



Document Processing Desk (APPL)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202-4501

Attn: Dr. Alan Reynolds

Subject: Application for registration of Bt11 x MIR162 corn

Dear Dr. Reynolds:

Please find enclosed our application for registration of the new plant-incorporated protectant (PIP) product, Bt11 x MIR162 corn. Bt11 x MIR162 corn is a combined insecticidal trait hybrid producing the Cry1Ab and Vip3Aa20 proteins from *Bacillus thuringiensis*. This combined trait hybrid is produced by a conventional breeding cross of event Bt11 corn with event MIR162 corn. Event Bt11 is a currently registered PIP and an application for registration of MIR162 corn is being submitted to the Agency concurrently with this one. We believe the requested regulatory action falls under fee category B88 (70 FR 32334). An application for registration of Bt11 x MIR162 x MIR604 corn is also being concurrently submitted to the Agency.

This application relies on the safety assessments that have already been conducted by EPA for the single trait parental event, Bt11 and the upcoming safety assessment of MIR162. Data supporting these earlier assessments are referenced in the enclosed Data Matrix and are referenced by MRID. Data volumes being submitted with this application characterize the genetic insert in Bt11 x MIR162, quantify the levels of Cry1Ab and Vip3Aa20 (as well as PAT and PMI) being produced, demonstrate product efficacy, address ecological risk, and describe an insect resistance management plan.

This application is comprised of eleven volumes plus a transmittal document. Volume 1 contains administrative materials and a product label. Three copies of each volume are being submitted. Should you have any questions regarding this application please contact me directly at: 919-765-5059. Thank you in advance for your review and acceptance of this application.

Sincerely,

A handwritten signature in black ink that reads "Erik Dunder". The signature is written in a cursive, flowing style.

Erik Dunder  
Regulatory Affairs Manager  
Syngenta Biotechnology, Inc.  
3054 Cornwallis Rd.  
Research Triangle Park, NC 27709-2257  
E-mail: erik.dunder@syngenta.com  
Fax: (919) 541-8585



**TRANSMITTAL DOCUMENT**

**Submitter**

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

**Regulatory Action in Support of Which This Document is Submitted**

**Registration for a Plant-incorporated Protectant Pursuant to FIFRA §3(c)(7)(C):  
*Bacillus thuringiensis* Cry1Ab and Vip3Aa20 Proteins and the Genetic  
Material Necessary for Their Production in Bt11 x MIR162 Corn**

**EPA File Symbol 67979-\_\_**

**Transmittal Date**

**May 17, 2007**

**Applicant Reference No.**

**Bt11x162-EPA-1**

**List of Accompanying Volumes**

<b>Vol.</b>	<b>Category<sup>1</sup></b>	<b>Volume/Study Title</b>	<b>MRID</b>
1	A	Dunder, E. (2007). Administrative materials in support of application for registration of Bt11 x MIR162 corn. Bt11x162-EPA-1	
1	C	Confidential Attachment to above volume	
2	B	Deframond, K. (2007). Comparative Southern analysis of a Bt11 x MIR162 x GA21 maize hybrid with the individual Bt11, MIR162 and GA21 event hybrids. SSB-111-07	
3	B	McDonald, J. (2007). Comparison of transgenic protein expression in event Bt11, event MIR162, event GA21 and stacked Bt11 x MIR162 x GA21 maize (corn) hybrids. SSB-010-07	
4	B	Raybould, A. (2007). The Environmental Fate and Potency of the Insecticidal Proteins Cry1Ab and Vip3Aa20 in Bt11 x MIR162 Stacked Maize Hybrids. SSB-524-07	
5	B	White, J., J. Sagers, and M. Meghji (2007). Insecticidal Efficacy of a Bt11 x MIR162 x GA21 Maize Hybrid Against European Corn Borer in the Field. SSB-512-07	
6	B	White, J., J. Sagers, and M. Meghji (2007). Insecticidal Efficacy of a Bt11 x MIR162 x GA21 Maize Hybrid Against Corn Earworm in the Field. SSB-514-07	
7	B	White, J., J. Sagers, and M. Meghji (2007). Insecticidal Efficacy of a Bt11 x MIR162 x GA21 Maize Hybrid against Fall Armyworm in the Field. SSB-516-07	
8	B	Kurtz, R., A. McCaffery and E. Dunder (2007). Insect Resistance Management Considerations for Bt11 x MIR162 maize. SSB-519-07	
9	B	E. Dunder (2007). Literature references supporting the application for registration of Bt11 x MIR162 corn - 1 of 3. Bt11x162-EPA-1-VOL9	
10	B	E. Dunder (2007). Literature references supporting the application for registration of Bt11 x MIR162 corn - 2 of 3. Bt11x162-EPA-1-VOL10	
11	B	E. Dunder (2007). Literature references supporting the application for registration of Bt11 x MIR162 corn - 3 of 3. Bt11x162-EPA-1-VOL11	

1 – Categorization code for placement of documents in the Public Docket



**Volume 1**

**Administrative Materials in Support of the Application for Registration  
of the Plant-incorporated Protectants in Bt11 x MIR162 Corn**

**Author**

**Erik M. Dunder**

**Submission Date**

**May 17, 2007**

**Submitter**

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

**Submitter Reference No.**

**Bt11x162-EPA-1**

**Volume 1 of 11**

**Statement of Data Confidentiality Claim**

A claim of confidentiality is being made for information in this volume on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B), or (C). This material is being submitted to EPA according to method and format specifications contained in PR Notice 86-5 and 40 CFR §158.33.

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

Company  
Agent:



Erik M. Dunder  
Regulatory Affairs Manager

Date: May 17, 2007

**Table of Contents**

Statement of Data Confidentiality Claim.....2

Section I: Administrative Forms.....4

Section II. Summary of the Application .....54

Section III. Product Label.....55

Section IV. Product Analysis.....56

Section V. Residue Data .....72

Section VI. Nontarget Organism Data.....73

Section VII. Toxicology Data.....74

Section VIII. Efficacy Data.....75


**Section I: Administrative Forms**

Application for Pesticide Registration (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number
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**Application for Pesticide – Section I**

1. Company/Product Number <p style="text-align: center;">67979-</p>	2. EPA Product Manager <p style="text-align: center;">Alan Reynolds</p>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) <p style="text-align: center;">Bt11 x MIR162 Corn</p>	PM # <p style="text-align: center;">BPPD</p>	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Seeds, Inc. - Field Crops - NAFTA P.O. Box 12257, 3054 East Cornwallis Road Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

**Section – II**


<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> “Me Too” Application. <input type="checkbox"/> Other – Explain below.
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)  
 Application for registration of a new end-use product containing the plant-incorporated protectants Cry1Ab and Vip3Aa20, and the genetic materials necessary for their production in Bt11 x MIR162 corn.  
 PROPOSED FEE CATEGORY IS ‘B88’. The pesticide registration service fee for this category is \$26,250.

**Section – III**

<b>1. Material This Product Will Be Packaged In:</b>			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* <b>Certification must be submitted</b>		If “Yes” Unit Packaging wgt.      No. per Container	If “Yes” Package wgt.      No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

**Section – IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <p style="text-align: center;">Dennis Ward</p>	Title <p style="text-align: center;">Regulatory Affairs Manager</p>	Telephone No. (Include Area Code) <p style="text-align: center;">(919) 597-3096</p>
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.		6. Date Application Received  <b>(Stamped)</b>
2. Signature 	3. Title <p style="text-align: center;">Regulatory Affairs Manager</p>	
4. Typed Name Erik M. Dunder      Tel. (919) 765-5059	5. Date <p style="text-align: center;">May 17, 2007</p>	



**Confidential Statement of Formula**

{CBI Cross Reference Number 1}


**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S. W.  
WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 (919) 765-5059	EPA Registration Number / File Symbol: 67979-
Active Ingredient(s) and/or representative test compound(s): <i>B.t. Cry1Ab and Vip3Aa20 proteins and the genetic material necessary for their production in Bt11 x MIR162 corn</i>	Date: May 17, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: Bt11 x MIR162 corn

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**


I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel, or suspend the registration of my product in conformity with FIFRA.

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

Signature 	Date May 17, 2007	Typed or Printed Name and Title Erik M. Dunder, Regulatory Affairs Manager
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EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.



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**DATA MATRIX**

Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 1 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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**Volumes Specifically Supporting the Combined Plant-Incorporated Protectants in the New Product, Bt11 x MIR162 Corn**

N/A	Dunder, E. (2007). Administrative materials in support of the application for registration of the Cry1Ab and Vip3Aa20 plant-incorporated protectants in Bt11 x MIR604 corn	N/A	Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 1 of this submission
151-20, 151-21, 151-22, 151-26 885.1100, 885.1200, 885.1300, 885.2100	Deframond, K. (2007). Comparative Southern analysis of a Bt11 x MIR162 x GA21 maize hybrid with the individual Bt11, MIR162 and GA21 event hybrids. SSB-111-07		Syngenta Seeds, Inc. –Field Crops - NAFTA	OWN	Volume 2 of this submission
151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	McDonald, J. (2007). Comparison of transgenic protein expression in event Bt11, event MIR162, event GA21 and stacked Bt11 x MIR162 x GA21 maize (corn) hybrids. SSB-010-07		Syngenta Seeds, Inc.	OWN	Volume 3 of this submission
885. Group D	Raybould, A. (2007). The Environmental Fate and Potency of the Insecticidal Proteins Cry1Ab and Vip3Aa20 in Bt11 x MIR162 Stacked Maize Hybrids. SSB-524-07		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 4 of this submission
N/A	White, J., Sagers, J. and M. Meghji (2007). Insecticidal Efficacy of a Bt11 x MIR162 x GA21 Maize Hybrid Against European Corn Borer in the Field. SSB-512-07		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 5 of this submission
N/A	White, J., Sagers, J. and M. Meghji (2007). Insecticidal Efficacy of a Bt11 x MIR162 x GA21 Maize Hybrid Against Corn Earworm in the Field. SSB-514-07		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 6 of this submission

Signature	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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**DATA MATRIX**

Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 2 of 23

Applicant's/Registrant's Name & Address: Product: Bt11 x MIR162 Corn  
 Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	White, J., Sagers, J. and M. Meghji (2007). Insecticidal Efficacy of a Bt11 x MIR162 x GA21 Maize Hybrid against Fall Armyworm in the Field. SSB-516-07		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 7 of this submission
N/A	Kurtz, R., A. McCaffery and E. Dunder (2007) Insect Resistance Management Considerations for Bt11 X MIR162 Corn. SSB-519-07		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 8 of this submission
N/A	E. Dunder (2007). Literature references supporting the application for registration of Bt11 x MIR162 corn - 1 of 3. Bt11x162-EPA-1-VOL9		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 9 of this submission
N/A	E. Dunder (2007). Literature references supporting the application for registration of Bt11 x MIR162 corn - 2 of 3. Bt11x162-EPA-1-VOL10		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 10 of this submission
N/A	E. Dunder (2007). Literature references supporting the application for registration of Bt11 x MIR162 corn - 3 of 3. Bt11x162-EPA-1-VOL11		Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 11 of this submission
OPPTS 885-4340	O'Reilly, D. (2006). Bioassay for interactions between Vip3A and full-length Cry1Ab in <i>Heliothis virescens</i> (Lepidoptera: Noctuidae). Syngenta Seeds Biotechnology Report No. SSB-155-05.	47017621	Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted December 14, 2006
OPPTS 885-4340	O'Reilly, D. (2006). Bioassay for interactions between Vip3A and full-length Cry1Ab in <i>Helicoverpa zea</i> (Lepidoptera: Noctuidae). Syngenta Seeds Biotechnology Report No. SSB-155-06.	47017622	Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted December 14, 2006

Signature  Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
May 17, 2007



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**DATA MATRIX**

Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 3 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Data Supporting MIR162 &amp; Vip3Aa20</b>					
885.4050	Pedersen, C. (1999). Acute avian oral toxicity (LD50) study with VIP3A-0198 in bobwhite quail. BLAL 160-001-03	457665-08	Syngenta Seeds, Inc	OWN	Submission dated September 24, 2002
885.4340	Teixeira, D. (2002). Assessment of chronic toxicity of VIP3A maize (corn) pollen and VIP3A/Cry1Ab maize pollen to the pink-spotted lady beetle ( <i>Coleomegilla maculata</i> ). 1781.6623	457665-09	Syngenta Seeds, Inc	OWN	Submission dated September 24, 2002
885.4240	Putt, A. (2002). VIP3A maize (corn) pollen –acute toxicity to daphnids ( <i>Daphnia magna</i> ) under static-renewal conditions. 1781.6616	457921-01	Syngenta Seeds, Inc	OWN	Submission dated October 29, 2002
885. Group D	Teixeira, D. (2002). VIP3A maize (corn) leaf protein – acute toxicity to earthworms ( <i>Eisenia foetida</i> ). 1781.6615	457921-02	Syngenta Seeds, Inc	OWN	Submission dated October 29, 2002
885.4340	Privalle, L. (2002). Impact of VIP3A and Cry1Ab transgenic maize (corn) leaf tissue on 28-day survival and reproduction of Collembola ( <i>Folsomia candida</i> ). SSB-006-01	458358-10	Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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**DATA MATRIX**

Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 4 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.5200	Privalle, L. (2002). Biological activity of VIP3A maize (corn) leaf protein (sample LPPACHA-0199) in various soils. SSB-006-01	458358-11	Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002
885.1100 885.1200	Ward, D. (2006). Application for an experimental use permit for event MIR162 corn. MIR162-EPA-2	468648-00	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.1100 885.1200 885.1300 885.2100	Long, N. and D. Pulliam (2006). Molecular characterization of event MIR162 maize. SSB-127-06	468648-01	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.1100 885.1300 885.1400 885.2100 885.2200	Graser, G. and C. Stacey (2006). Characterization of Vip3A protein expressed in event MIR162-derived maize (corn) and comparison with microbially-produced and plant-derived Vip3A test substance. SSB-017-06	468648-02	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.1400	Graser, G. (2004). Characterization of Vip3A protein test substance (VIP3A-0104) and certificate of analysis. SSB-026-04	468648-03	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.1400	Graser, G. (2004). Characterization of Vip3A protein test substance (VIP3A-0204) and certificate of analysis. SSB-029-04	468648-04	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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**DATA MATRIX**

Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 5 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1400	Graser, G. (2005). Re-characterization of Vip3A protein test substance (VIP3A-0204) and certificate of analysis. SSB-023-05	468648-05	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.2100 885.2200	Privalle, L. (2002). Characterization of Vip3A protein produced in Pacha-derived maize (corn) and comparison with Vip3A protein expressed in recombinant <i>Escherichia coli</i> . SSB-004-00	468648-06	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.2300	Hill, K. (2006). Analytical method for the detection of Vip3Aa20 protein in maize tissues from event MIR162. SSB-126-06	468648-07	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.3050	Harper, B. (2006). Vip3A as expressed in event MIR162 maize: Assessment of amino acid sequence homology with known toxins. SSB-112-06	468648-08	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.3400	Harper, B. (2006). Vip3A as expressed in event MIR162 maize: Assessment of amino acid sequence homology with known allergens. SSB-115-06	468648-09	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006

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Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 6 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885. Group D	Raybould, A. (2006). Environmental safety assessment of insecticidal proteins in MIR162 maize and in Bt11xMIR162 and Bt11xMIR162xMIR604 stacked maize hybrids.	468648-12	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.4340	Vinall, S. (2006). A laboratory test of the effects of microbially-produced Vip3A protein (Syngenta designated test item Vip3A-0104) on the predatory bug, <i>Orius insidiosus</i> (Hemiptera: Heteroptera: Anthocoridae). SYN-04-24	468648-14	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.4340	Vinall, S. (2006). A laboratory test of the effects of microbially-produced Vip3A protein (Syngenta designated test item Vip3A-0104) on the green lacewing <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae). SYN-04-32	468648-15	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
885.4340	Lee, et al. (2003). The mode of action of the <i>Bacillus thuringiensis</i> vegetative insecticidal protein Vip3A differs from that of Cry1Ab $\delta$ -endotoxin. <i>Appl. Environ. Microbiol.</i> <b>69</b> : 4648-4657. MIR162-EPA-2-VOL14	468808-01	Syngenta Seeds, Inc	PL	Submission dated June 7, 2006
885.4340	Vinall, S. (2006). A laboratory test of the acute effects of a partially-purified preparation of microbially-expressed Vip3A protein (VIP3A-0204) on adults of the ladybird beetle, <i>Coccinella septempunctata</i> (Coleoptera: Coccinellidae). SYN-04-23	468808-02	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006

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**DATA MATRIX**

Date: May 17, 2007 EPA Reg. No. / File Symbol:  
67979- Page 7 of 23

Applicant's/Registrant's Name & Address: Product:  
Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Mroczkiewicz, S. and D. Ward (2006). Field efficacy evaluations with event MIR162 corn in 2005. MIR162-EPA-2-VOL18	468808-03	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
	Ward, D. (2006). Literature references supporting the application for an experimental use permit for event MIR162 corn. MIR162-EPA-2-VOL19	468808-04	Syngenta Seeds, Inc	PL	Submission dated June 7, 2006
885.5200	Graser, G. and S. Song (2006). Analysis of Vip3A or Vip3A-like proteins in six different commercial microbial <i>Bacillus thuringiensis</i> products. SSB-036-06	470176-13	Syngenta Seeds, Inc.	OWN	Submission dated December 14, 2006
885.4200	Cafarella, M. (2005). Channel catfish ( <i>Ictalurus punctatus</i> ) feeding study with Vip3A maize (corn) fish feed. 1781.6617	470176-24	Syngenta Seeds, Inc.	OWN	Submission dated December 14, 2006
885.5200	Kramer, C. (2006). Biological activity of Vip3A maize (corn) leaf protein (sample LPPACHA-0199) in various soils – Amended report No. 1. SSB-016-02 A1	470176-30	Syngenta Seeds, Inc.	OWN	Submission dated December 14, 2006

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Date: May 17, 2007		EPA Reg. No. / File Symbol: 67979-		Page 8 of 23	
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709			Product: Bt11 x MIR162 Corn		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Ward, D. (2007). Application for manufacturing use registration of MIR162 corn. MRI162-EPA-12		Syngenta Seeds, Inc	OWN	Volume 1 of MIR162 submission dated May 17, 2007
885.1100 885.1300 885.1400 885.2100 885.2200	Graser, G. and C. Stacy (2006). Characterization of microbially-produced Vip3A test substance MIR162VIP3A-0106 and comparison with Vip3A expressed in event MIR162-derived maize (corn). SSB-023-06		Syngenta Seeds, Inc	OWN	Volume 2 of MIR162 submission dated May 17, 2007
885.2100	Long, N. (2007). Molecular characterization of the transgenic DNA in event MIR162 maize. SSB-119-07		Syngenta Seeds, Inc.	OWN	Volume 4 of MIR162 submission dated May 17, 2007
885.1100 885.1200 885.1300 885.2100 885.2200	Graser, G. and C. Stacy (2007). Supplemental information for study SSB-004-00: Characterization of Vip3A protein produced in Pacha-derived maize (corn) and comparison with Vip3A protein expressed in recombinant <i>Escherichia coli</i> . SSB-122-07		Syngenta Seeds, Inc.	OWN	Volume 5 of MIR162 submission dated May 17, 2007
885.2500 885.5200	Hill, K. (2006). Quantification of Vip3Aa20 and phosphomannose isomerase (PMI) in tissues of maize derived from transformation event MIR162. SSB-020-06		Syngenta Seeds, Inc.	OWN	Volume 6 of MIR162 submission dated May 17, 2007
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Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 9 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2300	Murray, J. (2007). Validation of the analytical method for qualitative detection of Vip3Aa20 protein in maize seed. SSB-016-07		Syngenta Seeds, Inc.	OWN	Volume 7 of MIR162 submission dated May 17, 2007
885.2300	Brady, J. (2007). Independent laboratory validation: Syngenta Biotechnology, Inc. SOP 2.91.1, "Extraction and qualitative detection of Vip3Aa20 protein from MIR162 maize seed. 1-2007		Syngenta Seeds, Inc.	OWN	Volume 8 of MIR162 submission dated May 17, 2007
885.3050	Draper, C. (2007). MIRVIP3A-0106 single dose oral toxicity study in mice. AM7543-REG		Syngenta Seeds, Inc.	OWN	Volume 9 of MIR162 submission dated May 17, 2007
885. Group C	Stacy, C. (2007). <i>In vitro</i> digestibility of Vip3Aa20 under simulated mammalian gastric conditions. SSB-038-06		Syngenta Seeds, Inc.	OWN	Volume 10 of MIR162 submission dated May 17, 2007
885. Group C	Stacy, C. (2007). <i>In vitro</i> digestibility of Vip3Aa20 (MIR162VIP3A-0106) under simulated mammalian intestinal conditions. SSB-002-07		Syngenta Seeds, Inc.	OWN	Volume 11 of MIR162 submission dated May 17, 2007
885. Group	Stacy, C. (2007). Effect of temperature on the stability of Vip3Aa20 protein. SSB-039-06		Syngenta Seeds, Inc.	OWN	Volume 12 of MIR162 submission dated May 17, 2007

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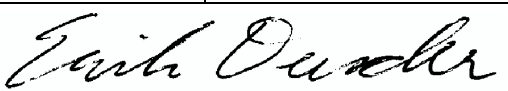


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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709			Product: Bt11 x MIR162 Corn		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Brake, J. (2007). Evaluation of event MIR162 transgenic maize in broiler chickens. Report No. SSB-507-07		Syngenta Seeds, Inc.	OWN	Volume 13 of MIR162 submission dated May 17, 2007
885.4340	Stacey, D. and R. Blake (2007). Vip3Aa20: A laboratory study to determine effects of Vip3Aa20 protein on the rove beetle <i>Aleochara bilineata</i> (Coleoptera: Staphylinidae). Report No. T002155-06-REG		Syngenta Seeds, Inc	OWN	Volume 14 of MIR162 submission dated May 17, 2007
885.4380	Jeker, L. (2006). Vip3Aa20: A honeybee brood study to evaluate the effects on brood development of the honeybee, <i>Apis mellifera</i> L. (Hymenoptera: Apidae). T002494-06		Syngenta Seeds, Inc	OWN	Volume 15 of MIR162 submission dated May 17, 2007
885. Group D	Raybould, A. (2007). The environmental fate of Vip3Aa20 in MIR162 maize: Expected environmental concentrations, margins of exposure in non-target organism hazard studies and endangered species assessment. Report No. SSB-523-07		Syngenta Seeds, Inc	OWN	Volume 16 of MIR162 submission dated May 17, 2007
	Huber et al. (2007). Insecticidal efficacy field evaluations with MIR162 maize in 2005 and 2006. SSB-522-07		Syngenta Seeds, Inc.	OWN	Volume 17 of MIR162 submission dated May 17, 2007
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709			Product: Bt11 x MIR162 Corn		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	White et al. (2007). Corn earworm tolerance of a MIR162 maize hybrid: 2006 field trial results. SSB-502-07		Syngenta Seeds, Inc.	OWN	Volume 18 of MIR162 submission dated May 17, 2007
	White et al. (2007). Fall armyworm tolerance of a MIR162 maize hybrid: 2006 field efficacy trial results. SSB-503-07		Syngenta Seeds, Inc.	OWN	Volume 19 of MIR162 submission dated May 17, 2007
	Ward, D. and D. Vlachos (2007). Public interest assessment supporting registration of MIR162, Bt11xMIR162 and Bt11xMIR162xMIR604 maize. Report No. SSB-518-07		Syngenta Seeds, Inc.	OWN	Volume 20 of MIR162 submission dated May 17, 2007
	Huber, S. (2007). Literature references supporting the application for registration of MIR162 corn – 1 of 3. MIR162-EPA-12-VOL20		Syngenta Seeds, Inc	PL	Volume 21 of MIR162 submission dated May 17, 2007
	Huber, S. (2007). Literature references supporting the application for registration of MIR162 corn – 2 of 3. MIR162-EPA-12-VOL21		Syngenta Seeds, Inc	PL	Volume 22 of MIR162 submission dated May 17, 2007
	Huber, S. (2007). Literature references supporting the application for registration of MIR162 corn – 3 of 3. MIR162-EPA-12-VOL22		Syngenta Seeds, Inc	PL	Volume 23 of MIR162 submission dated May 17, 2007
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67979- Page 12 of 23

Applicant's/Registrant's Name & Address: Product:  
 Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Data Supporting Marker Protein – PMI</b>					
885.3050	Kuhn, J. O. (1999). Phosphomannose isomerase (sample PMI-0198): Acute oral toxicity in mice. 4708-98	459344-07	Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
885.3050	Privalle, L. (1999). <i>In vitro</i> digestibility of PMI protein under simulated mammalian gastric and intestinal conditions. NSB-002-99	459344-08	Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
885.2400	Hill, K. (2003). Effects of temperature on the stability of phosphomannose isomerase. SSB-013-03	459344-09	Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
885.3050	Harper, B. (2006). Phosphomannose isomerase: Assessment of amino acid sequence homology with known toxins. SSB-114-06	468648-10	Syngenta Seeds, Inc.	OWN	Submission dated June 7, 2006

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 13 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.3400	Hart, H. (2005). Phosphomannose isomerase: Assessment of amino acid sequence homology with known allergens. SSB-140-05	468648-11	Syngenta Seeds, Inc.	OWN	Submission dated June 7, 2006
885.1100 885.1300 885.1400 885.2100 885.2200	Stacy, C. and G. Graser (2006). Characterization of phosphomannose isomerase (PMI) produced in MIR162 maize and comparison to PMI as contained in test substance PMI-0198. SSB-037-06		Syngenta Seeds, Inc.	OWN	Volume 3 of MIR162 submission dated May 17, 2007

**Data Supporting the Cry1Ab Plant-Incorporated Protectant in Bt11 Corn**

151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	Williams, D. (1994) Product Characterization: <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> (Btk) Protein in Corn: Lab Project No. NKJNV2	43130801	Northrup King Co.	OWN	Submitted February 2, 1994
151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	Williams, D. (1994) Product Characterization: <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> (Btk) Protein in Corn: Supplemental Information: Lab Project No. NK5PDCH	43352602	Northrup King Co.	OWN	Submitted September 26, 1994
151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	Williams, D. (1995) Product Characterization: <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> (Btk) Protein in Corn: Registration Application:	43754801	Northrup King Co.	OWN	Submitted June 15, 1995
151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	Hanten, J. and R. Meeusen (1994) Determination of Levels of Plant Produced <i>Bacillus thuringiensis</i> <i>kurstaki</i> HD-1 Protein in Transgenic Maize	43397201	Northrup King Co.	OWN	Submitted September 26, 1994

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 14 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

**Ingredient** *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-31, 152-34, 152-35 885.3100	Not applicable because Cry1Ab is a plant-incorporated active ingredient present at low levels and there is little opportunity for dermal or ocular contact.	N/A			
151-23, 151-25, 151-26, 153-4 885.1400, 885-1500, 885.2200, 885.2400, 885.2500	Privalle, L. Quantification of Cry1Ab Protein in Maize (Corn) Tissues and Whole Plants Derived from Transformation Event Bt11	45879803	Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted March 14, 2003
152-33, 885.3200	Not applicable because Cry1Ab is not a living organism.	N/A			
152-26, 152-37, 152-38 885.3400	There is no clear published evidence that has demonstrated clinical allergic reactions to <i>Bt</i> crystal proteins.	N/A			
152-32 885.3150	Not applicable because Cry1Ab is a plant-incorporated active ingredient present at low levels and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	N/A			
152-39, 885.3500	Not applicable because Cry1Ab is not a living organism.	N/A			
154-17 885.4100	A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	N/A			
154-18 885.4150	Not applicable because there is no evidence to indicate that wild mammals would be any more sensitive to Cry1Ab than laboratory animals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	N/A			

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 15 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* CryIAb protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-2 885.4300	CryIAb is an insect protein toxin and Cry proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outcrossing to weedy wild relatives is virtually nonexistent.	N/A			
885.2200	Lee et al. (1995). Assessment of the equivalence of the <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> HD-1 protein produced in <i>Escherichia coli</i> and European corn borer resistant corn. MSL-13879	435332-04	Monsanto Company	PAY	Submitted January 31, 1994
151-26 885.2200	Toxicity and Tolerance Considerations, Btk HD-1 Protein	43352603	Northrup King Co.	OWN	Submission dated August 25, 1994
151-26 885.2200	Toxicity, Btk Protein and PAT in Corn	43754802	Northrup King Co.	OWN	Submitted August 25, 1994
885.3050	Naylor, M. (1992). Acute oral toxicity study of Btk HD-1 tryptic core protein in albino mice. ML-92-029. A pathogenicity determination is not applicable since CryIAb is not a living organism.	434680-01	Monsanto Company	PAY	Submitted November 2, 1994
885. Group C	Ream, J. (1994). Assessment of the <i>in vitro</i> digestive fate of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> HD-1 protein. 93-01-39-04	434392-01	Monsanto Company	PAY	Submitted November 2, 1994

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 16 of 23

Applicant's/Registrant's Name & Address: Product: Bt11 x MIR162 Corn  
 Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709

**Ingredient** *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2200	Zawodny, J. (2003) Cry1Ab Protein as Expressed in Transgenic Maize Event Bt11: Assessment of Amino Acid Homology with Known Toxins.	45879801	Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted March 17, 2003
151-26 885.2200	Zawodny, J. (2003) Cry1Ab Protein as Expressed in Transgenic Maize Event Bt11: Assessment of Amino Acid Homology with Known Allergens. Syngenta report no. SSB-006-03	45879802	Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted March 17, 2003
N/A	Vlachos, D. (1994) Assessment and Summary of Characterization, Residue and Safety Data for Phosphinothricin Acetyltransferase (PAT), the Marker Protein in Bt Maize (Corn) Event 176	43323602	Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted July 29, 1994

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 17 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151-26 885.2200	Meeusen, R. (1994) Toxicity/Allergenicity Considerations – Phosphinothricin Acetyl Transferase	43352604	Northrup King Co.	OWN	Submitted September 26, 1994
870.1100	Kuhn, J. O. (1995) Phosphinothricin Acetyltransferase (Sample PAT-0195): Final Report; Acute Oral Toxicity Study in Mice. A pathogenicity determination is not applicable since PAT is not a living organism.	43642701	Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted May 10, 1995
152-30 885.3050	Privalle, L. (1994) <i>In vitro</i> Digestibility and Inactivation of the <i>bar</i> Marker Gene Product Phosphinothricin Acetyltransferase (PAT) Under Simulated Mammalian Gastric Conditions	43323607	Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted July 29, 1994
N/A	Wehrman, A., A. Van Vliet, C. Opsomer, J. Botterman, and A. Shulz (1996). The similarities of <i>bar</i> and <i>pat</i> gene products make them equally applicable for plant engineers. <i>Nature Biotechnology</i> 14, 1274-1278.	N/A	(published study)	PR	Study shows substantial equivalence of PAT protein from <i>bar</i> and <i>pat</i> genes.

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Date: May 17, 2007	EPA Reg. No./File Symbol: 67979-	Page 18 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885. Group D	Palmer, S. and J. Beavers (1995). CryIA(b) insecticidal protein: An acute toxicity study with the earthworm in an artificial soil substrate. WL-95-281. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	438879-02	Monsanto Company	PAY	Submitted January 11, 1996
885.4340	Effect of the <i>Bacillus thuringiensis</i> insecticidal proteins CryIA(b), CryIA(c), CryIIA and CryIIIA on <i>Folsomia candida</i> and <i>Xenylla grisea</i> (Insecta: Collembola). A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	43941601	Monsanto Company	PAY	Submitted January 11, 1996
885.4340	Sims, S.R. and J.W. Martin (1997) Effect of the <i>Bacillus thuringiensis</i> insecticidal proteins CryIA(b), CryIA(c), CryIIA, and CryIIIA on <i>Folsomia candida</i> and <i>Xenylla grisea</i> (Insecta: Collembola). <i>Pedobiologia</i> 41:412-416. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	43941601	(published study)	PR	Published study on Collembola.
885.4340	Chronic Exposure of <i>Folsomia candida</i> to Corn Tissue Expressing CryIA(b) Protein. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	44271501	Monsanto Company	PAY	Submitted January 11, 1996

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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Privalle, L. (2002) 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 ( <i>Folsomia candida</i> ). A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	45835810	Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted December 23, 2002
885.4340	Hoxter, K. and S. Lynn (1992). Activated Btk HD-1 protein: A dietary toxicity study with ladybird beetles. WL-92-156. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	434680-05	Monsanto Company	PAY	Submitted November 2, 1994
885.4380	Maggi, V. and S. Sims (1994). Evaluation of the dietary effects of purified B.t.k. endotoxin proteins on honeybee larvae. IRC-91-ANA-13. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	434392-02	Monsanto Company	PAY	Submitted November 2, 1994
885.4380	Maggi, V. and S. Sims (1994). Evaluation of the dietary effects of purified B.t.k. endotoxin proteins on honey bee adults. IRC-91-ANA-12. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	434392-03	Monsanto Company	PAY	Submitted November 2, 1994

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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Halliday, W.R. (1994) Host Range Comparison of Native and Maize Expressed CryIA(b) Protein	43323611	Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted July 29, 1994
885.4340	Hoxter, K. and S. Lynn (1992). Activated Btk HD-1 protein: A dietary toxicity study with green lacewing larvae. WL-92-155. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	434680-03	Monsanto Company	PAY	Submitted November 2, 1994
885.4340	Hoxter, K. and S. Lynn (1992). Activated Btk HD-1 protein: A dietary toxicity study with parasitic hymenoptera ( <i>Brachymeria intermedia</i> ). WL-92-157. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	434680-04	Monsanto Company	PAY	Submitted November 2, 1994
885.4050	Campbell, S. and J. Beavers (1994). A dietary toxicity study with MON 80187 meal in northern bobwhite. WL-94-150. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	435332-05	Monsanto Company	PAY	Submitted January 31, 1995

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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709		Product: Bt11 x MIR162 Corn

**Ingredient** *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Number	Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
885-4240		Comparison of CryIA(b) Levels in Transgenic Bt11-Derived Maize (Corn) Pollen and Event 176-Derived Maize Pollen and Justification for Citation of <i>Daphnia magna</i> Toxicity Study of Event 176-Derived Pollen in Support of Bt11 <i>Daphnia magna</i> Data Requirement	44274201	Novartis Seeds, Inc.	OWN	Justifies use of Bt176 pollen study to fulfill Bt11 data requirement. Submitted 5/13/97
885.4240		Collins, M. (1994). Bt maize pollen (PHO176-0194): acute toxicity to Daphnids ( <i>Daphnia magna</i> ) under static-renewal conditions. 94/3/5217. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	433236-10	Syngenta Seeds, Inc.	OWN	Submitted July 29, 1994
850.2100		Campbell, S. (1994) CryIA(b)-Enriched Maize Leaf Protein: An Acute Oral Toxicity Study with the Northern Bobwhite ( <i>Colinus virginianus</i> ). A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	43323609	Monsanto Company	PAY	Submitted January 31, 1995
850.2100		Evaluation of European Corn borer resistant corn line MON 801 as a feed ingredient for catfish. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	43887901	Monsanto Company	PAY	Submitted January 31, 1995
885.4200		Guyer, D. (2002) Evaluation of Transgenic Corn Event Bt11 in Broiler Chickens. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	45652101	Syngenta Seeds, Inc.	OWN	Submitted March 13, 2002
154-23 885.4340		McKee, M., G. Head and D. Vlachos (2001) Potential Risk to Endangered Lepidoptera from YieldGard® Corn Pollen (Bt Corn Events MON810 and Bt11) with Emphasis on the Karner Blue Butterfly. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	45512201	Syngenta Seeds, Inc and Monsanto Company.	OWN	Submitted October 9, 2001

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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Amended Revised Compendium of Published and Unpublished References Supporting the Response Document	45450102	Non-Target Organism Subcommittee of the Agricultural Biotechnology Stewardship Technical Committee	OWN	Data Call-In Response Submitted July 5, 2001
N/A	Dively, G. <i>et al.</i> (2003) Effects on Monarch Butterfly Larvae after Continuous Exposure to Cry1Ab-Expressing Corn Pollen during Anthesis. A pathogenicity determination is not applicable since Cry1Ab is not a living organism.	46162001	Monsanto Company, Syngenta Seeds, Inc.-Field Crops – NAFTA, and Syngenta Seeds, Inc. – Vegetables – NAFTA	OWN	Submitted December 30, 2003
N/A	ABSTC-Non-target Organism Subcommittee (2002) Field Surveys of Non-Target Invertebrate Populations in Bt Corn	45652001	Non-Target Organism Subcommittee of the Agricultural Biotechnology Stewardship Technical Committee	OWN	Submitted March 15, 2002
N/A	ABSTC-Non-target Organism Subcommittee (2006) Field Surveys of Non-Target Invertebrate Populations in Bt Corn: Supplement to MRID No. 45652001	46784601	Non-Target Organism Subcommittee of the Agricultural Biotechnology Stewardship Technical Committee	OWN	Submitted March 15, 2006
N/A	Williams, D. (1995) Environmental Fate: <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> Protein in Corn. Lab Project NK5EF.	43696001	Northrup King Co.	OWN	Submitted June 15, 1995
N/A	Dubelman, S. (2003) Assessment of the Potential for Persistence and Accumulation of Cry1Ab Protein in Soil as a Result of Sustained Bt Corn Use	46022401	Syngenta Seeds, Inc.-Field Crops – NAFTA, Syngenta Seeds, Inc. – Vegetables–NAFTA & Monsanto Co.	OWN	Submitted June 23, 2003
151-25	Analytical Method for the Detection of Cry1Ab Protein in Bt11 Corn Grain	45686701	Syngenta Seeds, Inc.	OWN	Submitted June 4, 2002

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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Research Reports Regarding the Interactions between Corn Earworm ( <i>Helicoverpa zea</i> ) and Novartis Seeds' Insect Resistant Corn	44347401	Novartis Seeds, Inc.	OWN	Submitted July 31, 1997
N/A	1997 Growing Season Report for Event 176-Derived and Bt11-Derived Corn	44475401	Novartis Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted January 30, 1998
N/A	1998 Growing Season Report for Event 176-Derived, Bt11-Derived Field Corn and Bt11-Derived Sweet Corn	44743901	Novartis Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted January 25, 1999
N/A	1999 Growing Season Report for Event 176-Derived, Bt11-Derived Field Corn and Bt11-Derived Sweet Corn	45056801	Novartis Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted February 3, 2000
N/A	2000 Growing Season Report for Event 176-Derived, Bt11-Derived Field Corn and Bt11-Derived Sweet Corn	45438101	Syngenta Seeds, Inc.	OWN	Submitted January 30, 2001
N/A	2001 Growing Season Report for Event 176-Derived, Bt11-Derived Field Corn and Bt11-Derived Sweet Corn		Syngenta Seeds, Inc.	OWN	Submitted January 2002
N/A	2002 Growing Season Report for Bt11-Derived Field Corn	45849601	Syngenta Seeds, Inc.	OWN	Submitted January 30, 2003
N/A	2003 Growing Season Report for Bt11-Derived Field Corn	46184001	Syngenta Seeds, Inc.	OWN	Submitted January 30, 2004
N/A	2004 Growing Season Report for Bt11-Derived Field Corn		Syngenta Seeds, Inc.	OWN	Submitted January 2005
N/A	2005 Growing Season Report for Bt11-Derived Field Corn	46746601	Syngenta Seeds, Inc.	OWN	Submitted January 31, 2006

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Applicant's/Registrant's Name & Address: Product: Bt11 x MIR162 Corn  
 Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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**Volumes Specifically Supporting the Combined Plant-Incorporated Protectants in the New Product, Bt11 x MIR162 Corn**

			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 1 of this submission
			Syngenta Seeds, Inc. –Field Crops - NAFTA	OWN	Volume 2 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 3 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 4 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 5 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 6 of this submission

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 2 of 23

Applicant's/Registrant's Name & Address: Product: Bt11 x MIR162 Corn  
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 7 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 8 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 9 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 10 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Volume 11 of this submission
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted December 14, 2006
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted December 14, 2006

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Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 3 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Data Supporting MIR162 &amp; Vip3Aa20</b>					
			Syngenta Seeds, Inc	OWN	Submission dated September 24, 2002
			Syngenta Seeds, Inc	OWN	Submission dated September 24, 2002
			Syngenta Seeds, Inc	OWN	Submission dated October 29, 2002
			Syngenta Seeds, Inc	OWN	Submission dated October 29, 2002
			Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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**DATA MATRIX**

Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 4 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Date: May 17, 2007 EPA Reg. No. / File Symbol:  
67979- Page 5 of 23

Applicant's/Registrant's Name & Address: Product:  
 Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006

Signature:  Name and Title: Erik M. Dunder, Regulatory Affairs Mgr. Date: May 17, 2007



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Date: May 17, 2007 EPA Reg. No. / File Symbol:  
67979- Page 6 of 23

Applicant's/Registrant's Name & Address: Product:  
 Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	PL	Submission dated June 7, 2006
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006

Signature:  Name and Title: Erik M. Dunder, Regulatory Affairs Mgr. Date: May 17, 2007



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**DATA MATRIX**

Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 7 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc	PL	Submission dated June 7, 2006
			Syngenta Seeds, Inc.	OWN	Submission dated December 14, 2006
			Syngenta Seeds, Inc.	OWN	Submission dated December 14, 2006
			Syngenta Seeds, Inc.	OWN	Submission dated December 14, 2006

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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**DATA MATRIX**

Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 8 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc	OWN	Volume 1 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc	OWN	Volume 2 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 4 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 5 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 6 of MIR162 submission dated May 17, 2007

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 9 of 23
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc.	OWN	Volume 7 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 8 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 9 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 10 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 11 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 12 of MIR162 submission dated May 17, 2007

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 10 of 23
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709	Product: Bt11 x MIR162 Corn
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc.	OWN	Volume 13 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc	OWN	Volume 14 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc	OWN	Volume 15 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc	OWN	Volume 16 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 17 of MIR162 submission dated May 17, 2007

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Date: May 17, 2007	EPA Reg. No. / File Symbol: 67979-	Page 11 of 23
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc.	OWN	Volume 18 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 19 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	OWN	Volume 20 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	PL	Volume 21 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	PL	Volume 22 of MIR162 submission dated May 17, 2007
			Syngenta Seeds, Inc.	PL	Volume 23 of MIR162 submission dated May 17, 2007

Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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67979- Page 12 of 23

Applicant's/Registrant's Name & Address: Product:  
 Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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<b>Data Supporting Marker Protein – PMI</b>					
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			Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
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			Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
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			Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
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			Syngenta Seeds, Inc.	OWN	Submission dated June 7, 2006
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Signature 	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709		Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc.	OWN	Submission dated June 7, 2006
			Syngenta Seeds, Inc.	OWN	Volume 3 of MIR162 submission dated May 17, 2007

**Data Supporting the Cry1Ab Plant-Incorporated Protectant in Bt11 Corn**

			Northrup King Co.	OWN	Submitted February 2, 1994
			Northrup King Co.	OWN	Submitted September 26, 1994
			Northrup King Co.	OWN	Submitted June 15, 1995
			Northrup King Co.	OWN	Submitted September 26, 1994

Signature <i>Erik M. Dunder</i>	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709		Product: Bt11 x MIR162 Corn

**Ingredient** *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted March 14, 2003

Signature <i>Erik Dunder</i>	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 15 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* CryIAb protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	PAY	Submitted January 31, 1994
			Northrup King Co.	OWN	Submission dated August 25, 1994
			Northrup King Co.	OWN	Submitted August 25, 1994
			Monsanto Company	PAY	Submitted November 2, 1994
			Monsanto Company	PAY	Submitted November 2, 1994

Signature *Erik M. Dunder* Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
May 17, 2007





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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 16 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

**Ingredient** *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted March 17, 2003
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted March 17, 2003
			Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted July 29, 1994

Signature *Erik M. Dunder* Name and Title: Erik M. Dunder, Regulatory Affairs Mgr. Date: May 17, 2007



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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 17 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Northrup King Co.	OWN	Submitted September 26, 1994
			Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted May 10, 1995
			Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted July 29, 1994
			(published study)	PR	Study shows substantial equivalence of PAT protein from <i>bar</i> and <i>pat</i> genes.

Signature *Erik M. Dunder* Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
May 17, 2007

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 18 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	PAY	Submitted January 11, 1996
			Monsanto Company	PAY	Submitted January 11, 1996
			Monsanto Company	PAY	Submitted January 11, 1996

Signature *Erik Dunder* Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
May 17, 2007

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Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 19 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Syngenta Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted December 23, 2002
			Monsanto Company	PAY	Submitted November 2, 1994
			Monsanto Company	PAY	Submitted November 2, 1994
			Monsanto Company	PAY	Submitted November 2, 1994

Signature *Erik Dunder* Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
May 17, 2007



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**Washington, D.C. 20460**

Form Approved OMB No. 2070-0060

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**DATA MATRIX**

Date: May 17, 2007 EPA Reg. No./File Symbol: 67979- Page 20 of 23

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709 Product: Bt11 x MIR162 Corn

Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Ciba Seeds/Ciba-Geigy Corp.	OWN	Submitted July 29, 1994
			Monsanto Company	PAY	Submitted November 2, 1994
			Monsanto Company	PAY	Submitted November 2, 1994
			(published study)	PR	Published study on Collembola.
			Monsanto Company	PAY	Submitted January 31, 1995

Signature *Erik M. Dunder* Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
May 17, 2007



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Date: May 17, 2007	EPA Reg. No./File Symbol: 67979-	Page 21 of 23
Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc. - Field Crops - NAFTA, P.O. Box 12257, Research Triangle Park, NC 27709		Product: Bt11 x MIR162 Corn

**Ingredient** *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Number	Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
				Novartis Seeds, Inc.	OWN	Justifies use of Bt176 pollen study to fulfill Bt11 data requirement. Submitted 5/13/97
				Syngenta Seeds, Inc.	OWN	Submitted July 29, 1994
				Monsanto Company	PAY	Submitted January 31, 1995
				Monsanto Company	PAY	Submitted January 31, 1995
				Syngenta Seeds, Inc.	OWN	Submitted March 13, 2002
				Syngenta Seeds, Inc and Monsanto Company.	OWN	Submitted October 9, 2001

Signature <i>Erik M. Dunder</i>	Name and Title Erik M. Dunder, Regulatory Affairs Mgr.	Date May 17, 2007
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Ingredient *Bacillus thuringiensis* Cry1Ab protein and Vip3Aa20 protein and the genetic material necessary for their production in corn

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Non-Target Organism Subcommittee of the Agricultural Biotechnology Stewardship Technical Committee	OWN	Data Call-In Response Submitted July 5, 2001
			Monsanto Company, Syngenta Seeds, Inc.-Field Crops – NAFTA, and Syngenta Seeds, Inc. – Vegetables – NAFTA	OWN	Submitted December 30, 2003
			Non-Target Organism Subcommittee of the Agricultural Biotechnology Stewardship Technical Committee	OWN	Submitted March 15, 2002
			Non-Target Organism Subcommittee of the Agricultural Biotechnology Stewardship Technical Committee	OWN	Submitted March 15, 2006
			Northrup King Co.	OWN	Submitted June 15, 1995
			Syngenta Seeds, Inc.-Field Crops – NAFTA, Syngenta Seeds, Inc. – Vegetables–NAFTA & Monsanto Co.	OWN	Submitted June 23, 2003
			Syngenta Seeds, Inc.	OWN	Submitted June 4, 2002

Signature *Erik M. Dunder* Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Novartis Seeds, Inc.	OWN	Submitted July 31, 1997
			Novartis Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted January 30, 1998
			Novartis Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted January 25, 1999
			Novartis Seeds, Inc. – Field Crops - NAFTA	OWN	Submitted February 3, 2000
			Syngenta Seeds, Inc.	OWN	Submitted January 30, 2001
			Syngenta Seeds, Inc.	OWN	Submitted January 2002
			Syngenta Seeds, Inc.	OWN	Submitted January 30, 2003
			Syngenta Seeds, Inc.	OWN	Submitted January 30, 2004
			Syngenta Seeds, Inc.	OWN	Submitted January 2005
			Syngenta Seeds, Inc.	OWN	Submitted January 31, 2006

Signature *Erik M. Dunder* Name and Title  
Erik M. Dunder,  
Regulatory Affairs Mgr. Date  
May 17, 2007



## **Section II. Summary of the Application**

Syngenta has developed the combined insecticidal trait product Bt11 x MIR162 maize (field corn) or “Agrisure<sup>TM</sup>2100” corn. This product was developed by combining the transgenic traits in Event Bt11 maize, which expresses a truncated *Bacillus thuringiensis* (*Bt*) Cry1Ab protein for control of certain lepidopteran pests and Event MIR162 maize, which expresses a *Bt* Vip3Aa20 protein for control of certain lepidopteran pests. The traits of these separate transgenic products were combined into the same maize variety through conventional breeding. Bringing these two insecticidal traits together in the same plant offers growers a convenient, reliable, and low-risk approach for limiting crop damage by a number of the major insect pests of maize.

This application for the FIFRA Section 3 registration of the active ingredients in “Agrisure<sup>TM</sup>2100” corn is accompanied by data volumes that describe the results of molecular characterization, transgenic protein level determination, product efficacy, environmental risk characterization and resistance management studies. These studies substantiate the equivalence of “Agrisure<sup>TM</sup> 2100” corn and corn derived from the component transformation events. This application further relies upon studies previously submitted to EPA for Vip3A and Cry1Ab, which are reference by MRID in the data matrix. The “Agrisure<sup>TM</sup> 2100” corn product will often be marketed as “Agrisure<sup>TM</sup> 2100GT” combined by conventional breeding with Event GA21 maize, which expresses a dmEPSPS protein conferring tolerance to glyphosate containing herbicides. This Bt11 x MIR162 x GA21 plant material was used in the majority of the studies submitted with this application.

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<sup>TM</sup> Agrisure is a trademark of a Syngenta Group company

### **Section III. Product Label**

Five copies of the proposed label for Bt11 x MIR162 Corn are attached. Once registered, this product will be marketed under the alternate brand name of “*Agrisure*<sup>™</sup> 2100” or “*Agrisure*<sup>™</sup> 2100GT” corn. This label contains detailed grower instructions for deployment of an insect resistance management plan.

---

<sup>™</sup> Agrisure is a trademark of a Syngenta Group company

## Bt11 x MIR162 Corn Seed

[Alternate brand name: *Agrisure*<sup>™</sup> 2100]

### Plant-incorporated protectant:

#### Cry1Ab and Vip3Aa20 proteins for control of corn borers and other lepidopteran pests

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and certain lepidopteran pests.

#### Active Ingredients:

*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (vector pZO1502) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4).....≤0.0204%\*

*Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production (vector pNOV1300) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.0865%\*

#### Other Ingredients:

A marker protein and the genetic material necessary for its production (vector pZO1502) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.000086%\*

A marker protein and the genetic material necessary for its production (vector pNOV1300) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.00422%\*

---

\*Percent (wt/wt) of whole plant on a dry weight basis

### CAUTION

#### KEEP OUT OF REACH OF CHILDREN

EPA Registration No. 67979-  
EPA Establishment No. 66736-NC-01

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

### DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with this labeling. All corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds or its distributors must be accompanied by informational material (e.g., a bag tag) indicating the registration number (67979- ) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed.

### **Insects Controlled or Suppressed**

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab and Vip3Aa20, for control or suppression of the following lepidopteran insects:

European corn borer (*Ostrinia nubilalis*)  
Southwestern corn borer (*Diatraea grandiosella*)  
Southern cornstalk borer (*Diatraea crambidoides*)  
Corn earworm (*Helicoverpa zea*)  
Fall armyworm (*Spodoptera frugiperda*)  
Beet armyworm (*Spodoptera exigua*)  
Black cutworm (*Agrotis ipsilon*)  
Western bean cutworm (*Striacosta albicosta*)  
Sugarcane borer (*Diatraea saccharalis*)  
Common stalk borer (*Papaipema nebris*)

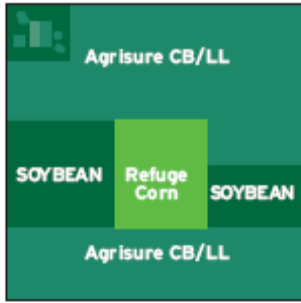
### **Insect Resistance Management**

The following information regarding commercial production Bt11 x MIR162 corn must be included in the Grower Guide (or equivalent).

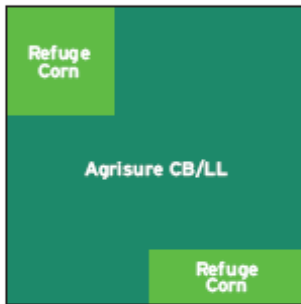
The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [Bt11 x MIR162] acres and refuge acres) and must be planted within ½ mile of these corn hybrids. The refuge may be planted as a separate field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least four, and preferably six consecutive rows wide. If strips within the [Bt11 x MIR162] field are implemented, then at least four, and preferably six consecutive rows should be planted (See diagrams below). The refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a foliar insecticide for control of corn pests only if the economic threshold for one or more pests is reached. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt maize refuges.

The following are schematics of the various refuge deployment options:

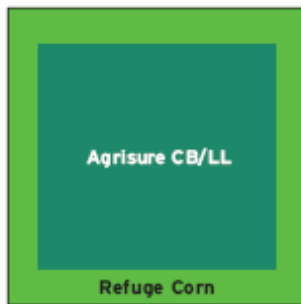
### Separate Fields



### Blocks



### Perimeter



-  Agrisure CB/LL
-  Corn Borer Refuge

# Bt11 x MIR162 Corn Seed

[Alternate brand name: *Agrisure*<sup>TM</sup> 2100]

## **Plant-incorporated protectant: Cry1Ab and Vip3Aa20 proteins for control of corn borers and other lepidopteran pests**

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and certain lepidopteran pests.

### **Active Ingredients:**

*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (vector pZO1502) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4).....≤0.0204%\*  
*Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production (vector pNOV1300) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.0865%\*

### **Other Ingredients:**

A marker protein and the genetic material necessary for its production (vector pZO1502) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.000086%\*  
A marker protein and the genetic material necessary for its production (vector pNOV1300) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.00422%\*

---

\*Percent (wt/wt) of whole plant on a dry weight basis

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EPA Establishment No. 66736-NC-01

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## **DIRECTIONS FOR USE**

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### **Insects Controlled or Suppressed**

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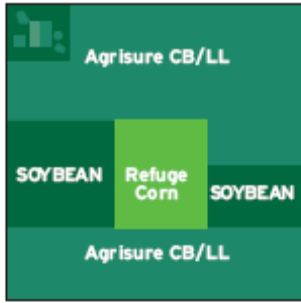
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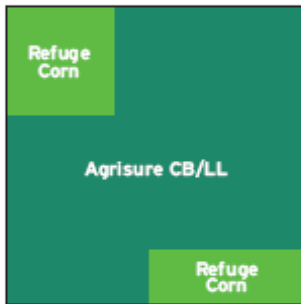
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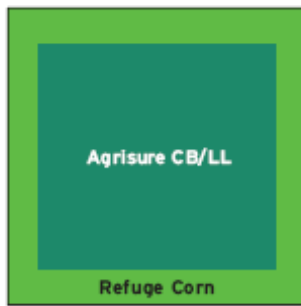
### Separate Fields



### Blocks



### Perimeter



-  Agrisure CB/LL
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# Bt11 x MIR162 Corn Seed

[Alternate brand name: *Agrisure*<sup>TM</sup> 2100]

## Plant-incorporated protectant:

### Cry1Ab and Vip3Aa20 proteins for control of corn borers and other lepidopteran pests

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#### Active Ingredients:

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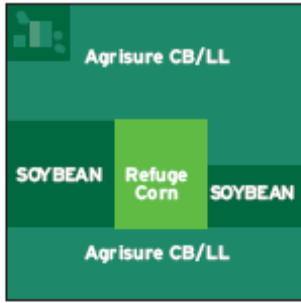
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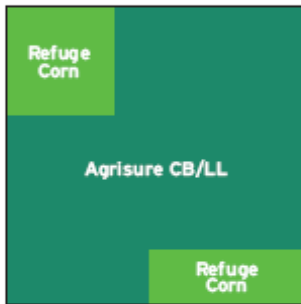
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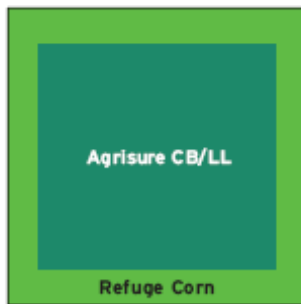
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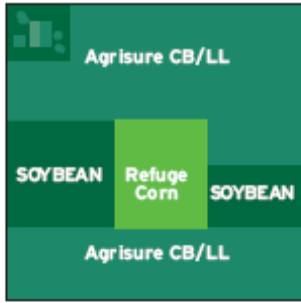
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The following information regarding commercial production Bt11 x MIR162 corn must be included in the Grower Guide (or equivalent).

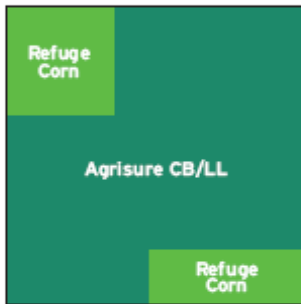
The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [Bt11 x MIR162] acres and refuge acres) and must be planted within ½ mile of these corn hybrids. The refuge may be planted as a separate field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least four, and preferably six consecutive rows wide. If strips within the [Bt11 x MIR162] field are implemented, then at least four, and preferably six consecutive rows should be planted (See diagrams below). The refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a foliar insecticide for control of corn pests only if the economic threshold for one or more pests is reached. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt maize refuges.

The following are schematics of the various refuge deployment options:

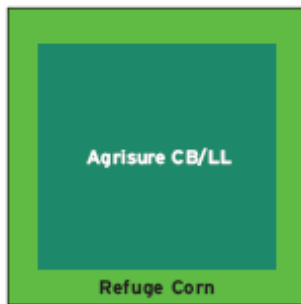
### Separate Fields



### Blocks



### Perimeter



-  Agrisure CB/LL
-  Corn Borer Refuge

# Bt11 x MIR162 Corn Seed

[Alternate brand name: *Agrisure*<sup>TM</sup> 2100]

## Plant-incorporated protectant:

### Cry1Ab and Vip3Aa20 proteins for control of corn borers and other lepidopteran pests

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and certain lepidopteran pests.

#### Active Ingredients:

*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production (vector pZO1502) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4).....≤0.0204%\*  
*Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production (vector pNOV1300) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.0865%\*

#### Other Ingredients:

A marker protein and the genetic material necessary for its production (vector pZO1502) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.000086%\*  
A marker protein and the genetic material necessary for its production (vector pNOV1300) in Bt11 x MIR162 corn (SYN-BTØ11-1; SYN-IR162-4) .....≤0.00422%\*

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\*Percent (wt/wt) of whole plant on a dry weight basis

## CAUTION KEEP OUT OF REACH OF CHILDREN

EPA Registration No. 67979-  
EPA Establishment No. 66736-NC-01

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

## DIRECTIONS FOR USE

It is a violation of federal law to use this product in any manner inconsistent with this labeling. All corn seed that contains the plant-incorporated protectant sold or distributed by Syngenta Seeds or its distributors must be accompanied by informational material (e.g., a bag tag) indicating the registration number (67979- ) and the active ingredients, and stipulating that growers read the Grower Guide (or equivalent guidance) prior to planting the seed.

### **Insects Controlled or Suppressed**

Field corn has been genetically transformed to produce the insecticidal proteins, Cry1Ab and Vip3Aa20, for control or suppression of the following lepidopteran insects:

European corn borer (*Ostrinia nubilalis*)  
Southwestern corn borer (*Diatraea grandiosella*)  
Southern cornstalk borer (*Diatraea crambidoides*)  
Corn earworm (*Helicoverpa zea*)  
Fall armyworm (*Spodoptera frugiperda*)  
Beet armyworm (*Spodoptera exigua*)  
Black cutworm (*Agrotis ipsilon*)  
Western bean cutworm (*Striacosta albicosta*)  
Sugarcane borer (*Diatraea saccharalis*)  
Common stalk borer (*Papaipema nebris*)

### **Insect Resistance Management**

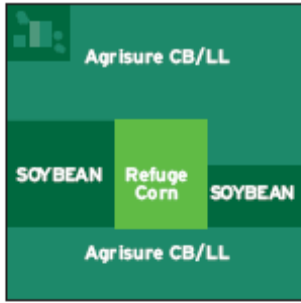
The following information regarding commercial production Bt11 x MIR162 corn must be included in the Grower Guide (or equivalent).

The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [Bt11 x MIR162] acres and refuge acres) and must be planted within ½ mile of these corn hybrids. The refuge may be planted as a separate field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least four, and preferably six consecutive rows wide. If strips within the [Bt11 x MIR162] field are implemented, then at least four, and preferably six consecutive rows should be planted (See diagrams below). The refuge may be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a foliar insecticide for control of corn pests only if the economic threshold for one or more pests is reached. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt maize refuges.

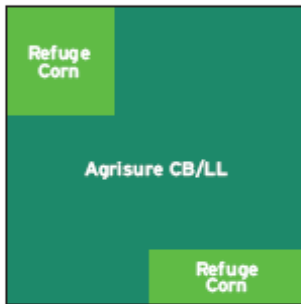
The following are schematics of the various refuge deployment options:



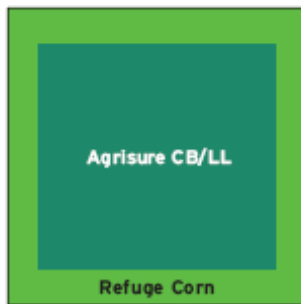
### Separate Fields



### Blocks



### Perimeter



-  Agrisure CB/LL
-  Corn Borer Refuge

#### **Section IV. Product Analysis**

Volume 2 of this application characterizes the genetic modifications made to corn that resulted in the transformation of events Bt11 and MIR162 (and GA21) (DeFramond, 2007). The transgenes associated with these events were brought together in a combined-trait hybrid by conventional breeding. Southern blot analyses demonstrated the intact presence of the transgenes from Bt11 and MIR162 (and GA21) in the combined trait hybrid.

Volume 3 describes the results of enzyme linked immunosorbent assay (ELISA) analyses to compare the levels of the transgenic proteins produced in a Bt11 x MIR162 (x GA21) hybrid to those produced in near-isogenic individual event hybrids Bt11, MIR162 (and GA21) (McDonald, 2007). These analyses demonstrate that levels of the transgenic proteins in the combined trait hybrid are comparable to levels found in the respective single trait parental lines. Two small and minor statistical differences were identified in Cry1Ab concentration in leaves at whorl stage and whole plants at anthesis. And one minor statistical difference was identified in Vip3Aa20 concentration in pollen. These differences are of no biological significance, and consequently do not warrant any additional analysis.

## Section V. Residue Data

The *Bacillus thuringiensis* Cry1Ab  $\delta$ -endotoxin and the genetic material necessary for its production in all plants are exempt from tolerance requirements under 40 CFR §174.511. The marker substance in Bt11, phosphinothricin acetyltransferase (PAT) enzyme, and the genetic material necessary for its production in all plants is exempt from the requirement of a tolerance under 40 CFR §174.522.

The *Bacillus thuringiensis* Vip3Aa20 and the genetic material necessary for its production in all plants is under a temporary exemption from tolerance requirements in MIR162 corn under 40 CFR §174.528. The marker substance in MIR162, phosphomannose isomerase (PMI) enzyme, and the genetic material necessary for its production in all plants is exempt from the requirement of a tolerance under 40 CFR §174.527.

Along with this application, a petition to establish a permanent tolerance for Vip3Aa20 in corn is being submitted. As part of that application, MIR162 protein expression analysis is described in:

Hill, K. (2006). Quantification of Vip3Aa20 and phosphomannose isomerase (PMI) in tissues of maize derived from transformation event MIR162. Syngenta Report #SSB-020-06 Volume 6 of the concurrent MIR162 application for registration.

## **Section VI. Nontarget Organism Data**

Studies have been conducted by Syngenta and others that adequately characterize the potential hazards of Bt11 corn and MIR162 corn. Studies have also been conducted assessing the potential for Cry1Ab and Vip3A to interact in a way that could increase their environmental risk when combined in the same plant. These studies were previously submitted to EPA and are referenced by MRID in the Data Matrix or are included in the concurrent MIR162 and Bt11 x MIR162 x MIR604 applications for registration.

**Section VII. Toxicology Data**

**Not Applicable to this application for registration**

## **Section VIII. Efficacy Data**

Data demonstrating the efficacy of Bt11 plants for limiting corn borer feeding damage and data demonstrating the efficacy of MIR162 plants for limiting corn earworm and fall armyworm feeding damage have previously been submitted to EPA and are referenced in the Data Matrix by MRID. Volumes 5, 6 and 7 of this application compare the efficacy of the combined-trait product Bt11 x MIR162 x GA21 to Bt11 corn for corn borer feeding damage and MIR162 corn for corn earworm feeding damage and fall armyworm feeding damage.