | | | | | | | | | | | 10 | 20 | 2 | 300,000 |
| MI | 59 | 253 | 28 | 4 | 16 | 5 | 3 | 17 | 5 | 46 | 126 | 8 | 6 | 94 | 10 | | | | 1,770,000 |
| MN | 228 | 890 | 72 | 14 | 14 | 8 | 10 | 134 | 16 | 188 | 628 | 36 | 6 | 94 | 10 | 10 | 20 | 2 | 6,840,000 |
| MO | 63 | 314 | 38 | 3 | 17 | 5 | 7 | 67 | 11 | 46 | 126 | 8 | 6 | 94 | 10 | 1 | 10 | 4 | 1,890,000 |
| MS | 5 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | 150,000 |
| NC | 11 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | 330,000 |
| NM | 10 | 10 | 6 | | | | 5 | 5 | 3 | | | | | | | 5 | 5 | 3 | 300,000 |
| NE | 202 | 1009 | 90 | 7 | 29 | 9 | 12 | 148 | 25 | 172 | 612 | 32 | 10 | 210 | 22 | 1 | 10 | 2 | 6,060,000 |
| ND | 5 | 50 | 1 | | | | | | | 5 | 50 | 1 | | | | | | | 150,000 |
| NY | 11 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | 330,000 |
| OH | 104 | 512 | 46 | 4 | 16 | 5 | 8 | 96 | 14 | 86 | 306 | 17 | 6 | 94 | 10 | | | | 3,120,000 |
| PA | 11 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | 330,000 |
| PR | 41 | 127 | 24 | 25 | 23 | 12 | | | | | | | 16 | 104 | 12 | | | | 1,230,000 |
| SD | 54 | 199 | 19 | 2 | 6 | 2 | 5 | 57 | 8 | 46 | 126 | 8 | | | | 1 | 10 | 1 | 1,620,000 |
| TN | 0 | 0 | 0 | | | | | | | | | | | | | | | | 0 |
| TX | 8 | 20 | 5 | 1 | 3 | 1 | 1 | 11 | 3 | 6 | 6 | 1 | | | | | | | 240,000 |
| VA | 11 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | 330,000 |
| WI | 64 | 304 | 36 | 5 | 15 | 5 | 7 | 69 | 13 | 46 | 126 | 8 | 6 | 94 | 10 | | | | 1,920,000 |
| **Tot.** | 2066 | 6989 | 744 | 131 | 209 | 99 | 143 | 1363 | 211 | 1255 | 3960 | 246 | 492 | 1342 | 170 | 45 | 115 | 18 | 61,980,000 |

**Table 2. Proposed Experimental Use Program for Stacked MIR604 X Bt11 Field Corn Plantings from March 2006 through February 2007**

| | Total Acres | | | | | Breeding & Obs'n | | | Efficacy Evaluation | | | Agronomic Observ'n | | | Inbred & Hybrid Production | | | | | Regulatory Studies | | | Max. No. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ST | MIR 604+ Bt11 | MIR 604 | Bt 11 | Oth. | Tot Loc. | MIR 604+ Bt11 Ac. | Oth Ac. | No. Loc | MIR 604+ Bt11 Ac. | Oth. Ac. | No Loc | MIR 604+ Bt11 Ac. | Oth. Ac. | No. Loc | 604+ Bt11 Ac. | MIR 604 Ac. | Bt11 Ac. | Oth. Ac. | No. Loc | 604+ Bt11 Ac. | Oth Ac. | No. Loc | MIR604 +/or, Bt11 Plants |
| AR | 5 | 0 | 0 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | | | 150,000 |
| CA | 5 | 0 | 0 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | | | 150,000 |
| CO | 54 | 0 | 0 | 134 | 12 | 1 | 3 | 1 | 1 | 19 | 3 | 52 | 112 | 8 | | | | | | | | | 1,620,000 |
| FL | 5 | 0 | 0 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | | | 150,000 |
| HI | 240 | 105 | 105 | 228 | 20 | 30 | 18 | 12 | | | | | | | 210 | 105 | 105 | 210 | 8 | | | | 7,200,000 |
| IA | 432 | 105 | 105 | 1067 | 114 | 10 | 38 | 12 | 13 | 167 | 30 | 192 | 632 | 36 | 210 | 105 | 105 | 210 | 34 | 7 | 20 | 2 | 12,960,000 |
| ID | 5 | 0 | 0 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | | | 150,000 |
| IL | 251 | 0 | 0 | 1355 | 117 | 10 | 50 | 15 | 13 | 367 | 30 | 208 | 648 | 42 | 10 | | | 270 | 28 | 10 | 20 | 2 | 7,530,000 |
| IN | 107 | 0 | 0 | 547 | 51 | 5 | 15 | 5 | 10 | 112 | 17 | 86 | 306 | 17 | 6 | | | 114 | 12 | | | | 3,210,000 |
| KS | 50 | 0 | 0 | 178 | 16 | 1 | 3 | 1 | 3 | 49 | 7 | 46 | 126 | 8 | | | | | | | | | 1,500,000 |
| KY | 7 | 0 | 0 | 9 | 3 | 1 | 3 | 1 | | | | 6 | 6 | 2 | | | | | | | | | 210,000 |
| LA | 5 | 0 | 0 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | | | 150,000 |
| MD | 15 | 0 | 0 | 25 | 5 | | | | 5 | 5 | 3 | | | | | | | | | 10 | 20 | 2 | 450,000 |
| MI | 53 | 0 | 0 | 247 | 26 | 4 | 16 | 5 | 3 | 17 | 5 | 40 | 120 | 6 | 6 | | | 94 | 10 | | | | 1,590,000 |
| MN | 222 | 0 | 0 | 900 | 72 | 8 | 24 | 8 | 10 | 134 | 16 | 188 | 628 | 36 | 6 | | | 94 | 10 | 10 | 20 | 2 | 6,660,000 |
| MO | 63 | 0 | 0 | 314 | 38 | 3 | 17 | 5 | 7 | 67 | 11 | 46 | 126 | 8 | 6 | | | 94 | 10 | 1 | 10 | 4 | 1,890,000 |
| MS | 5 | 0 | 0 | 5 | 3 | | | | 5 | 5 | 3 | | | | | | | | | | | | 150,000 |
| NC | 11 | 0 | 0 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | | | 330,000 |
| NM | 10 | 0 | 0 | 10 | 6 | | | | 5 | 5 | 3 | | | | | | | | | 5 | 5 | 3 | 300,000 |
| NE | 402 | 105 | 105 | 1009 | 90 | 7 | 29 | 9 | 12 | 148 | 25 | 172 | 612 | 32 | 210 | 105 | 105 | 210 | 22 | 1 | 10 | 2 | 12,060,000 |
| ND | 5 | 0 | 0 | 50 | 1 | | | | | | | 5 | 50 | 1 | | | | | | | | | 150,000 |
| NY | 11 | 0 | 0 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | | | 330,000 |
| OH | 104 | 0 | 0 | 512 | 46 | 4 | 16 | 5 | 8 | 96 | 14 | 86 | 306 | 17 | 6 | | | 94 | 10 | | | | 3,120,000 |
| PA | 11 | 0 | 0 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | | | 330,000 |
| PR | 41 | 0 | 0 | 127 | 24 | 25 | 23 | 12 | | | | | | | 16 | | | 104 | 12 | | | | 1,230,000 |
| SD | 54 | 0 | 0 | 199 | 19 | 2 | 6 | 2 | 5 | 57 | 8 | 46 | 126 | 8 | | | | | | 1 | 10 | 1 | 1,620,000 |
| TN | 3 | 0 | 0 | 34 | 1 | | | | | | | 3 | 34 | 1 | | | | | | | | | 90,000 |
| TX | 8 | 0 | 0 | 20 | 6 | 1 | 3 | 1 | 1 | 11 | 3 | 6 | 6 | 2 | | | | | | | | | 240,000 |
| VA | 11 | 0 | 0 | 11 | 5 | | | | 5 | 5 | 3 | 6 | 6 | 2 | | | | | | | | | 330,000 |
| WI | 64 | 0 | 0 | 304 | 36 | 5 | 15 | 5 | 7 | 69 | 13 | 46 | 126 | 8 | 6 | | | 94 | 10 | | | | 1,920,000 |
| **Tot** | 2259 | 315 | 315 | 7343 | 741 | 117 | 279 | 99 | 153 | 1373 | 218 | 1252 | 3988 | 240 | 692 | 315 | 315 | 1588 | 166 | 45 | 115 | 18 | 67,770,000 |

**Breeding and Observation Trial Protocol for**
**Event MIR604 Corn (Maize) Expressing Modified Cry3A Protein**

## Participants

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787-824-4224

Al Mousel
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507-645-5621

Greg Parker
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Slater, IA 50244
515-685-5000

The above participants are plant breeders and geneticists.

## Objectives

1. Introgress the *mcry3A* gene into elite parent inbred corn lines for the purposes of determining gene stability, inheritance pattern, and efficacy in different elite genetic backgrounds that may also include Event Bt11.

2. Make up hybrid test-crosses for future evaluation.

## Description

Plants derived from Event MIR604 corn may be crossed with non-genetically modified or genetically modified corn lines or selfed. Various MIR604, and/or stacked MIR604 X Bt11 lines will be planted in up to 10 replications in a randomized block design with each replication containing both the transgenic event and a non-transgenic isoline or other appropriate control. Appropriate herbicides may be applied to cull out negative segregant plants. The plants may be infested (artificially or naturally) with northern, western, southern and/or Mexican corn rootworms and/or other corn insect pests (e.g., corn borers) and may be sampled for various laboratory analyses to determine insect damage, genotype, segregation patterns and/or other phenotypic parameters.

**Genotypes**

Test materials will consist of dent field corn (maize) derived from Event MIR604, and/or breeding stacks of MIR604 X Bt11.

**Space Requirements**

In each test planting, the transgenic material will occupy no more than 20 acres, with no more than 30,000 plants per acre.

**Harvest Procedures**

Test plots will be harvested by hand or mechanically. Ears harvested by hand will be placed in bags of suitable construction such that loss of seed outside the bag is prevented. Ears harvested by machine will be shelled as part of the process and remnant seed/grain disposed of as per the gene containment guidelines described below. Harvest machinery will be thoroughly cleaned prior to exiting the test plot area.

**Schedule**

Planting dates will be scheduled according to need and availability of seed, during the period between mid-March 2006 through February 2007. Harvest at all sites will occur from 3.5 to 5 months after planting.

**Shipping and Storage**

- Regulated plant material (transgenic corn) must be shipped in a container capable of preventing material loss, surrounded by an outer container also capable of preventing seed loss.

- USDA notification numbers and EUP labels must be displayed on the outside of the shipping containers.

- The regulated material must be securely stored and handled in such a way that there is no accidental release into the environment.

- To prevent accidental mixing of regulated and non-regulated material, a uniform identification scheme, such as clear identification tag, color-coding or strict segregation of material must be implemented.

**Gene Containment**

To minimize pollen-mediated gene flow outside of the trial area, ***one*** of the following practices must be adhered to:

- Spatial isolation: A distance of at least 660 feet must separate the regulated transgenic corn from any sexually compatible species; open pollinated ears of any non-research corn within 660 feet of transgenic plants must be destroyed.

- Temporal isolation: The 660 feet isolation may be waived if there is assurance that there are no receptive silks on conventional corn that has the potential of entering the food and feed supply chain during the time of pollen shed from the regulated transgenic corn.

- Detassling or bagging of the tassels of the regulated transgenic corn, or bagging of ears on conventional corn that has the potential of entering the food and feed supply chain.

In addition:

- The identity of the regulated transgenic material must be maintained by planting in distinct plots.

- All machinery that may retain regulated transgenic corn seed or grain must be cleaned after use.

- Complete records must be kept of material received, planted, harvested, shipped and destroyed.

**Post-Planting and Post-Harvest Guidelines**

- Regulated plant material from a field trial, including guard rows, shall be destroyed only by methods approved by USDA-APHIS.

- All regulated plant material that is not retained shall be rendered non-viable and disposed of on site by dry heat, steam heat, crushing, deep burial, discing into the soil, burning, or treatment with appropriately labeled herbicides and/or chemicals.

- The Trial Manager shall monitor harvest of field trials to ensure that regulated plant material that is not retained is disposed of as described above.

- Grain or seed from any part of the research trial (including the post-harvest monitoring period) cannot be used as food or feed and therefore must be segregated from conventional grain or seed that has the potential of entering the food and feed supply chain in any way.

- Trial sites must be managed for volunteer plants to prevent persistence in the environment. Trial sites must be monitored for 1 year after harvest. Any volunteer plants found must be destroyed using an appropriate herbicide or by mechanical means before reaching the reproductive stage.

**Efficacy Evaluation Protocol for Event MIR604 Field Corn (Maize)**
**Expressing Modified Cry3A Protein**

## Participants

Moez Meghji
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New Trait Development
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Von Kaster
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515-685-5111

Moez Meghji is a plant breeder and Von Kaster is a product development specialist.

## Objective

To assess the efficacy of up to 100 Event MIR604 and/or stacked MIR604 X Bt11 lines towards corn insect pests, including northern, western, southern and Mexican corn rootworms and/or insects specifically controlled by Bt11 corn.

## Description

Plants derived from Event MIR604 may be crossed with non-genetically modified or genetically modified corn lines or selfed. Various Event MIR604 and/or stacked MIR604 X Bt11 lines will be planted in up to 10 replications in a randomized block design with each replication containing both the transgenic event and a non-transgenic isoline or other appropriate control. The plants may be infested (artificially or naturally) with northern, western, southern and Mexican corn rootworms and/or other corn insect pests and may be sampled for various laboratory analyses to determine insect damage, genotype, segregation patterns and/or other phenotypic parameters. Hybrids may be evaluated for herbicide tolerance. Hybrids may also be evaluated for yield at the end of the growing season.

## Genotypes

Test materials will consist of dent field corn (maize) derived from Event MIR604 and breeding stacks of MIR604 X Bt11.

**Space Requirements**

In each test planting, the transgenic material will occupy no more than 10 acres, with no more than 30,000 plants per acre.

**Harvest Procedures**

Test plots will be harvested by hand or mechanically. Ears harvested by hand will be placed in bags of suitable construction such that loss of seed outside the bag is prevented. Ears harvested by machine will be shelled as part of the process and remnant seed/grain disposed of as per the gene containment guidelines described below. Harvest machinery will be thoroughly cleaned prior to exiting the test plot area.

**Schedule**

Planting dates will be scheduled according to need and availability of seed, during the period between mid-March 2006 through February 2007. Harvest at all sites will occur from 3.5 to 5 months after planting.

**Shipping and Storage**

- Regulated plant material (transgenic corn) must be shipped in a container capable of preventing material loss, surrounded by an outer container also capable of preventing seed loss.

- USDA notification numbers and EUP labels must be displayed on the outside of the shipping containers.

- The regulated material must be securely stored and handled in such a way that there is no accidental release into the environment.

- To prevent accidental mixing of regulated and non-regulated material, a uniform identification scheme, such as clear identification tag, color-coding or strict segregation of material must be implemented.

**Gene Containment**

To minimize pollen-mediated gene flow outside of the trial area, ***one*** of the following practices must be adhered to:

- Spatial isolation: A distance of at least 660 feet must separate the regulated transgenic corn from any sexually compatible species; open pollinated ears of any non-research corn within 660 feet of transgenic plants must be destroyed.

- Temporal isolation: The 660 feet isolation may be waived if there is assurance that there are no receptive silks on conventional corn that has the potential of entering the

food and feed supply chain during the time of pollen shed from the regulated transgenic corn.

- Detassling or bagging of the tassels of the regulated transgenic corn, or bagging of ears on conventional corn that has the potential of entering the food and feed supply chain.

In addition:

- The identity of the regulated transgenic material must be maintained by planting in distinct plots.
- All machinery that may retain regulated transgenic corn seed or grain must be cleaned after use.
- Complete records must be kept of material received, planted, harvested, shipped and destroyed.

**Post-Planting and Post Harvest Guidelines**

- Regulated plant material from a field trial, including guard rows, shall be destroyed only by methods approved by USDA-APHIS.
- All regulated plant material that is not retained shall be rendered non-viable and disposed of on site by dry heat, steam heat, crushing, deep burial, discing into the soil, burning, or treatment with appropriately labeled herbicides and/or chemicals.
- The Trial Manager shall monitor harvest of field trials to ensure that regulated plant material that is not retained is disposed of as described above.
- Grain or seed from any part of the research trial (including the post-harvest monitoring period) cannot be used as food or feed and therefore must be segregated from conventional grain or seed that has the potential of entering the food and feed supply chain in any way.
- Trial sites must be managed for volunteer plants to prevent persistence in the environment. Trial sites must be monitored for 1 year after harvest. Any volunteer plants found must be destroyed using an appropriate herbicide or by mechanical means before reaching the reproductive stage.

**Agronomic Observation Trial Protocol for**
**Event MIR604 Field Corn (Maize) Expressing Modified Cry3A Protein**

**Participants**

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The Participants are plant breeders, geneticists, and agronomists.

**Objective**

Assess Event MIR604 and/or stacked MIR604 X Bt11 lines and inbred lines in small plots (packet plots) for a variety of agronomic traits pertinent to corn production, including germinability, early-season vigor, days to pollen shed, and yield.

Assess Event MIR604 hybrids in strip plots under a wide range of field conditions for numerous traits pertinent to corn production.

**Description**

For small plots, various Event MIR604 and/or stacked MIR604 X Bt11 corn lines expressing modified Cry3A (mCry3A) protein, including crosses with other non-genetically modified or genetically modified corn lines, will be planted in up to 10 replications in a randomized block design. Each replication may contain both the mCry3A-expressing event and a non-transgenic segregant or other appropriate control. The plants may be infested (artificially or naturally) with northern, western, southern and/or Mexican corn rootworms and/or other corn insect pests (e.g., corn borers) and may

be sampled for various field and laboratory analyses to determine genotype, segregation patterns and/or other phenotypic or agronomic parameters. Hybrids may be evaluated for herbicide tolerance. Hybrids may also be evaluated for yield at the end of the growing season.

For strip plots, various Event MIR604 and/or stacked MIR604 X Bt11 corn lines, including crosses with other non-genetically modified or genetically modified maize lines, will be planted in multiple-row strips up to 2640 feet long at up to 250 locations (each location serving as a replicate). Each location may contain hybrids of both the mCry3A-expressing event and a non-transgenic segregant or other appropriate control hybrid. The plants may be infested (artificially or naturally) with northern, western, southern and/or Mexican corn rootworms and/or other corn insect pests (e.g., corn borers).

**Genotypes**

Test materials will consist of dent field corn (maize) derived from Event MIR604 and breeding stacks of MIR604 X Bt11.

**Space Requirements**

In each test planting, the transgenic material will occupy no more than 20 acres, with no more than 30,000 plants per acre.

**Harvest Procedures**

Test plots will be harvested by hand or mechanically. Ears harvested by hand will be placed in bags of suitable construction such that loss of seed outside the bag is prevented. Ears harvested by machine will be shelled as part of the process and remnant seed/grain disposed of as per the gene containment guidelines described below. Harvest machinery will be thoroughly cleaned prior to exiting the test plot area.

**Schedule**

Planting dates will be scheduled according to need and availability of seed, during the period between mid-March 2006 through February 2007. Harvest at all sites will occur from 3.5 to 5 months after planting.

**Shipping and Storage**

- Regulated plant material (transgenic corn) must be shipped in a container capable of preventing material loss, surrounded by an outer container also capable of preventing seed loss.

- USDA notification numbers and EUP labels must be displayed on the outside of the shipping containers.

- The regulated material must be securely stored and handled in such a way that there is no accidental release into the environment.

- To prevent accidental mixing of regulated and non-regulated material, a uniform identification scheme, such as clear identification tag, color-coding or strict segregation of material must be implemented.

**Gene Containment**

To minimize pollen-mediated gene flow outside of the trial area, ***one*** of the following practices must be adhered to:

- Spatial isolation: A distance of at least 660 feet must separate the regulated transgenic corn from any sexually compatible species; open pollinated ears of any non-research corn within 660 feet of transgenic plants must be destroyed.

- Temporal isolation: The 660 feet isolation may be waived if there is assurance that there are no receptive silks on conventional corn that has the potential of entering the food and feed supply chain during the time of pollen shed from the regulated transgenic corn.

- Detassling or bagging of the tassels of the regulated transgenic corn, or bagging of ears on conventional corn that has the potential of entering the food and feed supply chain.

In addition:

- The identity of the regulated transgenic material must be maintained by planting in distinct plots.

- All machinery that may retain regulated transgenic corn seed or grain must be cleaned after use.

- Complete records must be kept of material received, planted, harvested, shipped and destroyed.

**Post-Planting and Post-Harvest Guidelines**

- Regulated plant material from a field trial, including guard rows, shall be destroyed only by methods approved by USDA-APHIS.

- All regulated plant material that is not retained shall be rendered non-viable and disposed of on site by dry heat, steam heat, crushing, deep burial, discing into the soil, burning, or treatment with appropriately labeled herbicides and/or chemicals.

- The Trial Manager shall monitor harvest of field trials to ensure that regulated plant material that is not retained is disposed of as described above.

- Grain or seed from any part of the research trial (including the post-harvest monitoring period) cannot be used as food or feed and therefore must be segregated from conventional grain or seed that has the potential of entering the food and feed supply chain in any way.

- Trial sites must be managed for volunteer plants to prevent persistence in the environment. Trial sites must be monitored for 1 year after harvest. Any volunteer plants found must be destroyed using an appropriate herbicide or by mechanical means before reaching the reproductive stage.

**Inbred and Hybrid Production Protocol for Event MIR604 Field Corn (Maize) Expressing Modified Cry3A Protein**

## Participants

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The Participants are plant breeders and geneticists.

## Objectives

1. Produce up to 60 hybrid crosses with Event MIR604, Bt11 and MIR604 X Bt11 and up to 20 inbred corn lines for future evaluations.

2. Increase seed of MIR604, Bt11 or stacked MIR604 X Bt11 inbreds for use in hybrid production, feeding and safety studies.

## Description

Plants derived from Event MIR604, Event Bt11 and stacks of MIR604 X Bt11 may be crossed with non-genetically modified or genetically modified corn lines or selfed and analyzed to determine genotype, segregation patterns and/or other phenotypic parameters. Appropriate herbicides may be applied to cull out negative segregant plants.

## Genotypes

Test materials will consist of dent field corn (maize) derived from Event MIR604 and Event Bt11 and breeding stacks of MIR604 X Bt11.

## Space Requirements

In each test planting, the transgenic material will occupy no more than 100 acres, with no more than 30,000 plants per acre.

**Harvest Procedures**

Test plots will be harvested by hand or mechanically. Ears harvested by hand will be placed in bags of suitable construction such that loss of seed outside the bag is prevented. Ears harvested by machine will be shelled as part of the process and remnant seed/grain disposed of as per the gene containment guidelines described below. Harvest machinery will be thoroughly cleaned prior to exiting the test plot area.

**Schedule**

Planting dates will be scheduled according to need and availability of seed, during the period between mid-March 2006 through February 2007. Harvest at all sites will occur from 3.5 to 5 months after planting.

**Shipping and Storage**

- Regulated plant material (transgenic corn) must be shipped in a container capable of preventing material loss, surrounded by an outer container also capable of preventing seed loss.

- USDA notification numbers and EUP labels must be displayed on the outside of the shipping containers.

- The regulated material must be securely stored and handled in such a way that there is no accidental release into the environment.

- To prevent accidental mixing of regulated and non-regulated material, a uniform identification scheme, such as clear identification tag, color-coding or strict segregation of material must be implemented.

**Gene Containment**

To minimize pollen-mediated gene flow outside of the trial area, ***one*** of the following practices must be adhered to:

- Spatial isolation: a distance of at least 660 feet must separate the regulated transgenic corn from any sexually compatible species; open pollinated ears of any non-research corn within 660 feet of transgenic plants must be destroyed.

- Temporal Isolation: the 660 feet isolation may be waived if there is assurance that there are no receptive silks on conventional corn that has the potential of entering the food and feed supply chain during the time of pollen shed from the regulated transgenic corn.

- Detassling or bagging of the tassels of the regulated transgenic corn, or bagging of ears on conventional corn that has the potential of entering the food and feed supply chain.

In addition:

- The identity of the regulated transgenic material must be maintained by planting in distinct plots.

- All machinery that may retain regulated transgenic corn seed or grain must be cleaned after use.

- Complete records must be kept of material received, planted, harvested, shipped and destroyed.

**Post-Planting and Post-Harvest Guidelines**

- Regulated plant material from a field trial, including guard rows, shall be destroyed only by methods approved by USDA-APHIS.

- All regulated plant material that is not retained shall be rendered non-viable and disposed of on site by dry heat, steam heat, crushing, deep burial, discing into the soil, burning, or treatment with appropriately labeled herbicides and/or chemicals.

- The Trial Manager shall monitor harvest of field trials to ensure that regulated plant material that is not retained is disposed of as described above.

- Grain or seed from any part of the research trial (including the post-harvest monitoring period), grain or seed from any part of the research trial (including the post-harvest monitoring period) cannot be used as food or feed and therefore must be segregated from conventional grain or seed that has the potential of entering the food and feed supply chain in any way.

- Trial sites must be managed for volunteer plants to prevent persistence in the environment. Trial sites must be monitored for 1 year after harvest. Any volunteer plants found must be destroyed using an appropriate herbicide or by mechanical means before reaching the reproductive stage.

**Regulatory Studies Protocol for Event MIR604 Field Corn (Maize) Expressing Modified Cry3A Protein**

## Participants

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Henry-York Steiner is a regulatory scientist and Moez Meghji is a plant breeder and geneticist.

## Objective

Obtain regulatory-quality data for the development and support of the assessment of Event MIR604 corn and/or stacked MIR604 X Bt11 corn which will include but not be limited to insect resistance management field trials and large-scale, non-target insect field trials.

## Description

Plants derived from Event MIR604 may be crossed with non-genetically modified or genetically modified corn lines or selfed. Various Event MIR604 and stacked MIR604 X Bt11 lines will be planted in up to 10 replications in a randomized block design with each replication containing both the transgenic event and a non-transgenic isoline or other appropriate control. The plants may be infested (naturally or artificially) with northern, western, southern and/or Mexican corn rootworms and/or other corn insect pests and may be sampled for various field and laboratory analyses to determine insect damage, number of surviving larvae and/or adult insects, impact on non-target insects and/or other phenotypic or agronomic parameters. Hybrids may also be evaluated for herbicide tolerance.

## Genotypes

Test materials will consist of dent field corn (maize) derived from Event MIR604 and breeding stacks of MIR604 X Bt11.

**Space Requirements**

In each test planting, the transgenic material will occupy no more than 10 acres, with no more than 30,000 plants per acre.

**Harvest Procedures**

Test plots will be harvested by hand or mechanically. Ears harvested by hand will be placed in bags of suitable construction such that loss of seed outside the bag is prevented. Ears harvested by machine will be shelled as part of the process and remnant seed/grain disposed of as per the gene containment guidelines described below. Harvest machinery will be thoroughly cleaned prior to exiting the test plot area.

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food and feed supply chain during the time of pollen shed from the regulated transgenic corn.

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