

Renewal Assessment Report

***Bacillus thuringiensis ssp.
aizawai strain ABTS-1857***

Volume 2

List of the tests, studies and information submitted

Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Germany

Version history

When	What
September 2018	Initial RAR

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A List of the tests, studies and information submitted

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The list of references, alphabetically by first author, includes all study reports, documents, and published articles submitted, by the applicant or any other parties, or included in the DAR by the RMS, and whether relied upon or not. This should include references on the active substance as well as references on product(s).

References identified in literature search in accordance with Article 8(5) of Regulation (EC) No 1107/2009 and not submitted or requested should not be listed here. The full outcome of the literature search is presented in the summary dossier which is available on the EFSA website.

For draft renewal assessment reports the reference lists for each section should include also those studies that were submitted to support the approval or subsequent renewals.

For (draft) renewal assessment reports the reference lists at the end of each section/chapter (sorted by data requirement) should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal. However these studies should be clearly identified in the reference list as well as in the individual study sections. This could be done by consistent use of a statement for each study: Previous evaluation: responded “N.A.” for NAS, “Submitted for the purpose of renewal”, or “In DAR (year)”, “In addendum to DAR (year)” or any other appropriate

Lists of studies should be prepared according to the "Guidance Document on preparing list of tests and study reports according to Article 60 of Regulation (EC) No 1107/2009" (GD SANCO/12580/2012).

A.1 Identity

OECD data point / number	Author(s)	Year	Title <i>Source (where different from Company)</i> <i>Company Report No.</i> <i>GLP or GEP status (where relevant),</i> <i>Published or not</i>	Data Protection Claimed Y/N	Owner
IIM 1.3.1/01	Glare, T.R., O'Callaghan, M.	2000	<i>Bacillus thuringiensis</i> , Biology, Ecology and Safety. Publ. Wiley. Not GLP; Published	N	--

A.2 Biological, physical and chemical properties

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KMA 1.3/03	Böhm, M-E. et al	2016	Comparative Bioinformatics and Experimental Analysis of the Intergenic Regulatory Regions of <i>Bacillus cereus</i> hbl and nhe Enterotoxin Operons and the Impact of CodY on Virulence Heterogeneity. Frontiers in Microbiology, Vol. 7, Art. 768. GLP: No Published	N	N	-	-
KMA 2.3/01	Mohan et al.	2014	Relative toxicity of subspecies of <i>Bacillus thuringiensis</i> against lepidopterous insect pests of agricultural importance. Journal of Biological Control, Vol. 28, No. 4, pp. 197-203. GLP: No Published	N	N	-	-
KMA 2.5/01	Ruan, L., Crickmore,	2015	Is there sufficient evidence to consider <i>Bacillus thuringiensis</i> a multihost pathogen?	N	N	-	-

	N., & Sun, M.		Trends in Microbiology, 23(10): 587 GLP: No Published				
KMA 2.7/01	Hu X, Hansen BM, Eilenberg J, Hendriksen NB, Smidt L, Yuan Z, Jensen GB.	2004	Conjugative transfer, stability and expression of a plasmid encoding a cry1Ac gene in <i>Bacillus cereus</i> group strains. FEMS Microbiology Letters 231 (2004) 45-52 GLP: No Published	N	N	-	-
KMA 2.7/02	Santos CA, Vilas-Bôas GT, Lereclus D, Suzuki MT, Angelo EA, Arantes O.M.	2010	Conjugal transfer between <i>Bacillus thuringiensis</i> and <i>Bacillus cereus</i> strains is not directly correlated with growth of recipient strains. Journal of Invertebrate Pathology, Vol. 105, No. 2, pp. 171-5. GLP: No Published	N	N	-	-
KMA 2.7/03	Thomas DJI, Morgan JAW, Whipps JM, Saunders JR	2000	Plasmid transfer between the <i>Bacillus thuringiensis</i> subspecies <i>kurstaki</i> and <i>tenebrionis</i> in laboratory culture and soil and in Lepidopteran and Coleopteran larvae. Appl Environ Microbiol 66:118–124 GLP: No	N	N	-	-

			Published				
KMA 2.7/04	Yuan YM, Hu XM, Liu HZ, Hansen BM, Yan JP and Yu- an ZM	2007	Kinetics of plasmid transfer among <i>Bacillus cereus</i> group strains within lepidopteran larvae. Archives of Microbiology, Vol. 187, No. 6, pp. 425-431. GLP: No Published	N	N	-	-
KMA 2.7/05	Ferreira, L., Leme HP; Suzuki MT; Itano EN; Ono MO; Arantes OMN	2003	Ecological aspects of <i>Bacillus thuringiensis</i> in an oxisol. Scientia Agricola, 60(1): 19-22 GLP: No Published	N	N	-	-
KMA 2.7/06	Van der Auwera, G.A., Timmery, S., Hoton, F. and Mahillon, J	2007	Plasmid exchanges among members of the <i>Bacillus cereus</i> group in foodstuffs. International Journal of Food Microbiology, Vol. 113, No. 2, pp. 164-172. GLP: No Published	N	N	-	-
KMA 2.7/07	Short, F.L., Monson, R. E., & Salmond, G.	2015	A Type III protein-RNA toxin-antitoxin system from <i>Bacillus thuringiensis</i> promotes plasmid retention during spore development. RNA Biology, Vol. 12, No. 9, pp. 933-937.	N	N	-	-

			GLP: No Published				
KMA 2.8/01	de la Vega, L. M. et al.	2006	Purification and characterization of an exo-chitinase from <i>Bacillus thuringiensis</i> subsp <i>aizawai</i> and its action against phytopathogenic fungi. Canadian Journal of Microbiology, Vol. 52, No. 7, pp. 651-657. GLP: No Published	N	N	-	-
KMA 2.8/02	Hsieh, F-C. et al..	2008	Comparing methods for identifying <i>Bacillus</i> strains capable of producing the antifungal lipopeptide iturin A. Current Microbiology, Vol. 56, No. 1, pp. 1-5. GLP: No Published	N	N	-	-
KMA 2.8/03	Pardo-López, L., Soberón, M. & Bravo, A.	2013	<i>Bacillus thuringiensis</i> insecticidal three-domain Cry toxins: mode of action, insect resistance and consequences for crop protection FEMS Microbiol Rev 37 (2013) 3–22 GLP: No Published	N	N	-	-

KMA 2.8/04	Palma, L., Muñoz, D., Berry, C., Murillo, J. & Caballe- ro, P.	2014	<i>Bacillus thuringiensis</i> Toxins: An Overview of Their Biocidal Activity Toxins (2014), 6, 3296-3325 GLP: No Published	N	N	-	-
KMA 2.8/05	Cahan, R., Friman, H. & Nitzan, Y.	2008	Antibacterial activity of Cyt1Aa from <i>Bacillus</i> <i>thuringiensis</i> subsp. <i>israelensis</i> Microbiology (2008), 154, 3529–3536 GLP: No Published	N	N	-	-
KMA 2.8/06	Liu, X., Ruan, L., Peng, D., Li, L., Sun, M. & Yu, Z.	2014	Thuringiensin: A Thermostable Secondary Me- tabolite from <i>Bacillus thuringiensis</i> with Insecti- cidal Activity against a Wide Range of Insects Toxins (2014), 6, 2229-2238 GLP: No Published	N	N	-	-
KMA 2.8/07	Wiest, S.L.F., Pilz Júnior, H.L. & Fiuza, L.M.	2015	Thuringiensin: a toxin from <i>Bacillus thurin-</i> <i>giensis</i> Bt Research (2015), Vol.6, No.4, 1-12 GLP: No Published	N	N	-	-
KMA 2.8/08	Kim, M-J., Han, J-K.,	2015	Various Enterotoxin and Other Virulence Factor Genes Widespread	N	N	-	-

	Park, J-S., Lee, J-S., Lee, S-H., Cho, J-I. & Kim, K-S.		Among <i>Bacillus cereus</i> and <i>Bacillus thuringiensis</i> Strains J. Microbiol. Biotechnol. (2015), 25(6), 872–879 GLP: No Published				
KMA 2.8/09	Silo-Suh, L.A., Stabb, E.V., Raf- fel, S.J. & Handels- man, J.	1998	Target Range of Zwittermicin A, an Amino- polyol Antibiotic from <i>Bacillus cereus</i> Current Microbiology (1998), Vol. 37, pp. 6-11 GLP: No Published	N	N	-	-
KMA 3.5/01	Forrester, N.W	1994	Resistance management options for convention- al <i>Bacillus thuringiensis</i> and transgenic plants in Australian summer field crops. Biocontrol Science and Technology (1994) 4, 549-553 GLP: No Published	N	N	-	-
KMA 3.5/02	Tabashnik, B.E.	1994	Evolution of resistance to <i>Bacillus thuringiensis</i> . Annual Review of Entomology, Vol. 39, pp. 47-79. GLP: No Published	N	N	-	-

KMA 3.5/03	Tang, J.D. et al.	1997	Inheritance, stability, and lack-of-fitness costs of field-selected resistance to <i>Bacillus thuringiensis</i> in Diamondback moth (Lepidoptera: Plutellidae) from Florida. Journal of Economic Entomology, Vol. 90 (3), pp. 732-741. GLP: No Published	N	N	-	-
KMA 3.5/04	Wirth, M.C. et al	2005	Cyt1A of <i>Bacillus thuringiensis</i> delays evolution of resistance to Cry11A in the mosquito <i>Culex quinquefasciatus</i> . Applied and Environmental Microbiology (2005) January 185-189 GLP: No Published	N	N	-	-
KMA 3.5/05	Janmaat, A. F. & Myers, J.H..	2007	Host-plant effects the expression of resistance to <i>Bacillus thuringiensis</i> kurstaki in <i>Trichoplusia ni</i> (Hubner): an important factor in resistance evolution. Journal of Evolutionary Biology, Vol. 20, No. 1, pp. 62-69. GLP: No Published	N	N	-	-
KMA	Wojda, I	2013	<i>Galleria mellonella</i> infected with <i>Bacillus thu-</i>	N	N	-	-

3.5/06			ringiensis involves Hsp90. Central European Journal of Biology, Vol. 8, No. 6, pp. 561-569. GLP: No Published				
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Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIM 2.3.2/01	Schnepf, E., Crickmore, N., van Rie, J., Lereclus, D., Baum, J., Feitelson, J., Zeigler, D.R. and Dean, D.H.	1998	BACILLUS THURINGIENSIS AND ITS PESTICIDAL CRYSTAL PROTEINS - Report-no. GLP: no Published: no		No		-
IIM 2.3.2/02	Höfte, H. and Whiteley, H.R.	1989	INSECTICIDAL CRYSTAL PROTEINS OF BACILLUS THURINGIENSIS - Microbiological Reviews, June 1989, p. 242-255 Report-no. GLP: no Published: yes Submitted in: K IIM 2.3/01				

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIM 2.3.2/03	Hofmann, C., Vanderbruggen, H., Höfte, H.; van Rie, J., Jansens, S. and van Mellaert, H.	1988a	SPECIFICITY OF BACILLUS THURINGIENSIS ENDOTOXINS IS CORRELATED WITH THE PRESENCE OF HIGH-AFFINITY BINDING SITES IN THE BRUSH BORDER MEMBRANE OF TARGET INSECT MIDGUTS - Proc. Natl. Acad. USA Vol. 85, pp. 7844-7848 Report-no. GLP: no Published: yes		No		-
IIM 2.3.2/04	Hofmann, C., Lüthy, P., Hütter, R. and Pliska, V.	1988b	BINDING OF THE DELTA ENDOTOXIN FROM BACILLUS THURINGIENSIS TO BRUSH-BORDER MEMBRANE VESICLES OF THE CABBAGE BUTTERFLY (PIERIS BRASSICAE) - Eur. J. Biochem. 173, 85-91 (1988) Report-no. GLP: no Published: yes		No		-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIM 2.3.2/05	Schwartz, J.L., Garneau, L., Masson, L. and Brousseau, R.	1991	EARLY RESPONSE OF CULTURED LEPIDOPTERAN CELLS TO EXPOSURE TO ENDOTOXIN FROM BACILLUS THURINGIENSIS: INVOLVEMENT OF CALCIUM AND ANIONIC CHANNELS - Biochimica et Biophysica Acta, 1065 (1991) 250-260 Report-no. GLP: no Published: yes		No		-

Data point number	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
MMP 2.1/01 2.2/01 2.2.1/01 2.2.2 2.5 2.7.1 2.7.2 2.7.3 2.7.4 2.7.5	Comb	2004	Xentari WG: Two years storage stability Huntingdon Life Sciences Ltd. Company report No.: ZZAB018/042800 GLP; Unpublished Originally submitted for DAR(2008), B.2.2.1 (IIM 2.1/01))	N	N		VBC

MMP 2.3 2.4 2.8	Young	1997	Xentari WDG: Physical, chemical and technical properties Huntingdon Life Sciences Ltd. Company report No.: ABT 372/973849 GLP; Unpublished Originally submitted for DAR(2008), B.2.2.3 (IIIM 2.3/01))	N	N		VBC
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A.3 Data on application

No references provided for this section since this concerns a renewal.

A.4 Further information

Confidential (volume 4)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KMA 1.3/01	van der Vossen <i>et al.</i>	2008	Strain identification of Valent BioSciences Corp.'s strain collection Laboratory report / project number: V8278 GLP: No Unpublished	N	Y	Confidential information, Valent Biosciences Corp. Trade Secret	VBC
KMA 1.3/02	van der Vossen et al	2015	A rapid quantitative discriminatory PCR method for detection of <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> strain HD-1, <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> strain ABI-SI 857 and <i>Bacillus thuringiensis</i> subsp. <i>israelensis</i> AM65-52 in a possible background of <i>Bacillus cereus</i> group species Laboratory report / project number: R10428 GLP: No	N	Y	Confidential information, Valent Biosciences Corp. Trade Secret	VBC

			Unpublished				
KMA 1.3/03	Anon.	2015	Annotation of three strains of Bacillus thuringiensis Bta, Bti and Btk.	N	Y	Confidential information, Valent Biosciences Corp. Trade Secret	VBC
KMA 1.4.2/01	Nei-Long Lyang, M.S	2016	Five spore titer and bioburden analysis of Xentari DF. Laboratory report / project number: 2605 SN1 GLP: Yes Published: No	N	Y	New data submitted for first time	VBC
KMA 1.4.3/01			⇒ KMA 1.4.2/01				
KMA 4.1.1/01	van der Vossen, J.M.B.M et al	2008	Strain Identification of Valent BioSciences Corp.'s Strain Collection Document No. V8279 TNO GLP: Not stated Unpublished <u>Filed at KMA 1.3-01</u>	N	Y	New data submitted for first time	VBC
KMA 4.1.1/02,	van der Vossen, J.M.B.M et al	2015	A Rapid Quantitative Discriminatory PCR Method for Detection of Three Different Bacillus thuringiensis Strains in a Possible Background of Bacillus cereus Group Species Document No. TNO 2015 R10428	N	Y	New data submitted for first time	VBC

			GLP: Not stated Unpublished <u>Filed at KMA 1.3-01</u>				
IIM 1.3.3/01	Smith, R.A.	1990	Microbiological characterisation of ABG-6305 production strains. Unpublished report No.: 1859-91Y GLP: Yes Unpublished This study was presented in the DAR (2007)	N	Y	-	VBC
IIM 1.3.3/02	Benson, T.	2005	Summary Report: Genetic comparison of Bacillus thuringiensis subsp. aizawai strain ABTS-1857 to other Bacillus strains using AFLP Project No: Not available GLP: Yes Unpublished This study was presented in the DAR (2007)	N	Y	-	VBC
IIM 1.3.3/03	Rowell R.L	2005	Method of production and quality control for XenTari products (<i>Bacillus thuringiensis</i> subsp. <i>aizawai</i>). Document No: Valent Biosciences Corporation, Unpublished report No.: VBC-08/15-1 GLP: Yes Unpublished This study was presented in the DAR (2007)	N	Y	-	VBC
IIM 1.4.1/01	Short, M.	1990	Quantification of the active ingredient ABG-6305 technical powder by SDS-PAGE Document No. Abbot Laboratories, Report No.:	N	Y	-	VBC

			45-255-62 GLP: Yes Unpublished This study was presented in the DAR (2007)				
KMA 4.1.5/01	Crespo, A.L.B et al	2008	Comparison and Validation of Methods to Quantify Cry1Ab Toxin from Bacillus thuringiensis for Standardization of Insect Bioassays Applied and Environmental Microbiology, Jan 2008, p 130-135, Vol. 74, No. 1. GLP: Not stated Published	N	N	-	Published
KMA 4.1.5/02	Hart, H.	2016	Effect of XenTari and DiPel Technical Powders on Recovery and Enumeration of Generic <i>E. coli</i> in Drinking Water Document No. Research Project Number GNV-160008 GLP: No	N	Y	New data submitted for first time	VBC
IIM 1.4.2/03	Brand, R.A.	2004	Bioburden analysis of XenTari WG Document No. Abbot Laboratories, Report No.: 78-134-04 GLP: Yes Unpublished This study was presented in the DAR (2007).	N	Y	-	VBC
IIM 4.3.5/03	Lee, J.Y.	1990	Validation of HPLC assay for β -exotoxin impurity in ABG-6305, technical powder, (Project number 45-254-62) – Addendum to MRID 41722510 Document No. Abbot Laboratories, Report No.:	N	Y	-	VBC

			45-254-62 GLP: Yes Unpublished This study was presented in the DAR (2007)				
IIM 4.3.5/04	Lee, J.Y.	1990	HPLC assay for Beta-exotoxin in ABG-6305 (Cen-Tari) technical powder – Second addendum to MRID 41722510 Document No. Abbot Laboratories, Unpublished report No.: 60-825-62 GLP: Yes Unpublished This study was presented in the DAR (2007)	N	Y	-	VBC
IIM 1.4.2/05	Jaronski, S.T.	1991	Analysis of beta-exotoxin (<i>thuringiensis</i>) content of five lots of ABG-6305 technical powder by housefly bioassay. Document No. Abbot Laboratories, Report No.: 910-9009 GLP: Yes Unpublished This study was presented in the DAR (2007)	N	Y	-	VBC
IIM 1.4.2/07	Benzon, G.L.	2005	Bioassays for the presence of beta-exotoxin in samples of Xentari® Technical Slurry using house fly larvae. Document No. Benzon Research Inc., Report No.: VB05016b larvae. GLP: Yes Unpublished This study was presented in the DAR (2007)	N	Y	-	VBC

IIM 1.4.2/09	Bowman, L	2004	Summary report: Detection of enterotoxin in Valent BioSciences Bt fermentation beers and BT products Document No. Not available Report No. Not available GLP: No Unpublished The study was presented in the DAR (2007).	N	Y	-	VBC
IIM 4.3.6/01	Jacobsen, S.D.	1993	<i>Bacillus thuringiensis</i> : Acute toxicity in mice, subcutaneous dosing. GLP: No Unpublished The study was presented in the DAR (2007)	Y	Y	-	VBC
KMA 5.2.2.3/01	Doig, A.J. (2015)	2015	Microbial Pest Control Agent (MPCA) Safety Test in Mice <i>Bacillus thuringiensis</i> subsp. Aizawai Laboratory report / project number: 18643-15, 18673-15, 19188-15, 19495-15 GLP: No Unpublished	Y	Y	New data submitted for the first time	VBC
KMP 5.1.1/01	Wicker, N.	2016	Method validation of bioassay potency tests for the Cabbage Looper, <i>Trichoplusia ni</i> Document No. Laboratory Project ID: S16-01397 Eurofins Agrosience Services, Inc., Mebane, NC 27302 GLP: Yes Unpublished	N	Y	-	
IIM			⇒ IIM 1.3.3/03				

1.3.3/03							
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A.5 Analytical methods

See B.6 MA for summary literature search.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KMA 4.1.6/06	Hernandez, C.S.	2001	Update on the detection of β -exotoxin in <i>Bacillus thuringiensis</i> strains by HPLC analysis Document No. Journal of Applied Microbiology 2001, 90, 643-647 GLP: No Published	N	N	-	Published

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KMP 5.1.1/01	Wicker, N.	2016	Method validation of bioassay potency tests for the Cabbage Looper, <i>Trichoplusia ni</i>	N			

			Laboratory Project ID: S16-01397 Eurofins Agroscience Services, Inc., Mebane, NC 27302				
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A.6 Effects on human health

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
MMA 5.1/01	Shimada N, Miyamoto K, Kanda K & Murata H	2006	<i>Bacillus thuringiensis</i> insecticidal Cry1Ab toxin does not affect the membrane integrity of the mammalian intestinal epithelial cells: An <i>in vitro</i> study. In Vitro Cellular & Developmental Biology Animal 42 (1-2):45-49. GLP: no Published	N	N	-	-
MMA 5.1/02	Berlitz DL	2006	Toxicology effects of δ -endotoxins and β -exotoxins of <i>Bacillus thuringiensis</i> in Wistar rats. Neotropical Biology and Conservation 1(1):35-38 GLP: no Published	Y	N	-	-
MMA 5.1/03	Wilcks A, Hansen BM, Hendricksen NB & Licht TR	2006	Persistence of <i>Bacillus thuringiensis</i> bioinsecticides in the gut of human-flora-associated rats. FEMS Immunology & Medical Microbiology 48:410-418. GLP: no Published	Y	N	-	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
MMA 5.1/04	van der Wiele <i>et al</i>	2015	Evaluation of the germination behavior of DiPel and XenTari during passage through the GIT and their impact on the gut microbiota. <i>In vitro</i> study of immune effects mediated by the fermentation-derived metabolites using Caco-2 / THP1 co-cultures	N	N	New data submitted for the first time	VBC
MMA 5.1/05	Anon	2018	Evaluation of the effect of Bacillus thuringiensis XenTari on Caco-2 cells (follow up Deal 312)	N	Y	New data submitted for the first time	VBC
MMA 5.1.1/01	Glyn S	2016	XenTari® - Bta Untitled Report GLP: no Unpublished	N	N	-	VBC
MMA 5.1.3/01	Baelum J, Larsen P, Doekes G & Sisgaard T	2012	Health effects of selected microbiological control agents: a 3-year follow-up study. Annals of Agricultural and Environmental Medicine 19(4):631-636 GLP: no Published	N	N	-	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
MMA 5.1.4/01	McIntyre L, Bernard K, Beniac D, Isaac-Renton JL & Naseby DC	2008	Identification of <i>Bacillus cereus</i> Group Species Associated with Food Poisoning Outbreaks in British Columbia, Canada. Applied & Environmental Microbiology 74(23):7451-7453 GLP: no Published	N	N	-	-
MMA 5.1.4/02	Forrester MB	2012	<i>Bacillus thuringiensis</i> pesticide exposures reported to Texas poison centers. Toxicological & Environmental Chemistry 94(4):799-804 GLP: no Published	N	N	-	-
IIM 5.3.1/01	██████	1997a	XenTari Technical Powder (ABG-6305): Dermal sensitization study in Guinea pig Report number 3088-96 GLP Unpublished (Previously considered in the DAR)	Y	N	-	VBC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIM 5.3.2/01	██████	1995	Acute oral toxicity/pathogenicity study of <i>Bacillus thuringiensis</i> ABG-6305 in rats Report number M94AG90.222.008 GLP Unpublished (Previously considered in the DAR)	Y	N	-	VBC
IIM 5.3.2/02	██████	1996a	XenTari Technical Powder (ABG-6305): Acute oral toxicity study in rats Report number 3084-96 GLP Unpublished (Previously considered in the DAR)	Y	N	-	VBC
IIM 5.3.3/02	██████	1999	XenTari Technical Powder (ABG-6305): Acute inhalation toxicity study in rats Report number 4432-98 GLP Unpublished (Previously considered in the DAR)	Y	N	-	VBC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIM 5.3.4/02	██████	1991a	Acute pulmonary toxicity and infectivity/ pathogenicity to rats of <i>Bacillus thuringiensis</i> ABG-6305 Report number 901292D/ABT 143-2/AC GLP Unpublished (Previously considered in the DAR)	Y	N	-	VBC
IIM 5.3.4/01	██████	1990	Intraperitoneal and subcutaneous injection tests with ABG-6305 Technical Powder Report number 85K-11/9 GLP Unpublished (Previously considered in the DAR)	Y	N	-	VBC
IIM 5.3.4/02	██████	1991b	Acute intravenous toxicity and infectivity/ pathogenicity to rats of ABG-6305 Report number 901291D/ABT 143-1/AC GLP Unpublished (Previously considered in the DAR)	Y	N	-	VBC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIM 5.3.5/01	Lawlor T	1997	Mutagenicity test with XenTari Technical Powder (ABG-6305) in the Salmonella – Escherichia coli/mammalian- microsome reverse mutation assay Report number 18447-0-409 GLP Unpublished (Previously considered in the DAR)	N	N	-	VBC
MMA 5.2.5.1/01	Hammond BG, Dudek R, Lemen JK & Nemeth MA	2006	Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food and Chemical Toxicology 44: 1092-1099. GLP: no Published	Y	N	-	-
MMA 5.2.5.1/02	Onose J, Imai T, Hasumura M, Ueda M, Ozeki Y & Hirose M	2008	Evaluation of subchronic toxicity of dietary administered Cry1Ab protein from <i>Bacillus thuringiensis</i> var. <i>Kurstaki</i> HD-1 in F344 male rats with chemically induced gastrointestinal impairment. Food and Chemical Toxicology 46: 2184–2189. GLP: no Published	Y	N	-	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
MMA 5.3/01	Lemos AJJM, Wanderley-Teixera V, Teixeira AAC, Silva FdCA, Oliveira JV , & Siquiera HAA	2011	Response of blastocyst–endometrium interactions in albino rats to sublethal doses of biological and synthetic insecticides. Food & Chemical Pathology 49:2541-2547 GLP: no Published	Y	N	-	-
MMA 5.3/02	Lemos AJJM, Siquiera HAA, Wanderley-Teixera V, Maia FCL, Teixeira AAC, Silva EJ & Oliveira JV	2013	Effect of sub-lethal doses of <i>Bacillus thuringiensis</i> subsp. <i>aizawai</i> and deltamethrin with regard to fertility and organ toxicity in pregnant albino rats GLP: no Published	Y	N	-	-
MMA 5.4/01	Freire IS, Miranda-Vilela AL, Barbosa LCP, Martins ES, Monnerat RG & Grisolia CK	2014a	Evaluation of Cytotoxicity, Genotoxicity and Hematotoxicity of the Recombinant Spore-Crystal Complexes Cry1Ia, Cry10Aa and Cry1Ba6 from <i>Bacillus thuringiensis</i> in Swiss Mice. Toxins 6: 2872-2885 GLP: no Published	Y	N	-	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
MMA 5.4/02	Freire IS, Miranda-Vilela AL, Fascineli ML, Oliveira-Filho EC, Martins ES, Monnerat RG & Grisolia CK	2014b	Genotoxic evaluation in <i>Oreochromis niloticus</i> (Fish: <i>Characidae</i>) of recombinant spore–crystal complexes Cry1Ia, Cry10Aa and Cry1Ba6 from <i>Bacillus thuringiensis</i> . Ecotoxicology 23:267-272. GLP: no Published	Y	N	-	-
MMA 5.4/03	Mezzomo BP, Miranda-Vilela AL, de Souza Freire I, Barbosa LCP, Portilho FA & Grisolia CK	2013	Hematotoxicity of <i>Bacillus thuringiensis</i> as Spore-crystal Strains Cry1Aa, Cry1Ab, Cry1Ac or Cry2Aa in Swiss Albino Mice. Journal of Hematology & Thromboembolic Diseases 1(1). GLP: no Published	Y	N	-	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
MMA 5.4/03	Mezzomo BP, Miranda-Vilela AL, Barbosa LCP, Albernaz VL & Grisolia CK	2015	Hematotoxicity and Genotoxicity Evaluations in Swiss Mice Intraperitoneally Exposed to <i>Bacillus thuringiensis</i> (var <i>kurstaki</i>) Spore Crystals Genetically Modified to Express Individually Cry1Aa, Cry1Ab, Cry1Ac, or Cry2Aa Environmental Toxicology 31(8):970-978. GLP: no Published	Y	N	-	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIIM 7.1.1/01	██████ ██████	1991	Acute oral toxicity and clearance study in rats with ABG-6314 ██████ Company report No.: 3774-90-0470-TX-001 GLP Unpublished (Previously evaluated in the DAR)	Y	N	-	VBC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIIM 7.1.3/01	██████	1991	Acute inhalation toxicity study with ABG-6314 in rats ██████ Company report No.: 7788-91 GLP Unpublished (Previously evaluated in the DAR)	Y	N	-	VBC
MMP 7.1.2 /02	██████	2011	XenTari DF – Acute Inhalation Toxicity Study in Rats ██████ Company report No.: 33230 GLP Unpublished	Y	Y	Study submitted for the first time	VBC
IIIM 7.1.2/01	██████	1991a	Acute dermal toxicity study in albino rabbits with ABG-6314 ██████ Company report No.: 90-0471 GLP Unpublished (Previously evaluated in the DAR)	Y	N	-	VBC
IIIM 7.1.4/01	██████	1991b	Primary dermal irritation study in albino rabbits with ABG-6314 ██████ Company report No.: 90-0473 GLP Unpublished (Previously evaluated in the DAR)	Y	N	-	VBC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIIM 7.1.5/01	██████	1991c	Primary eye irritation study in albino rabbits with ABG-6314 ██████ Company report No.: 90-0472 GLP Unpublished (Previously evaluated in the DAR)	Y	N	-	VBC
IIIM 7.1.6/01	██████	1994	Maximization test of ZenTari in guinea pigs ██████████████████ Company report No.: M94AU50.246 GLP Unpublished (Previously evaluated in the DAR)	Y	N	-	VBC

A.7 Residue data

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KMA6.1 /01	Konecka E, Baranek J, Bielińska I, Tadeja A, Kaznowski A	2014	Persistence of the spores of <i>B. thuringiensis</i> subsp. <i>kurstaki</i> from Foray bioinsecticide in gleysol and on leaves. Journal of Science of the Total Environment (2014), Vol. 472, pp 296-301. Not GLP Published	N	N	N/A	N/A
KMA6.1 /02	Frederiksen, K, Rosenquist, H, Jørgensen, K, Wilcks, A.	2006	Occurrence of Natural <i>Bacillus thuringiensis</i> Contaminants and Residues of <i>Bacillus thuringiensis</i> -Based Insecticides on Fresh Fruits and Vegetables. Journal of Applied and Environmental Microbiology (May 2006), Vol. 72, No.5, pp 3435-3440. Not GLP Published	N	N	N/A	N/A
KMA6.1 /03	Choma, C, Guinebre-tière, MH, Carlin, F, Schmitt, P, Velge, P,	2000	Prevalence, characterisation and growth of <i>Bacillus cereus</i> in commercial cooked chilled foods containing vegetables. Journal of Applied Microbiology 2000, 88: 617-625. Not GLP	N	N	N/A	N/A

	Garnum, PE. & Nguyen-The, C.		Published				
KMA6.1 /04	Colla, F	2010	Study of <i>Bacillus thuringiensis</i> behaviour in food environment by genome-wide transcriptome analysis. University of Verona. Not GLP Published	N	N	N/A	N/A
KMA6.1 /06	Zhou, G, Yan, J, Dasheng, Z, Zhou, X, Yuan, Z.	2008	The residual occurrences of <i>Bacillus thuringiensis</i> bio pesticides in food and beverages. International Journal of Food Microbiology 127 (2008) 68-72. Not GLP Published	N	N	N/A	N/A
KMA6.2 .2/ 01	Pedersen, Damgard and Eilenberg	1995	Dispersal of <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> in an experimental cabbage field. Canadian. Journal of Microbiology. 41 (2) 118-125) Not GLP Published PREVIOUSLY EVALUATED IN BTK DAR DENMARK (2008)	N	N	N/A	N/A
KMA6.2 .2/02	Haddad, M, Polanczyk, R, Alves, S & de Olivera Garica, M	2005	Field Persistence of <i>Bacillus thuringiensis</i> on maize leaves. Brazilian Journal of Microbiology, 36: 309-314 Not GLP Published	N	N	N/A	N/A
KMA6.2	Stephan D;	2013a	Investigation of the spore concentration of <i>Bacillus thu-</i>	N	N	N/A	N/A

.2/03			<i>ringiensis</i> on marketable Salanova Lettuce Heads after application with XenTari® WG Julius Kühn -Institut Federal Research Institute for Cultivated Plants Institute for Biological Plant Protection Not GLP Not Published				
KMA6.2 .2/04	Stephan D	2013b	Summary of investigations on residues of <i>Bacillus thuringiensis</i> on lettuce and tomato. Julius Kühn -Institut Federal Research Institute for Cultivated Plants Institute for Biological Plant Protection Not GLP Not Published	N	N	N/A	N/A
KMA6.2 .2/05	Ehrhardt J	2016	Residue study (decline) on tomato following three foliar applications of XenTari® WG under protected conditions in Germany 2015. Versuchswesen Pflanzenschutz Report No: VP15-1-74 GLP Unpublished	N	Y	New data submitted for the first time	VBC
KMA6.2 .2/06	Wagner A	2016	Trials of Residue on Tomatoes and Peppers, Part of the Residues Research by the Minor Uses Working group. Julius Kühn -Institut Federal Research Institute for Cultivated Plants Institute for Biological Plant Protection GLP Unpublished	N	N	N/A	N/A

A.8 Environmental fate and behaviour

A.9 Ecotoxicology data

Active substance

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protec- tion claimed Y/N	Justification if data protection is claimed	Owner
IIM 8.1/01	██████ ██.	1991a	ABG-6305: An avian oral pathogenicity and toxicity study in the bobwhite Report No. 161-117 Source: ██████████. GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	Y	N	N/A	VBC
IIM 8.1/02	██████ ██	1991b	ABG-6305: An avian oral pathogenicity and toxicity study in the mallard Report No. 161-118 Source: ██████████ GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	Y	N	N/A	VBC

IIM 8.2.1/01	████████	1991a	Acute toxicity of ABG-6305 to the rainbow trout <i>Oncorhynchus mykiss</i> Report No. 9107A Source: ██████████ GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	Y	N	N/A	VBC
IIM 8.2.1/02	████████	1993	Xentari Technical Powder (ABG-6305) – Infectivity and pathogenicity to rainbow trout (<i>Oncorhynchus mykiss</i>) during a 20-day static renewal test Report No. 93-6-4837 Source: ██████████ GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	Y	N	N/A	VBC
IIM 8.2.1/03	████████	1995a	Xentari technical powder (ABG-6305) – toxicity to rainbow trout (<i>Oncorhynchus mykiss</i>) during a 30-day static renewal test Report No. 95-7-5977 Source: ██████████ GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	Y	N	N/A	VBC
IIM 8.2.2/01	Collins, M.K.	1995b	ABG-6305 – Toxicity to water fleas (<i>Daphnia</i>	N	N	N/A	VBC

			<p>magna) under static renewal conditions.</p> <p>Report No. 95-5-5855</p> <p>Source: Springborn Laboratories Inc.</p> <p>GLP</p> <p>Not published</p> <p>PREVIOUSLY EVALUATED. IN DAR (2008)</p>				
IIM 8.2.2/02	Boeri, R.L.	1991b	<p>Chronic toxicity of ABG-6305 to the daphnid <i>Daphnia magna</i></p> <p>Report No. 90162-A</p> <p>Source: Resource Analysts Inc.</p> <p>GLP</p> <p>Not published</p> <p>PREVIOUSLY EVALUATED. IN DAR (2008)</p>	N	N	N/A	VBC
IIM 8.2.2/03	Ward, T.J., Kowalski, P.L., Boeri, R.L.	1993	<p>Acute Toxicity of Components of ABG-6305 to the Daphnid <i>Daphnia magna</i> - addendum to MRID 41974802</p> <p>Report No. 123-AB</p> <p>Source: T.R. Wilbury Laboratories Inc.</p> <p>GLP</p> <p>Not published</p> <p>PREVIOUSLY EVALUATED. IN DAR (2008)</p>	N	N	N/A	VBC
IIM 8.2.2/04	Collins, M.K.	1995c	<p>Comparative toxicity test exposing Daphnids (<i>Daphnia magna</i>) to XenTari technical powder produced by two different recovery processes</p>	N	N	N/A	VBC

			Report No. 95-2-5717 Source: Springborn Laboratories Inc. GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)				
IIM 8.2.2/05	Feng, S.Y.	1966	Experimental bacterial infections in the oyster <i>Crassostrea virginica</i> <i>Journal of Invertebrate Pathology</i> . Vol. 8 pp 505-511 (1966) Non-GLP Published PREVIOUSLY EVALUATED. IN DAR (2008)	N	N	N/A	N/A
IIM 8.3/01	Kirkland, R.L.	1991a	The effect of <i>Bacillus thuringiensis</i> , ABG-6305 technical powder, on the honey bee, <i>Apis mellifera</i> L. Report No. CAR 19-690 Source: California Agricultural Research, Inc. GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	N	N	N/A	VBC
IIM 8.3/02	Gray, J.	2016	BTC Aizawi: Honey bee (<i>Apis mellifera</i>) larval toxicity test, single exposure Report No. XY58HS Envigo CRS, Ltd. GLP Unpublished	N	Y	New data submitted for first time	VBC

			SUBMITTED FOR THE PURPOSE OF RENEW-AL				
IIM 8.4/01	Nelson, R.D.	1991a	<p>The effect of <i>Bacillus thuringiensis</i>, ABG-6305 technical powder, on the predatory mite <i>Metaseiulus occidentalis</i> (Nesbit) and their host prey the twospotted spider mite <i>Tetranychus urticae</i> (Koch).</p> <p>Report No. 91.042</p> <p>Source: Plant Sciences, Inc.</p> <p>GLP</p> <p>Not published</p> <p>PREVIOUSLY EVALUATED. IN DAR (2008)</p>	N	N	N/A	VBC
IIM 8.4/02	Kirkland, R.L.	1991b	<p>The effect of <i>Bacillus thuringiensis</i>, ABG-6305 technical powder, on the insect egg parasitoid (<i>Trichogramma pretiosum</i> Riley)</p> <p>Report No. CAR 104L-91</p> <p>Source: California Agricultural Research</p> <p>GLP</p> <p>Not published</p> <p>PREVIOUSLY EVALUATED. IN DAR (2008)</p>	N	N	N/A	VBC
IIM 8.4/03 (supplemental report)	Castellon, A.	1991c	<p>The effect of <i>Bacillus thuringiensis</i>, ABG-6305 technical powder, on the insect egg parasitoid (<i>Trichogramma pretiosum</i> Riley)- supplemental report</p> <p>Report No. CAR 104L-91</p>	N	N	N/A	VBC

			Source: California Agricultural Research GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)				
IIM 8.4/04	Palmer, S.J., Bea- vers, J.B.	1993	Xentari technical powder (ABG-6305): a dietary pathogenicity and toxicity study with the ladybird beetle (<i>Hippodamia convergens</i>). Report No. 161-126A Source: Wildlife International, Ltd. GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	N	N	N/A	VBC
IIM 8.4/05	Nelson, R.D.	1991b	The effect of <i>Bacillus thuringiensis</i> , ABG-6305 technical powder, on the common green lacewing <i>Chrysoperla carnea</i> (Stephens). Report No. 91.043 Source: Plant Sciences, Inc. GLP Not published PREVIOUSLY EVALUATED. IN DAR (2008)	N	N	N/A	VBC
IIM 8.5/01	Smirnoff, W.A. Heim- pel, A.M.	1961	Notes on the pathology of <i>Bacillus thuringiensis</i> var. <i>thuringiensis</i> Berliner for the earthworm <i>Journal of Insect Pathology</i> . Vol. 3 pp 403-408 Not GLP; Published		N		--

			PREVIOUSLY EVALUATED. IN DAR (2008)				
IIM 8.5/02	Sindermann, A.B.	2005	Protocol: <i>Bacillus thuringiensis</i> subspecies <i>aizawai</i> technical powder: A pathogenicity study with the earthworm in an artificial soil substrate Wildlife International, Ltd. Company report No.: 529/1107005/EW-NCa/SUB529 Not GLP; Unpublished PREVIOUSLY EVALUATED. IN DAR (2008)		Y		VBC
IIM 8.5/03	Sindermann, A.B., Porch, J.R., Krueger, H.O.	2006	<i>Bacillus thuringiensis</i> subspecies <i>aizawai</i> , Strain ABTS-1857 Technical Powder: A pathogenicity study with the earthworm in an artificial soil substrate Report No. 529-110 Source: Wildlife International, Ltd. GLP Not published SUBMITTED FOR THE PURPOSE OF RENEW-AL	N	Y	New data submitted for first time	VBC

Product

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
IIIM 10.2/01	Dorgerloh,	2001	XenTari WG - Influence on the growth of the green alga, <i>Selenastrum capricornutum</i>	N	N	N/A	VBC

	M.		Report No. E 323 2084-2 Source: Bayer AG GLP Unpublished PREVIOUSLY EVALUATED. IN DAR (2008)				
IIIM 10.3/01	Rhodes, J.E., Down- ing, J.	1997	Toxicological effect of XenTari WDG (ABG-6314) on a colony of honey bees Report No. 43052 Source: ABC Laboratories, Inc. GLP Unpublished PREVIOUSLY EVALUATED. IN DAR (2008)	N	N	N/A	VBC
IIIM 10.3/02	Bolckmans, K.	1995	Toxicity of the biological insecticide ABG-6314 for bumblebees (Bombus terrestris L.) Report No. 9505151F Source: BIOBEST N.V. Non-GLP Unpublished PREVIOUSLY EVALUATED. IN DAR (2008)	N	N	N/A	VBC
IIIM 10.4/01	Schuld, M.	2002	XenTari WG: Toxicity test on the egg parasitoid, Trichogramma cacoeciae Marchal (Hymenoptera, Trichogrammatidae) under laboratory conditions Report No. 20011423/01-NLTc Source: GAB Biotechnologie & IFU Umweltanalytik GLP Unpublished PREVIOUSLY EVALUATED. IN DAR (2008)	N	N	N/A	VBC
IIIM 10.5/01	Benz, G., Altweg, A.	1975	Safety of Bacillus thuringiensis for earthworms Journal of Insect Pathology 26, 125-126		N		--

			Not GLP; Published PREVIOUSLY EVALUATED. IN DAR (2008)				
IIIM 10.7/01	Barnes, S.P.	2004	<i>Bacillus thuringiensis</i> subspecies <i>israelensis</i> , strain SA3A. Activated sludge- respiration inhibi- tion test. Report No. ZAB 040/033471 Source: Huntingdon Life Sciences Ltd., Cam- bridgeshire, UK GLP Unpublished SUBMITTED FOR THE PURPOSE OF RE- NEWAL	N	Y	New data sub- mitted for first time	VBC