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Guideline Reference Number	Gene Name	Gene Study Name	IM/ID Number	Submitter	Status	Note
151-20, 151-21, 151-22, 151-26, 885.1100, 885.1200, 885.1300, 885.2100	<i>Bacillus thuringiensis</i> Cry3Bb1	Volume 1 Administration Materials for the Application to Register the Plant-Incorporated Protectant Containing <i>Bacillus thuringiensis</i> Cry3Bb1 Protein and the Genetic Material (vector ZMIR39) Necessary for its Production in MON 88017		Monsanto Company	OWN	This Submission
151-20, 151-21, 151-22, 151-26, 885.1100, 885.1200, 885.1300, 885.2100	<i>Bacillus thuringiensis</i> Cry3Bb1	Volume 2 Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Produced in MON 88017. MSL-18835; an unpublished report prepared by Monsanto Company.		Monsanto Company	OWN	This Submission
151-20, 151-21, 151-22, 151-26, 885.1100, 885.1200, 885.1300, 885.2100	<i>Bacillus thuringiensis</i> Cry3Bb1	Volume 3 Molecular analysis of YieldGard <i>Bacillus thuringiensis</i> Cry3Bb1 Ready <sup>®</sup> corn event MON 88017. MSL-17669; an unpublished study conducted by Monsanto Company.		Monsanto Company	OWN	This Submission
151-23, 151-25, 153-4, 151-26, 885.1400, 885.1500, 885.2200, 885.2400, 885.2500	<i>Bacillus thuringiensis</i> Cry3Bb1	Volume 4 (2003). Cry3Bb1 and CP4 EPSPS protein levels in corn tissues collected from MON 88017 corn produced in U.S. field trials conducted in 2002. MSL-18823; an unpublished study conducted by Monsanto Company.		Monsanto Company	OWN	This Submission
151-26, 885.2100	<i>Bacillus thuringiensis</i> Cry3Bb1	Volume 5 Evaluation of functional equivalence of two Cry3Bb1 protein variants against susceptible Coleopteran species. MSL-18799; an unpublished study conducted by Monsanto Company.		Monsanto Company	OWN	This Submission
Signature				Regulatory Affairs Manager		

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Guideline Reference Number	Guideline Sub-Item Name	MAD Number	Submitter	Status	Note
151-26 885.2100	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry3Bb Protein and the Genetic Material (vector ZMIR39) Necessary for its Production in <i>Agrobacterium</i> ; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance	431568-80	Monsanto Company	OWN	
151-26 885.2100	Administrative Materials in Support of the Registration of <i>Bacillus thuringiensis</i> Cry I, Cry2a, and Cry3 C Proteins and the Genetic Material Necessary for the Production of These Proteins in <i>Agrobacterium</i> ; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance	PP 714888	Monsanto Company	OWN	
151-26 885.2100	Administrative Materials in Support of the Registration of the Plant-Expressed Protein <i>Bt toxin thuringiensis</i> (Zea mays, L.) and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7E4888	449043-86	Monsanto Company	OWN	
151-26 885.2100	Characterization of the Cry3Bb I Protein Produced in MON 863. MSL-17137.	454240-11	Monsanto Company	OWN	
151-26 885.2100	Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154.				
Signature	Name and Title	Date			

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Monsanto Company

03-CR-099E-1

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DATA MATRIX

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30 885 3050 885 4150	<p>Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from MSL-17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.</p> <p>Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from MSL-17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.</p>	455382-02	Monsanto Company	OWN	
152-30 885 3050	<p>Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from MSL-17530. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.</p>	455382-03	Monsanto Company	OWN	
152-31 152-34 152-35 885 3100	<p>Not applicable because Cry3Bb1 is a plant-incorporated active ingredient present at low levels, and there is little opportunity for dermal or ocular contact.</p>			OWN	
152-32 885 3150	<p>Not applicable because Cry3Bb1 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 Cry3Bb1 is not a living organism.</p>			OWN	
Signature			Name and Title	Date	

January 2, 2004

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**DATA MATRIX**

Ingredient	Guideline Reference Number	Guideline Study Name	AFRID Number	Submitter	Status	Note
Date: January 27, 2004 Applicant's/Registrant's Name: Monsanto Company Address: 800 13th Street, N.W., Suite 600, Washington, D.C. 20005 Product: MON 88017 EPA Reg. No./File Symbol: 524-XXX Page 5 of 18						
152-33 885-3200		<i>Bacillus thuringiensis</i> Cry3Bb and the genetic material necessary for its production (vector ZMIR39) in MON 88017		Monsanto Company		
151-36 885-2260		Not applicable because Cry3Bb protein is neither infective nor pathogenic.	424-240-08	Monsanto Company	OWN	
152-36 152-37 152-38 885-3400		2001 Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140.  There is no clear published evidence that has demonstrated clinical allergic reactions to Bt crystal proteins.				
152-39 885-3500		Not applicable because Cry3Bb1 is not a living organism.				
154-16 885-4050		<i>Bacillus thuringiensis</i> Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-15	Monsanto Company	OWN	
Signature				Name and Title [Redacted]	Date January 27, 2004	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-17 885-4100	Pathogenicity determination is that applicable because Cry3Bb1 is not a living organism. Not applicable because there is no reason to suspect that wild mammals would be any more sensitive to Cry3Bb1 than laboratory mammals. Mammals do not possess protein receptors. Pathogenicity determination is not applicable because Cry3Bb1 is not a living organism.	449043-19	Monsanto Company	OWN	
154-19 885-4200	Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSI-16164. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-19	Monsanto Company	OWN	
154-20 885-4240	2001). Bluegill Dietary Toxicity Study for the <i>Bacillus thuringiensis</i> Cry3Bb1 Protein Variant: A Waiver Request. MSI-17383. 1999). <i>Bacillus thuringiensis</i> Protein 1098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran ( <i>Daphnia magna</i> ). MSI-16163. A pathogenicity determination is not applicable because Cry3Bb1 is not a living organism.	449043-18	Monsanto Company	OWN	
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Date: January 22, 2004		EPA Reg. No./File Symbol: 524-XXX	Page 7 of 18
Applicant's/Registrant's Name & Address: Monsanto Company, 60627th Street, N.W., Suite 660, Washington, D.C. 20005		Product: MON 88017	
Ingredient	Bacillus thuringiensis Cry3Bb1 and its genetic material necessary for its production (vector ZMIR39) in MON 88017	Submitter	Note
Guideline Reference Number	Guideline Study Name	MRID Number	Status
154-21 885.4320	Results of acute toxicity tests with <i>B. thuringiensis</i> and <i>B. thuringiensis</i> Cry3Bb1 on <i>Spodoptera frugiperda</i> larvae. Test results do not provide any evidence of adverse effects. Test results with vegetable and ornamental species are not warranted because of very low risk potential for exposure to the Cry3Bb1 protein in field crops. A pathogenicity determination is not applicable because Cry3Bb1 is not a living organism.		
154-22 885.4300	Cry3Bb1 is an insect toxin and its proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outcrossing to weed wild relatives is virtually nonexistent.		
154-23 885.4340	(1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Toxicity Study with the Ladybird Beetle ( <i>Hippodamia convergens</i> ). MSL-16166. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		
154-23 885.4340	<i>Bacillus thuringiensis</i> Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.		
Signature			
	Name and Title	Monsanto Company	Date: January 27, 2004
	Regulatory Affairs Manager		

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885.4340	(1999). Assessment of Genotoxic Toxicity of <i>Bacillus thuringiensis</i> Protein 11231 to <i>Drosophila melanogaster</i> (MSL-16167). A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-11	Monsanto Company	OWN	
154-23 885.4340	(1999). <i>Bacillus thuringiensis</i> Protein 11231: A Dietary Study with the Laccase-producing Strain (Cry3Bb1) (MSL-16167). A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-12	Monsanto Company	OWN	
154-23 885.4340	(1999). <i>Bacillus thuringiensis</i> Protein 11231: Dietary Study with the Parasitic Hymenoptera ( <i>Nasonia vitripennis</i> ) (MSL-16167). A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	449043-13	Monsanto Company	OWN	
154-23 885.4340	(2001). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Report. Monsanto Ref. No. 99-894E. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453484-01	Monsanto Company	OWN	
154-23 885.4340	(2001). Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16936. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	453613-01	Monsanto Company	OWN	
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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885 4340	Dietary Effects of Transgenic Bt Corn Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle <i>Hippodamia convergens</i> . MSL-1717. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Company	OWN	
154-23 885 4340	(2002) Field Evaluation for the Ecological Impact of Corn Rootworm Insect Protected Corn on Non-Target Organisms. MSL-1717. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Company	OWN	
154-23 885 4340	Dietary Effects of Transgenic <i>Bacillus thuringiensis</i> (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, <i>Coleomegilla maculata</i> . MSL-16907. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Company	OWN	
154-23 885 4340	Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae ( <i>Danais plexippus</i> ) via Laboratory Bioassay. MSL-17235. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-05	Monsanto Company	OWN	
154-23 885 4340	(2001) Insecticidal Spectrum of Activity for Cry3Bb Protein <i>in vitro</i> . C3NTO. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455382-07	Monsanto Company	OWN	
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			Regulatory Affairs Manager	January 27, 2004	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-23 885-4340	[Redacted] Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. MSL-17614 A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	455770-01	Monsanto Company	OWN	
154-23 885-4340	[Redacted] Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 40-CR-032E. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	456530-03	Monsanto Company	OWN	
154-23 885-4340	[Redacted] Ecological Assessment of Nontarget Organisms in Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event. 2000 - 2001 Field Trials Report MSL-17531. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	457916-01	Monsanto Company	OWN	
154-23 885-4340	[Redacted] Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.	457571-01	Monsanto Company	OWN	
Signature	[Redacted] Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	
Name and Title			Date		
[Redacted] Regulatory Affairs Manager			January 23, 2004		

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
154-24 885 4380	<p>Date: January 22, 2004</p> <p>Applicant's Registrant Name &amp; Address: Monsanto Company, 6063<sup>rd</sup> Street, N.W., Sioux Falls, S.D. 57105</p> <p>Ingredient: <i>Bacillus thuringiensis</i> Cry3Bb1 and its genetic material necessary for its production (vector ZMR139) in MON 88017</p>	449043-11	Monsanto Company	OWN	
885 5200	<p>Guideline Study Name: [Redacted]</p> <p>1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Adult Honey Bees (<i>Apis mellifera</i> L.). MSL-16169. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.</p>	451568-04	Monsanto Company	OWN	
885 5200	<p>2002). Aerobic Soil Degradation of the Protein 11098 of a Composite of Insect Protein MSL-16440, an unpublished study conducted by Monsanto Company.</p>	457492	Monsanto Company	OWN	
885 5200	<p>2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMR12L, ZMR13L, and ZMR14L). Monsanto Ref. No. 99-781E.</p>	450297-01	Monsanto Company	OWN	
154-24 885 4380	<p>Signature: [Redacted]</p> <p>1999). Evaluation of the Dietary Effects of Purified <i>Bacillus thuringiensis</i> Protein 11231 on Honey Bee Larvae. MSL-16168. A pathogenicity determination is not applicable since Cry3Bb1 is not a living organism.</p>	449043-10	Monsanto Company	OWN	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151.26	[REDACTED] (1993). Production, Cloning, and characterization of a highly Glyphosate-Tolerant Enolpyruvate-shikimate-3-phosphate synthase from <i>Arabidopsis thaliana</i> sp. Strain CP4. MSL-12738, an unpublished study prepared by Monsanto Company.	438076-01	Monsanto Company	OWN	
151.20	[REDACTED] (1993). Production of CP4 EPSP in a 100 Liter Recombinant <i>Escherichia coli</i> Fermentation. MSL-12389; an unpublished study prepared by Monsanto Company.	438076-02	Monsanto Company	OWN	
151.26	[REDACTED] (1993). The purification of Recombinant <i>Escherichia coli</i> CP4 5-enolpyruvate-shikimate-3-phosphate synthase for Equivalence Studies. MSL-12574; an unpublished study prepared by Monsanto Company.	438076-03	Monsanto Company	OWN	
151.20 151.21 151.22	[REDACTED] (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Anticipated Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPs. Transmittal of studies.	436433-00	Monsanto Company	OWN	
151.26	[REDACTED] (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPs. Lab Project Number: 92/01/30/14; 12901; an unpublished study prepared by Monsanto Company.	436433-01	Monsanto Company	OWN	
Signature	[REDACTED]		Name and Title [REDACTED] Regulatory Affairs Manager	Date January 22, 2004	

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Guideline Reference Number	Guideline Study Name	MIRID Number	Submitter	Status	Note
151.26	Assessment of the Equivalence of CP4 EPSPS Protection Produced in <i>A. thuringiensis</i> and European Corn Borer Resistant Corn. Lab Project Number: 92-01-39-18; 92-01-39-19; an unpublished study prepared by Monsanto Company.	436433-02	Monsanto Company	OWN	
152.30	Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92-01-30-15; unpublished study prepared by Monsanto Company.	436433-03	Monsanto Company	OWN	
152.30	Assessment of the in vitro Digestive Toxicity of CP4 EPSPS Synthese. Lab Project Number: 92-01-30-15; 12949; an unpublished study prepared by Monsanto Company.	436433-04	Monsanto Company	OWN	
152.30	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient. Transmittal of 1 Study.	436433-09-00	Monsanto Company	OWN	
152.30	Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12; 92-419-719; an unpublished study prepared by Monsanto Company.	436919-01	Monsanto Company	OWN	
Signature	[Redacted]		Name and Title Regulatory Affairs Manager	Date January 27, 2004	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	(2002) Public Interest Assessment Supporting Registration of <i>Cy3Bb1</i> and <i>Cy3Bb2</i> Proteins and the Genetically Modified Material (V vector ZMIR134) Necessary for its Production in MON 88017	456530-01	Monsanto Company	OWN	
	(2003) Yield Benefit of MON 863	456530-02	Monsanto Company	OWN	
	(2000) An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistance Genetic Technology - Yield <sup>(8)</sup> Rootworm. MSL-17243	459438-01	Monsanto Company	OWN	
	(2001) Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459438-01	Monsanto Company	OWN	
	(2003) Estimating <i>Cy3Bb1</i> Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Company	OWN	
Signature	[Redacted Name]		Regulatory Affairs Manager		Date: January 2004

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DATA MATRIX

Date	Applicant's Name & Address	Product	EPA Reg. No./File Symbol	Page	
January 2, 2004	Monsanto Company 700 13 <sup>th</sup> Street, N.W. Suite 660 Washington, D.C. 20005	MON 88017	524-XXX	16 of 18	
	Ingredient: <i>Bacillus thuringiensis</i> Cry3Bb1 and the genetic material necessary for its production (vector ZMIR39) in MON 88017				
Guideline Reference Number	Study Name	Method Number	Submitter	Status	Note
885 4340	[REDACTED] Dairy Cow Request Toxicity Study Cry3Bb1 Protein in the Root-kissed Beetle ( <i>Tetraopes</i> ) MSL-1874		Monsanto Company	OWN	
151-20, 153-4 885 1100 885 2200	[REDACTED] (2001) Amended report for MSL-16598 Immunotoxicity of Cry3Bb1 MON 88017 and Cry3Bb1 112547 proteins in the Grain of Insect-Selected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17266	45424547	Monsanto Company	OWN	
151-23, 151-25, 153-4, 151-26. 885 1400, 885 1500 885 2200 885 2400 885 2500	[REDACTED] (2001) Amended Report for MSL-16559: Cry3Bb1 11098 and NPTII Protein Levels in Insect Samples Collected From Corn Events MON 863 and 1999 Field Trials. MSL-17181	45498-02	Monsanto Company	OWN	
152-30 185 3050 885 4150	[REDACTED] (1999) Acute Oral Toxicity of B.t. Protein 11231 in Mice. MSL-16216	449043-05	Monsanto Company	OWN	
Signature	[REDACTED]		Name and Title: [REDACTED] Regulatory Affairs Manager	Date: January 2, 2004	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152-30	Acute Oral Toxicity of Bt Protein	449043-06	Monsanto Company	OWN	
185-3050	Biostatistical Analysis of Bt Protein	449043-09	Monsanto Company	OWN	
885-4150	Biostatistical Analysis of Bt Protein	449043-08	Monsanto Company	OWN	
151-36	Biostatistical Analysis of Bt Protein	449043-07	Monsanto Company	OWN	
885-2200	Biostatistical Analysis of Bt Protein	449043-06	Monsanto Company	OWN	
151-36	Biostatistical Analysis of Bt Protein	449043-05	Monsanto Company	OWN	
885-2200	Biostatistical Analysis of Bt Protein	449043-04	Monsanto Company	OWN	
152-30	Biostatistical Analysis of Bt Protein	449043-03	Monsanto Company	OWN	
151-4	Biostatistical Analysis of Bt Protein	449043-02	Monsanto Company	OWN	
885-2500	Biostatistical Analysis of Bt Protein	449043-01	Monsanto Company	OWN	
Signature					

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**DATA MATRIX**

Date: January 22, 2004	EPA Reg. No./File Symbol: 524-XXX	Page 18 of 18
Applicant's Registrant Name & Address: Monsanto Company, 600 17th Street, N.W., Suite 660, Washington, D.C. 20005	Product: MON 88017	
Ingredient: <i>Bacillus thuringiensis</i> CryII and genetic material necessary for its production (vector ZMIR39) in MON 88017	Submitter	Status
Guideline Reference Number: 885-2500	MRID Number: 85240-05	Note: OWN
<p>153-4 885-2500</p> <p>Approved by MSLS 10/96. Assessment of the Physical-Chemical Stability (3Bb1.11988 and NP111) Pesticides in Consequent MOA-863 to Micro-organisms. MSLS 7/220 (2001).</p>		

Signature: [Redacted]  
 Name and Title: [Redacted]  
 Date: January 22, 2004  
 Regulatory Affairs Manager

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