Dennis P. Ward, Ph.D.
Regulatory Affairs Manager
Tel. 919-597-3096
Fax 919-541-8535
dennis.ward@syngenta.com

Syngenta Biotechnology, Inc.
3054 E. Cornwallis Road
P.O. Box 12257
Research Triangle Park,
North Carolina 27709

syngenta

May 17, 2007

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Alan Reynolds
Biopesticides and Pollution Prevention Division

Subj: Application for registration of a new plant-incorporated protectant, Vip3Aa20 insecticidal protein in MIR162 maize

Dear Mr. Reynolds:

Please find attached to this letter an application for a manufacturing-use registration under FIFRA §3(c)(5) for the new plant-incorporated protectant, Vip3Aa20, as produced in MIR162 maize. This application is comprised of one administrative volume, which describes the scope and limitations of the registration being sought, and 22 data volumes.

This application is being submitted simultaneously with applications for registration of two combined trait maize products that have been made through conventional breeding. These two products are designated Bt11xMIR162 and Bt11xMIR162xMIR604. As the three applications are being submitted together, Syngenta requests that they be linked for purposes of assigning fee categories under the Pesticide Registration Improvement Act.

A petition to establish a permanent exemption from the requirement of tolerance for Vip3Aa19 and Vip3Aa20 in commodities of cotton and corn is being submitted concurrently under separate cover.

An electronic copy of the administrative volumes for placement in the EDocket is also included with this submission.

Thank you in advance for consideration of this application. Should you have questions concerning any of the materials contained in the applications please feel free to contact me directly (919.597.3096).

Sincerely,

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Att. Volumes 1-23

cc: Lisa Zannoni / Syngenta Biotechnology
Larry Zeph / Syngenta Biotechnology

Title

Application for Manufacturing-Use Registration of MIR162 Maize (SYN-IR162-4)

Data Requirement

40 CFR Part 174

Author

Dennis P. Ward, Ph.D.

Date

May 17, 2007

Submitter

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

Submitter Reference No.

MIR162-EPA-12

Volume 1 of 23

Statement of Data Confidentiality Claim

A claim of confidentiality is being made for information in this application on the basis of its falling within the scope of FIFRA §10(d)(1)(C). The information claimed confidential has been removed to a confidential appendix and is cited by cross reference number in the body of this volume.

Syngenta submits this material to the United States Environmental Protection Agency specifically under provisions contained in FIFRA as amended, and consents to use and disclosure of this material by EPA according to FIFRA. In submitting this material to EPA according to method and format requirements contained in Pesticide Registration Notice 86-5 and 40 CFR §158.33, Syngenta does not waive any protection of rights involving this material that would have been claimed by the company if this material had not been submitted to the EPA.

Company: Syngenta Seeds, Inc. – Field Crops

Agent: Dennis P. Ward

Dennis P. Ward, Ph.D.
Regulatory Affairs Manager

Date: May 17, 2007

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Page No.

Transmittal Document

Submitter

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

Regulatory Action in Support of Which This Document is Submitted

Application for Registration of a Plant-Incorporated Protectant Pursuant to FIFRA §3(c)(5): *Bacillus thuringiensis* Vip3Aa20 Protein Encoded by Vector pNOV1300 in MIR162 maize (OECD Unique Identifier: SYN-IR162-4)

File Symbol 67979-

Transmittal Date

May 17, 2007

Submitter Reference No.

MIR162-EPA-12

List of Accompanying Volumes

Vol.	Category[1]	Volume/Study Title	MRID
1	A	Ward, D. (2007). Application for manufacturing-use registration of MIR162 maize (SYN-IR162-4). Reference No. MIR162-EPA-12	
1	C	Confidential Attachment	
Product Analysis Data			
2	B	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). Report No. SSB-023-06	
3	B	Stacy, C. and G. Graser (2006). Characterization of phosphomannose isomerase (PMI) produced in event MIR162 maize and comparison to PMI as contained in test substance PMI-0198. Report No. SSB-037-06	
4	B	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 *Escherichia coli*. Report No. SSB-122-07	
5	B	Long, N. (2007). Molecular characterization of the transgenic DNA in event MIR162 maize. Report No. SSB-119-07	
Residue Data			
6	B	Hill, K. (2006). Quantification of Vip3Aa20 and phosphomannose isomerase (PMI) in tissues of maize derived from transformation event MIR162. Report No. SSB-020-06	
7	B	Murray, J. (2006). Validation of the analytical method for qualitative detection of Vip3Aa20 protein in maize seed. Report No. SSB-016-07	
8	B	Brady, J. (2007). Independent laboratory validation: Syngenta Biotechnology, Inc. SOP 2.91.1, "Extraction and qualitative detection of Vip3Aa20 protein from MIR162 maize seed". Report No. 1-2007	
Toxicology Data			
9	B	Draper, C. (2007). MIRVIP3A-0106 single dose oral toxicity study in mice. Report No. AM7543-REG	
10	B	Stacy, C. (2007). *In vitro* digestibility of Vip3Aa20 under simulated mammalian gastric conditions. Report No. SSB-038-06	
11	B	Stacy, C. (2007). *In vitro* digestibility of Vip3Aa20 (MIR162VIP3A-0106) under simulated mammalian intestinal conditions. Report No. SSB-002-07	

List of Accompanying Volumes (cont.)

Vol.	Category[1]	Volume/Study Title	MRID
12	B	Stacy, C. (2007). Effect of temperature on the stability of Vip3Aa20 protein. Report No. SSB-039-06	
		Nontarget Organism Data	
13	B	Brake, J. (2007). Evaluation of event MIR162 transgenic maize in broiler chickens. Report No. SSB-507-07	
14	B	Stacey, D. and R. Blake (2007). A laboratory study to determine effects of Vip3Aa20 protein on the rove beetle *Aleochara bilineata* (Coleoptera: Staphylinidae). Report No. T002155-06-REG	
15	B	Jeker, L. (2006). Vip3Aa20: A honeybee brood study to evaluate the effects on brood development of the honeybee, *Apis mellifera* L. (Hymenoptera: Apidae). Report No. T002494-06	
16	B	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	
		Product Performance and Other Data	
17	B	Huber, S., J. White, S. Mroczkiewicz, and D. Ward (2007). Insecticidal efficacy field evaluations with MIR162 maize hybrids in 2005 and 2006. Report No. SSB-522-07	
18	B	White, J., M. Meehan, and M. Meghji (2007). Corn earworm tolerance of a MIR162 maize hybrid: 2006 field trial results. Report No. SSB-502-07	
19	B	White, J., J. Sagers, M. Meehan, and M. Meghji (2007). Fall armyworm tolerance of a MIR162 maize hybrid: 2006 field trial results. Report No. SSB-503-07	
20	B	Ward, D. and D. Vlachos (2007). Public interest assessment supporting registration of MIR162, Bt11xMIR162, and Bt11xMIR162xMIR604 maize. Report No. SSB-518-07	
21	A	Huber, S. (2007). Literature references supporting the application for registration of MIR162 maize – 1 of 3. Reference No. MIR162-EPA-12-VOL21	
22	A	Huber, S. (2007). Literature references supporting the application for registration of MIR162 maize – 2 of 3. Reference No. MIR162-EPA-12-VOL22	
23	A	Huber, S. (2007). Literature references supporting the application for registration of MIR162 maize – 3 of 3. Reference No. MIR162-EPA-12-VOL23	

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

Transmittal Document (cont.)

Company Official:	Dennis P. Ward Dennis P. Ward, Ph.D. Regulatory Affairs Manager	May 17, 2007 Date

Company Name: Syngenta Seeds, Inc. – Field Crops

Company Contact: Dennis P. Ward / Tel. 919.597.3096

Section I. Administrative Materials

A. Form 8570-1

Application for Pesticide Registration (next page).

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
67979-	Sheryl Reilly	☒ None ☐ Restricted
Company/Product (Name): MIR162 maize	PM #: 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Syngenta Seeds, Inc. - Field Crops
P.O. Box 12257, 3054 East Cornwallis Road
Research Triangle Park, NC 27709
☐ Check if this is a new address

6. **Expedited Review.** 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

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated ____________
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated ____________
☐ "Me Too" Application.
☒ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Application for a limited manufacturing-use registration of MIR162 maize to allow for breeding and seed production.

Proposed PRIA category: **B81** ($315,000 less the $50,000 credit from EUP application)

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper w/ polyurethane liner ☐ Other
**** Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	*(Specify)*____________

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
☐ Lithograph
☐ Paper glued
☐ Stenciled
☐ Other: ____________

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Dennis P. Ward	Regulatory Affairs Manager	919.597.3096

Certification

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.

2. Signature	3. Title	6. Date Application Received
Dennis P. Ward	Regulatory Affairs Manager	**(Stamped)**
4. Typed Name: Dennis P. Ward, Ph.D.	5. Date: May 17, 2007	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. **White - EPA File Copy (original)** **Yellow - Applicant Copy**

B. Form 8570-4

Confidential Statement of Formula for MIR162 maize.

{CBI Cross Reference Number 1}

C. Form 8570-34

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N. 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, Inc., P.O. Box 12257, Research Triangle Park, NC 27709 (919) 597-3096	EPA Registration Number / File Symbol: 67979-
Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300	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: MIR162 maize

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 of misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature	Date	Typed or Printed Name and Title
Dennis P. Ward	May 17, 2007	Dennis P. Ward, Regulatory Affairs Manager

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D. Form 8570-35

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: May 17, 2007 | EPA Reg. No. / File Symbol: 67979- | Page 1 of 12

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Data Supporting MIR162 & Vip3Aa20					
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 (*Coleomegilla maculata*). 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 (*Daphnia magna*) 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 (*Eisenia foetida*). 1781.6615	457921-02	Syngenta Seeds, Inc	OWN	Submission dated October 29, 2002

Signature: Dennis P. Ward

Name and Title: Dennis P. Ward, Ph.D.
Regulatory Affairs Mgr.

Date: May 17, 2007

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DATA MATRIX

Date: May 17, 2007

EPA Reg. No. / File Symbol: 67979-

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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

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 on 28-day survival and reproduction of Collembola (*Folsomia candida*). SSB-006-01	458358-10	Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002
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

Signature: Dennis P. Ward

Name and Title: Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.

Date: May 17, 2007

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Date: May 17, 2007

EPA Reg. No. / File Symbol: 67979-

Page 3 of 12

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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
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 *Escherichia coli*. 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

Signature: Dennis P. Ward

Name and Title: Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.

Date: May 17, 2007

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EPA Reg. No. / File Symbol: 67979-

Applicant's/Registrant's Name & Address:
Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product:
MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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
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, *Orius insidiousus* (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 *Chrysoperla carnea* (ANeuroptera: Chrysopidae). SYN-04-32	468648-15	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006

Signature	Name and Title	Date
Dennis P. Ward	Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	May 17, 2007

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Date: May 17, 2007

EPA Reg. No. / File Symbol: 67979-

Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Lee, et al. (2003). The mode of action of the *Bacillus thuringiensis* vegetative insecticidal protein Vip3A differs from that of Cry1Ab δ-endotoxin. *Appl. Environ. Microbial.* **69**: 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, *Coccinella septempunctata* (Coleoptera: Coccinellidae). SYN-04-23	468808-02	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
	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 *Bacilus thuringiensis* products. SSB-036-06	470176-13	Syngenta Seeds, Inc.	OWN	Submission dated December 14, 2006

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Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4200	Cafarella, M. (2005). Channel catfish (*Ictalurus punctatus*) 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
885.1100	Ward, D. (2007). Application for manufacturing-use registration of MIR162 maize (SYN-IR162-4). MRI162-EPA-12		Syngenta Seeds, Inc	OWN	Volume 1 of this submission
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 this submission
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 *Escherichia coli*. SSB-122-07		Syngenta Seeds, Inc.	OWN	Volume 4 of this submission

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Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2100	Long, N. (2007). Molecular characterization of the transgenic DNA in event MIR162 maize. SSB-119-07		Syngenta Seeds, Inc.	OWN	Volume 5 of this submission
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 this submission
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 this submission
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 this submission
885.3050 885.4150	Draper, C. (2007). MIRVIP3A-0106 single dose oral toxicity study in mice. AM7543-REG		Syngenta Seeds, Inc	OWN	Volume 9 of this submission

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Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885. 3050	Stacy, C. (2007). *In vitro* digestibility of Vip3Aa20 under simulated mammalian gastric conditions. SSB-038-06		Syngenta Seeds, Inc	OWN	Volume 10 of this submission
885. 3050	Stacy, C. (2007). *In vitro* digestibility of Vip3Aa20 (MIR162VIP3A-0106) under simulated mammalian intestinal conditions. SSB-002-07		Syngenta Seeds, Inc.	OWN	Volume 11 of this submission
885. 2400	Stacy, C. (2007). Effect of temperature on the stability of Vip3Aa20 protein. SSB-039-06		Syngenta Seeds, Inc.	OWN	Volume 12 of this submission
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 this submission
885.4340	Stacey, D. and R. Blake (2007). Vip3Aa20: A laboratory study to determine effects of Vip3Aa20 protein on the rove beetle *Aleochara bilineata* (Coleoptera: Staphylinidae). Report No. T002155-06-REG		Syngenta Seeds, Inc	OWN	Volume 14 of this submission

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Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Jeker, L. (2006). Vip3Aa20: A honeybee brood study to evaluate the effects on brood development of the honeybee, *Apis mellifera* L. (Hymenoptera: Apidae). T002494-06		Syngenta Seeds, Inc	OWN	Volume 15 of this submission
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 this submission
	Huber et al. (2007). Insecticidal efficacy field evaluations with MIR162 maize hybrids in 2005 and 2006. SSB-522-07		Syngenta Seeds, Inc.	OWN	Volume 17 of this submission
	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 this submission
	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 this submission

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Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Ward, D. and D. Vlachos (2007). Public interest assessment supporting registration of MIR162, Bt11xMIR162, and Bt11xMIR161xMIR604 maize. Report No. SSB-518-07		Syngenta Seeds, Inc.	OWN	Volume 20 of this submission
	Huber, S. (2007). Literature references supporting the application for registration of MIR162 maize – 1 of 3. MIR162-EPA-12-VOL20		Syngenta Seeds, Inc	PL	Volume 21 of this submission
	Huber, S. (2007). Literature references supporting the application for registration of MIR162 maize – 2 of 3. MIR162-EPA-12-VOL21		Syngenta Seeds, Inc	PL	Volume 22 of this submission
	Huber, S. (2007). Literature references supporting the application for registration of MIR162 maize – 3 of 3. MIR162-EPA-12-VOL22		Syngenta Seeds, Inc	PL	Volume 23 of this submission

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Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Data Supporting Marker Protein – PMI					
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). *In vitro* 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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Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

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 this submission

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Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

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[redacted]					
[redacted]			Syngenta Seeds, Inc.	OWN	Submission dated September 24, 2002
[redacted]			Syngenta Seeds, Inc	OWN	Submission dated September 24, 2002
[redacted]			Syngenta Seeds, Inc	OWN	Submission dated October 29, 2002
[redacted]			Syngenta Seeds, Inc	OWN	Submission dated October 29, 2002

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[redacted]			Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002
			Syngenta Seeds, Inc	OWN	Submission dated December 23, 2002
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			Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
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[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc	OWN	Submission dated June 7, 2006
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc	PL	Submission dated June 7, 2006
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc	OWN	Submission dated December 14, 2006

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[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc	OWN	Volume 1 of this submission
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

DATA MATRIX

Date: May 17, 2007

EPA Reg. No. / File Symbol: 67979-

Applicant's/Registrant's Name & Address:
Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product:
MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Syngenta Seeds, Inc	OWN	Volume 10 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 11 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 12 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 13 of this submission
			Syngenta Seeds, Inc.	OWN	Volume 14 of this submission

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DATA MATRIX

Date: May 17, 2007

EPA Reg. No. / File Symbol: 67979-

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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Volume 15 of this submission
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Volume 16 of this submission
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Volume 17 of this submission
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Volume 18 of this submission
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Volume 19 of this submission

Signature	Name and Title	Date
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Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Syngenta Seeds, Inc.	PL	Volume 20 of this submission
			Syngenta Seeds, Inc.	PL	Volume 21 of this submission
			Syngenta Seeds, Inc.	PL	Volume 22 of this submission
			Syngenta Seeds, Inc.	PL	Volume 22 of this submission

Signature	Name and Title	Date
Dennis P. Ward	Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	May 17, 2007

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Applicant's/Registrant's Name & Address: Syngenta Seeds, Inc., P.O. Box 12257, Research Triangle Park, NC 27709

Product: MIR162 maize

Ingredient *Bacillus thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]	[redacted]	[redacted]			
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Submitted May 1, 2003
[redacted]	[redacted]	[redacted]	Syngenta Seeds, Inc.	OWN	Submitted June 7, 2006

Signature: Dennis P. Ward

Name and Title: Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.

Date: May 17, 2007

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[redacted]			Syngenta Seeds, Inc.	OWN	Submitted June 7, 2006
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Signature	Name and Title	Date
Dennis P. Ward	Dennis P. Ward, Ph.D. Regulatory Affairs Mgr.	May 17, 2007

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Section II. Summary of the Application

A. Introduction

Syngenta has developed a new line of maize that resists damage caused by insect feeding. Many lepidopteran insects are major pests of maize in North America. The transgenic maize described in this application has been transformed with a gene that encodes an insecticidal protein which has activity against many significant lepidopteran insect pests.

MIR162 maize was produced by *Agrobacterium*-mediated transformation using elements of a vector (pNOV1300) containing a variant of the *vip3Aa1* gene from *Bacillus thuringiensis* (*Bt*). The *vip3Aa1* gene was isolated from *Bt* strain AB88. This gene encodes a vegetative insecticidal protein (Vip) that is highly toxic to the following lepidopteran pests of maize: *Spodoptera frugiperda* (fall armyworm), *Helicoverpa zea* (corn earworm / cotton bollworm), *Agrotis ipsilon* (black cutworm), and *Striacosta albicosta* (western bean cutworm). A maize-optimized variant of the gene has been incorporated into the genome of MIR162 maize and encodes a protein assigned the following toxin designation: Vip3Aa20. MIR162 maize also contains the *manA* gene from *Escherichia coli* which encodes the selectable marker enzyme, phosphomannose isomerase.

B. Nature of Registration Being Requested

An application for registration of a plant-incorporated protectant pursuant to FIFRA §3(c)(5) is being sought for the *B. thuringiensis* Vip3Aa20 protein encoded by vector pNOV1300 in MIR162 maize. The results of laboratory bioassays and field efficacy trials demonstrate that the Vip3Aa20 protein produced in MIR162 maize will not protect the plants against feeding damage caused by *Ostrinia nubilalis* (European corn borer). Crop losses attributable to *O. nubilalis* are one of U.S. maize growers' greatest concern. Due to its lack of efficacy against *O. nubilalis*, MIR162 will be made available to growers as a combined-trait offering with Bt11 or another corn borer resistant line. A hybrid containing both Bt11 and MIR162 traits will offer growers protection against a broad range of both major and minor lepidopteran pests of maize.

Syngenta is not planning on offering the MIR162 trait by itself to growers at this time. Therefore, a manufacturing-use registration is being sought that allows planting for breeding purposes, agronomic testing, increasing inbred seed stocks, and producing hybrid seed on up to 30,000 acres annually. Under this registration MIR162 maize will not be planted for purposes of insect control or grain production. Approval is also being requested to combine the MIR162 trait through conventional breeding techniques with other registered plant-incorporated protectants, such as those in Bt11 and MIR604. Plantings under this MIR162 registration will not be carried out under a formal insect resistance management (IRM) plan. Section VI of this volume includes an assessment of insect resistance risk for undertaking these plantings without a formal IRM plan. The resultant risk of resistance developing is extremely low.

Section III. Satisfaction of Data Requirements

Specific data requirements for obtaining registration of a plant-incorporated protectant (PIP) have not been promulgated under 40 CFR §174 Subpart H. In the absence of PIP-specific data requirements EPA has utilized those requirements delineated for microbial pesticides (40 CFR §158.740) as a partial guide for determining if an Applicant has provided all of the required data. In addition to the microbial data requirements there is a core set of studies more pertinent to PIPs that EPA has been requiring of applicants in recent years. These latter data requirements are not published and become know to the Applicant through presubmission consultations with the Agency.

The tables in this section provide a listing of the data requirements applicable to registration of a plant-incorporated protectant as known to Syngenta. An explanation of how each data requirement is satisfied in this application is included in the table. Specific study reports addressing a data requirement are cited either by the volume number within this submission or by MRID if previously submitted. Not all of the microbial pesticide data requirements are applicable to a PIP given the inherent differences between the two types of products. Where appropriate, a brief explanation is provided in the table for those data requirements that are not applicable. The data requirements are organized by OPPTS Microbial Pesticide Test Guideline number, using the 885- guideline series. OPPTS guideline numbers are not assigned (N/A) to some PIP data requirements.

A. Product Analysis Data Requirements

OPPTS #	Data Requirement	Method of Satisfaction
885.1100	Product identity	Volume 1 (CSF) & data volumes 2, 3 & 5; MRIDs 468648-01 & 468648-02
885.1200	Manufacturing process	Volume 5; MRID 468648-01
885.1300	Formation of unintentional ingredients	Volumes 2, 3 & 5; MRIDs 468648-01 & 468648-02
885.1400	Analysis of samples	Volumes 2 & 3; MRID 468648-02
885.1500	Certification of limits	Volume 1 (CSF) & data volume 6

B. Residue Data Requirements

OPPTS #	Data Requirement	Method of Satisfaction
885.2100	Chemical identity	Volumes 2, 3 & 5; MRIDs 468648-01 & 468648-02
885.2200	Nature of residue in plants	Volume 2 & 3; MRID 468648-02

OPPTS #	Data Requirement	Method of Satisfaction
885.2250	Nature of residue in animals	No adverse effects associated with mammalian exposure to Vip3Aa20 or the marker protein in MIR162 maize have been observed, thus they are not of toxicological concern and do not trigger this data requirement.
885.2300	Analytical methods - plants	Volumes 7 & 8
885.2350	Analytical methods - animals	Vip3Aa20 and the marker protein in MIR162 maize are exempt from the requirement of tolerances, thus an analytical enforcement method is not needed.
885.2400	Storage stability	Volume 12; MRID 459344-09
885.2500	Magnitude of residues in plants	Volume 6
885.2550	Magnitude of residues in meat, milk, poultry, and eggs	Vip3Aa20 and the marker protein in MIR162 maize are exempt from the requirement of tolerances, thus residue studies are not required.
885.2600	Magnitude of residues in potable water, fish, and irrigated crops	The Vip3Aa20 protein is a plant-incorporated pesticide and will not be used in aquatic sites. MIR162 maize seed may be planted near aquatic sites and there is the potential for pollen drift into bodies of water. However, there are no residues of toxicological concern in MIR162 maize; thus, aquatic residue studies are not required.

C. Toxicology Data Requirements

OPPTS #	Data Requirement	Method of Satisfaction
885.3050	Acute oral toxicity/pathogenicity	Volume 9, 10 & 11; MRIDs 468648-08, 459344-07, 459344-08 & 468648-10
885.3100	Acute dermal toxicity/pathogenicity	Vip3Aa20 is plant-incorporated, contained within individual plant cells. There is minimal opportunity for human dermal contact because corn is not a hand harvested crop. Furthermore, Vip3Aa20 is of no toxicological concern; thus, dermal toxicity data are not required. As the protein is not a living organism, a pathogenicity determination is not applicable.
885.3150	Acute pulmonary toxicity/pathogenicity	Vip3Aa20 is a plant-incorporated protein and is not volatile. There is minimal opportunity for human inhalation exposure. The protein is of no toxicological concern; thus, inhalation toxicity data are not required. As the protein is not a living organism, a pathogenicity determination is not applicable.

OPPTS #	Data Requirement	Method of Satisfaction
885.3200	Acute injection toxicity/pathogenicity	Vip3Aa20 is plant-incorporated and of no toxicological concern. There is minimal opportunity for direct entry of the protein into the blood stream via injury during handling because corn is not a hand harvested crop. As the protein is not a living organism, a pathogenicity determination is not applicable.
885.3400	Hypersensitivity incidents	468648-09 & 468648-11. Syngenta is aware of no incidents of hypersensitivity reactions to Vip3Aa20 or the marker protein in MIR162 maize.
885.3500	Cell culture	Vip3Aa20 is not a living organism and therefore, has no infectivity potential. A cell culture study is not required.
885.3550	Acute toxicology, Tier II	Volume 9 and MRID 459344-07. No adverse effects were observed at the maximum attainable oral doses for Vip3Aa20 and the marker protein; LD_{50} determinations are therefore, not possible. Criteria needed to trigger this Tier II study were not met in the Tier I studies.
885.3600	Subchronic toxicity/pathogenicity	No evidence of infectivity, pathogenicity, or toxicity was observed in Tier I studies with Vip3Aa20 or the marker protein in MIR162 maize. Criteria needed to trigger this Tier II study were not met in Tier I studies.
885.3650	Reproductive/fertility effects	No evidence of infectivity, pathogenicity, or toxicity was observed in Tier I studies with Vip3Aa20 or the marker protein in MIR162 maize. Criteria needed to trigger this Tier II study were not met in Tier I studies.

D. Nontarget Organism Data Requirements

OPPTS #	Data Requirement	Method of Satisfaction
885.4050	Avian oral, Tier I	Volume 13 and MRID 457665-08
885.4100	Avian inhalation, Tier I	Vip3Aa20 is plant-incorporated and is not ‘applied’ in aerosol or dust formulations as microbial pesticide products would be. The only airborne route of exposure for Vip3Aa20 would be via pollen drift and maize pollen is not of a size that is respirable.
885.4150	Wild mammal testing, Tier I	Volume 9
885.4200	Freshwater fish testing, Tier I	MRID 470176-24

OPPTS #	Data Requirement	Method of Satisfaction
885.4240	Freshwater aquatic invertebrate testing, Tier I	MRID 457921-01
885.4280	Estuarine and marine animal testing, Tier I	There will be no 'direct application' of Vip3Aa20 to fresh, estuarine, or marine waters. Furthermore, Vip3Aa20 does not display a broad spectrum of activity. This data requirement does not apply.
885.4300	Nontarget plant studies, Tier I	Vip3Aa20 is not a living organism and therefore, is not pathogenic to plants.
885.4340	Nontarget insect testing, Tier I	Volumes 14 & 16; MRIDs 457665-09, 458358-10, 468648-14, 468648-15, 468808-01 & 468808-02
885.4380	Honey bee testing, Tier I	Volume 15
885.4600	Avian chronic pathogenicity and reproduction test, Tier III	No adverse effects were observed in Tier I studies and Vip3Aa20 is not persistent in the environment. Criteria needed to trigger higher tier testing are not met.
885.4650	Aquatic invertebrate range testing, Tier III	No adverse effects were observed in Tier I studies and Vip3Aa20 is not persistent in the environment. Criteria needed to trigger higher tier testing are not met.
885.4700	Fish life cycle studies, Tier III	No adverse effects were observed in Tier I studies and Vip3Aa20 is not persistent in the environment. Criteria needed to trigger higher tier testing are not met.
885.4750	Aquatic ecosystem test	No adverse effects were observed in Tier I studies and Vip3Aa20 is not persistent in the environment. Criteria needed to trigger higher tier testing are not met.
N/A	Other nontarget organism tests	MRID 457921-02

E. Environmental Expression Data Requirements

OPPTS #	Data Requirement	Method of Satisfaction
885.5200	Expression in a terrestrial environment	Volume 6; MRIDs 458358-11, 470176-13 & 470176-30
885.5300	Expression in a freshwater environment	Vip3Aa20 and MIR162 maize do not have the ability to invade, survive, or replicate in a freshwater environment. Criteria needed to trigger higher tier testing are not met.
885.5400	Expression in a marine or estuarine environment	Vip3Aa20 and MIR162 maize do not have the ability to invade, survive, or replicate in a marine or estuarine environment. Criteria needed to trigger higher tier testing are not met.

F. Undocumented Data Requirements

OPPTS #	Data Requirement	Method of Satisfaction
N/A	Product efficacy	Volumes 17, 18 & 19; MRID 468808-03
N/A	Public interest assessment	Volume 20

Section IV. Product Label

Three copies of the label for MIR162 maize are presented on the following pages.

MIR162 maize

Insect Control Protein
(OECD Unique Identifier: SYN-IR162-4)

Active Ingredient:
Bacillus thuringiensis Vip3Aa20 protein encoded by vector pNOV1300
in event MIR162 maize (SYN-IR162-4) …………………….…………… 0.00167 – 0.00751%*

Other Ingredient:
A marker protein encoded by vector pNOV1300
in event MIR162 maize (SYN-IR162-4) …….……………………….…… 0.00014 – 0.00073%*

---

*Percent dry weight, whole plant

CAUTION
Keep Out of Reach of Children

EPA Registration Number 67979-
EPA Establishment Number 66736-NC-1

NET CONTENTS: _______

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

DIRECTIONS FOR USE

Use of this plant-incorporated protectant in a manner inconsistent with the terms of this label is a violation of Federal law. MIR162 maize seed may only be planted for research and breeding purposes, increasing inbred seed, or producing hybrid seed. Planting of MIR162 seed to enable breeding crosses with other inbred cultivars containing registered plant-incorporated protectants is permitted.

Total plantings of this seed cannot exceed 30,000 acres in any calendar year.

STORAGE AND DISPOSAL

Planting seed, as well as harvested seed, should be stored in a secure, cool, and dry place. Do not contaminate bodies of water by storage or disposal.

MIR162 maize

Insect Control Protein
(OECD Unique Identifier: SYN-IR162-4)

Active Ingredient:
Bacillus thuringiensis Vip3Aa20 protein encoded by vector pNOV1300
in event MIR162 maize (SYN-IR162-4) …………………….………… 0.00167 – 0.00751%*

Other Ingredient:
A marker protein encoded by vector pNOV1300
in event MIR162 maize (SYN-IR162-4) …….……………………….…… 0.00014 – 0.00073%*

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*Percent dry weight, whole plant

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in event MIR162 maize (SYN-IR162-4) …………………….………………. 0.00167 – 0.00751%*

Other Ingredient:
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in event MIR162 maize (SYN-IR162-4) ……..………………..…………..…… 0.00014 – 0.00073%*

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*Percent dry weight, whole plant

CAUTION
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EPA Registration Number 67979-
EPA Establishment Number 66736-NC-1

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Total plantings of this seed cannot exceed 30,000 acres in any calendar year.

STORAGE AND DISPOSAL

Planting seed, as well as harvested seed, should be stored in a secure, cool, and dry place. Do not contaminate bodies of water by storage or disposal.

Section V. Tolerance Exemptions for Vip3Aa20 and PMI

A petition to establish a permanent exemption from the requirement of tolerance for residues of Vip3Aa20 protein when used as a plant-incorporated protectant in corn accompanies this application for registration.

Phosphomannose isomerase, the marker protein in MIR162 maize, is exempt from the requirement of a tolerance in all plants, 40 CFR §180.1252.

Section VI. Insect Resistance Management Implications

This application is for a manufacturing-use registration of MIR162 maize that allows for Syngenta and its licensees to engage in plantings of MIR162 cultivars for purposes of developing new lines, breeding, agronomic testing, increasing inbred seed stocks, and producing hybrid seed corn. This registration will also allow for the production of inbreds and hybrids that contain combinations of registered plant-incorporated protectants (*i.e.* breeding stacks). A registration under FIFRA §3(c)(5) is being sought that allows for manufacturing-use plantings on up to 30,000 acres annually. Commercial plantings for the purpose of controlling corn insect pests and grain production are prohibited. Plantings under this registration will not require adherence to a formal IRM plan. Adherence to an IRM plan is not currently required for the production of seed corn containing registered plant-incorporated protects. It is not feasible to apply the IRM plans for registered *Bt* corn varieties to standard seed production practices. This practice is not considered to present a significant risk for development of insect resistance for the reasons described below.

A. Description of Seed Production Practices

Nearly 80 million acres of hybrid field corn were planted in the United States during 2006 and planting of approximately 90 million acres is forecast for 2007. By comparison, approximately one million acres are annually committed to commercial hybrid seed production for the entire domestic seed industry. A much smaller number of acres are committed to raising parental inbred stocks (< 20,000 acres).

Hybrid seed production is fundamentally a two step process. The first step is to develop and produce high purity parental inbred seed stocks and the second step involves planting two parental inbred lines in close proximity and allowing them to cross pollinate. The harvested hybrid seed is sold to farmers.

1. Propagation of Inbred Seed

Inbred lines are developed by plant breeders and are made by self-pollination of the plants in isolated fields. Inbred lines are required to have a high level of genetic purity otherwise desirable traits can be lost and undesirable traits can be amplified in the hybrid production process. Producing inbreds in isolated fields prevents contamination from other pollen sources and is critical to preserving the genetic purity of a line.

At Syngenta, the production of parental inbred seed is a two generation process. In the first generation, fields committed to raising an inbred parental line are typically three acres in size. The harvested seed is then increased in a second generation in fields of up to 60 acres. The seed harvested from the second generation is used for hybrid seed production. Large and small inbred seed increase fields are spatially isolated from other corn fields by a ¼ mile to protect the genetic purity of a line. Inbred fields are intensively managed and prophylacticly treated with insecticides and fungicides to protect yield. The fields are regularly scouted during the season and very low thresholds for additional insecticide applications are employed. Due to the very high replacement cost of inbred seed (~$16,000/acre), finding more than one insect pest or egg mass in a field would trigger an insecticide application.

2. Hybrid Seed Production

The hybrid seed corn sold to farmers is produced by cross-pollinating two inbred parental lines. Hybrid production fields are typically 60 acres in size but can be as large as 300 acres. Large scale production of any single hybrid is usually split between multiple fields to minimize the risk of losing a field to uncontrollable factors such as a hail storm. Similar to inbred seed increase fields, hybrid production fields are isolated from other open-pollinating corn fields. Isolation distances will vary by location and planting configuration. Surrounding fields in the Midwest will likely be planted to soybeans.

Each hybrid production field will be planted with two inbred parents: the pollen parent (male parent) and the seed parent (female parent). Female and male inbreds are typically planted in a repeating 4:1 or 2:1 ratio but other ratios can also be used. A 4:1 planting ratio is illustrated in Figure 1. This illustration shows the deployment of female and male rows in a production field. Each block of four female rows is bracketed on each side with an inbred male row.

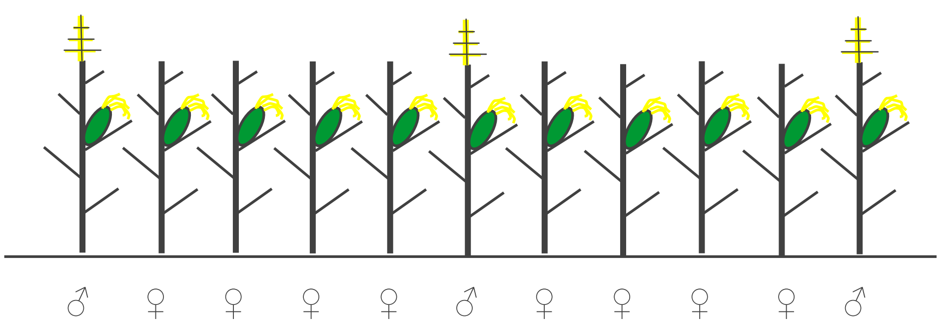

Figure 1. Diagram showing planting arrangement of male and female inbreds within a hybrid seed corn production field. ♂ = male inbred (pollen donor); ♀ = detasseled female inbred (seed parent).

The female plants are detasseled prior to anthesis or emergence of silks to ensure that only pollen from the male parent is available to pollinate the ears of the female plants. After pollination, the male plants are typically destroyed so that ears are harvested only from the female plants. The MIR162 transgene will be contained in the genome of only one parent in a hybrid production field. The perimeter of each hybrid production field will be planted with rows of pollen parents to dilute contaminating external pollen that may blow into the seed production field.

Hybrid seed corn production fields are actively managed. They are scouted on a weekly basis for early signs of pest or plant growth problems. Foliar insecticides and fungicides are applied as needed to ensure seed quality. Although insecticide application thresholds are higher than for inbred seed increase fields, they are significantly lower than thresholds used for grain production because of the high value of each seed corn acre. Due to these stringent management practices, hybrid seed production fields are virtually insect free.

B. Assessment of Insect Resistance Risk

Current IRM requirements for *Bt* maize cultivars are not applied to breeding, propagation, inbred seed propagation, and or hybrid seed production plantings. These IRM requirements are only applied to plantings by farmers for grain and forage production. Existing IRM plans require growers to plant a 20% structured refuge. The refuge can be deployed within the *Bt* field, adjacent to it, or within a ½ mile, and preferable a ¼ mile (for lepidopteran-resistant varieties). Planting these structured refugia are not practical with current seed corn production practices and are unwarranted given that acres committed to seed production account for less than two percent of the total maize acres planted in the U.S. in any given year. A number of other factors further mitigate any risk of insect resistance developing as a result of seed production plantings.

Plantings of MIR162 under this registration will be used to increase inbred parental seed stocks and to produce combined-trait hybrids with Bt11 and MIR604. In the context of this registration, there will be three insects of concern for potential development of resistance in these fields: *H. zea* in inbred fields and *O. nubilalis*, *H. zea*, and *Diabrotica* species in hybrid fields.

It is not feasible to have a conventional maize refuge in-field, adjacent to, or near a MIR162 inbred increase field. There is too great a risk for contamination of the inbred germplasm by foreign pollen. Resistance risk without a refuge will be insignificant because the total number of acres planted to increase MIR162 inbred stocks will be trivial by comparison to the 80-90 million acres of hybrid field corn planted annually in the U.S. and individual fields will typically be small in size (*i.e.*, 4 to 60 acres). Furthermore, MIR162 maize is very active against *H. zea* and few, if any larvae will survive to adulthood. Inbred fields are intensively managed and prophylactically treated with insecticides and fungicides to protect yield. The fields are regularly scouted during the season and very low thresholds for additional insecticide applications are employed. Inbred fields are IRM neutral since essentially no larvae survive to contribute alleles, either resistant or susceptible, to the next generation from these fields. Inbred increase fields will typically be surrounded by soybean which is an alternate host for *H. zea* and can serve as a source of susceptible moths for mating in the unlikely event that a resistant individual survives feeding on MIR162 maize and insecticide sprays.

Hybrid production fields such as the one diagrammatically shown in Figure 2 will have an effective in-field refuge for *O. nubilalis* and corn rootworms. Vip3Aa20 has no insecticidal activity against these species and thus, MIR162 maize will serve as a host for development of susceptible moths and beetles for mating with potentially resistant insects emerging from either Bt11 maize or MIR604 maize. For *H. zea* there will be no in-field refuge because both Bt11 and MIR162 maize have activity against this pest. However, resistance risk will be inconsequential because of the small number of acres utilized in Bt11xMIR162 hybrid production compared to the 90 million acres of field corn that are planted annually.

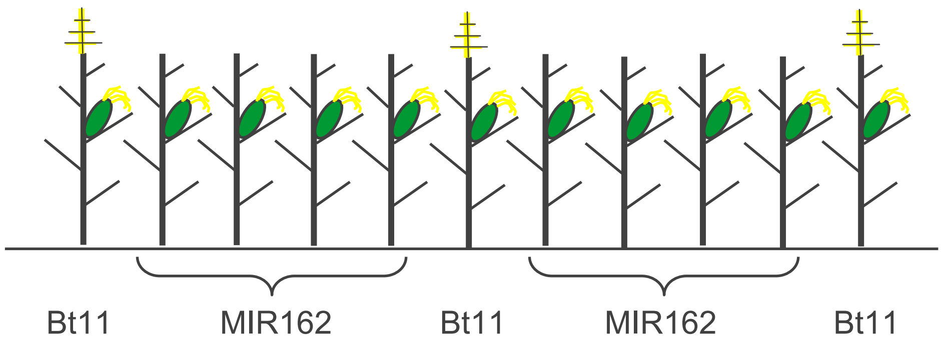

Figure 2. Planting arrangement of Bt11 and MIR162 inbreds in a Bt11xMIR162 hybrid production field. In this arrangement the Bt11 inbred is the pollen donor and the MIR162 inbred is the seed parent. MIR162 rows serve as a 80% refuge for *O. nubilalis*.

Collectively, the small number of acres that will be planted under this registration, aggressive production management practices, and the presence of effective in-field and external refugia will result in minimal risk of resistance development to insect species of concern.