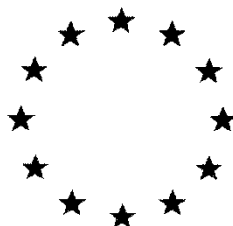


European Commission



**Draft Renewal Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

***Microbial Pest Control Agent (MPCA)
Bacillus thuringiensis
subsp. *kurstaki* SA-12***

Volume 2 (MPCA)

List of the tests, studies and information submitted

Rapporteur Member State: Denmark

Co- Rapporteur Member State: The Netherlands

Version history

When	What
2008	DAR
Nov 2011	Addendum to DAR
2019	Initial RAR

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A List of the tests, studies and information submitted

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A.1 Identity

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 1.3.3 /04	Barbera, P.W.	1990	NCCLS STANDARD DISK SUSCEPTIBILITY TEST OF BACILLUS THURINGIENSIS Ecogen Incorporated, Langhorne, PA 19047 Certis USA LLC, Columbia Report-no.: EC-02 GLP/GEP: no Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 1.4.1 /03 1.4.2 /01	Chen, C.Y.	2005	Confidential information Vol. 4	no	yes	not protected	Certis USA	In Addendum to DAR 2011
KMA 1.4.1 /05	Chen, C.Y.	2016	Confidential information Vol. 4	no	yes	not protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 1.4.1 /02	Chen, C.Y., Hargrove, J.L.	2003	Confidential information Vol. 4	no	yes	not protected	Certis USA	DAR 2008
KMA 1.3.3 /13	Chen, C.Y., Macuga, R.	1990 a	FLAGELLA ANTIGEN SEROTYPING OF BACILLUS THURINGIENSIS SSP. KURSTAKI STRAIN SA11001C98-1-1 ██████████ ██████████ Palo Alto, CA, USA Certis USA LLC, Columbia Report-no.: 90/02/12A GLP/GEP: yes Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 1.3.3 /14	Chen, C.Y., Macuga, R.	1990 b	FLAGELLA ANTIGEN SEROTYPING OF BACILLUS THURINGIENSIS SSP. KURSTAKI STRAIN SA12 ██████████ ██████████ Palo Alto, CA, USA Certis USA LLC, Columbia Report-no.: 90/02/12B GLP/GEP: yes Published: no	no	no	not protected	Certis USA	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 1.4.1/06	Cheng, M., Chen, C.-Y.	2016	Confidential information Vol. 4	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 1.3.3 /15	Currier, T.C., Gawron-Burke, C. and Silver, R.S.	1988	Confidential information Vol. 4	no	yes	not protected	Certis USA	DAR 2008
KMA 1.3.3 /08	de Barjac, H.	1981	IDENTIFICATION OF H-SEROTYPES OF BACILLUS THURINGIENSIS Microbial control of pest and plant diseases, Burges, H.D. ed., London, Academic press, pp. 35-43 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 1.3.4 /01	Dively, C.A.	2005	STATEMENT OF STRAIN SYNONYMS Certis USA LLC, Columbia Report-no.: not applicable GLP/GEP: no Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 1.4.1 /01	Dulmage, H.T., Boening, O.P., Rehnborg, C.S., Hansen, G.D.	1971	A PROPOSED STANDARDIZED BIOASSAY FOR FORMULATIONS OF BACILLUS THURINGIENSIS BASED ON THE INTERNATIONAL UNIT Journal of Invertebrate Pathology Volume 18, pp. 240-245 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 1.3.3 /11	González, J.M., Carlton, B.C.	1980	PATTERN OF PLASMID DNA IN CRYSTALLIFEROUS AND ACRYSTALLIFEROUS STRAINS OF BACILLUS THURINGIENSIS Plasmid 3, p. 92-98 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 1.3.3 /16	Hill, K.K., Ticknor, L.O., Okina, R.T., Asay, M., Blair, H., Bliss, K.A., Laker, M., Pardington, P.E., Richardson, A.P., Tonks, M., Beecher, D.J., Kemp, J.D., Kolsto, A.- B., Wong, A.C.L., Keim, P., Jackson, P.J.	2004	FLOURESCENT AMPLIFIED FRAGMENT LENGTH POLYMORPHISM ANALYSIS OF BACILLUS ANTHRACIS, BACILLUS CEREUS AND BACILLUS THURINGIENSIS ISOLATES Applied and Environmental Microbiology, 70(2), 1068-1080. Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 1.3.3 /12	Iizuka, T., Faust, R.M., Travers, R.S.	1981	ISOLATION AND PARTIAL CHARACTERIZATION OF EXTRACHROMOSOMAL DNA FROM SEROTYPES OF BACILLUS THURINGIENSIS PATHOGENIC TO LEPIDOPTERAN AND DIPTERAN LARVAE BY AGAROSE GEL ELECTROPHORESIS J. Sericult. Sic. Japan, pp. 120-133 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 1.4.1 /04	Iqbal, M., Chen, C.-Y.	2005	Confidential information Vol. 4	no	yes	Not protected	Certis USA	In Addendum to DAR 2011
KMA 1.3.3 /09	Ohba, M., Aizawa, K.	1978	SEROLOGICAL IDENTIFICATION OF BACILLUS THURINGIENSIS AND RELATED BACTERIA ISOLATED IN JAPAN Journal of Invertebrate Pathology Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 1.3.3 /02	Smith, R.W., Regan, K.M.	1990 a	BIOCHEMICAL AND MORPHOLOGICAL CHARACTERISTICS OF BACILLUS THURINGIENSIS SPP. KURSTAKI STRAIN SA11001C98-1-1 WITH A DISCUSSION OF STRAIN HISTORY INCLUDED ██████████ Palo Alto, CA, USA Certis USA LLC, Columbia Report-no.: 90/02/02E GLP/GEP: yes Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 1.3.3 /03	Smith, R.W., Regan, K.M.	1990 b	BIOCHEMICAL AND MORPHOLOGICAL CHARACTERISTICS OF BACILLUS THURINGIENSIS SPP. KURSTAKI STRAIN SA12 WITH A DISCUSSION OF STRAIN HISTORY INCLUDED ████████████████████ ████████████████████ ██████████ Certis USA LLC, Columbia Report-no.: 90/02/02F GLP/GEP: yes Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 1.3.3 /01 NOT SUBMITTED	Sneath, P.H.A.	1986	ENDOSPORE-FORMING GRAM-POSITIVE RODS AND COCCI in Bergey's Manual of Systematic Bacteriology Vol. 2. Eds. Sneath, P.H.A. Mair N.S., Sharpe, M.E: and Holt, J.G. Williams and Wilkins, pp. 1104-1207 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	Certis USA	DAR 2008
KMA 1.3.3 /05	Strauss, S.	2005 a	FATTY ACID COMPOSITION AND CHROMATOGRAMM OF SA11 Certis USA LLC, Columbia Report-no.: not applicable GLP/GEP: no Published: no	no	yes	not protected	Certis USA	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 1.3.3 /06	Strauss, S.	2005 b	FATTY ACID COMPOSITION AND CHROMATOGRAMM OF SA12 Certis USA LLC, Columbia Report-no.: not applicable GLP/GEP: no Published: no	no	yes	not protected	Certis USA	DAR 2008
KMA 1.3.3 /07	Strauss, S.	2005 c	FATTY ACID COMPOSITION AND CHROMATOGRAMM OF HD-1 Certis USA LLC, Columbia Report-no.: not applicable GLP/GEP: no Published: no	no	yes	not protected	Certis USA	DAR 2008
KMA 1.3.3 /10	Yamamoto T. and Chen C.-Y.	2006	Confidential information Vol. 4	no	yes	not protected	Certis USA	DAR 2008

A.2 Biological, physical and chemical properties

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.8 /18	Abdoarrahem, M.M., Gammon, K., Dancer, B.N., Berry, C.	2009	GENETIC BASIS FOR ALKALINE ACTIVATION OF GERMINATION IN BACILLUS THURINGIENSIS SUBSP. ISRAELENIS Applied and Environmental Microbiology, 75(19), 6410-6413 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.5 /14	Addison, J.A.	1993	PERSISTENCE AND NONTARGET EFFECTS OF BACILLUS THURINGIENSIS IN SOIL – A REVIEW Canadian Journal of Forest Research - Revue Canadienne De Recherche Forestiere 23 (11): 2329-2342 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /17	Akiba, Y.	1986	MICROBIAL ECOLOGY OF BACILLUS THURINGIENSIS VI. GERMINATION OF BACILLUS THURINGIENSIS SPORES IN THE SOIL Appl. Ent. Zool. 21 (1): 76-80 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /19	Andersson, A., Granum, P.E., Römer, U.	1998	THE ADHESION OF BACILLUS CEREUS SPORES TO EPITHELIAL CELLS MIGHT BE AN ADDITIONAL VIRULENCE MECHANISM International Journal of Food Microbiol. 39, p. 93-99 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /02	Anonymous	2004	ANTHRAX FACT SHEET Report-no.: not applicable GLP/GEP: no Published: no	no	no	not protected	-	DAR 2008
KMA 2.2.2 /15 2.5 /01	Aronson, A.I.	1993	THE TWO FACES OF BACILLUS THURINGIENSIS: INSECTICIDAL PROTEINS AND POST-EXPONENTIAL SURVIVAL Molecular Microbiology 7: 489-496 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.3 /03	Aronson, A.I., Han, E.-S., McGaughey, W., Johnson, D.	1991	THE SOLUBILITY OF INCLUSION PROTEINS FROM BACILLUS THURINGIENSIS IS DEPENDENT UPON PROTOXIN COMPOSITION AND IS FACTOR IN TOXICITY TO INSECTS Applied and Environmental Microbiology, 57(4): 981-986 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /06	Asimeng, E.J., Mutinga, M.J.	1992	ISOLATION OF MOSQUITO-TOXIC BACTERIA FROM MOSQUITO-BREEDING SITES IN KENYA Journal of the American Mosquito Control Association, 8:86-88 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /24	Auger, S., Ramarao, N., Faille, C., Fouet, A., Aymerich, S., Gohar, M.	2009	BIOFILM FORMATION AND CELL SURFACE PROPERTIES AMONG PATHOGENIC AND NON-PATHOGENIC STRAINS OF THE BACILLUS CEREUS GROUP Applied and Environmental Microbiology, 75(20), 6616-6618 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.9 /03	Barbera, P.W.	1990	NCCLS STANDARD DISK SUSCEPTIBILITY TEST OF BACILLUS THURINGIENSIS STRAINS Ecogen Incorporated, Langhorne, PA 19047 Certis USA LLC, Columbia Report-no.: EC-02 GLP/GEP: no Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 2.7 /07	Battisti, L., Green, B.D., Curtis, B.T.	1985	MATING SYSTEM FOR TRANSFER OF PLASMIDS AMONG BACILLUS ANTHRACIS, BACILLUS CEREUS AND BACILLUS THURINGIENSIS Journal of Bacteriology, pp. 543-550 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.5 /28	Beegle, C.C., Dulmage, H.T., Wolfenbarger, D.A., Martinez, M.	1981	PERSISTENCE OF BACILLUS THURINGIENSIS BERLINER INSECTICIDAL ACTIVITY ON COTTON FOLIAGE Environ. Entomol. 10, p. 400-401 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.2 /06	Bel, Y., Granero, F., Alberola, T.M., Martínez-Sebastián, M., Ferré, J.	1997	DISTRIBUTION, FREQUENCY AND DIVERSITY OF BACILLUS THURINGIENSIS IN OLIVE TREE ENVIRONMENTS IN SPAIN System. Appl. Microbiol. 20, 652-658 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.2 /01 2.5 /06	Bernhard, K., Jarrett, P., Meadows, M., Butt, J., Ellis, D.J., Roberts, G.M., Pauli, S., Rodgers, P., Burgess, H.D.	1997	NATURAL ISOLATES OF BACILLUS THURINGIENSIS: WORLDWIDE DISTRIBUTION, CHARACTERIZATION, AND ACTIVITY AGAINST INSECT PESTS Journal of Invertebrate Pathology, Vol. 70, pp. 59-68 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.7 /13	Bizzarri, M.F., Bishop, A.H.	2008	THE ECOLOGY OF BACILLUS THURINGIENSIS ON THE PHYLLOPLANE: COLONIZATION FROM SOIL, PLASMID TRANSFER, AND INTERACTION WITH LARVAE OF PIERIS BRASSICAE Microb Ecol, 56, 133-139 Report-no.: not applicable GLP/GEP: no Published: yes.	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.4 /04	Bravo, A.	1997	PHYLOGENETIC RELATIONSHIPS OF BACILLUS THURINGIENSIS Journal of Bacteriol. 179, p. 2793-2801 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.1.1 /15	Bravo, A., Likitvivatanavong, S., Gill, S.S., Soberon, M.	2011	BACILLUS THURINGIENSIS: A STORY OF A SUCCESSFUL BIOINSECTICIDE. Insect Biochemistry and Molecular Biology 41(7):423-431 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.2.2 /08	Broderick, N.A., Raffa, K.F., Handelsman J	2006	MIDGUT BACTERIA REQUIRED FOR BACILLUS THURINGIENSIS INSECTICIDAL ACTIVITY Proc Natl Acad Sci USA 103(41): 15196-15199 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /19	Broderick, N.A., Robinson, C.J., McMahon, M.D., Holt, J., Handelsman, J., Raffa, K.F.	2009	CONTRIBUTIONS OF GUT BACTERIA TO BACILLUS THURINGIENSIS-INDUCED MORTALITY VARY ACROSS A RANGE OF LEPIDOPTERA BMC Biology, 7(11): 1-9 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.1.1 /05	Brownbridge, M., Margalit, J.	1986	NEW BACILLUS THURINGIENSIS STRAINS ISOLATED IN ISRAEL HIGHLY TOXIC TO MOSQUITO LARVAE Journal of Invertebrate Pathology 48, p. 216-222 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /16 2.5 /02	Burges, H.D.	1982	CONTROL OF INSECTS BY BACTERIA. Parasitology 84: 79-117 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /03	Carlson, C.R., Johansen, T., Kolsto, A.-B.	1996	THE CHROMOSOME MAP OF BAC. THUR. SUBSP. CANADENSIS HD224 IS HIGHLY SIMILAR TO THAT OF THE BAC. CEREUS TYPE STRAIN ATCC 14579 FEMS Microbiology Letters 141, pp. 163-167 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.7 /05	Carlton, B.C.	1993	GENETICS OF BT INSECTICIDAL PROTEINS AND STRATEGIES FOR THE CONSTRUCTION OF IMPROVED STRAINS American Chemical Society, pp. 326-334 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.3 /09	Cerf, D.C.	1990	SUSCEPTIBILITY OF FOUR ORDERS OF INSECTS (LEPIDOPTERA, DIPTERA, COLEOPTERA, AND ORTHOPTERA) TO TECHNICAL GRADE ACTIVE INGREDIENTS (TGAIS), MANUFACTURING PRODUCTS (MP'S) AND END-USE PRODUCTS (EP'S) PRODUCED FROM FERMENTATION OF BACILLUS THURINGIENSIS Analyt. Services, ██████████ ██████████ Palo Alto, CA Certis USA LLC, Columbia Report-no.: 90/03/12 GLP/GEP: yes Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 2.8 /22	Ceuppens, S., Uyttendaele, M., Drieskens, K., Heyndrickx, M., Rajkovic, A., Boon, N., Van de Wiele, T.	2012a	SURVIVAL AND GERMINATION OF BACILLUS CEREUS SPORES WITHOUT OUTGROWTH OR ENTEROROXIN PRODUCTION DURING IN VITRO SIMULATION OF GASTROINTESTINAL TRANSIT Applied and Environmental Microbiology, 78(21), 7698-7705 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.8 /23	Ceuppens, S., Van de Wiele, T., Rajkovic, A., Ferrer-Cabaceran, T., Heyndrickx, M., Boon, N., Uyttendaele, M.	2012b	IMPACT OF INTESTINAL MICROBIOTA AND GASTROINTESTINAL CONDITIONS ON THE IN VITRO SURVIVAL AND GROWTH OF BACILLUS CEREUS Int. J. Food Microbiology, 155(3), 241-246 Report-no.: not applicable GLP/GEP: no Published: yes	no	yes	Not protected	-	New data for active ingredient, not previously submitted nor evaluated

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KMA 2.1.2 /02	Chaufaux, J., Marchal, M., Gilois, N., Jehanno, I., Buisson, C.	1997	RECHERCHE DE SOUCHES NATURELLES DU BACILLUS THURINGIENSIS DANS DIFFERENTS BIOTOPES, A TRAVERS LE MONDE Report-no.: not applicable GLP/GEP: no Published: no	no	no	not protected	-	DAR 2008
KMA 2.8 /08	Chen, C.-Y.	2004	Confidential information Vol. 4	no	yes	protected	Certis USA	DAR 2008
KMA 2.6 /10 2.8 /03	Chen, C.Y.	2005a	FINGERPRINTS OF BACILLUS THURINGIENSIS Certis USA LLC, Columbia Report-no.: not applicable GLP/GEP: no Published: no	no	yes	not protected	Certis USA	DAR 2008
KMA 2.7 /09 2.8 /04	Chen, C.Y.	2005b	Confidential information Vol. 4	no	yes	not protected	Certis USA	DAR 2008
KMA 2.7 /10 2.8 /05	Chen, C.Y.	2005c	Confidential information Vol. 4	no	yes	not protected	Certis USA	DAR 2008
KMA 2.7 /11 KMA 2.8 /06	Chen, C.Y.	2005d	Confidential information Vol. 4	no	yes	not protected protected	Certis USA	DAR 2008
KMA 2.7 /03	Chen, C.Y., Hargrove, J.L.	2003	Confidential information Vol. 4	no	yes	not protected protected	Certis USA	DAR 2008
KMA 2.1.1 /14	Chilcott, C. N., Wigley, P. J.	1988	TECHNICAL NOTE: AN IMPROVED METHOD FOR DIFFERENTIAL STAINING OF BACILLUS THURINGIENSIS CRYSTALS. Lett. Appl. Microbiol., 7: 67-70 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /26	Damgaard, P.H.	1995	DIARRHOEAL ENTEROTOXIN PRODUCTION BY STRAINS OF BACILLUS THURINGIENSIS ISOLATED FROM COMMERCIAL BACILLUS THURINGIENSIS-BASED INSECTICIDES FEMS Immunology and Medical Microbiology, 12(3-4), 245-250 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.1.2 /12	Damgaard, P.H., Abdel-Hameed, A., Eilenberg, J., Smits, P.H.	1998	NATURAL OCCURRENCE OF BACILLUS THURINGIENSIS ON GRASS FOLIAGE World Journal of Microbiology & Biotechnology, 14: 239-242 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /26	Damgaard, P.H., Granum, P.E., Bresciani, J., Torregrossa, M.V., Eilenberg, J., Valentino, L.	1997b	CHARACTERIZATION OF BACILLUS THURINGIENSIS ISOLATED FROM INFECTIONS IN BURN WOUNDS FEMS Immunology and Medical Microbiology 18, p. 47-53 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.2 /11	Damgaard, P.H., Hansen, B.M., Pedersen, J.C., Eilenberg, J.	1997a	NATURAL OCCURRENCE OF BACILLUS THURINGIENSIS ON CABBAGE FOLIAGE AND IN INSECTS ASSOCIATED WITH CABBAGE CROPS not applicable Journal of Applied Microbiology, 82, 253-258 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /11	de Castilhos-Fortes, R., Matsumura, A.T.S., Diehl E., Fiuza, L.M.	2002	SUSCEPTIBILITY OF NASUTITERMES EHRHARDTI (ISOPTERA: TERMITIDAE) TO BACILLUS THURINGIENSIS SUBSPECIES Braz. J. Microbiol. 2002, 33(3): 219-222 Report-no.: not applicable GLP/GEP: no Published:	no	no	not protected	-	DAR 2008
KMA 2.1.1 /08 2.1.2 /15	Delucca, A.J., Palmgren, M.S., Ciegler, A.	1982	BACILLUS THURINGIENSIS IN GRAIN ELEVATOR DUSTS Can. J. Microbiol., 28:452-456 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /03 2.1.2 /14	Delucca, A.J., Simonson, J.G., Larson, A.D.	1981	BACILLUS THURINGIENSIS DISTRIBUTION IN SOILS OF THE UNITED STATES Can. J. Microbiol., 27: 865-870 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.5 /23	Dent, D.R.	1993	THE USE OF BACILLUS THURINGIENSIS AS AN INSECTICIDE In: Exploitation of Microorganisms, D.G. Jones (ed.), Chapman & Hall, London Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.7 /16	Donnarumma, F., Paffetti, D., Stotzky, G., Giannini, R., Vettori, C.	2010	POTENTIAL GENE EXCHANGE BETWEEN BACILLUS THURINGIENSIS SUBSP. KURSTAKI AND BACILLUS SPP. IN SOIL IN SITU Soil Biology and Biochemistry, 42, 1329-1337 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.5 /18	Donnellan, J.E., Stafford, R.S.	1968	THE ULTRAVIOLET PHOTOCHEMISTRY AND PHOTOBIOLOGY OF VEGETATIVE CELLS AND SPORES OF BACILLUS MEGATERIUM Biophys. J. 8:17-27 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /01	Drobniewski, F.A.	1993	BACILLUS CEREUS AND RELATED SPECIES Clinical Microbiology Reviews, 4, p. 324-338 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /17	Du, C., Nickerson, K.W.	1996b	BACILLUS THURINGIENSIS HD-73 SPORES HAVE SURFACE-LOCALIZED CryAc TOXIN: PHYSIOLOGICAL AND PATHOGENIC CONSEQUENCES Applied and Environmental Microbiology, 62(10): 3722-3762 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.1.1 /07 2.1.2 /16	Dulmage, H.T.	1970	INSECTICAL ACTIVITY OF HD-1, A NEW ISOLATE OF BACILLUS THURINGIENSIS VAR. ALESTI Journal of Invertebrate Pathology, Volume 15, pp. 232-239 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

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KMA 2.2.2 /14	Dulmage, H.T., Boening, O.P., Rehnborg, C.S., Hansen, G.D.	1971	A PROPOSED STANDARDIZED BIOASSAY FOR FORMULATIONS OF BACILLUS THURINGIENSIS BASED ON THE INTERNATIONAL UNIT Journal of Invertebrate Pathology Volume 18, pp. 240-245 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /15	EFSA	2005	OPINION OF THE SCIENTIFIC PANEL OF BIOLOGICAL HAZARD ON BACILLUS CEREUS AND OTHER BACILLUS SPP IN FOODSTUFFS The EFSA Journal 175, p. 1-48 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /23	Ehling-Schulz, M., Vukov, N., Schulz, A., Shaheen, R., Andersson, M., Martlbauer, E., Sherer, S.	2005	IDENTIFICATION AND PARTIAL CHARACTERIZATION OF THE NONRIBOSOMAL PEPTIDE SYNTHETASE GENE RESPONSIBLE FOR PRODUCTION IN EMETIC BACILLUS CEREUS Applied and Environmental Microbiology 71(1): 105-113 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.4 /05	Estruch, J.J., Warren, G.W., Mullins, M.A., Nye, G.J., Craig, J.A., Koziel, M.-G.	1996	VIP3A, A NOVEL BAC. THUR. VEGETATIVE INSECTICIDAL PROTEIN WITH A WIDE SPECTRUM OF ACTIVITIES AGAINST LEPIDOPTERAN INSECTS Proc. Natl. Acad. Sci. 93, p. 5389-5394 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /10 2.2.2 /02	Feitelson, J.F., Payne, J., Kim, L.	1992	BACILLUS THURINGIENSIS: INSECTS AND BEYOND Biotechnology Vol. 10 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.5 /31	Furlaneto, L., Saridakis, H.O., Arantes, O.M.N.	2000	SURVIVAL AND CONJUGAL TRANSFER BETWEEN BACILLUS THURINGIENSIS STRAINS IN AQUATIC ENVIRONMENT Brazilian Journal of Microbiology, Volume 31, No. 4, pp. 233-238 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /21	Germaine, G.R., Murrell, W.G.	1973	EFFECT OF DIPICOLINICACID ON THE ULTRAVIOLET RADIATION RESISTANCE OF BACILLUS CEREU SPORES. Photochem. Photobiol. 17:145-154 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /13	Gilliland, A., Chambers, C.E., Bone, E.J., Ellar, D.J.	2002	ROLE OF BACILLUS THURINGIENSIS CRY1 DELTA ENDOTOXIN BINDING IN DETERMINING POTENCY DURING LEPIDOPTERAN LARVAL DEVELOPMENT Applied and Environmental Microbiology, 68(4): 1509-1515 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /12	Glare, T.R., O'Callaghan, M.	2000	BACILLUS THURINGIENSIS: BIOLOGY, ECOLOGY AND SAFETY in <i>Bacillus thuringiensis: Biology, Ecology and Safety</i> , Glare, T.R., O'Callaghan, M. (eds.) John Wiley & Sons, Ltd. Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /28 2.7 /04	González, J.M., Brown, B.J., Carlton, B.C.	1982	TRANSFER OF BACILLUS THURINGIENSIS PLASMIDS CODING FOR Proc. Natl. Acad. Sci. 79, p. 6951-6955 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

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KMA 2.6 /20	Granum, P.E.	2001	FOOD MICROBIOLOGY: FUNDAMENTALS AND FRONTIERS Food Microbiology: fundamentals and frontiers, 2 nd Ed., M.P. Doyle (ed.), pp. 373-381, ASM Press, Washington, D.C Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /18	Granum, P.E., Lund, T.	1997	BACILLUS CEREUS AND ITS FOOD POISONING TOXINS FEMS Microbiology Letters 157: 223-228 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /17 2.4 /01 2.5 /03	Griego, V.M., Spence, K.D.	1978	INACTIVATION OF BACILLUS THURINGIENSIS SPORES BY ULTRAVIOLET AND VISIBLE LIGHT Applied and Environmental Microbiology, 35(5): 906-910 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /31	Guinebretiére, M.-H., Thompson, F.L., Sorokin, A., Normand, P., Dawyndt, P., Ehling-Schulz, M., Svensson, B., Sanchis, V., Nguyen-The, C., Heyndrickx, M., De Vos, P.	2008	ECOLOGICAL DIVERSIFICATION IN THE BACILLUS CEREUS GROUP Environ Microbiol., 10(4):851-865 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.6 /32	Guinebretiére, M.-H., Velge, P., Couvert, O., Carlin, F., Debuyser, M.-L., Nguyen-The, C.	2010	ABILITY OF BACILLUS CEREUS GROUP STRAINS TO CAUSE FOOD POISONING VARIES ACCORDING TO PHYLOGENETIC AFFILIATION (GROUPS I TO VII) RATHER THAN SPECIES AFFILIATION J Clin Microbiol., 48(9):3388-3391 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

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KMA 2.6 /07	Guttmann, D.M., Ellar, D.J.	2000	PHENOTYPIC AND GENOTYPIC COMPARISONS OF 23 STRAINS FROM THE BACILLUS CEREUS COMPLEX FOR A SELECTION OF KNOWN AND PUTATIVE B. THURINGIENSIS VIRULENCE FACTOR FEMS Microbiology Letters 188, pp. 7-13 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.3 /06	Haider, M.Z., Knowles, B.H., Ellar, D.J.	1986	SPECIFICITY OF BACILLUS THURINGIENSIS VAR. COLMERI INSECTICIDAL Eur. J. Biochem. 156, p. 531-540 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /29	Hansen, B.M., Damgaard, P.H., Eilenberg, J., Pedersen J.C.	1998	MOLECULAR AND CLASSICAL CHARACTERIZATION OF BACILLUS THURINGIENSIS ISOLATED FROM LEAVES AND INSECTS Journal of Invertebrate Pathology 71, 106-114 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /01	Hansen, B.M., Salamatou, S.	2000	VIRULENCE OF BACILLUS THURINGIENSIS In: Charles, J.-F., Delécluse, A. & Nielsen-Le Roux, C. (eds.): Entomopathogenic Bacteria: From Laboratory to Field Application Kluwer Academic Publishers. Chapter 1.3 pp. 41-64 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /20	Hansen, B.M., Thorsen, L., Nielsen-LeRoux, C., Wilcks, A., Hendriksen, N.B.	2011	NEW EXPERIMENTAL APPROACHES FOR HUMAN RISK ASSESSEMENT OF MICROBIAL PEST CONTROL AGENTS – EXEMPLIFIED BY THE BACTERIUM BACILLUS THURINGIENSIS Danish EPA, Pesticides Research, 136 2011, 1-128 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.7 /02	Hargrove, J.L.	1990	Confidential information Vol. 4	no	no	not protected	Certis USA	DAR 2008

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KMA 2.7 /01 2.8 /07	Hargrove, J.L., Iqbal, M., Chen, C.Y., Gouker, T.	2003	Confidential information Vol. 4	no	yes	not protected	Certis USA	DAR 2008
KMA 2.6 /11	Helgason, E., D. A. Caugant, I. Olsen, A.-B. Kolstø	2000b	GENETIC STRUCTURE OF POPULATION OF BACILLUS CEREUS AND B. THURINGIENSIS ISOLATES ASSOCIATED WITH PERIODONTIS AND OTHER HUMAN INFECTIONS J. Clin. Microbiol. 38:1615-1622 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /04	Helgason, E., Okstad, O.A., Caugnat, D.A., Johansen, H.A., Fouet, A., Mock, M., Hegna, I., Kolsto	2000a	BACILLUS ANTHRACIS, BACILLUS CEREUS, AND BACILLUS THURINGIENSIS-ONE SPECIES ON THE BASIS OF GENETIC EVIDENCE Appl. And Environ. Microbiol. 66(6): 2627-2630 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /05	Hendriksen, N.B., Hansen, B.M.	2002	LONG-TERM SURVIVAL AND GERMINATION OF BACILLUS THURINGIENSIS VAR. KURSTAKI IN A FIELD TRIAL Canadian Journal of Microbiology 48: 256-261 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /09	Hill, K.K., Ticknor, L.O., Okinaka, R.T., Asay, M., Blair, H., Bliss, K. A., Laker, M., Pardington, P.E., Richardson, A.P., Tonks, M., Beecher, D.J., Kemp, J.D., Kolsto, A.-B., Wong, A.C.L., Keim, P., Jackson, P.J.	2004	FLUORESENT AMPLIFIED FRAGMENT LENGTH POLYMORPHISM ANALYSIS OF BACILLUS ANTHRACIS, BACILLUS CEREUS AND BACILLUS THURINGIENSIS ISOLATES Applied and Environmental Microbiology, 70(2), 1068-1080. Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

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KMA 2.2.2 /06	Hofmann, C., Lüthy, P., Hütter, R., 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 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /05	Hofmann, C., Vanderbruggen, H., Höfte, H., van Rie, J., Jansens, S., 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.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.3 /07	Honée, G. and Visser, B.	1993	THE MODE OF ACTION OF BACILLUS THURINGIENSIS CRYSTAL PROTEINS Entomol. exp. appl. 69, p. 145-155 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /22 NOT SUBMITTED	Hoton FM, Andrup L, Swiecicka I, Mahillon, J.	2005	THE CEREULIDE GENETIC DETERMINANTS OF EMETIC BACILLUS CEREUS ARE PLASMID-BORNE Microbiology-SGM 151: 2121-2124 Report-no.: not applicable GLP/GEP: no Published:	no	no	not protected	-	DAR 2008
KMA 2.2.2 /01 2.3 /01	Höfte, H., Whiteley, H.R.	1989	INSECTICIDAL CRYSTAL PROTEINS OF BACILLUS THURINGIENSIS Microbiological Reviews, p. 242-255 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

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KMA 2.7 /08	Hu, X.M., Hansen, B.M., Eilenberg, J., Hendriksen, N.B., Smidt, L., Yuan, Z.M., Jensen, G.B.	2004	CONJUGATIVE TRANSFER, STABILITY AND EXPRESSION OF A PLASMID ENCODING A cry1Ac GENE IN BACILLUS CEREUS GROUP STRAINS FEMS Microbiology Letters 231(1): 45-52 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /22	Ignoffo, C.M.	1992	ENVIRONMENTAL FACTORS AFFECTING PERSISTENCE OF ENTOMOPATHOGENS The Florida Entomologist, 75(4), 516-525 Report-no.: not applicable GLP/GEP: no Published: yes		no	not protected	-	DAR 2008
KMA 2.1.2 /05	Iriarte, J., Bel, Y., Ferrandis, M.D., Andrew, R., Murillo, J., Ferré, J., Caballero, P.	1998	ENVIRONMENTAL DISTRIBUTION AND DIVERSITY OF BACILLUS THURINGIENSIS IN SPAIN System. Appl. Microbiol. 21, 97-106 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /01	Ishiwata S,	1901	ON A KIND OF SEVERE FLACHERIE (SOTTO DISASE). Dainihon Sanshi Kaiho 9, 1-5 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /08	Ivanova, N., Sorokin, A., Anderson, I., Galleron, N., Candelon, B., Kapatral, V., Bhattacharyya, A., Reznik, G., Mikhailova, N., Lapidus, A., Chu, L., Mazur, M., Goltsman, E., Larsen, N., D	2003	GENOME SEQUENCE OF BACILLUS CEREUS AND COMPARATIVE ANALYSIS WITH BACILLUS ANTHRACIS Nature, 423, p. 87-91 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /25	Jackson, S.G., Goodbrand, R.B., Ahmed, R., Kasatiya, S.	1995	BACILLUS CEREUS AND BACILLUS THURINGIENSIS ISOLATED IN A GASTRO-ENTERITIS OUTBREAK INVESTIGATION Letters in Appl. Microbiol. 21, p. 103-105 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

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KMA 2.3 /04	Jaquet, F., Hütter, R, Lüthy, P.	1987	SPECIFICITY OF BACILLUS THURINGIENSIS DELTA-ENDOTOXIN Appl. and Environ. Microbiol. 53(3): 500-504 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /26	Jarret, P., Stephenson, M.	1990	PLASMID TRANSFER BETWEEN STRAINS OF BACILLUS THURINGIENSIS INFECTING GALLERIA MELLONELLA AND SPODOPTERA LITTORALIS Appl. And Environ. Microbiol. 56(6): 1608-1614 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.2 /07	Kim, H.S., Lee, D.W., Woo, S.O., Yu, Y.M., Kang, S.K.	1998	SEASONAL DISTRIBUTION AND CHARACTERIZATION OF BACILLUS THURINGIENSIS ISOLATED FROM SERICULTURAL ENVIRONMENTS IN KOREA J. Gen. Appl. Microbiol., 44, 133-138 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /15	Kim, M.J., Han, J.K., Park, J.S., Lee, J.S., Lee, S.H., Cho, J.I., Kim, K.S.	2015	VARIOUS ENTEROTOXIN AND OTHER VIRULENCE FACTOR GENES WIDESPREAD AMONG BACILLUS CEREUS AND BACILLUS THURINGIENSIS STRAINS J. Microbial Biotechnology, 25(6), pp. 872-879 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.8 /19	King, P.J.H., Ong, K.H., Sipeh, P., Mahadi, N.M.	2012	TOXICITY OF LOCAL MALAYSIAN BACILLUS THURINGIENSIS SUBSPECIES KURSTAKI AGAINST PLUTELLA XYLOSTELLA African Journal of Biotechnology, 11(56), 11925-11930 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

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KMA 2.6 /14	Kramer, J.M., Gilbert, R.J.	1989	BACILLUS CEREUS AND OTHER BACILLUS SPECIES In: Foodborne Bacterial Pathogens, Ch. 2, MP Doyle (ed.), pp. 21-70 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.2 /04	Landén, R., Bryne, M., Abdel-Hameed, A.	1994	DISTRIBUTION OF BACILLUS THURINGIENSIS STRAINS IN SOUTHERN SWEDEN World Journal of Microbiology & Biotechnology, Vol 10, pp. 45-50 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /30	Leong, K.L.H., Cano, R.J., Kubinski, A.M.	1980	FACTORS AFFECTING BACILLUS THURINGIENSIS TOTAL FIELD PERSISTENCE Environmental Entomology, Volume 9, pp. 593-599 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /11	Luo, K., Banks, D., Adang, M.J.	1999	TOXICITY, BINDING AND PERMEABILITY ANALYSES OF FOUR BACILLUS THURINGIENSIS CRYL ENDOTOXINS USING BRUSH BORDER MEMBRANE VESICLES OF SPODOPTERA EXIGUA AND SPODOPTERA FRUGIPERDA Applied and Environmental Microbiology, 65(2): 457-464 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /24	Lüthy, P.	1986	INSECT PATHOGENIC BACTERIA AS PEST CONTROL AGENTS Fortschr. Zool., 32:201 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /02 2.1.2 /03	Martin, P.A.W., Travers, R.S.	1989	WORLDWIDE ABUNDANCE AND DISTRIBUTION OF BACILLUS THURINGIENSIS ISOLATES Applied and Environmental Microbiology, 55(10), 2437-2442 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

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KMA 2.5 /19	Mason, J.M., Setlow, P.	1986	ESSENTIAL ROLE OF SMALL, ACID.SOLUBLE SPORE PROTEINS IN RESISTANCE OF BACILLUS SUBTILIS SPORES TO UV LIGHT J. of Bacteriology 167, p. 174-178 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.3 /05	McGaughey, W.H., Whalon, M.E.	1992	MANAGING INSECT RESISTANCE TO BACILLUS THURINGIENSIS TOXINS Science 258, pp. 1451-1455 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /32	Menon, A.S., De Mestral, J.	1985	SURVIVAL OF BACILLUS THURINGIENSIS VAR. KURSTAKI IN WATERS Water, Air, and Soil Pollution 25, p. 265-274 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /24	Mikkola, R., Saris, N.-E.L., Grigoriev, P.A., Andersson, M.A., Salkinoja-Salonen, M.S.	1999	IONOPHORETIC PROPERTIES AND MITOCHONDRIAL EFFECTS OF CEREULIDE Eur. J. Biochem. 263, p. 112-117 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /13	Nakamura, L.K.	1994	DNA RELATEDNESS AMONG BACILLUS THURINGIENSIS SEROVARs International Journal of Systematic Bacteriology 44(1): 125-129 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /14	Obeidat, M., Khyami-Horani, H., Al-Momani, F.	2012	TOXICITY OF BACILLUS THURINGIENSIS BETA-EXOTOXINS AND DELTA-ENDOTOXINS TO DROSOPHILA MELANOGASTER, EPHESTIA KUHNIELLA AND HUMAN ERYTHROCYTES African Journal of Biotechnology, 11(46), 10504-10512 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

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KMA 2.5 /33	Ohana, B., Margalit, J., Barak, Z.	1987	FATE OF BACILLUS THURINGIENSIS SUBSP. ISRAELENIS UNDER SIMULATED FIELD CONDITIONS Appl. And Environ. Microbiol. 53(4), 828-831 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.2 /10	Ohba, M., Aizawa, K.	1978	SEROLOGICAL IDENTIFICATION OF BACILLUS THURINGIENSIS AND RELATED BACTERIA ISOLATED IN JAPAN Journal of Invertebrate Pathology, Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /04	Ohba, M., Aizawa, K.	1986	DISTRIBUTION OF BACILLUS THURINGIENSIS ON SOILS OF JAPAN Journal of Invertebrate Pathology, Volume 47, pp. 277-282 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /12	Onose, J.-I., Imai, T., Hsumura, M., Ueda, M., Ozeki, Y., Hirose, M.	2008	EVALUATION OF SUBCHRONIC TOXICITY OF DIETARY ADMINISTERED CRY1Ab PROTEIN FROM BACILLUS THURINGIENSIS VAR. KURSTAKI HD-1 IN F344 MALE RATS WITH CHEMICALLY INDUCED GASTROINTESTINAL IMPAIRMENT Food Chem. Toxicol., 46(6), 2184-2189 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.2.2 /20 2.8 /11	Palma, L., Munoz, D., Berry, C., Murillo, J., Caballero, P.	2014	BACILLUS THURINGIENSIS TOXINS: AN OVERVIEW OF THEIR BIOLOGICAL ACTIVITY Toxins, 6(12), 3296-3325 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.5 /13	Pedersen, J.C., Damgaard, P.H., Eilenberg, J., Hansen, B.M.	1995	DISPERSAL OF BACILLUS THURINGIENSIS VAR. KURSTAKI IN AN EXPERIMENTAL CABBAGE FIELD Can. J. Microbiol. 41, p. 118-125 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /12	Petras, S.F., Casida, L.E.	1985	SURVIVAL OF BACILLUS THURINGIENSIS SPORES IN SOIL Appl. And Environ. Microbiol. P. 1496-1501 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /25	Phelps, R.J., McKillip, J.L.	2002	ENTEROTOXIN PRODUCTION IN NATURAL ISOLATES OF BACILLACEAE OUTSIDE THE BACILLUS CEREUS GROUP Applied and Environmental Microbiology, 68(6), 3147-3151 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.5 /11	Pruett, C.J.H., Burges, H.D., Wyborn, C.H.	1980	EFFECT OF EXPOSURE TO SOIL ON POTENCY AND SPORE VIABILITY OF BACILLUS THURINGIENSIS Journal of Invertebrate Pathology 35, p. 168-174 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /06	Prüß, B.M., Dietrich, R., Nibler, B., Märtlbauer, E., Scherer, S.	1999	THE HEMOLYTIC ENTEROTOXIN HBL IS BROADLY DISTRIBUTED AMONG SPECIES OF THE BACILLUS CEREUS GROUP Appl. And Environ. Microbiol. 65(12): 5436-5442 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /18 2.4 /02 2.5 /04	Pusztai, M., Fast, P., Gring-orten, L., Kaplan, H., Les-sard, T., Carey, P.R.	1991	THE MECHANISM OF SUNLIGHT-MEDIATED INACTIVATION OF BACILLUS THURINGIENSIS CRYSTALS Biochem. J. 273, p. 43-47 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.2.2 /12	Rausell, C., Martinez-Ramirez, C.M., García-Robles, I., Real, M.D.	2000	A BINDING SITE FOR BACILLUS THURINGIENSIS CRY1AB TOXIN IS LOST DURING LARVAL DEVELOPMENT IN TWO FOREST PESTS Applied and Environmental Microbiology, 66(4): 1553-1558 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /25	Reardon, R.C., Haissig, K.	1983	SPRUCE BUDWORM (LEPIDOPTERA:TORTRICIDAE) LARVAL POPULATIONS AND FIELD PERSISTENCE OF BACILLUS THURINGIENSIS AFTER TREATMENT IN WISCONSIN Journal of Eco. Entomol. 76, p. 1139-1143 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /16	Rosenquist, H., Smidt, L., Andersen, S.R., Jensen, G.B. and Wilcks, A.	2005	OCCURRENCE AND SIGNIFICANCE OF BACILLUS CEREUS AND BACILLUS THURINGIENSIS IN READY-TO-EAT FOOD FEMS Microbiol Lett., 250(1):129-36 Report-no.: not applicable GLP/GEP: no Published: yes		no	not protected	-	DAR 2008
KMA 2.5 /08	Saleh, S.M., Harris, R.F., Allen, O.N.	1970	FATE OF BACILLUS THURINGIENSIS IN SOIL: EFFECT OF SOIL PH AND ORGANIC AMENDMENT Can. J. Microbiol. 16, p. 677-680 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.7 /15	Santos, C.A., Vilas-Bôas, G.T., Lereclus, D., Suzuki, M.T., Angelo, E.A., Arantes, O.M.N.	2010	CONJUGAL TRANSFER BETWEEN BACILLUS THURINGIENSIS AND BACILLUS CEREUS STRAINS IS NOT DIRECTLY CORRELATED WITH GROWTH OF RECIPIENT STRAINS Journal of Invertebrate Pathology, 105, 171-175 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.2.2 /04 2.3 /02 2.4 /08 2.6 /05	Schnepf, E., Crickmore, N., van Rie, J., Lereclus, D., Baum, J., Feitel- son, J., Zeigler, D.R., Dean, D.H.	1998	BACILLUS THURINGIENSIS AND ITS PESTICIDAL CRYSTAL PROTEINS Microbiol Mol Biol Rev, 62(3): 775-806 Report-no.: not applicable GLP/GEP: no Published: no	no	no	not protected	-	DAR 2008
KMA 2.2.2 /07	Schwartz, J.L., Garneau, L., Masson, L., 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, 250-260 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /10	Sechase, S.	2016	LITERATURE REVIEW ON BACILLUS THURINGIENSIS SUBSP. KURSTAKI SA-12: TOXICOLOGY Certis USA LLC, 2281384-MA-05-01_SA-12 GAB Consulting GmbH, Stade, Germany Report-no.: not applicable GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 2.4 /07	Selvapandiyan, A., Arora, N., Rajagopal, R., Jalali, S.K., Venkatesan, T., Singh, S.P., Bhatnagar, R.K.	2001	TOXICITY ANALYSIS OF N- AND C-TERMINUS-DELETED VEGETATIVE INSECTICIDAL PROTEIN FROM BACILLUS THURINGIENSIS Appl. and Environ. Microbiol. 67(12): 5855-5858 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /20	Setlow, P.	1988	SMALL, ACID-SOLUBLE SPORE PROTEINS OF BACILLUS SPECIES: STRUCTURE, SYNTHESIS, GENETICS, FUNCTION AND DEGRADATION Ann. Rev. Microbiol. 42, p. 319-383 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.9/04	Shaw, G.	2019	ANTIBIOTIC RESISTANCE AND SENSITIVITY TESTING OF THE MICROBIAL PEST CONTROL AGENT BACILLUS THURINGIENSIS SUBSP. KURSTAKI STRAIN SA-12 Certis USA LLC APIS-016-002 Applied Insect Science Ltd. Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 2.8 /13	Shimada, N., Miyamota, K., Kanda, K., Murata, H.	2006	BACILLUS THURINGIENSIS INSECTICIDAL Cry1Ab TOXIN DOES NOT AFFECT THE MEMBRANE INTEGRITY OF THE MAMMALIAN INTESTINAL EPITHELIAL CELLS: AN IN VITRO STUDY In Vitro Cellular & Developmental Biology – Animal, 42(1), 45-49 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.6 /17	Shinagawa et al	1984	SURVEILLANCE OF RAW MEAT PRODUCTS AND MEAT-PRODUCT ADDITIVES FOR CONTAMINATION WITH BACILLUS SEREUS AND ENTEROTOXIGENICITY OF THE ISOLATED STRAIN J. Fac. Agric. Iwate Univ. 17:175-182 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /27	Siegel, J.P.	2001	THE MAMMALIAN SAFETY OF BACILLUS THURINGIENSIS-BASED INSECTICIDES Journal of Invertebrate Pathology 77, 13-21 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.1 /09 2.1.2 /13	Smith, R.A., Couche, G.A.	1991	THE PHYLLOPLANE AS A SOURCE OF BACILLUS THURINGIENSIS VARIANTS Applied and Environmental Microbiology, 57(1): 331-315 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.9 /01	Smith, R.W., Regan, K.M.	1989a	ANTIBIOTIC SENSITIVITY PATTERNS FOR BACILLUS THURINGIENSIS SUBSP. KURSTAKI STRAIN SA11001C98-1-1 ██████████ ██████████ Palo Alto, CA, USA Certis USA, LLC, Columbia Report-no. 89/12/12 GLP/GEP: no Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 2.9 /02	Smith, R.W., Regan, K.M.	1989b	ANTIBIOTIC SENSITIVITY PATTERNS FOR BACILLUS THURINGIENSIS SUBSP. KURSTAKI STRAIN SA-12 ██████████ ██████████ Palo Alto, CA, USA Certis USA, LLC, Columbia Report-no. 89/12/12F GLP/GEP: no Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 2.7 /12	Süß, J.	2016	LITERATURE REVIEW ON BACILLUS THURINGIENSIS SUBSP. KURSTAKI SA-12 BIOLOGICAL PROPERTIES Certis USA LLC Report-no.: 2281384-MA-02-01_SA-12 GLP/GEP: no Published: no	no	yes	Protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 2.6 /12	Ticknor, L.O., Kolsto, A.-B., Hill, K.K., Keim P., Laker, M.T., Tonks, M., Jackson, P.J.	2001	FLUORESENT AMPLIFIED FRAGMENT LENGTH POLYMORPHISM ANALYSIS OF NORWEGIAN BACILLUS CEREUS AND BACILLUS THURINGIENSIS SOIL ISOLATES Applied and Environmental Microbiology, 67(10), 4863-4873. Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /33	Tourasse, N.J., Helgason, E., Klevan, A., Sylvestre, P., Moya, M., Haustant, M., Okstad, O.A., Fouet, A., Mock, M., Kolsto, A.-B.	2011	EXTENDED AND GLOBAL PHYLOGENETIC VIEW OF THE BACILLUS CEREUS GROUP POPULATION BY COMBINATION OF MLST, AFLP AND MLEE GENOTYPING DATA Food Microbiol., 28(2):236-244 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

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KMA 2.1.1 /13	Travers, R.S., Martin, P.A.W., Rewichelderfer, C.F.	1987	SELECTIVE PROCESS FOR EFFICIENT ISOLATION OF SOIL BACILLUS SPP. Applied and Environmental Microbiology, 53(6): 1263-1266 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /21	Turnbull, P.C.B.	2005	BACILLUS Medimicro Chapter, http://gsbs.utmb.edu/microbook/ch015.htm , 2005 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.6 /30	Valadares de Amorim, G., Whittome, B., Shore, B., Levin D.B.	2001	IDENTIFICATION OF BACILLUS THURINGENSIS SUBSP. KURSTAKI STRAIN HD1-LIKE BACTERIA FROM ENVIRONMENTAL AND HUMAN SAMPLES AFTER AERIAL SPRAYING OF VICTORIA, BRITISH COLUMBIA, CANADA, WITH FORAY 48 Applied and Environmental Microbiology, 67(3): 1035-1043 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.1.2 /08	Valicente, F.H., Barreto, M.R.	2003	BACILLUS THURINGIENSIS SURVEY IN BRAZIL: GEOGRAPHICAL DISTRIBUTION AND INSECTICIDAL ACTIVITY AGAINST SPODOPTERA FRUGIPERDA (J.E. SMITH) (LEPIDOPTERA: NOCTUIDAE) Neotropical Entomology 32(4): 639-644 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.7 /19	Van der Auwera, G.A., Timmery, S., Hoton, F., Mahillon, J.	2007	PLASMID EXCHANGES AMONG MEMBERS OF THE BACILLUS CEREUS GROUP IN FOODSTUFFS International Journal of Food Microbiology 113, 164-172 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

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KMA 2.1.2 /09	Vásquez, M., Parra, C., Hubert, E., Espinoza, P., Theoduloz, C., Meza-Basso, L.	1995	SPECIFICITY AND INSECTICIDAL ACTIVITY OF CHILEAN STRAINS OF BACILLUS THURINGIENSIS Journal of Invertebrate Pathology 66, 143-148 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.7 /06	Vilas-Boas, G., Sanchis, V., Lereclus, D., Lemos, M.V., Bourguet, D.	2002	GENETIC DIFFERENTIATION BETWEEN SYMPATRIC POPULATIONS OF BACILLUS CEREUS AND BACILLUS THURINGIENSIS Appl. And Environ. Microbiol., 68(3): 1414-1424 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /09	Vilas-Bôas, L.A., Vilas-Bôas, G.F.L.T., Saridakis, H.O., Lemos, M.V.F., Lereclus, D., Arantes O.M.N.	2000	SURVIVAL AND CONJUGATION OF BACILLUS THURINGIENSIS IN A SOIL MICROORGANISM FEMS Microbiology Ecology 31, p. 255-259 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /03	Wei, J.Z., Hale, K., Carta, L., Platzer, E., Wong, C., Fang, S.-C., Aroian, R.V.	2003	BACILLUS THURINGIENSIS CRYSTAL PROTEINS THAT TARGET NEMATODES Proc Natl Acad Sci USA, 100: 2760-2765 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /10	West, A.W., Burges H.D.	1985	PERSISTENCE OF BACILLUS THURINGIENSIS AND BACILLUS CEREUS IN SOIL SUPPLEMENTED WITH GRASS OR MANURE Plant and Soil 83, p. 388-398 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /07	West, A.W., Burges, H.D., Dixon, T.J., Wyborn, C.H.	1985	SURVIVAL OF BACILLUS THURINGIENSIS AND BACILLUS CEREUS SPORE INOCULA IN SOIL: EFFECTS OF PH, MOISTURE, NUTRIENT AVAILABILITY AND INDIGENOUS MICROORGANISMS Soil Biol. Biochem, Vol. 17, p. 657-665 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.5 /16	West, A.W., Burges, H.D., White, R.J., Wyborn, C.H.	1984b	PERSISTENCE OF BACILLUS THURINGIENSIS PARASPORAL CRYSTAL INSECTICIDAL ACTIVITY IN SOIL Journal of Invertebrate Pathology 44, p. 128-133 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.5 /15	West, A.W. Burges, H.D., Wyborn, C.H.	1984a	EFFECT OF INCUBATION IN NATURAL AND AUTOCLAVED SOIL UPON POTENCY AND VIABILITY OF BACILLUS THURINGIENSIS Journal of Invertebrate Pathology 44, p. 121-127 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.3 /10 2.4 /03 2.5 /29 2.8 /02	WHO-EHC	1999	ENVIRONMENTAL HEALTH CRITERIA 217 – MICROBIAL PEST CONTROL AGENT BACILLUS THURINGIENSIS World Health Organization. Geneva Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.8 /16	Wilcks, A., Hansen, B.M., Hendriksen, N.B., Licht, T.R.	2006a	PERSISTENCE OF BACILLUS THURINGIENSIS BIOINSECTICIDES IN THE GUT OF HUMAN-FLORA-ASSOCIATED RATS FEMS Immunol. Med. Microbiol., 48(3), 410-418 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.8 /21	Wilcks, A., Hansen, B.M., Hendriksen, N.B., Licht, T.R.	2006b	FATE AND EFFECT OF INGESTED BACILLUS CEREUS SPORES AND VEGETATIVE CELLS IN THE INTESTINAL TRACT OF HUMAN-FLORA-ASSOCIATED RATS FEMS Immunol. Med. Microbiol., 46, 70-77 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 2.7 /20	Wilcks, A., Jacobsen, B.B.	2010	LACK OF DETECTABLE DNA UPTAKE BY TRANSFORMATION OF SELECTED RECIPIENTS IN MONO-ASSOCIATED RATS BMC research notes, 3, 49 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.3 /08	Wolfsberger, M.G.	1991	INHIBITION OF POTASSIUM-GRADIENT DRIVEN PHENYLALANINE UPTAKE IN LARVAL LYMANTRIA DISPAR MIDGUT BY TWO BACILLUS THURINGIENSIS DELTA-ENDOTOXINS CORRELATES WITH THE ACTIVITY OF THE TOXINS AS GYPSY MOTH LARVICIDES J. Exp. Biol. 161: 519-525 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.2.2 /09	Yamamoto T., Chen, C.-Y.	2006	DELTA-ENDOTOXIN COMPONENT ANALYSIS OF DELFIN, COSTAR AND CONDOR CERTIS USA LLC Report-no.: not applicable GLP/GEP: no Published: no	no	yes	protected	Certis USA	DAR 2008
KMA 2.2.2 /10	Yamamoto, T., Iizuka, T.	1983	TWO TYPES OF ENTOMOCIDAL TOXINS IN THE PARASPORAL CRYSTALS OF BACILLUS THURINGIENSIS KURSTAKI Archives of Biochemistry and Biophysics Vol. 227, No.1, pp. 233-241 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 2.4 /06	Yu, C.-G., Mullins, M.A., Warren, G.W., Koziel, M.G., Estruch, J.J.	1997	THE BACILLUS THURINGIENSIS VEGETATIVE INSECTICIDAL PROTEIN VIP3A Lyses MIDGUT EPITHELIUM CELLS OF SUSCEPTIBLE INSECTS Appl. and Environ. Microbiol. 63(2): 532-536 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

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KMA 2.7 /18	Yuan, Y., Zheng, D., Hu, X., Cai, Q., Yuan, Z.	2010	CONJUGATIVE TRANSFER OF INSECTICIDAL PLASMID pHT 73 FROM BACILLUS THURINGIENSIS TO B. ANTHRACIS AND COMPATIBILITY OF THIS PLASMID WITH pXO1 AND pXO2 Applied and Environmental Microbiology, 76, 468-473 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.7 /14	Yuan, Y.M., Hu, X.M., Liu, H.Z., Hansen, B.M., Yan, J.P., Yuan, Z.M.	2007	KINETICS OF PLASMID TRANSFER AMONG BACILLUS CEREUS GROUP STRAINS WITHIN LEPIDOPTERAN LARVAE Archives of Microbiology, 187, 425-431 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 2.7 /17	Zhang, Q., Sun, M., Xu, Z., Yu, Z.	2007	CLONING AND CHARACTERIZATION OF pBMB9741, A NATIVE PLASMID OF BACILLUS THURINGIENSIS SUBSP. KURSTAKI STRAIN YBT-1520 Current Microbiology, 55, 302-307 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 2.2/01	Ahrens, A.	2011 a	COSTART WG EXPLOSIVE PROPERTIES A.14 Certis USA LLC, 20100638.02 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 2.2/02	Ahrens, A.	2011 b	COSTAR WG OXIDIZING PROPERTIES A.17 Certis USA LLC, 20100638.04 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 2.3/02	Ahrens, A.	2011 c	COSTAR WG FLAMMABILITY (SOLIDS) A.10 Certis USA LLC, 20100638.01 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 2.3/03	Ahrens, A.	2011 d	COSTAR WG AUTO-FLAMMABILITY (SOLIDS - DETERMINATION OF RELATIVE SELF-IGNITION TEMPERATURE) A.16 Certis USA LLC, 20100638.03 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 2.6/02 2.8.2/01 2.8.5.1/02 2.8.5.2/01 2.8.5.3/01 2.8.7/01	Aversa, S.	2011 b	PHYSICO-CHEMICAL PROPERTIES: FLOWABILITY, BULK DENSITY AND PERSISTENT FOAMING OF PRODUCT COSTAR. Certis USA LLC, BT121/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy Report-no.: not applicable GLP/GEP: yes Published: no Submitted in: KMP 2.7.2/01	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 2.1/01 2.4/02 2.7/02 2.8.1/01 2.8.3/01 2.8.3/02 2.8.5.1/01	Aversa, S.	2013	PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR AFTER 2 YEARS SHELF LIFE Certis USA LLC, BT123/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 2.7/01	Aversa, S.	2011 a	PHYSICO-CHEMICAL PROPERTIES OF PRODUCT COSTAR BEFORE AND AFTER ACCELERATED STORAGE AT 30 ± 2°C FOR 18 WEEKS. Certis USA LLC, BT122/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 2.7/03	Gallager, S.	2013	STATEMENT ON PACKAGING COSTAR WG Certis USA LLC, not stated ██████████ Columbia, Maryland Report-no.: not applicable GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated

A.3 Data on application

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 3.5/04	Ferré, J., Real, M.D., van Rie, J., Jansens, S., Peferoen, M.	1991	RESISTANCE TO THE BACILLUS THURINGENSIS INSECTICIDE IN A FIELD POPULATION OF PLUTELLA XYLOSTELLA IS DUE TO A CHANGE IN A MIDGUT MEMBRANE RECEPTOR Proc. Natl. Acad. Sci USA, 88, 5119-5123 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 3.5/17	Franklin, M., Ritland, C.E., Myers, J.H.	2010	SPATIAL AND TEMPORAL CHANGES IN GENETIC STRUCTURE OF GREENHOUSE AND FIELD POPULATIONS OF CAGGAGE LOOPER, TRICHOPLUSIA NI Mol. Ecol., 19(6), 1122-1133 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/09	Gong, Y., Wang, C., Yang, Y., Wu, S., Wu, Y.	2010	CHARACTERIZATION OF RESISTANCE TO BACILLUS THURINGIENSIS TOXIN Cry1Ac IN PLUTELLA XYLOSTELLA FROM CHINA Journal of Invertebrate Pathology, 104(2), 90-96 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/10	Janmaat, A., Franklin, M., Myers, J.H.	2015	RESISTANCE OF CABBAGE LOOPERS TO BTK IN A GREENHOUSE SETTING: OCCURRENCE, SPREAD AND MANAGEMENT Bt Resistance (M. Soberón, T. Gao and A. Bravo, ed.), 5:49-55 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 3.5/03	Janmaat, A.F., Myers, J.	2003	RAPID EVOLUTION AND THE COST OF RESISTANCE TO BACILLUS THURINGIENSIS IN GREENHOUSE POPULATIONS OF CABBAGE LOOPERS, TRICHOPLUSIA NI Proc. Royal Soc. London, 270, 2263-2270 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 3.5/11	Jiang, T., Wu, S., Yang, T., Zhu, C., Gao, C.	2015	MONITORING FIELD POPULATIONS OF PLUTELLA XYLOSTELLA (LEPIDOPTERA: PLUTELLIDAE) FOR RESISTANCE TO EIGHT INSECTICIDES IN CHINA Florida Entomologist, 98(1), 65-73 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/18	Kalia, V., Kumari, A., Mittal, A., Singh, B.P., Nair, R., Gujar, G.T.	2006	TEMPORAL VARIATION IN SUSCEPTIBILITY OF AMERICAN BOLLWORM, HELICOVERPA ARMIGERA TO BACILLUS THURINGIENSIS (BT) VAR. KURSTAKI HD-73, IST Cry1Ac TOXIN AND BT COTTON Pesticide Research Journal, 18(1), 47-50 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/05	McGaughey, W.H Whalon, M.E.	1992	MANAGING INSECT RESISTANCE TO BACILLUS THURINGIENSIS TOXINS Science 258:1451-1455 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 3.5/08	Mittal, A., Kumari, A., Kalia, V., Kumar Singh, D., Gujar, G.T.	2007	SPATIAL AND TEMPORAL BASELINE SUSCEPTIBILITY OF DIAMONDBACK MOTH, PLUTELLA XYLOSTELLA (LINNAEUS) TO BACILLUS THURINGIENSIS SPORE CRYSTAL MIXTURE, PURIFIED CRYSTAL TOXINS AND MIXTURES OF cry TOXINS IN INDIA Biopesticides International, 3(1), 58-70 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 3.5/14	Pereira, S. G., Sannaveerapanavar, V. T., Murthy, M. S.	2006	GEOGRAPHICAL VARIATION IN THE SUSCEPTIBILITY OF DIAMONDBACK MOTH, PLUTELLA XYLOSTELLA (L.) (LEPIDOPTERA: YPONOMEUTIDAE) TO BACILLUS THURINGENSIS PRODUCTS AND ACYLUREA COPOUNDS Resistant Pest Management Newsletter, 15(2), 26-28 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/15	Sannaveerapanavar, V.T., Virktamath, C.A.	2006	RESISTANCE TO INSECTICIDES IN AN INDIAN STRAIN OF DIAMONDBACK MOTH, PLUTELLA XYLOSTELLA (L.) (LEPIDOPTERA: YPONOMEUTIDAE) Resistant Pest Management Newsletter, 15(2), 32-35 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/13	Sarmiento, G.M., Ocampo, V.R.	2010	VARIABILITY IN RESPONSE TO INSECTICIDES OF FIELD POPULATIONS OF DIAMONDBACK MOTH, PLUTELLA XYLOSTELLA (LINNAEUS), IN THE PHILIPPINES Philipp. Ent., 24(1), 39-76 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/01	Schnepf, E. Crickmore, N. Van Rie, J. Lereclus, D. Baum, J. Feitelson, J. Zeigler, D.R. Dean, D.H.	1998	BACILLUS THURINGENSIS AND ITS PESTICIDAL CRYSTAL PROTEINS Microbiol. Mol. Biol. Rev. 62:775-806 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 3.5/06	Süß, J.	2016	LITERATURE REVIEW ON BACILLUS THURINGENSIS SUBSP. KURSTAKI SA-12 BIOLOGICAL PROPERTIES Certis USA LLC, Report-no.: 2281384-MA-02-01 SA-12 GLP/GEP: no Published: no	no	yes	Protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/02	Tabashnik, B.E.	1994	EVOLUTION OF RESISTANCE TO BACILLUS THURINGENSIS Ann. Rev. Entomol., 39, 47-79 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 3.5/07	Wang, L., Li, X.-F., Zhang, J., Zhao, J.-Z., Wu, Q.-J., Xu, B., Zhang, Y.-J.	2007	MONITORING OF RESISTANCE FOR THE DIAMONDBACK MOTH TO BACILLUS THURINGIENSIS Cry1Ac AND Cry1Ba TOXINS AND A BT COMMERCIAL FORMULATION Journal of Applied Entomology, 131(7), 441-446 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/12	Xia, Y., Lu, Y., Shen, J., Gao, X., Qiu, H., Li, J.	2014	RESISTANCE MONITORING FOR EIGHT INSECTICIDES IN PLUTELLA XYLOSTELLA IN CENTRAL CHINA Crop Protection, 63, 131-137 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 3.5/16	Zago, H.B., Siqueira, H.A.A., Pereira, E.J.G., Picanco, M.C., Barros, R.	2014	RESISTANCE AND BEHAVIOURAL RESPONSE OF PLUTELLA XYLOSTELLA (LEPIDOPTERA: PLUTELLIDAE) POPULATIONS TO BACILLUS THURINGIENSIS FORMULATIONS Pest Management Science, 70(3), 488-495 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

A.4 Further Information

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 4.4/01 4.5/01 4.6/01	Anonymous	2016	SDS COSTAR WG 2016 Certis USA LLC Report-no.: not applicable GLP/GEP: no Published: no	no	no	not protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated
KMP 4.1/01	Gallager, S.	2013	STATEMENT ON PACKAGING COSTAR WG Certis USA LLC, not stated [REDACTED] Columbia, Maryland Report-no.: not applicable GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated

A.5 Analytical methods

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 5.2 /01	Muetting, S.A., Strain, K.E., Lydy, M.J	2014	VALIDATION OF AN EXTRACTION METHOD FOR Cry1Ab PROTEIN FROM SOIL Environmental Toxicology and Chemistry, 33(1), 18-25 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 5.2 /02	Strain, K.E., Whiting, S.A., Lydy, M.J.	2014	LABORATORY AND FIELD VALIDATION OF A Cry1Ab PROTEIN QUANTITATION METHOD FOR WATER Talanta, 128, 109-116 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 5.1/01	Coranelli, S	2011	ANALYTICAL METHOD VALIDATION FOR THE DETERMINATION OF THE ACTIVE INGREDIENT CONTENT IN THE FORMULATED PRODUCT COSTAR AND IN AQUEOUS DILUTIONS Certis USA LLC, BT120/10 Biotechnologie BT Srl, Fraz. Pantalla, Italy Report-no.: not applicable GLP/GEP: yes Published: no	no	no	protected	Certis USA	New data for existing formulation, not previously submitted nor evaluated

A.6 Effects on human health

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 6.1.1 /12 6.1.1.1 2 /03 6.1.1.1 3 /06 6.1.2. 1 /01	Baelum, J., Larsen, P., Doekes, G., Sigsgaard, T.	2012	HEALTH EFFECTS OF SELECTED MICROBIOLOGICAL CONTROL AGENTS. A 3-YEAR FOLLOW-UP STUDY Ann Agric Environ Med, 19(4), 631-636 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.2. 2 /08 6.1.2. 5 /03	Barfod, K.K., Poul- sen, S.S., Hammer, M., Larsen, S.T.	2010	SUB-CHRONIC LUNG INFLAMMATION AFTER AIRWAY EXPOSURES TO BACILLUS THURINGIENSIS BIOPESTICIDES IN MICE BMC Microbiology, 3, 10:233 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.1 /08 6.1.2. 2 /05	Berlitz, D.L., Gio- venardi, M., Charles, J.F., Fiuza, L.M.	2012	TOXICITY INTRAPERITONEAL AND INTRAGASTRIC ROUTE OF BACILLUS THURINGIENSIS AND MELIA AZEDARACH IN MICE Arquivos do Instituto Biologico, 79(4):511-517 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.1. 3 /01	Bernstein, I.L., Bern- stein, J.A., Miller, M., Tierzieva, S., Bern- stein, D.I., Lumms, Z., Selgrade, M.K., Do- erfler, D.L., Seligy, V.L.	1999	IMMUNE RESPONSES IN FARM WORKERS AFTER EXPOSURE TO BACILLUS THURINGIENSIS PESTICIDES Environ. Health Perspec. 107:575-582 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 6.1.1. 1 /07	Callegan, M.C., Cochran, D.C., Kane, S.T., Rama- dan, R.T., Chodosh, J., McLean, C., Stroman, D.W.	2006	VIRULENCE FACTORS PROFILES AND ANTIMICROBIAL SUSCEPTIBILITIES OF OCULAR BACILLUS ISOLATES Curr. Eye Res. 31:693-702 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 6.1.1.1 /02	Damgaard, P.H., Granum, P.E., Bre-sciana, J., Torregrossa, M.V., Eilen-berg, J., Valentino, L.	1997	CHARACTERIZATION OF BACILLUS THURINGIENSIS ISOLATED FROM INFECTIONS IN BURN WOUNDS FEMS Immunol. Med. Microbiol. 18:47-53 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protect-ed	-	DAR 2008
KMA 6.1.1.2 /01	Dively, C.A.	2005	LONG TERM EXPOSURE OF BT TO EMPLOYEES DURING PRODUCTION Certis USA LLC, Columbia Report no. not applicable GLP/GEP: no Published: yes	no	yes	protected	Certis USA	DAR 2008
KMA 6.1.1.2 /02	Doak, B.	2016	BTZ MEDICAL VERIFICA-TION Certis USA LLC, not stated [REDACTED] Report-no.: not applicable GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previ-ously submitted nor evalu-ated
KMA 6.1.1.3 /03	Doekes, G., Larsen, P., Sigsgaard, T., Baelum, J.	2004	IGE SENSITIZATION TO BACTERIAL AND FUNGAL BIOPESTICIDES IN A CO-HORT OF DANISH GREENHOUSE WORKERS: THE BIOGART STUDY Am. J. Indust. Med. 46:404-407 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protect-ed	-	DAR 2008
KMA 6.1.1 /01	Glare, T.R., O'Callaghan, M.	2000	BACILLUS THURINGIENSIS: BIOLOGY, ECOLOGY AND SAFETY Bacillus thuringiensis: Biology, Ecology and Safety, Glare, T.R., O'Callaghan, M. (eds.) John Wiley & Sons, Ltd., 2000 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protect-ed	-	DAR 2008
KMA 6.1.1.1 /06 6.1.1.4 /04 v	Green, M., Heumann, M., Soko-low, R., Foster, L.R., Bryant, R., Skeels, M.	1990	PUBLIC HEALTH IMPLICA-TIONS OF THE MICROBIAL PESTICIDE BACILLUS THURINGIENSIS: AN EPI-DEMOLOGICAL STUDY, OREGON, 1985-86 Am. J. Publ. Health 80:848-852 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protect-ed	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 6.1.2.3 /01	Grisolia, C.K., Oliveira-Filho, E.C., Ramos, F.R., Lopes, M.C., Muniz, D.H.F., Monnerat, R.G.	2009	ACUTE TOXICITY AND CYTOTOXICITY OF BACILLUS THURINGIENSIS AND BACILLUS SPHAERICUS STRAINS ON FISH AND MOUSE BONE MARROW. Ecotoxicology, 18(1), 22-26 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.2.5 /01	Hadley, W.M., Burchiel, S.W., McDowell, T.D., Thilsted, J.P., Hibbs, C.M., Whornton, J.A., Day, P.W., Friedman, M.B., Stoll, R.E.	1987	FIVE-MONTH ORAL (DIET) TOXICITY/INFECTIVITY STUDY OF BACILLUS THURINGIENSIS INSECTICIDES IN SHEEP Fund. Appl. Toxicol 8:236-242 Report no. not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008
KMA 6.1.1 /10 6.1.1.2 /04 6.1.1.3 /05	Hansen, V.M., Eilenberg, J., Madsen, A.M.	2010	OCCUPATIONAL EXPOSURE TO AIRBORNE BACILLUS THURINGIENSIS KURSTAKI HD1 AND OTHER BACTERIA IN GREENHOUSES AND VEGETABLE FIELDS. Biocontrol Science and Technology, 20(6), 605-619 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.1.1 /03	Hernandez, E., Ramisse, F., Ducoureaux, J., Cruel, T., Cavallo, J.	1998	BACILLUS THURINGIENSIS SUBSP. KONKUKIAN (SEROTYPE H34) SUPERINFECTION: CASE REPORTS AND EXPERIMENTAL EVIDENCE OF PATHOGENICITY IN IMMUNOSUPPRESSED MICE J. Clin. Microbiol. 36:2138-2139 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 6.1.1.1 /04	Hernandez, E., Ramisse, F., Cruel, T., Vagueresse, R., Cavallo, J.	1999	BACILLUS THURINGIENSIS SEROTYPE H34 ISOLATED FROM HUMANS AND INSECTICIDAL STRAINS SEROTYPES 3A3B AND H14 CAN LEAD TO DEATH OF IMMUNOCOMPETENT MICE AFTER PULMONARY INFECTION FEMS Immunol. Med. Microbiol. 24:43-47 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008
KMA 6.1.1 /06	Itoh, T., Arai, T., Hirata, I.	1991	ENTEROPATHOGENICITY OF BACILLUS THURINGIENSIS FOR HUMANS Shokubutsu Boeki 45:18-22 Report-no. not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008
KMA 6.1.1.1 /05	Jackson, S.G., Goodbrand, R.B., Ahmed, R. and Kasatiya, S.	1995	BACILLUS CEREUS AND BACILLUS THURINGIENSIS ISOLATED IN A GASTROENTERITIS OUTBREAK INVESTIGATION Letters in Appl. Microbiol. 21, p. 103-105, 1995 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 6.1.2.2 /02	[REDACTED]	1999a	COSTAR TECHNICAL CONCENTRATE – ACUTE ORAL TOXICITY STUDY IN RATS Certis USA LLC, Colombia [REDACTED] Report no. 5397-99 GLP/GEP: yes Published: no	yes	yes	protected	Certis USA	DAR 2008
KMA 6.1.1 /11	Levin, D.B.	2009	HUMAN HEALTH EFFECTS RESULTING FROM EXPOSURE TO BACILLUS THURINGIENSIS APPLIED DURING INSECT CONTROL PROGRAMS Use of Microbes for Control and Eradication of Invasive Arthropods, 6: 291-303 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 6.1.1.4 /03	Pearce, M., Behie, G., Chappell, N.	2002 b	THE EFFECTS OF AERIAL SPRAYING WITH BACILLUS THURINGIENSIS KURSTAKI ON AREA RESIDENTS Env. Health Rev. Spring 2002:19-22 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 6.1.1.4 /01	Pearce, M., Habbick, B., Williams, J., Eastman, M., Newman, M.	2002a	THE EFFECTS OF AERIAL SPRAYING WITH BACILLUS THURINGIENSIS KURSTAKI ON CHILDREN WITH ASTHMA Can. J. Public Health 93:21-25 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 6.1.1.4 /02	Petrie, K., Thomas, M., Broadbent, E.	2003	SYMPTOM COMPLAINTS FOLLOWING AERIAL SPRAYING WITH BIOLOGICAL INSECTICIDE FORAY 48B New Zealand Med. J. 116 (1170):1-7 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 6.1.1 /04 6.1.1.3 /04	McClintock, J.T., Schaffer, C.R., Sjobald, R.D.	1995	A COMPARATIVE REVIEW OF THE MAMMALIAN TOXICITY OF BACILLUS THURINGIENSIS-BASED PESTICIDES Pestic. Sci. 45:95-105 Report-no. not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008
KMA 6.1.2.2 /03	██████████ ██████████	2015a	THURICIDE SC - ACUTE ORAL TOXICITY/PATHOGENICITY STUDY IN RATS (RATTUS NORVEGICUS) Certis USA LLC, 1372/2015PO, RL1372/2015PO-B ████████████████████ ████████████████████ Report-no. not applicable GLP/GEP: yes Published: no	yes	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 6.1.2.2 /07	████████	2015b	THURICIDE SC - ACUTE PULMONARY TOXICITY/PATHOGENICITY STUDY IN RATS (RATTUS NORVEGICUS) Certis USA LLC, 1398/2015PP, RL1398/2015PP-B ████████████████████ ████████████████████ Report-no.: not applicable GLP/GEP: yes Published: no	yes	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.2.2 /10	████████	2015c	THURICIDE SC - ACUTE INTRAVENOUS TOXICITY/PATHOGENICITY STUDY IN RATS (RATTUS NORVEGICUS) Certis USA LLC, 1375/2015PIV, RL1375/2015PIV-B ████████████████████ ████████████████████ Report-no.: not applicable GLP/GEP: yes Published: no	yes	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.1.1 /08	Samples, J.R., Buettner, H.	1983	CORNEAL ULCER CAUSED BY A BIOLOGICAL INSECTICIDE (BACILLUS THURINGIENSIS) Am. J. Ophthalmol. 95:258-260 Report no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 6.1.1 /07 6.1.2.5 /02	Seehase, S.	2016	LITERATURE REVIEW ON BACILLUS THURINGIENSIS SUBSP. KURSTAKI SA-12: TOXICOLOGY Certis USA LLC GAB Consulting GmbH, Stade, Germany Report-no.: 2281384-MA-05-01_SA-12 GLP/GEP: no Published: no	no	yes	Protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.1 /03	Siegel, J.P.	2001	THE MAMMALIAN SAFETY OF BACILLUS THURINGIENSIS-BASED INSECTICIDES Journal of Invertebrate Pathology 77, 13-21, 2001 Report-no. not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 6.1.2.2 /09	Tayabali, A.F., Nguyen, K.C., Seligy, V.L.	2011	EARLY MURINE IMMUNE RESPONSES FROM ENDOTRACHEAL EXPOSURES TO BIOTECHNOLOGY-RELATED BACILLUS STRAINS Toxicological & Environmental Chemistry, 93(1), 314-331 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.1.1 /01	Warren, R.E., Rubenstein, D., Ellar, D.J., Kramer, J.M., Gilbert, R.J.	1984	BACILLUS THURINGIENSIS VAR. ISRAELEN-SIS: PROTOXIN ACTIVATION AND SAFETY Lancet 24:678-679 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008
KMA 6.1.2.2 /01		1992	ACUTE ORAL TOXICITY STUDY OF SA12[PSB337] IN RATS Certis USA LLC, Colombia Report no. G-7409.210 GLP/GEP: yes Published: no	yes	yes	protected	Certis USA	DAR 2008
KMA 6.1.1 /02 6.1.1.3 /02	WHO	1999	MICROBIAL PEST CONTROL AGENT BACILLUS THURINGIENSIS Environmental Health Criteria 217, WHO Report no. not applicable GLP/GEP: no Published: Yes	no	no	not protected	-	DAR 2008
KMA 6.1.1 /09 6.1.2.2 /04	Wilcks, A., Hansen, B.M., Hendriksen, N.B., Licht, T.R.	2006a	PERSISTENCE OF BACILLUS THURINGIENSIS BIO-INSECTICIDES IN THE GUT OF HUMAN-FLORA-ASSOCIATED RATS FEMS Immunol Med Microbiol, 48, 410-418 Report-no.: not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 6.1.1 /05 6.1.2.2 /06	Wilcks, A., Hansen, B.M., Hendriksen, N.B., Licht, T.R.	2006b	FATE AND EFFECT OF INGESTED BACILLUS CEREUS SPORES AND VEGETATIVE CELLS IN THE INTESTINAL TRACT OF HUMAN-FLORA-ASSOCIATED RATS FEMS Immunol Med Microbiol 46:70-77 Report-no. not applicable GLP/GEP: no Published: Yes	yes	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 6.2.1/01	[REDACTED]	1999c	Costar technical concentrate – acute dermal irritation study in rabbits Certis USA LLC, Colombia [REDACTED] Report no. 5400-99 GLP/GEP: yes Published: no	yes	no	not protected	Certis USA	DAR 2008
KMP 6.2.2/01	[REDACTED]	1992	Eye irritation to the rabbit of SAN 420I (SA-12) technical Certis USA LLC, Colombia [REDACTED] [REDACTED] Report no. 920159D/SNC 151/SE GLP/GEP: yes Published: no	yes	no	not protected	Certis USA	DAR 2008

A.7 Residue data

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 7.1/04	Akiba, Y.	1986	MICROBIAL ECOLOGY OF <i>BACILLUS THURINGIENSIS</i> VI. GERMINATION OF <i>BACILLUS THURINGIENSIS</i> SPORES IN THE SOIL Japanese Journal of Applied Entomology and Zoology, 21(1), 76-80 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.1/08	Bac, S., Fleet, G.H., Heard, G.M.	2004	OCCURRENCE AND SIGNIFICANCE OF <i>BACILLUS THURINGIENSIS</i> ON WINE GRAPES International Journal of Food Microbiol. 94(3):301-312 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.1/09	Beegle, C.C., Dulmage, H.T., Wolfenbarger, D.A., Martinez, E.	1981	PERSISTENCE OF <i>BACILLUS THURINGIENSIS</i> BERLINER INSECTICIDAL ACTIVITY ON COTTON FOLIAGE Environ. Entomol. 10(3), 400-401 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.1/03	Benoit, T.G., Wilson, G.R., Bull, D.L., Aronson, A.I.	1990	PLASMID-ASSOCIATED SENSITIVITY OF <i>BACILLUS THURINGIENSIS</i> TO UV LIGHT Appl. and Environ. Microbiol. 56(8): 2282-2286 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7/01 7.2.1/01	Cornelese, A.	2016a	LITERATURE REVIEW ON <i>BACILLUS THURINGIENSIS</i> SUBSP. KURSTAKI STRAIN SA-12 AND METABOLITES: RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED Certis USA LLC GAB Consulting GmbH, Heidelberg, Germany Report-no.: 2281384-MA-06-01_SA-12 GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 7.1/12	Damgaard, P.H., Hansen, B.M., Pedersen, J.C., Eilenberg, J.	1997	NATURAL OCCURRENCE OF <i>BACILLUS THURINGIENSIS</i> ON CABBAGE FOLIAGE AND IN INSECTS ASSOCIATED WITH CABBAGE CROPS Journal of Applied Microbiology, 82(2): 253-258 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.3/01	EFSA	2005	OPINION OF THE SCIENTIFIC PANEL ON BIOLOGICAL HAZARD ON <i>BACILLUS CEREUS</i> AND OTHER <i>BACILLUS</i> SPP. IN FOODSTUFF The EFSA Journal 2005, 175, 3-45 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	Addendum to the DAR
KMA 7.3/05	Fisher, R., Rosner, L.	1959	INSECTICIDE SAFETY, TOXICOLOGY OF THE MICROBIAL INSECTICIDE, THUTICIDE J. Agric. Food Chem. 7(10), 686-688 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.2.2/01	Frederiksen, K., Rosenquist, H., Jorgensen, 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 Applied and Environmental Microbiology, 72(5): 3435-3440 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 7.1/01	Griego, V.M., Spence, K.D.	1978	INACTIVATION OF <i>BACILLUS THURINGIENSIS</i> SPORES BY ULTRAVIOLET AND VISIBLE LIGHT Applied and Environmental Microbiology, 35(5): 906-910 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 7.1/11	Hendriksen, N.B., Hansen, B.M.	2002	LONG-TERM SURVIVAL AND GERMINATION OF <i>BACILLUS THURINGIENSIS</i> VAR. <i>KURSTAKI</i> IN A FIELD TRIAL Canadian Journal of Microbiology, 48(3), 256-261 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.2.2/03	Hendriksen, N.B., Munk Hansen, B.	2006	DETECTION OF <i>BACILLUS THURINGIENSIS</i> <i>KURSTAKI</i> HD1 ON CABBAGE FOR HUMAN CONSUMPTION FEMS Microbiology Letters, 257(1): 106-111 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 7.1/14	Hostetter, D.L., Ignoffo, C.M., Kearby, W.H.	1975	PERSISTENCE OF FORMULATIONS OF <i>BACILLUS THURINGIENSIS</i> SPORES AND CRYSTALS ON EASTERN RED CEDAR FOLIAGE IN MISSOURI Journal of the Kansas Entomological Society, 48(2), 189-193 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.1/13	Ignoffo, C.M., Hostetter, D.L., Pinnell, R.E.	1974	STABILITY OF <i>BACILLUS THURINGIENSIS</i> AND <i>BACULOVIRUS HELIOTHIS</i> ON SOYBEAN FOLIAGE Environmental Entomology, 3(1), 117-119 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.3/03	Itoh, T., Arai, T., Hirata, I.	1991	ENTEROPATHOGENICITY OF <i>BACILLUS THURINGIENSIS</i> FOR HUMANS Shokubutsu Boeki 45:18-22 Report-no. not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 7.1/16	Madsen, A.M., Hansen, V.M., Meyling, N.V., Hendriksen, N.B., Winding, A., Kock, K.T., Eilenberg, J.	2011	HUMAN EKSPONERING FOR MIKROBIOLOGI-SKE BEKÆMPELSES-MIDLER, DERES NATURLIGT FOREKOMMENDE SLÆGTNINGE OG ANDRE MIKROORGANISMER Bekæmpelsesmiddelforskning fra Miljøstyrelsen, Nr. 132, 93 pp. Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 7.1/10 7.2.2/04	Pedersen, J.C., Damgaard, P.H., Eilenberg, J., Hansen, B.M.	1995	DISPERSAL OF <i>BACILLUS THURINGIENSIS</i> VAR. <i>KURSTAKI</i> IN AN EXPERIMENTAL CABBAGE FIELD Canadian Journal of Microbiology, Volume 41(2): 118-125 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.1/07	Pinnock, D.E., Brand, R.J., Jackson, K.L., Milstead, J.E.	1974	THE FIELD PERSISTENCE OF <i>BACILLUS THURINGIENSIS</i> SPORES ON <i>CERCIS OCCIDENTALIS</i> LEAVES Journal of Invertebrate Pathology, 23(3), 341-346 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.1/02	Pusztai, M., Fast, P., Gringorten, L., Kaplan, H., Lessard, T., Carey, P.R.	1991	THE MECHANISM OF SUNLIGHT-MEDIATED INACTIVATION OF <i>BACILLUS THURINGIENSIS</i> CRYSTALS Biochem. J. 273(Pt 1)(1): 43-47 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.2.2/02	Rosenquist, H., Smidt, L., Andersen, S.R., Jensen, G.B., Wilcks, A.	2005	OCCURRENCE AND SIGNIFICANCE OF <i>BACILLUS CEREUS</i> AND <i>BACILLUS THURINGIENSIS</i> IN READY-TO-EAT FOOD FEMS Microbiology Letters, 250(1): 129-136 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 7.1/15	Sánchez-Yáñez, J.M., Peña-Cabriaes, J.J.	2000	PERSISTANCE OF BACILLUS THURINGIENSIS SPORES ON SOIL AND MAIZE AND BEAN LEAVES (IN SPANISH WITH ENGLISH ABSTRACT) Terra, 18 (4), 325-331 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.3/04	Siegel, J.P.	2001	THE MAMMALIAN SAFETY OF BACILLUS THURINGIENSIS-BASED INSECTICIDES Journal of Invertebrate Pathology 77, 13-21, 2001 Report-no. not applicable GLP/GEP: no Published: yes	yes	no	not protected	-	DAR 2008
KMA 7.1/06	Smith, R.A., Barry, J.W.	1998	ENVIRONMENTAL PERSISTENCE OF <i>BACILLUS THURINGIENSIS</i> SPORES FOLLOWING AERIAL APPLICATION Journal of Invertebrate Pathology 71(3): 263-267 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.1/05	Smith, R.A., Couche, G.A.	1991	THE PHYLLOPLANE AS A SOURCE OF <i>BACILLUS THURINGIENSIS</i> VARIANTS Applied and Environmental Microbiology, 57(1): 331-315 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 7.2.2/05	Stephan, S., Scholz-Döbelin, H., Reintges, T., Pelz, J., Jehle, J.A. Keßler, J.	2014	INVESTIGATIONS ON RESIDUES OF XENTARI® (BACILLUS THURINGIENSIS SUBSPEC. AIZAWAI) ON GREENHOUSE TOMATOES Journal für Kulturpflanzen, 66(9) 312 - 318 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 7.3/02	Wilcks, A., Hansen, B.M., Hendriksen, N.B., Licht, T.R.	2006 b	FATE AND EFFECT OF INGESTED BACILLUS CEREUS SPORES AND VEGETATIVE CELLS IN THE INTESTINAL TRACT OF HUMAN-FLORA-ASSOCIATED RATS FEMS Immunol Med Microbiol 46:70-77 Report-no. not applicable GLP/GEP: no Published: Yes	yes	no	not protected	-	DAR 2008
KMA 7.2.2/06	Zhou, G., Yan, J., Dasheng, Z., Zhou, X., Yuan, Z.	2008	THE RESIDUAL OCCURRENCES OF BACILLUS THURINGIENSIS BIOPESTICIDES IN FOOD AND BEVERAGES International Journal of Food Microbiology, 127(1-2): 68-72 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

A.8 Environmental fate and behaviour

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1.1/19	Accinelli, C., Koskinen, W.C., Becker, J.M., Sadowsky, M.J.	2008	MINERALIZATION OF THE BACILLUS THURINGIENSIS CRY1AC ENDOTOXIN IN SOIL Journal of Agricultural and Food Chemistry, 56(3), 1025-1028 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1/09	Akiba, Y.	1986	MICROBIAL ECOLOGY OF BACILLUS THURINGIENSIS VI. GERMINATION OF BACILLUS THURINGIENSIS SPORES IN THE SOIL Appl. Ent. Zool. 21 (1): 76-80 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.2/02	Akiba, Y.	1991	ASSESSMENT OF RAINWATER-MEDIATED DISPERSION OF FIELD-SPRAYED BACILLUS THURINGIENSIS IN THE SOIL Japanese Journal of Applied Entomology and Zoology, 26 (4), 447-483 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.3/02	Al-Wasify, R.S., Al-Sayed, A.A., Kamel, M.M.	2013	SENSITIVITY AND SPECIFICITY OF CHROMOGENIC MEDIA FOR DETECTION OF SOME PATHOGENS IN WATER Int. J. Environ.Sustain., 2(1):1-9 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1/13	Bizzarri, M.F., Bishop, A.H.	2008	THE ECOLOGY OF BACILLUS THURINGIENSIS ON THE PHYLLOPLANE: COLONIZATION FROM SOIL, PLASMID TRANSFER, AND INTERACTION WITH LARVAE OF PIERIS BRASSICAE Microb. Ecol. 56(1): 133-139 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1.1/26	Chen, Z.H., Chen, L.J., Zhang, Y.L., Wu, Z.J.	2011	MICROBIAL PROPERTIES, ENZYME ACTIVITIES AND THE PERSISTENCE OF EXOGENOUS PROTEINS IN SOIL UNDER CONSECUTIVE CULTIVATION OF TRANSGENIC COTTONS (GOSSYPIMUM HIRSUTUM L.). Plant Soil Environ, 57(2), 67-74 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1/01 8.1.2/02 8.2/07	Cornelese, A.	2016b	LITERATURE REVIEW ON BACILLUS THURINGIENSIS SUBSP. KURSTAKI STRAIN SA-12 AND METABOLITES: FATE AND BEHAVIOUR IN THE ENVIRONMENT Certis USA / CBC (Europe) GAB Consulting GmbH, Heidelberg, Germany Report-no.: S.r.l. 2281384-MA-07-01 GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.1/11 8.2/05	Crecchio, C., Stotzky, G.	1998	INSECTICIDAL ACTIVITY AND BIODEGRADATION OF THE TOXIN FROM BACILLUS THURINGIENSIS SUBSP. KURSTAKI BOUND TO HUMIC ACIDS FROM SOIL Soil Biology & Biochemistry, 30(4), 463-470 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/12 8.2/06	Crecchio, C., Stotzky, G.	2001	BIODEGRADATION AND INSECTICIDAL ACTIVITY OF THE TOXIN FROM BACILLUS THURINGIENSIS SUBSP. KURSTAKI BOUND ON COMPLEXES OF MONTMO-RILLONITE-HUMIC ACIDS-A1 HYDROXYPOLYMERS Soil Biology & Biochemistry, 33(4), 573-581 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1/04	Dent, D.R.	1993	THE USE OF BACILLUS THURINGIENSIS AS AN INSECTICIDE In: Exploitation of Microorganisms, D.G. Jones (ed.), Chapman & Hall, London Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.2/05	Douville, M., Gagné, F., Blaise, C., André, C.	2007	OCCURRENCE AND PERSISTENCE OF BACILLUS THURINGIENSIS (BT) AND TRANSGENIC BT CORN CRY1AB GENE FROM AN AQUATIC ENVIRONMENT Ecotoxicology and Environmental Safety, 66(2): 195-203 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.3/02	Emanuel P.A., Buckley P.E., Sutton T.A., Edmonds J.M., Bailey A.M., Rivers B.A., Kim M.H., Ginley W.J., Keiser C.C., Doherty R.W., Kragl F.J., Narayanan F.E., Katoski S.E., Paikoff S., Leppert S.P., Strawbridge J.B., VanReenen D.R., Biberos S.S., Moore D., Phillips D.W., Mingioni L.R., Melles O., Ondercin D.G., Hirsh B., Bieschke K.M., Harris C.L., Omberg K.M., Rastogi V.K., Van Cuyk S., Gibbons H.S.	2012	DETECTION AND TRACKING OF A NOVEL GENETICALLY TAGGED BIOLOGICAL SIMULANT IN THE ENVIRONMENT Applied and Environmental Microbiology, 78(23):8281-8288 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.2/13	Fu, Q., Deng, Y., Li, H., Liu, J., Hu, H., Chen, S., Sa, T.	2009	EQUILIBRIUM, KINETIC AND THERMODYNAMIC STUDIES ON THE ADSORPTION OF THE TOXINS OF BACILLUS THURINGIENSIS SUBSP. KURSTAKI BY CLAY MINERALS Appl Surface Sci, 255(8), 4551-4557 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1/02 8.1.1/13	Griego, V.M., Spence, K.D.	1978	INACTIVATION OF BACILLUS THURINGIENSIS SPORES BY ULTRAVIOLET AND VISIBLE LIGHT Applied and Environmental Microbiology, 35(5), 906-910 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.3/01	Hansen, B.M., Thorsen, L., Nielsen-LeRoux, C., Wilcks, A., Hendriksen, N.B.	2011	NEW EXPERIMENTAL APPROACHES FOR HUMAN RISK ASSESSEMENT OF MICROBIAL PEST CONTROL AGENTS – EXEMPLIFIED BY THE BACTERIUM BACILLUS THURINGIENSIS Danish EPA, Pesticides Research, 136 2011, 1-128 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.1/22	Helassa, N., M'Charek, A., Quiquampoix, H., Noinville, S., Dejardin, P., Frutos, R., Staunton, S.	2011	EFFECTS OF PHYSICO-CHEMICAL INTERACTIONS AND MICROBIAL ACTIVITY ON THE PERSISTENCE OF CRY1AA BT (BACILLUS THURINGIENSIS) TOXIN IN SOIL Soil Biol. Biochem., 43(5), 1089-1097 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.2/11	Helassa, N., Quiquampoix, H., Noinville, S., Szponarski, W., Quiquampoix, H., Staunton, S.	2009	ADSORPTION AND DESORPTION OF MONOMERIC BT (BACILLUS THURINGIENSIS) CRY1AA TOXIN ON MONTMORILLONITE AND KAOLINITE Soil Biol. Biochem., 41(3), 498-504 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1.1/18	Hendriksen, N.B., Carstensen, J.	2013	LONG-TERM SURVIVAL OF BACILLUS THURINGIENSIS SUBSP. KURSTAKI IN A FIELD TRIAL Can.J.Microbiol. 59(1), 34-38 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
8.1/12 8.1.1/02	Hendriksen N.B., Hansen, B.M.	2002	LONG-TERM SURVIVAL AND GERMINATION OF BACILLUS THURINGIENSIS VAR. KURSTAKI IN A FIELD TRIAL Canadian Journal of Microbiology 48(3): 256-261 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1/08	Hostetter, D.L., Ignoffo, C.M., Kearby, W.H.	1975	PERSISTENCE OF FORMULATIONS OF BACILLUS THURINGIENSIS SPORES AND CRYSTALS ON EASTERN RED CEDAR FOLIAGE IN MISSOURI not applicable Journal of the Kansas ENTOMOLOGICAL Society, 48, 189-193 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.2/10	Hung, T.P., Truong, L.V., Binh, N.D., Frutos, R., Quiquapoix, H., Staunton, S.	2016	COMPARISON OF THE AFFINITY AND EXTRACTION YIELD OF TRACE AMOUNTS OF THREE CRY PROTEINS FROM BACILLUS THURINGIENSIS IN CONTRASTING TYPES OF SOIL European J Soil Sci, 67(1), 90-98 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.1/21	Icoz, I., Stotzky, G.	2008	CRY3BB1 PROTEIN FROM BACILLUS THURINGIENSIS IN ROOT EXUDATES AND BIOMASS OF TRANSGENIC CORN DOES NOT PERSIST IN SOIL Transgenic Research 17(4):609-620 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1/07	Ignoffo, C.M., Hostetter, D.L., Pinnell, R.E.	1974	STABILITY OF BACILLUS THURINGIENSIS AND BACULOVIRUS HELIOTHIS ON SOYBEAN FOLIAGE NOT APPLICABLE ENVIRON ENTOMOL, 3 (4), 117-119 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/17	Konecka, E., Baranek, J., Bielinska, I., Tadeja, A., Kaznowski, A.	2014	PERSISTENCE OF THE SPORES OF B. THURINGIENSIS SUBSP. KURSTAKI FROM FORAY BIOINSECTICIDE IN GLEYSOL SOIL AND ON LEAVES Sci. Total Environ. 472:296-301 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.1/23 8.1.2/04	Li, Y.-L., Du, J., Fang, Z.-X., You, J.	2013	DISSIPATION OF INSECTICIDAL CRY1AC PROTEIN AND ITS TOXICITY TO NONTARGET AQUATIC ORGANISMS Journal of Agricultural and Food Chemistry, 61(46):10864- 10871 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.1/20	Marchetti, E., Accinelli, C., Talamé, V., Epifani, R.	2007	PERSISTENCE OF CRY TOXINS AND CRY GENES FROM GENETICALLY MODIFIED PLANTS IN TWO AGRICULTURAL SOILS Agronomy for Sustainable Development, 27(3), 231-236 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.1/03	Martin, P.A.W.	1991	DYNAMICS OF BACILLUS THURINGIENSIS TURN-OVER IN SOIL The General Meeting of the American Society for Microbiology, p. 315 (Abst.) Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1/05	Martin, P.A.W., Traversers, R.S.	1989	WORLDWIDE ABUNDANCE AND DISTRIBUTION OF BACILLUS THURINGIENSIS ISOLATES Applied and Environmental Microbiology, Oct. 1989, p. 2437-2442 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.2/01	Menon, A.S., de Mestral, J.	1985	SURVIVAL OF BACILLUS THURINGIENSIS VAR. KURSTAKI IN WATERS Water, Air, & Soil Pollution, 25(3), 265-274 Report-no. not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/14	Myasnik, M., Manasherob, R., Ben-Dov, E., Zaritsky, A., Margalith, Y., Barak Z.	2001	COMPARATIVE SENSITIVITY TO UV-B RADIATION OF TWO BACILLUS THURINGIENSIS SUBSPECIES AND OTHER BACILLUS SP. Current Microbiology, 43(2), 140-143 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.2/12	Pagel-Wieder S., Niemeyer J., Fischer W.R., Gessler F.	2007	EFFECTS OF PHYSICAL AND CHEMICAL PROPERTIES OF SOILS ON ADSORPTION OF THE INSECTICIDAL PROTEIN (CRY1AB) FROM BACILLUS THURINGIENSIS AT CRY1AB PROTEIN CONCENTRATIONS RELEVANT FOR EXPERIMENTAL FIELD SITES Soil Biol. Biochem., 39, 3034-3042 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1/03 8.1.1/01 8.2/01	Pedersen, J.C., Darmgaard, P.H., Eilenberg, J., Hansen, B.M.	1995	DISPERSAL OF BACILLUS THURINGIENSIS VAR. KURSTAKI IN AN EXPERIMENTAL CABBAGE FIELD Canadian Journal of Microbiology, 41(2), 118-125 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1/11 8.1.1/04	Petras, S.F., Casida Jr., L.E.	1985	SURVIVAL OF BACILLUS THURINGIENSIS SPORES IN SOIL Appl. Environ. Microbiol., 50(6): 1496-1501 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/15	Pusztal, M., Fast, P., Gringorten, L., Kaplan, H., Lessard, T., Carey, P.R.	1991	THE MECHANISM OF SUNLIGHT-MEDIATED INACTIVATION OF BACILLUS THURINGIENSIS CRYSTALS Biochemical Journal, 273(1), 43-47 Report-no.: not applicable GLP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1/10	Saleh, S.M., Harris, R.F., Allen, O.N.	1970	FATE OF BACILLUS THURINGIENSIS IN SOIL: EFFECT OF SOIL PH AND ORGANIC AMENDMENT Can. J. Microbiol. 16, p. 677-680 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
8.1/06	Smith, R.A., Couche, G.A.	1991	THE PHYLLOPLANE AS A SOURCE OF BACILLUS THURINGIENSIS VARIANTS Applied and Environmental Microbiology, 57(1): 331-315 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.2/06	Strain, K.E., Lydy, M.J.	2015	THE FATE AND TRANSPORT OF THE CRY1AB PROTEIN IN AN AGRICULTURAL FIELD AND LABORATORY AQUATIC MICRO-COSMS Chemosphere, 132:94-100 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.2/07	Strain, K.E., Whiting, S.A., Lydy, M.J.	2014	LABORATORY AND FIELD VALIDATION OF A CRY1AB PROTEIN QUANTITATION METHOD FOR WATER Talanta, 128:109-116 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1.1/16	Sundaram, K.M.S., Sundaram, A., Huddleston, E., Nott, R., Sloane, L., Ross, J., Ledson, M.	1997	DEPOSITION, DISTRIBUTION, PERSISTENCE AND FATE OF BACILLUS THURINGIENSIS VARIETY KURSTAKI (BTK) IN PECAN ORCHARDS FOLLOWING AERIAL AND GROUND APPLICATIONS TO CONTROL PECAN NUT CASEBEARER LARVAE Journal of Environmental Science and Health, 32 (5), 741-788 Report-no.: not applicable GLP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/10 8.2/04	Tapp, H., Stotzky, G.	1995	INSECTICIDAL ACTIVITY OF THE TOXINS FROM BACILLUS THURINGIENSIS SUBSPECIES KURSTAKI AND TENEBRIONIS ADSORBED AND BOUND ON PURE AND SOIL CLAYS Applied and Environmental Microbiology, 61(5), 1768-1790 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.3/01	Teschke, K., Chow, Y., Bartlett, K., Ross, A., van Netten, C.	2001	SPATIAL AND TEMPORAL DISTRIBUTION OF AIRBORNE BACILLUS THURINGIENSIS VAR. KURSTAKI DURING AN AERIAL SPRAY PROGRAM FOR GYPSY MOTH ERADICATION Environmental Health Perspectives, 109, (1), 47-54 Report-no.: not applicable GLP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1/14	van Cuyk, S., Deshpande, A., Hollander, A., Duval, N., Ticknor, L., Layshock, J., Gallegos-Graves, L., Omberg, K.M.	2011	PERSISTENCE OF BACILLUS THURINGIENSIS SUBSP. KURSTAKI IN URBAN ENVIRONMENTS FOLLOWING SPRAYING Appl. and Environ. Microbiol., 77(22), 7954 - 7961 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1.1/9 8.2/03	Venkateswerlu, G., Stotzky, G.	1992	BINDING OF THE PROTOXIN AND TOXIN PROTEINS OF BACILLUS THURINGIENSIS SUBSP. KURSTAKI ON CLAY MINERALS Current Microbiology, 25(4), 225-233 Report-no.: not applicable GLP: no Published: Yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/08	Visser, S., Addison, J.A., Holmes, S.B.	1994	EFFECTS OF DIPEL® 176, A BACILLUS THURINGIENSIS SUBSP. KURSTAKI (B.T.K.) FORMULATION, ON THE SOIL MICROFLORA AND THE FATE OF B.T.K. IN AN ACID FOREST SOIL: A LABORATORY STUDY Canadian Journal for Forestry Research, 24(3), 462-471 Report-no.: not applicable GLP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/24 8.1.2/03	Wang, H., Ye, Q., Gan, J., Wu, L.	2007	BIODEGRADATION OF CRY1AB PROTEIN FROM BT TRANSGENIC RICE IN AEROBIC AND FLOODED PADDY SOILS Journal of Agricultural and Food Chemistry, 55(5), 1900-1904 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.1.1/05	West, A.W., Burges, H.D., Dixon, T.J., Wyborn, C.H.	1985	SURVIVAL OF BACILLUS THURINGIENSIS AND BACILLUS CEREUS SPORE INOCULA IN SOIL: EFFECTS OF PH, MOISTURE, NUTRIENT AVAILABILITY AND INDICENOUS MICROORGANISMS Soil Biology & Biochemistry, Volume 17(5), 657-665 Report-no.: not applicable GLP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/06	West, A.W., Burges, H.D., White, R.J., Wyborn, C.H.	1984a	PERSISTENCE OF BACILLUS THURINGIENSIS PARASPO-RAL CRYSTAL INSECTICIDAL ACTIVITY IN SOIL Journal of Invertebrate Pathology, 44(2), 128-133 Report-no. not applicable GLP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 8.1.1/07	West, A.W., Burges, H.D., Wyborn, C.H.	1984b	EFFECT OF INCUBATION IN NATURAL AND AUTOCLAVED SOIL UPON POTENCY AND VIABILITY OF BACILLUS THURINGIENSIS Journal of Invertebrate Pathology, Volume 44 (2), 121-127 Report-no. not applicable GLP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 8.1.1/25	Xue, K., Diaz, B.R., Thies, J.E.	2014	STABILITY OF CRY3BB1 PROTEIN IN SOILS AND ITS DEGRADATION IN TRANS-GENIC CORN RESIDUES Soil Biology and Biochemistry, 76, 119-126 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.2/08	Zhou, X., Gao, J., Huang, Q., Xiong, J.	2010	CONFIRMATION STUDIES OF THE INTERACTION OF THE PEST-RESISTANT TOXIN FROM BACILLUS THURINGIENSIS WITH BROWN AND RED SOILS International Journal of Chemical Reactor Engineering, 8, 1-14 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 8.2/09	Zhou, X.-Y., Liu, H.F., Lu, X.-Z., Hao, J.-C., Dong, Q.-J.	2013	ADSORPTION THERMODYNAMIC CHARACTERISTICS OF CRY1AB TOXIN FROM BACILLUS THURINGIENSIS IN CHINESE LATOSOL Asian J Chemistry, 25(13), 7319-7322 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

A.9 Ecotoxicology data

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 9.4/09	Amichot, M., Curty, C., Benguettat-Magliano, O., Gallet, A., Wajnberg, E.	2016	SIDE EFFECTS OF BACILLUS THURINGIENSIS VAR. KURSTAKI ON THE HYMENOPTEROUS PARASITIC WASP TRICHOGRAMMA CHILONIS Environmental Science & Pollution Research 23(4), 3097-3103 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.4/04	Bernard, M.B., Cole, P., Ko-belt, A., Horne, P.A., Altmann, J., Wratten, S.D., Yen, A.L.	2010	REDUCING THE IMPACT OF PESTICIDES ON BIOLOGICAL CONTROL IN AUSTRALIAN VINEYARDS: PESTICIDE MORTALITY AND FECUNDITY EFFECTS ON AN INDICATOR SPECIES, THE PREDATORY MITE EUSEIUS VICTORIENSIS (ACARI: PHYTOSEIIDAE) Journal of Economic Entomology, 103(6), 2061-2071 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.5/01	Bilej, M., Procházková, P., Šilerová, M., Josková, R.	2010	EARTHWORM IMMUNITY Invertebrate Immunity, Kenneth Söderhäll (ed.), Landes Bioscience and Springer Science+Business Media, 66-79 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.1/01 9.3/01 9.4/02	Buckner, C.H., Kingsbury, P.D., Mcleod, B.B., Mortensen, K.L., Ray, D.G.H	1974	EVALUATION OF COMMERCIAL PREPARATIONS OF BACILLUS THURINGIENSIS WITH AND WITHOUT CHITINASE AGAINST SPRUCE BUDWORM. F. IMPACT OF AERIAL TREATMENT ON NON-TARGET ORGANISMS, ALGONQUIN PARK, ONTARIO AND SPRUCE WOODS, MANITOBA Chemical Control Research Institute, Canadian Forestry Service, Ottawa, Ontario, Canada, 1974 Report-no.: Information Report CC-X-59 GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 9.1/03	[REDACTED]	2015 a	THURICIDE SC - AVIAN (COTURNIX COTURNIX JAPONICA) ORAL ACUTE TOXICITY/PATHOGENICITY STUDY Certis USA LLC, RL1364/2015PAVO-B [REDACTED] [REDACTED] Report-no. not applicable GLP/GEP: yes Published: no	yes	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 9.2.1/01	[REDACTED]	2015 b	THURICIDE SC - FISH (DANIO RERIO) TOXICITY TEST Certis USA LLC, RL1371/2015PX-B [REDACTED] [REDACTED] Report-no.: not applicable GLP/GEP: yes Published: no	yes	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 9.7/01	Cañez, V.M.	1988 a	NONTARGET PHYTOTOXICITY TEST: VEGETATIVE VIGOUR, TIER 2 Pan-Agricultural laboratories, Inc., Fresno, California, USA Certis USA LLC, Columbia Report-no.: LR88-52 GLP/GEP: yes Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 9.7/02	Cañez, V.M.	1988 b	NONTARGET PHYTOTOXICITY TEST: SEED GERMINATION/SEEDLING EMERGENCE, TIER 1 Pan-Agricultural laboratories, Inc., Fresno, California, USA Certis USA LLC, Columbia Report-no.: LR88-53 GLP/GEP: yes Published: no	no	no	not protected	Certis USA	DAR 2008
KMA 9.3/03	Cantwell, G.E., Lehnert, T., Fowler, J.	1972	ARE BIOLOGICAL INSECTICIDES HARMFUL TO THE HONEY BEE? American Bee Journal, pp. 255-258 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.4/05	Carvalho, G.A., Moura, A.P., Bueno, V.H.P.	2006	SIDE EFFECTS OF PESTICIDES ON TRICHOGRAMMA PRETIOSUM (HYMENOPTERA: TRICHOGRAMMATIDAE) Integrated Control in Protected Crops, Mediterranean Climate, IOBC/wprs Bulletin, 29(4), 355-359 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 9.3/09	del Mar Leza, M., Llado, G., Petro, A.B., Alemany, A.	2014	FIRST FIELD ASSESSMENT OF BACILLUS THURINGIENSIS SUBSP. KURSTAKI AERIAL APPLICATION ON THE COLONY PERFORMANCE OF APIS MEL-LIFERA L. (HYMENOPTERA: APIDAE) Spanish J. of Agricultural Research, 12(2), 405-408 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.2.2/01	Eidt, D.C.	1985	TOXICITY OF BACILLUS THURINGIENSIS VAR. KURSTAKI TO AQUATIC INSECTS The Canadian Entomologist, Volume 117, pp. 829-837 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.4/07	Garantonakis, N., Varikou, K., Birouraki, A.	2016	COMPARATIVE SELECTIVITY OF PESTICIDES USED IN GREENHOUSES, ON THE APHID PARASITOID APHIDIUS COLEMANI (HYMENOPTERA: BRACONIDAE) Biocontrol Science and Technology, 26 (5), 678-690 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.4/06	Garcia, P.V., Pereira, N., Oliveira, L.M.	2008	SIDE-EFFECTS OF ORGANIC AND SYNTHETIC PESTICIDES ON COLD-STORED DIAPAUSING PREPUPAE OF TRICHOGRAMMA CORDUBENSIS BioControl, 54, 451-458 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.4/03	Hamed, A.R.	1979	ZUR WIRKUNG VON BACILLUS THURINGIENSIS AUF PARASITEN UND PRÄDATOREN VON YPONOMEUTA EVONYMELLUS (LEP. YPONOMEUTIDAE) Zeitschrift für Angewandte Entomologie, 1978/1979, Volume 87, pp. 294-311 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 9.2.3/01	Koskella, J., Stotzky, G.	2002	LARVICIDAL TOXINS FROM BACILLUS THURINGIENSIS SUBSP. KURSTAKI, MORRISONI (STRAIN TENEBRIONIS), AND ISRAELENIS HAVE NO MICROBICIDAL OR MICROBIOSTATIC ACTIVITY AGAINST SELECTED BACTERIA, FUNGI AND ALGAE IN VITRO Canadian Journal of Microbiology, Volume 48, pp. 262-267 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.2.2/03	Kreutzweiser, D.P., Capell, S.S., Thomas, D.R.	1994	AQUATIC INSECT RESPONSE TO BACILLUS THURINGIENSIS VAR. KURSTAKI IN A FOREST STREAM Canadian Journal of Forest Research, Volume 24, pp. 2041-2049 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.2.2/04	Kreutzweiser, D.P., Holmes, S.B., Capell, S.S., Eichenberg, D.C.	1992	LETHAL AND SUBLETHAL EFFECTS OF BACILLUS THURINGIENSIS VAR KURSTAKI ON AQUATIC INSECTS IN LABORATORY BIOASSAYS AND OUTDOOR STREAM CHANNELS Bulletin of Environmental Contamination and Toxicology, Volume 49, pp. 252-258 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.3/05	Krieg, A.	1973	ÜBER DIE TOXISCHE WIRKUNG VON BACILLUS CEREUS – UND BACILLUS THURINGIENSIS-KULTUREN AUF DIE HONIGBIENE (APIS MELLIFERA) Zeitschrift für Pflanzenkrankheiten und Pflanzenschutz, Volume 8, pp. 483-486 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.3/04	Lehnert, T., Cantwell, G.E.	1978	THE EFFECTS OF MICROBIAL INSECTICIDES ON THE HONEY BEE - A REVIEW American Bee Journal, October 1978, pp. 674-675 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 9.3/02	Malone, L.A., Burgess, E.P.J., Stefanovic, D.	1999	EFFECTS OF A BACILLUS THURINGIENSIS TOXIN, TWO BACILLUS THURINGIENSIS BIOPESTICIDE FORMULATIONS, AND A SOYBEAN TRYPSIN INHIBITOR ON HONEY BEE (APIS MELLIFERA L.) SURVIVAL AND FOOD CONSUMPTION Apidologie, Volume 30, pp. 465-473 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.3/08	Mayer, D.F.	1990	EFFECT OF SANDOZ BT PRODUCTS ON ADULT HONEY BEE (APIS MELLIFERA L.) MORTALITY Certis USA LLC, 90/01 Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 9.2.2/02 9.4/01	Melin, B.E., Cozzi, E.M.	1990	SAFETY TO NONTARGET INVERTEBRATES OF LEPIDOPTERAN STRAINS OF BACILLUS THURINGIENSIS AND THEIR BETA-EXOTOXINS Safety of Microbial Insecticides (M. Laird, <i>et al.</i> , editors), CRC Press, Boca Raton, Florida, USA, pp. 149-167 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.3/06	Minei, C.C.	2015 a	THURICIDE SC - HONEYBEES (APIS MELLIFERA), ACUTE ORAL TOXICITY TEST Certis USA LLC, RL1299/2015ABO-B TECAM Tecnologia Ambiental, Sao Paulo, Brasil Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 9.3/07	Minei, C.C.	2015 b	THURICIDE SC - HONEYBEES (APIS MELLIFERA), ACUTE CONTACT TOXICITY TEST Certis USA LLC, RL1300/2015ABC-B TECAM Tecnologia Ambiental, Sao Paulo, Brasil Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 9.4/08	Momanyi, G., Maranga, R., Sithanatham, S., Agong, S., Matoka, C.M., Hassan, S.A.	2012	EVALUATION OF PERSISTENCE AND RELATIVE TOXICITY OF SOME PEST CONTROL PRODUCTS TO ADULTS OF TWO NATIVE TRICHOGRAMMATID SPECIES IN KENYA BioControl, 57, 591-601 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.3/10	Mommaerts, V., Jans, K., Smaghe, G.	2010	IMPACT OF BACILLUS THURINGIENSIS STRAINS ON SURVIVAL, REPRODUCTION AND FORAGING BEHAVIOUR IN BUMBLEBEES (BOMBUS TERRESTRIS) Pest Management Science, 66, 520-525 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.2.2/05	Mrotzeck Maschetto, A.	2015	THURICIDE SC - DAPHNIA MAGNA TOXICITY TEST Certis USA LLC, RL1339/2015DP-B TECAM Tecnologia Ambiental, Sao Paulo, Brasil Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated
KMA 9.1/02	Nagy, L.R., Smith, K.G.	1997	EFFECTS OF INSECTICIDE-INDUCED REDUCTION IN LEPIDOPTERAN LARVAE ON REPRODUCTIVE SUCCESS OF HOODED WARBLERS The Auk, 1997, Volume 114, pp. 619-627 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	DAR 2008
KMA 9.6/01	O'Callaghan, M., Gerard, E., Sarathchandra, U.	2007	ANALYSIS OF NON-TARGET IMPACTS OF FORAY 48B ON SOIL MICRO-ORGANISMS Proceedings of the 6 th PRC on the Biot. of <i>B. thur.</i> and its Env. Impact, 133-134 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMA 9.2.2/06	Oliveira-Filho, E.C., Muniz, D.H., Freire, I.S., Ramos, F.R. Alves, R.T., Jonsson, C.M., Grisolia, C.K., Monnerat, R.G.	2011	SUSCEPTIBILITY OF NON-TARGET INVERTEBRATES TO BRAZILIAN MICROBIAL PEST CONTROL AGENTS Ecotoxicology, 20, 1354-1360 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9.6/02	Scheepmaker, J. W. A., Van de Kasstele, J.	2011	EFFECTS OF CHEMICAL CONTROL AGENTS AND MICROBIAL BIOCONTROL AGENTS ON NUMBERS OF NON-TARGET MICROBIAL SOIL ORGANISMS: A META-ANALYSIS Biocontrol Science and Technology, 21, 1225-1242 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for active ingredient, not previously submitted nor evaluated
KMA 9/01	Schöbinger, U.	2016	LITERATURE REVIEW ON <i>BACILLUS THURINGIENSIS</i> SUBSP. <i>KURSTAKI</i> STRAIN SA-12: EFFECTS ON NON-TARGET ORGANISMS Certis USA LLC GAB Consulting GmbH, Stade, Germany Report-no.: 228-1384-MA-08-01_SA-12 GLP/GEP: no Published: no	no	yes	protected	Certis USA	New data for active ingredient, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 9.7/03 1 st add sub	Blaszyk, K., Krzyśko-Łupicka, T.	2013	MICROBIAL DIVERSITY OF SEWAGE SLUDGE Proceedings of ECOpole. 2013;7(2) Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for existing formulation, not previously submitted nor evaluated
KMP 9.4.2/01	Broderick, N.A., Raffa, K.F., Handelsman, J.	2006	MIDGUT BACTERIA REQUIRED FOR BACILLUS THURINGIENSIS INSECTICIDAL ACTIVITY Proc Natl Acad Sci USA, 103(41): 15196-15199 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for existing formulation, not previously submitted nor evaluated
KMP 9.4.2/02	Broderick, N.A., Robinson, C.J., McMahon, M.D., Holt, J., Handelsman, J., Raffa, K.F.	2009	CONTRIBUTIONS OF GUT BACTERIA TO BACILLUS THURINGIENSIS-INDUCED MORTALITY VARY ACROSS A RANGE OF LEPIDOPTERA BMC Biology, 7:11, 1-9 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for existing formulation, not previously submitted nor evaluated
KMP 9.2.2/01	Dengler, D.	2010	ASSESSMENT OF TOXIC EFFECTS OF COSTAR ON DAPHNIA MAGNA USING THE 48 H ACUTE IMMOBILISATION TEST Certis USA LLC Eurofins Agroscience Services GmbH Report-no.: S10-02549 GLP/GEP: yes Published: no	no	yes	Protected	Certis USA	New data for existing formulation, submitted for zonal authorisation in 2012
KMP 9.7/01 1 st add sub	Franklin R.B., Mills, A.L.	2006	STRUCTURAL AND FUNCTIONAL RESPONSES OF A SEWAGE MICROBIAL COMMUNITY TO DILUTION-INDUCED REDUCTIONS IN DIVERSITY. Microbial Ecology 52(2):280-288 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for existing formulation, not previously submitted nor evaluated

Data point	Author(s)	Year	Title Owner Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KMP 9.2.1/01		2010	COSTAR - ACUTE TOXICITY TESTING IN RAINBOW TROUT (ONCORHYNCHUS MYKISS) (TELEOSTEI, SALMONIDAE) Certis USA LLC Report-no.: S10-02547 GLP/GEP: yes Published: no	yes	yes	Protected	Certis USA	New data for existing formulation, submitted for zonal authorisation in 2012
KMP 9.7/02 1 st add sub	McLellan, S.L., Huse, S.M., Mueller-Spitz, S.R., Andreishcheva, E.N., Sogin, M.L.	2010	DIVERSITY AND POPULATION STRUCTURE OF SEWAGE DERIVED MICROORGANISMS IN WASTEWATER TREATMENT PLANT INFLUENT. Environmental Microbiology 12(2): 378–392 Report-no.: not applicable GLP/GEP: no Published: yes	no	no	not protected	-	New data for existing formulation, not previously submitted nor evaluated
KMP 9.3.1/01	Vergé, E.	2016	DELFIN WG - ACUTE ORAL AND CONTACT TOXICITY TO THE HONEY BEE, APIS MELLIFERA L. UNDER LABORATORY CONDITIONS Certis USA LLC Eurofins Agroscience Services EcoChem GmbH Report-no.: S15-05620 GLP/GEP: yes Published: no	no	yes	Protected	Certis USA	New data for existing formulation, submitted for authorisation in 2016 to several MS
KMP 9.4.1/01	Walter, C.	2014	COSTAR: TOXICITY TO THE PREDATORY MITE, TYPHLODROMUS PYRISCHEUTEN (ACARI, PHYTOSEIIDAE) UNDER LABORATORY CONDITIONS Certis USA LLC, S13-04875 Eurofins Agroscience Services EcoChem GmbH Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, submitted for zonal authorisation in 2015

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KMP 9.4.1/ 02	Walter, C.	2016	COSTAR WG: TOXICITY TO THE APHID PARASITOID APHIDIUS RHOPALOSIPHII DE STEFANI PEREZ (HYMENOPTERA, BRACONIDAE) UNDER LABORATORY CONDITIONS Certis USA LLC, S15-01102 Eurofins Agroscience Services EcoChem GmbH Report-no.: not applicable GLP/GEP: yes Published: no	no	yes	protected	Certis USA	New data for existing formulation, submitted for authorisation in 2016 to several MS
KMP 9.2.3/ 01	Weber, K.	2011	TESTING OF EFFECTS OF COSTAR TO THE SINGLE CELL ALGA DESMODESMUS SUBSPICATUS Certis USA LLC Eurofins Agroscience Services GmbH Report-no.: S10-02550 GLP/GEP: yes Published: no	no	yes	Protected	Certis USA	New data for existing formulation, submitted for zonal authorisation in 2012