



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 (Form 8570-35)

Date: November 8, 2009	EPA Reg. No./File Symbol: 524-594	Page 1 of 8	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 87701	
Ingredient: <i>Bacillus thuringiensis</i> Cry1Ac Protein and the Genetic Material (Vector PV-GMIR9) Necessary for its Production in MON 87701 (OECD Unique Identifier: MON-87701-2)	MRID Number	Status	
Guideline Reference Number	Study Name	Submitter	
		Note	
885.1100	Administrative Materials for an Application to Amend Section 3 of the Insecticide Registration Act for the Incorporated Protein, <i>Bacillus thuringiensis</i> Cry1Ac Protein and the Genetic Material (Vector PV-GMIR9) Necessary for its Production in MON 87701 (OECD Unique Identifier: MON-87701-2)	Monsanto Company OWN	Administrative
885.1100	Administrative Materials for an Application for a Section 3 Registration of the Plant-Incorporated Protein, <i>Bacillus thuringiensis</i> Cry1Ac Protein and the Genetic Material (Vector PV-GMIR9) Necessary for its Production in MON 87701 (OECD Unique Identifier: MON-87701-2)	Monsanto Company AG OWN	Administrative
N/A	2009. Human Health and Environmental Assessment of the Plant-Incorporated Protein, <i>Bacillus thuringiensis</i> Cry1Ac Protein Produced in Soybean MON 87701	Monsanto Company OWN	Product Characterization
885.1100	2009. Amended Report for MSL0022176: Molecular Analysis of Insect-Protected Soybean MON 87701. Monsanto Technical Report MSL0022327	Monsanto Company OWN	Product Characterization
885.1100	2008. Assessment of the Cry1Ac Protein Levels in Soybean Tissues from MON 87701 Produced in U.S. Field Trials During 2007. Monsanto Technical Report MSL0021531	Monsanto Company OWN	Product Characterization
Signature: [Redacted]	Name and Title: [Redacted] Regulatory Affairs Manager	Date: November 8, 2010	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	2008. Characterization of the CryI Ac Protein Produced from the Harvested Seed of MON 87701 Soybean and Comparison of the Physicochemical and Functional Properties of the MON 87701 Produced and Engineered CryI Ac Proteins. Monsanto Technical Report MSL002146	47841704	Monsanto Company	OWN	Product Characterization
885.1100	2008. Functional Equivalence of E. coli-produced Full Length CryI Ac Protein and the CryI Ac Trypsin Core Protein. Monsanto Technical Report MSL0021404	47841705	Monsanto Company	OWN	Product Characterization
870.1100	2009. An Acute Toxicity Study of CryI Ac Protein Administered by the Oral (Gavage) Route to Mice. Monsanto Study Number CRO-2007-325	47841707	Monsanto Company	OWN	Human Health Assessment
885.1100	2008. Assessment of <i>In Vitro</i> Digestibility of the CryI Ac Protein in Simulated Gastric and Simulated Intestinal Fluids. Monsanto Technical Report MSL0021376	47841708	Monsanto Company	OWN	Product Characterization
885.1100	2008. Bioinformatics Evaluation of the CryI Ac Protein Present in MON 87701 Soybean Utilizing the AD8, TOXIN6, and PROTEIN Databases. Monsanto Technical Report MSL0021658	47841709	Monsanto Company	OWN	Human Health Assessment
Signature			Name and Title, [Redacted] Regulatory Affairs Manager	Date	September 8, 2010

Date: November 8, 2010

EPA Reg. No./File Symbol: 524-594

Product: MON 87701

Product: MON 87701 (OECD Unique Identifier: MON-87701-2)

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Date: November 8, 2010	EPA Reg. No./File Symbol: 524-594	Page 3 of 8			
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167					
Product: MON 7701					
Ingredient: Bacillus thuringiensis CryI Ac Protein and the Genetic Material (Vector BY-GMIR9) Necessary for its Production in MON 87701 (OECD Unique Identifier: MON-87701-2)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	2008a. Effect of Conventional Raw Soybean Meal on the Development of the Northern Bobwhite. Monsanto Technical Report MSK0021213.	4789660	Monsanto Company	OWN	Environmental Assessment
885.4050	2008b. Evaluation of Potential Dietary Effects of Grain from Insect-Protected Soybean MON87701 on the Northern Bobwhite in an Eight-day Study. Monsanto Technical Report MSL0021303.	4784171	Monsanto Company	OWN	Environmental Assessment
885.4050	2009. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing Soybean Meal Produced from MON87701. Control, or References Soybean. Monsanto Technical Report MSL0021800.	4784172	Monsanto Company	OWN	Human Health Assessment
885.4380	2009. Evaluation of the Dietary Effects of a CryI Ac Protein on Honey Bee Larvae (<i>Apis mellifera</i> L.). Monsanto Technical Report MSL0021849.	4784173	Monsanto Company	OWN	Environmental Assessment
885.4380	2009. Evaluation of the Dietary Effects of a CryI Ac Protein on Honey Bee Adults (<i>Apis mellifera</i> L.). Monsanto Technical Report MSL0021850.	4784174	Monsanto Company	OWN	Environmental Assessment
885.4340	2009. Evaluation of the Potential effects of the CryI Ac Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL0021680.	4784175	Monsanto Company	OWN	Environmental Assessment
Signature	Name and Title		Regulatory Affairs Manager		
	Date		November 8, 2010		

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Date: November 8, 2010		EPA Reg. No./File Symbol: 524-594		Page 4 of 8	
Applicant/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63107		Product: MON 87701			
Ingredient: <i>Bacillus thuringiensis</i> CryI Ac Protein, and the Genetic Material (Vector PV2-MIR) Necessary for its Production in MON 87701 (OECD Unique Identifier: MON-87701-2)		Submitter: Monsanto Company		Status: OWN	
Guideline Reference Number	Guideline Study Name	MRID Number	MRID Title	Status	Note
885.4340	2009 Evaluation of Potential Diet Effects of CryI Ac Protein on the Parasitic Wasp, <i>Pseudaugus foveolatus</i> (Hymenoptera: Eulophidae), Monsanto Technical Report MSL0021716	47841716	Evaluation of Potential Diet Effects of CryI Ac Protein on the Parasitic Wasp, <i>Pseudaugus foveolatus</i> (Hymenoptera: Eulophidae), Monsanto Technical Report MSL0021716	OWN	Environmental Assessment
885.6200	2009 Evaluation of the potential effects of the CryI Ac Protein on the Earthworm <i>Eisenia fetida</i> using an artificial soil substrate. Monsanto Technical Report MSL001716	47841717	Evaluation of the potential effects of the CryI Ac Protein on the Earthworm <i>Eisenia fetida</i> using an artificial soil substrate. Monsanto Technical Report MSL001716	OWN	Environmental Assessment
885.5200	2009 Acrobasis Degradation of the Purified CryI Ac Protein. Monsanto Technical Report MSL0020174	47841718	Acrobasis Degradation of the Purified CryI Ac Protein. Monsanto Technical Report MSL0020174	OWN	Environmental Assessment
N/A	2006 Endangered Species Risk Assessment for Insect-Protected Soybean MON 87701. Monsanto Technical Report MSL0022082	47841719	Endangered Species Risk Assessment for Insect-Protected Soybean MON 87701. Monsanto Technical Report MSL0022082	OWN	Environmental Assessment
885.1100	2006. Data in Support of an Application for Experimental Use Permit for Insect-Protected Soybean MON 87701, Which Produces a Protein that Provides Control of Lepidopteran Pests: Protein Expression	469461-01	Data in Support of an Application for Experimental Use Permit for Insect-Protected Soybean MON 87701, Which Produces a Protein that Provides Control of Lepidopteran Pests: Protein Expression	OWN	Product Characterization
885.1100	2006. Data in Support of an Application for Experimental Use Permit for Insect-Protected Soybean MON 87701: Qualitative Detection Method for the CryI Ac Protein in Soybean Leaf and Seed	469461-02	Data in Support of an Application for Experimental Use Permit for Insect-Protected Soybean MON 87701: Qualitative Detection Method for the CryI Ac Protein in Soybean Leaf and Seed	OWN	Product Characterization
Signature	[Redacted]	Name and Title [Redacted] Regulatory Affairs Manager		Date November 8, 2010	

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Date: November 8, 2010		EPA Reg. No./File Symbol: 524-594		Page 5 of 8	
Applicant's Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd, St. Louis, MO 63167		Product: MON 87701			
Ingredient: <i>Bacillus thuringiensis</i> CryIAc Protein and the Genetic Material (Vector PV-GM10) Necessary for its Production in MON 87701 (OECD Unique Identifier: MON-87701-2)		Submitter: Monsanto Company		Status: OWN	
Guideline Reference Number	Guideline Study Name	MRID Number	Product Characterization	Note	
885.1100	2007. Supplemental information for the Amended Application for Experimental Use Permit 524-594 (MRID 431452-01); Test information for insect-protected CryIAc protein MON 87701 and Protein Amino Acid Sequence Similarity Comparisons between CryIAc Protein produced in Insect-Protected Soybean MON 87701 and Commercially Registered CryIAc Proteins	431452-00	OWN		
N/A	Monsanto Company, 1994. Submission of product chemistry, toxicology and environmental fate data in support of registration and tolerance petition for B.t.k. insect control protein (CryIAc) Transmittal of studies	431452-02	OWN	Tolerance Exemption	
885.1100	1994. Assessment of equivalence between <i>E. coli</i> -produced and cotton-produced B.t.k. HD-73 protein. Monsanto number 92-01-36-14, MSS-13170	431452-04	OWN	Product Characterization	
885.1100	1994. Sensitivity of insect species to the purified CryIAc insecticidal protein from <i>Bacillus thuringiensis</i> var. <i>turkistanii</i> (B.t.k. HD-73). Monsanto number 92-01-36-17 and 92-427-720, MSL-13273		OWN	Product Characterization	
Signature	[Redacted]	Name and Title: [Redacted] Regulatory Affairs Manager	Date: November 8, 2010	Publishing Regime: Agency Internal Use Copy	

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Date: November 8, 2010	EPA Reg. No./File Symbol: 524-594	Page 6 of 8			
Applicant/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63107		Product: MON 87701			
Ingredient: Bacillus thuringiensis var. kurstaki (B.t.k. HD-73) in sucrose and honey solutions under non-refrigerated temperature conditions. Monsanto number 92-01-36-15 and 92-01-427-718, MON-13288					
Guideline Reference Number	Guideline Study Name	MIRID Number	Submitter	Status	Note
885.4380	1994. Stability of the CryI Ac insecticidal protein from <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> (B.t.k. HD-73) in sucrose and honey solutions under non-refrigerated temperature conditions. Monsanto number 92-01-36-15 and 92-01-427-718, MON-13288	431452-05	Monsanto Company	OWN	Environmental Assessment
885.4380	1993. Evaluation of the dietary effect(s) of purified B.t.k. endotoxin proteins on honey bee larvae. Monsanto number CAR-181-92-01-36-10, and 92-01-427-709	431452-06	Monsanto Company	OWN	Environmental Assessment
885.4380	1993. Evaluation of the dietary effect(s) of purified B.t.k. endotoxin proteins on honey bee adults. Monsanto number CAR-181-92-01-36-10 and 92-01-427-708	431452-07	Monsanto Company	OWN	Environmental Assessment
885.4340	1993. B.t.k. HD-73 protein: A dietary toxicity study with parasitic hymenoptera (<i>Nasonia vitripennis</i>). Lab project number WIL-139-369 and WL-93-234	431452-08	Monsanto Company	OWN	Environmental Assessment
885.4340	1993. B.t.k. HD-73 protein: A dietary toxicity study with ladybird beetles (<i>Hippodamia convergens</i>). Lab project number WIL-139-370, WL-93-232, and 92-01-36-25	431452-09	Monsanto Company	OWN	Environmental Assessment
Signature	[Redacted]	[Redacted]	Name and Title: Regulatory Affairs Manager	Date: November 8, 2010	

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Date: November 8, 2010		EPA Reg. No./File Symbol: 524-594	Page 7 of 8
Applicant's (Registrant's) Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 87701	
Ingredient: <i>Bacillus thuringiensis</i> CryIAC-Delta and the Genetic Material Vector (t-GMIR) Necessary for the Production in MON 87701 (OECD Unique Identifier: MON-87701-2)			
Guideline Reference Number	Guideline Study Name	MIR Number	Status
885.4340	1991. B.i.k. HD-73 protein: Acute toxicity study with green pre-crawling larvae (<i>Chrysopa carnea</i>) of project number WIL-135471. WL-93-947 and 92-01-362	431452-10	OWN
885.4340	1994. Effect of the <i>Bacillus thuringiensis</i> insecticidal proteins CryIA(b), CryIA(c), CryIIA, and CryIIA on <i>Folsomia candida</i> and <i>Xenylla grisea</i> (Insecta: Collembola)	431452-11	OWN
885.3050	1994. B.i.k. HD-73 protein: Acute formulation and determination of dose for an acute mouse feeding study ML-92-493. Monsanto number 92-073-13 and 92-427-716, MSL-13169	431452-12	OWN
885.3050	1993. Acute oral toxicity of <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> (CryIAc) HD-73 protein in albino mice. Monsanto number 92197 and ML-92-493	431452-13	OWN
885.1100	1994. Assessment of the in-vitro digestive fate of <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> HD-73 protein. Monsanto number 92-01-36-22 and 92-427-728	431452-14	OWN
Signature	[Redacted]	Name and Title of Regulatory Affairs Manager	Date: November 8, 2010

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MRID Number	Submitter	Status	Note
885.5200	Monsanto Company	OWN	Environmental Assessment
885.1100	Monsanto Company	OWN	Human Health Assessment
885.1100	Monsanto Company	OWN	Human Health Assessment
885.1100	Monsanto Company	OWN	Human Health Assessment
Signature	Regulatory Affairs Manager		Human Health Assessment

Date: November 8, 2010 EPA Reg. No./File Symbol: 524-594 Page 8 of 8

Applicant's Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63107 Product: MON 87701

Ingredient: *Bacillus thuringiensis* CryI Ac Protein and the Genetic Material (Vector PV-CMIR) Necessary for its Production in MON 87701 (OECD Unique Identifier: MON-87701-2)

Guideline Reference Number: Guide to Study Name

885.5200: 994: Aerobic soil degradation of *Bacillus thuringiensis* var. *Kaisaki* HD-73 protein bioactivity. Monsanto number 92-01-36-18 and 92-01-36-19, MSL-18205 and 18204

885.1100: 2001: *Bacillus thuringiensis* subsp. *Kaisaki* HD-73 insecticidal protein (B.t.k. HD-73 protein) shares no significant sequence similarity with proteins associated with allergy or cell disease. Monsanto number 94-041E and 01-CT-053E

885.1100: 2000: Comparative alignment of full-length B.t.k. HD-73 protein to known protein allergens and toxins using the FASTA algorithm. Monsanto number 94-041E and 01-CT-053E

885.1100: 2002: Bioinformatic analysis of the CryI Ac protein utilizing an allergen sequence database. Monsanto number 94-041E, 00-CT-006E, and 02-01-36-19. MSL-18205

885.1100: 2002: Bioinformatic analysis of the CryI Ac protein utilizing toxin and public domain sequence databases. Monsanto number 94-041E, 00-CT-006E, and 02-01-36-18. MSL-18204

Signature: [Redacted Name and Title] Regulatory Affairs Manager

Date: November 8, 2010

Product: MON 87701

OECD Unique Identifier: MON-87701-2

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