



**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 August 16, 2002  
 Applicant's/Registrant's Name & Address  
 Monsanto Company, 600 13th Street N.W., Suite 660, Washington, D.C 20005  
 EPA Reg No./File Symbol: 524-522 Page 1 of 7  
 Product: Bollgard® II Cotton  
 Ingredient A *Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production in Bollgard® II cotton event 15985

Guideline Reference Number	Guideline Study Name	RPD Number	Submitter	Status	Note
	Administrative Materials in Support of the Request for the Exemption from the Requirement of Tolerance for Glucuronidase (GUS) as a Plant-Incorporated Protectant Formulation Inert Ingredient.	4493940	Monsanto Company	OWN	
	Administrative Materials in Support of the Amendment for the Request for Exemption from the Requirement of Tolerance for Cry2Ab2 (Petition PP 7F4888).	4496600	Monsanto Company	OWN	
	Validated Method for Detection and Direct ELISA Analysis of Cry2Ab2 in Cottonseed - An unpublished study conducted by Monsanto Company	Not yet assigned	Monsanto Company	OWN	Submitted 13-Apr-01
	Insect Resistance Management Plan for Bollgard® II Cotton: An unpublished study conducted by Monsanto Company	45545701	Monsanto Company	OWN	
	Public Interest Document Supporting the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton ( <i>Gossypium hirsutum</i> L.)	Not yet assigned	Monsanto Company	OWN	Submitted 11-Dec-01
	Administrative Materials in Support of the Request for the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Corn ( <i>Zea mays</i> L.) and Cotton ( <i>Gossypium hirsutum</i> L.)	45086300	Monsanto Company	OWN	
Signature	[Redacted]		Name and Title	Date	
	[Redacted]		Regulatory Affairs Mgr.	August 16, 2002	

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Date August 16, 2002  
 Applicant's/Registrant's Name & Address: Monsanto Company, 600 13th Street N W , Suite 660, Washington, D C. 20005  
 EPA Reg No./File Symbol: 524-522 Page 2 of 7  
 Product Bollgard II Cotton

Ingredient A *Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production in Bollgard II cotton event 15985

Guideline Reference Number	Guideline Study Name	RFID Number	Submitter	Status	Note
	The Purification of D-Glucuronidase (GUS) from Recombinant E coli for Use in Equivalence Studies MSL-12235, an unpublished study conducted by Monsanto Company	449394-01	Monsanto Company	OWN	
	Acute Oral Toxicity Study of Glucuronidase (GUS) Protein in Albino Mice MSL-12485, an unpublished study conducted by Monsanto Company	449888-01	Monsanto Company	OWN	
	Preparation, Characterization, and Confirmation of Doses for an Acute Mouse Feeding Study with D-Glucuronidase MSL-12979, an unpublished study conducted by Monsanto Company	449394-04	Monsanto Company	OWN	
	Assessment of the In vitro Digestive Fate of Glucuronidase MSL-14607, an unpublished study conducted by Monsanto Company	449394-07	Monsanto Company	OWN	
	Characterization of Insect Protection Protein 2 (IPP2) Produced by Fermentation MSL-17742, an unpublished study conducted by Monsanto Company	449993-01	Monsanto Company	OWN	
	Field Report Production of Tissue Samples from Insect Protected Cotton Plants Grown in 1998 U.S. Field Trials MSL-16019, an unpublished study conducted by Monsanto Company	450863-01	Monsanto Company	OWN	

Signature [Redacted] Name and Title [Redacted] Regulatory Affairs Mgr.  
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**DATA MATRIX**

Date August 16, 2002 EPA Reg No/File Symbol: 524-522 Page 3 of 7

Applicant's/Registrant's Name & Address: Monsanto Company, 600 13th Street N.W., Suite 660, Washington, D.C. 20005 Product: Bollgard II Cotton

Ingredient: A *Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production in Bollgard II cotton event 15985

Guideline Reference Number	Guideline Study Name	MFRD Number	Submitter	Status	Note
	Assessment of the Equivalence of Proteins Expressed in Cotton Events 15813 and 15985 MSL-16096, an unpublished study conducted by Monsanto Company	449394-03	Monsanto Company	OWN	
	Bioinformatics Analysis of Insect Protection Protein 2 (IP2) Sequence Utilizing an Allergen Database MSL-16094, an unpublished study conducted by Monsanto Company	449666-04	Monsanto Company	OWN	
	GUS Protein Levels in Insect Protected Cotton Samples Produced in the U S Field Trials MSL-16097, an unpublished study conducted by Monsanto Company	449394-02	Monsanto Company	OWN	
	Insect Protection Protein 2 A Dietary Toxicity Study with Green Lacewing Larvae ( <i>Chrysopa carnea</i> ) MSL-16171, an unpublished study conducted by Monsanto Company	450863-09	Monsanto Company	OWN	
	Insect Protection Protein 2 A Dietary Toxicity Study with the Ladybird Beetle ( <i>Hippodamia convergens</i> ) MSL-16172, an unpublished study conducted by Monsanto Company	450863-11	Monsanto Company	OWN	

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Date: August 16, 2002 EPA Reg No./File Symbol: 524-522 Page 4 of 7  
 Applicant's/Registrant's Name & Address: Monsanto Company, 600 13th Street N.W., Suite 660, Washington, D.C. 20005 Product: Bollgard® II Cotton  
 Ingredient: *A Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production in Bollgard® II cotton event 15985

Guideline Reference Number	Guideline Study Name	RFID Number	Submitter	Status	Note
	Insect Protection Protein 2. A Dietary Toxicity Study with Parasitic Hymenoptera ( <i>Nasonia vitripennis</i> ) MSL-16173, an unpublished study conducted by Monsanto Company	450863-10	Monsanto Company	OWN	
	Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to <i>Collembea</i> ( <i>Folsomia candida</i> ) MSL-16174, an unpublished study conducted by Monsanto Company	450863-11	Monsanto Company	OWN	
	Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Honey Bee Larvae MSL-16175, an unpublished study conducted by Monsanto Company	450863-07	Monsanto Company	OWN	
	Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees ( <i>Apis mellifera</i> ) MSL-16176, an unpublished study conducted by Monsanto Company	450863-08	Monsanto Company	OWN	
	Insect Protection Protein 2. An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate MSL-16177, an unpublished study conducted by Monsanto Company	450863-13	Monsanto Company	OWN	

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Date: August 16, 2002 EPA Reg No./File Symbol: 524-522 Page 5 of 7  
 Applicant's/Registrant's Name & Address: Monsanto Company, 600 13th Street N W, Suite 660, Washington, D.C. 20005 Product Bollgard® II Cotton

Ingredient: *A Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production in Bollgard® II cotton event 15985

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Insect Protection Protein 2 in Cottonseed Meal A Dietary Toxicity Study with the Northern Bobwhite MSL-16178, an unpublished study conducted by Monsanto Company	450863-16	Monsanto Company	OWN	
	Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish - ORIGINAL MSL-16179, an unpublished study conducted by Monsanto Company	450863-18	Monsanto Company	OWN	
	Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish - AMENDED MSL-16179, an unpublished study conducted by Monsanto Company	453371-03	Monsanto Company	OWN	
	Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Insect Protection Protein 2 in Cotton Leaf Tissue MSL-16185, an unpublished study conducted by Monsanto Company	453371-01	Monsanto Company	OWN	
	Bioinformatics Analysis of GUS Protein Sequence Utilizing an Allergen Database MSL-16263, an unpublished study conducted by Monsanto Company	449394-05	Monsanto Company	OWN	

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Ingredient <i>A Bacillus thuringiensis</i> Cry2Ab2 protein and the genetic material necessary for its production in Bollgard® II cotton event 15985		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Bioinformatics Analysis of GUS Protein Sequence Utilizing Toxin and Public Domain Genetic Databases MSL-16264, an unpublished study conducted by Monsanto Company	449394-06	Monsanto Company	OWN	
	Protein Levels in Insect Protected Cotton Samples Produced in the 1998 U S Field Trials MSL-16612, an unpublished study conducted by Monsanto Company	449666-01	Monsanto Company	OWN	
	Amended Report for Molecular Characterization of Cotton Event 15985 MSL-16628, an unpublished study conducted by Monsanto Company	450863-03	Monsanto Company	OWN	
	Assessment of the in vitro Digestibility of Insect Protection Protein 2 (IPP2) Utilizing Mammalian Digestive Path Models MSL-16640, an unpublished study conducted by Monsanto Company	449666-03	Monsanto Company	OWN	
	Acute Oral Toxicity Study of Insect Protection Protein 2 (IPP2) in Mice MSL-16649, an unpublished study conducted by Monsanto Company	449666-02	Monsanto Company	OWN	

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Date August 16, 2002 EPA Reg No / File Symbol 524-522 Page 7 of 7

Applicant's/Registrant's Name & Address.  
 Monsanto Company, 600 13th Street N W, Suite 660, Washington, D C. 20005 Product Bollgard II Cotton

Ingredient *A Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production in Bollgard II cotton event 15985

Guideline Reference Number	Guideline Study Name	MFID Number	Submitter	Status	Note
	Bioinformatics Analysis of Insect Protection Protein (IPP2) Sequence Utilizing Toxin and Public Domain Genetic Databases MSL-16710, an unpublished study conducted by Monsanto Company	449666-03	Monsanto Company	OWN	
	Molecular Analysis of the Stability of Cotton Event 15985 MSL-16749, an unpublished study conducted by Monsanto Company	Not yet assigned	Monsanto Company	OWN	Submitted 21-Feb-01
	Effect of Heat Treatment on the Immunodetection of Cry2Ab2, GUS, Cry1Ac and NPTII Proteins Produced in Cotton Event 15985 MSL-16810, an unpublished study conducted by Monsanto Company	Not yet assigned	Monsanto Company	OWN	Submitted 13-Apr-01
	Evaluation of the Dietary Effects of Insect Protection Protein 2 on Honey Bee Larvae MSL-16960 an unpublished study conducted by Monsanto Company.	453371-02	Monsanto Company	OWN	
	Endangered species impact assessment for the Cry1Ac and Cry2Ab2 proteins in Bollgard II cotton MSL-17674 an unpublished study conducted by Monsanto Company	456089-01	Monsanto Company	OWN	
	Administrative Materials for Application to Amend the Registration of the Plant Incorporated Protectant <i>Bacillus thuringiensis</i> Cry2Ab2 Insect Control Protein from Seed Increase/Plant Propagation to Full Commercial Use for Cotton, EPA Reg No 524-522	Not yet assigned	Monsanto Company	OWN	Submitted August 16, 2002

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