

European Commission



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

***Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV)**

Volume 2. List of Studies

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Version History

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INTRODUCTION

The company Andermatt Biocontrol GmbH submits the current dossier for the approval of the baculovirus (BV) *Spodoptera exigua* multi nucleopolyhedrovirus (SeMNPV) as a new microbial pest control agent (MPCA) and SPEXIT as its reference microbial pest control product (MPCP) to the European Authorities.

BVs used as MPCA in the EU are regulated as microorganism according to Regulation 1107/2009¹. Data requirements for the registration of BVs as an active substance and their products are laid down in part B of the regulation documents 283/2013² and 284/2013³ and the principles for evaluation and authorization of plant protection products contained microorganism according to regulation 546/2011⁴.

BV isolates however, represent a unique case in which the wild type isolates are genetically heterogeneous (mixture of different genotypes or pool of isolates). These variations may influence in some biological properties, such as the virulence, but it has no consequences on the safety towards non-target organisms or the environment. Isolation of a single genotype is difficult and even not appropriated, since genetic variation is needed to account for variation in the target organisms and obtain better efficacy in the control of insect populations. Therefore, the BVs were not necessary evaluated at strain level (Sanco/0253/2008).⁵ The high similarity between BVs justifies a general assessment at the level of the family *Baculoviridae*, considering species-specific information where necessary. The proposed procedure to include BVs at species level was adopted by the member states and the European Regulatory Authorities already in 2007, when the first BV species was included in Annex I, and for the REBECA proposal 2008⁶, for a simplified inclusion of BVs on the species level into Annex I. Most of the formally required data are published and equal for all BVs, already assessed by MS and EU authorities and therefore, some data on the isolate or species level are not mandatory.

The BVs are included on species level in Annex I of directive 1107/2009 and the different pool of isolates were added after they have been evaluated to a separate list, to be maintained in the Review Report and to be amended by taking note in the Standing Committee (Sanco/0253/2008). This approach has been confirmed by a decision in the Standing Committee on May 15, 2007⁷ where *S. exigua* NPV was listed at species level in Annex I. The experience that BVs present no risk for the environment have been confirmed by numerous studies during the last fifty years, since their first use as biocontrol agents. With regard to safety considerations, it is important to note that the whole *Baculoviridae* family are naturally present in our environment and are closely associated with their host occurrence. Therefore, their application in pest control would only produce a non-permanent fluctuation of the virus titre in the biotope of the pest insect. Due to their host specificity, BVs do not affect other organisms like vertebrates, arthropods other than their host species, microorganisms, or plants. BVs do not produce any metabolites at all.

For the BV specie *S. exigua* multicapsid nucleopolyhedrovirus (SeMNPV) a DAR with a reference isolate (Florida isolate SeNPV-F1, the first applied for) was approved in 2006 and the isolate SeNPV-F1 was listed on Annex I. Two new more isolates were further applied for at Member State level: the SeMNPV-SP2, approved in 2008 and the SeNPV-BV0004, approved in 2010. Conversely, the current dossier was based on the data already assessed by the MS and EU authorities:

- The previous DAR document for the approval of a new active substance SeNPV-F1 submitted by Mitsui Agri Science International S.A and evaluated by The Netherlands in 2007.

¹Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Official Journal of the European Union L 309, 1-50.

² Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Official Journal of the European Union L 93, 1-84.

³Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Official Journal of the European Union L 93, 85-152.

⁴Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. Official Journal of the European Union L155, 127-175.

⁵SANCO/0253/2008 rev. 2, 22 January 2008. Guidance Document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC.

⁶Ehlers RU., 2011 Regulation of Biological Control Agents and the EU Policy Support Action REBECA. In Ehlers RU. (eds) Regulation of Biological Control Agents. Springer, Dordrecht.

⁷Review report for the active substance *Spodoptera exigua* nuclear polyhedrosis virus. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 May 2007 in view of the inclusion of *Spodoptera exigua* nuclear polyhedrosis virus in Annex I of Directive 91/414/EEC. *Spodoptera exigua* NPV SANCO/T14/2007 - rev. final1 12 March 2007.

- The evaluation report of the new isolate of SeMNPV, BV0004 previously submitted by the company Andermatt Biocontrol GmbH and evaluated by the Netherlands in 2010.

Active substances are approved for maximum period of 10 years under Directive 91/414/EEC⁸. The active substance SeMNPV was under programme of renewal Regulation EU 686/2012 (AIR-III programme⁹). According to draft working document AIR III renewal programme SANCO/2012/11284¹⁰, *Spodoptera exigua* nuclear polyhedrosis virus was included in Batch 9” Active substance *Spodoptera exigua* nuclear polyhedrosis virus No application for renewal of approval has been submitted. Previous expiry date 30/11/2017”

Commission implementing regulation (EU) No 844/2012¹¹ setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 establishes in its Art 1: “the application for the renewal of an approval of an active substance shall be submitted by a producer of the active substance to the rapporteur Member State, no later than three years before the expiry of the approval”

The application for the renewal of the active substance *Spodoptera exigua* nuclear polyhedrosis virus was not submitted before of three years before the expiry date of the approval of the active substance SeMNPV (30/11/2017).

The applicant then have submitted an application for SeMNPV as a new active substance.

In this RAR, the information submitted regarding *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) is evaluated as new active substance, therefore, all information is considered and evaluated as new.

Literature reference included by the applicant comes from a literature search according to EFSA (2011)¹² in order to identify relevant recent published peer reviewed references covering the last 10 years. The RMS has also included relevant studies considered important to support the application for the approval of *Spodoptera exigua* multipolyhedrovirus (SeMNPV) genotype pool BV-0004 and the microbial product SPEXIT.

⁸Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230 of 19.8.1991.C.

⁹Programme of renewal Regulation EU 686/2012 (AIR-III programme).

¹⁰SANCO/2012/11284 –rev. 22, December 2018. Draft working document AIR III renewal programme.

¹¹Commission implementing regulation (EU) No 844/2012, of 18 September 2012. Setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

¹²Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2) 2092.

A.1 IDENTITY OF THE MICROORGANISMS

Data point	Author(s)	Year	Title Company Report No Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Data Protec- tion Claimed Y/N	Owner
KMA 1.3/06 MA B.1/01	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application Z Angew Entomol, 82, 129-134 Not available; Not applicable. GLP/GEP: no Published: yes	N	N	Public
KMA1.3/01 MA B.1/02 MA B.1.3.2/05 MA B.1.3.3/01 MA B1.3.2/05	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculoviruses not available, not applicable OECD Organisation for Economic Co-operation and Development, 2002 Not available; Not applicable. GLP/GEP: no Published: yes	N	N	Public
KMA 1.3/04 MA B.1.3.1/01	Schöenfelder, M.	2006	The baculovirus preparation SENPV Andermatt Biocontrol AG, CH, not applicable not available GLP/GEP: no Published: no	N	N	ABA
KMA 1.3/07 MA B.1.3.1/02 MA B1.3.2/01	Jehle, J.A., Lange, M., Wang, H., Hu, Z., Wang, Y., Hauschild, R.	2006	Molecular identification and phylogenetic analysis of baculoviruses from lepidoptera. Virology, 346, 180-193 Not available; Not applicable. GLP/GEP: no Published: yes	N	N	Public
KMA 1.3/03 MA B.1.3.2/02	Rohrmann, G.F.	2013	Chapter 1: introduction to the baculoviruses, their taxonomy and evolution Baculovirus Molecular Biology, 3rd edition, 1-24 Not available; Not applicable. GLP/GEP: no Published: yes	N	N	Public
KMA 1.3/11 MA B.1.3.2/03 MA B1.3.3/11	Thèzè, J., Cabodevilla, O., Palma, L., Williams, T., Caballero, P., Herniou, E.A.	2014	Genomic diversity in european <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus isolates not available, not applicable Journal of General Virology, 95, 2297-2309 GLP/GEP: no Published: yes	N	N	-

Data point	Author(s)	Year	Title Company Report No Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Data Protec- tion Claimed Y/N	Owner
MA B.1.3.2/04	King, A. M.; Lefkowitz, E.; Adams, M. J.; Carstens, E. B.	2011	Baculoviridae. In Virus Taxonomy: Ninth Report of the International Committee on Taxonomy of Viruses; Eds.; Elsevier, 2011; pp. 163–173. GLP/GEP: no Published: yes	N	N	
MA B.1.3.2/05	Yingjian Chen	2019	Identification and genomic sequence analysis of a new <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus, SeMNPV-QD, isolated from Qingdao, China. Journal of Invertebrate Pathology 160 (2019) 8–17	N	N	
MA B.1.3.2/06	Thézé, J.; Lopez- Vaamonde, C.; Cory, J.S.; Herniou, E.A.,	2018	Biodiversity, Evolution and Ecological Specialization of Baculoviruses: A Treasure Trove for Future Applied Research. Viruses 2018, 10, 366. Not available; Not applicable. GLP/GEP: no Published: yes	N	N	Public
MA B.1.3.3/01	R. Murillo, M.S. Hussey, and R. D. Possee	2011	Evidence for covert baculovirus in 4 fections in a <i>Spodoptera exigua</i> laboratory culture	N	N	
MA B.1.3.30/02	Gelernter, W. D. and Federici, B. A.	1986	Isolation, identification and determination of virulence of a nuclear polyhedrosis virus from the beet army worm, <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae). Environmental Entomology 15, 240-245.	N	N	
KMA 1.3/07 MA B.1.3.3/03 MA B1.1.3.4/01	Jehle, J., Matt- Schmid, A.	2007	comparative restriction analysis of <i>Spodoptera exigua</i> nucleopolyhedrovirus (SPEMNPV) SPEXIT with SEMNPV SPOD-X Andermatt Biocontrol AG, CH, not applicable not available GLP/GEP: no Published: no	N	N	ABA

Data point	Author(s)	Year	Title Company Report No Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Data Protec- tion Claimed Y/N	Owner
MA B.1.3.3/04 B.1.3.3/01	Jehle, J.A., Lange, M., Wang, H., Hu, Z., Wang, Y., Hauschild, R	2006	Molecular identification and phylogenetic analysis of baculoviruses from Lepidoptera not available, not applicable Virology, 346, 180-193 GLP/GEP: no Published: yes	N	N	
KMA 1.3/05 MA B.1.3.3/05	Jianfeng, Z.	2005	the identity of <i>Spodoptera exigua</i> nuclear polyhedrosis virus (SENPV) strain Andermatt Biocontrol AG, CH, not applicable not available GLP/GEP: no Published: no	N	N	ABA
KMA2.7/03 MA B.1.3.3/06	Heldens, J. G., E. A. Van Strien, A. M. Feldmann, P. Kulcsar, D. Mu~noz, D. J. Leisy, D. Zuidema, R. W. Goldbach, and J. M. Vlak	1996	<i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus deletion mutants generated in cell culture lack virulence in vivo. J. Gen. Virol. 77: 3127–3134.	N	N	

Data point	Author(s)	Year	Title Company Report No Source (where different from company) GLP or GEP status Published or not	Verte- brate study Y/N	Data Protec- tion Claimed Y/N	Owner
MA B.1.3.3/07	Caballero, P., T. Williams Y M. López-Ferber	2001	Estructura y clasificación de los baculovirus. pp. 15-46. En: P. Caballero, M. López-Ferber y T. Williams [editores], Los baculovirus y sus aplicaciones como bioinsecticidas en el control biológico de plagas. Phytoma-España, Valencia, España.	N	N	open literature
MA B.1.3.3/08	Lasa, R., Williams, T., Caballero, P	2008	Insecticidal Properties and Microbial Contaminants in a <i>Spodoptera exigua</i> Multiple Nucleopolyhedrovirus (Baculoviridae) Formulation Stored at Different Temperatures.	N	N	open literature
MA B.1.3.3/09	Sonia Elvira, M. Angeles Ibargutxi, Noelia Gorria, Delia Muñoz, Primitivo caballero, and Trevor Williams	2013	Insecticidal Characteristics of Two Commercial <i>Spodoptera exigua</i> Nucleopolyhedrovirus Strains Produced on Different Host Colonies. J. Econ. Entomol. 106(1): 50-56	N	N	open literature
MA B.1.3.3/10	Zamora-Avilés	2018	Zamora-Avilés, N., Murillo, R., Lasa, R., Pineda, S., Figueroa, J.I., Bravo-Patiño, A., Díaz, O., Corrales, J.L., Martínez, A.M., 2017. Genetic and biological characterization of four nucleopolyhedrovirus isolates collected in Mexico for the control	N	N	open literature
KMA 1.3/10 MA B.1.3.3/11	Wang, Q., Bosch, B.-J., Vlak, J.M., van Oers, M.M., Rottier, P.J., van Lent, J.W.M.	2016	Budded baculovirus particle structure revisited not available, not applicable Journal of Invertebrate Pathology, 134, 15-22 GLP/GEP: no Published: yes	N	N	-
KMA 1.3/09 MA B.1.3.5/01	Gueli Alletti, G.	2018	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus (semnpv: Biological properties Andermatt Biocontrol AG, CH, 356159-MA-02-01 GAB Consulting GmbH, Heidelberg, Germany GLP/GEP: no Published: no	N	Y	ABA ¹³

¹³ ABA – Andermatt Biocontrol AG

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
KMP 1.4/01 MP B.1.3	Schoenfelder, M.	2006	THE BACULOVIRUS PREPARATION SENPV Andermatt Biocontrol AG, CH, not applicable not available GLP/GEP: no Published: no	no	no	not protected	ABA

A.2 BIOLOGICAL PROPERTIES OF THE MICROORGANISMS

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 on claimed Y/N	Justification if data protection is claimed	Owner
KMA 1.3/02 MA B.2/01 MAB.2.1.1/22	Jehle, J.A., Lange, M., Wang, H., Hu, Z., Wang, Y., Hauschild	2006	Molecular identification and phylogenetic analysis of baculoviruses from Lepidoptera not available, not applicable Virology, 346, 180-193 GLP/GEP: no Published: yes	N	N	not protected	
KMA 2.3/03 MA B.2/02 MA B.2.3/01/03	Gröner, A.	1986	Specificity and safety of baculoviruses. not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes	N	N	Open literature	
KMA 2.3/03 MA B.2/3	Martignoni, M.E. and Iwai, P.J.	1986	Propagation of multinucleocapsid nuclear polyhedrosis virus of <i>Orygia pseudotsugata</i> in larvae of <i>Trichoplusia ni</i> . Journal of Invertebrate Pathology 47, 32-41.	N	N	Open literature	
KMA 2.3/03 MA B.2/04	Moscardi, F.	1990	Development and use of soybean caterpillar baculovirus in Brazil. pp. 184-187 In: Proceedings and Abstracts, Vth International Colloquium on Invertebrate Pathology and Microbial Control, Adelaide, Australia, 20-24	N	N	Open literature	
KMA 2.3/03 MA B.2/05 MA B.2.1/07 MA B.2.8.4/05	Myers, J. H., and J. S. Cory.	2013	.Population Cycles in Forest Lepidoptera Revisited. Pages 565-592 in D. J. Futuyma, editor. Annual Review of Ecology, Evolution, and Systematics, Vol 44.	N	N	Open literature	
KMA 2.3/03 MA B.2/06	Erlandson, M. A.	2009	Genetic variation in field populations of baculoviruses: mechanisms for generating variation and its potential role in baculovirus epizootiology. Virol Sin 24, 458-469.	N	N	Open literature	

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 on claimed Y/N	Justification if data protection is claimed	Owner
KMA 2.3/03 MA B.2/07	EFSA supporting publication	2013	Scientific support, literature review and data collection and analysis for risk assessment on microbial organisms used as active substance in plant protection products –Lot 1 Environmental Risk characterization (2013:EN-518).	N	N	Open literature	
KMA 1.3/01 KMA 2.1.1/01 KMA 2.3/03 MA B.2/08 MA B.2.1/06 MA B.2.3/01/04 MA B.2.4/01 MA B.2.6/01 MA B.2.9/01	OCDE document	2002	Consensus document on information used in the assessment of environmental applications involving baculoviruses not available, not applicable OECD Organisation for Economic Co-operation and Development, 2002 GLP/GEP: no Published: yes	N	N	Open literature	
KMA 2.1.1/06 MA B.2/09 MA B.2.7.2/01	Ijkel, W.F.J., van Strien, E.A., Heldens, J.G.M., Broer, R., Zuidema, D., Goldbach, R.W., Vlak, J.M.	1999	Sequence and organization of the <i>spodoptera exigua</i> multicapsid nucleopolyhedrovirus genome not available, not applicable Journal of General Virology, 80, 3289-3304 GLP/GEP: no Published: yes	N	N	Open literature	
MA B.2.1/01	Cunningham J.C.	1995	Baculoviruses as microbial insecticides. In R. Reuveni (ed.). Novel Approaches to Integrated Pest Management. pp. 261–292. Lewis Publishers, Boca Raton, FL.	N	N	Open literature	
KMA 2.1.1/03 MA B.2.1/02 MA B.2.5.1/01	Rohrmann, G.F.	2013	Chapter 1: Introduction to the baculoviruses, their taxonomy and evolution not available, not applicable Baculovirus Molecular Biology, 3rd edition, 1-24 GLP/GEP: no Published: yes	N	N	Open literature	
MA B.2.1/03	Huber, J.	1986	Use of baculovirus in pest management programs. In R.R. Granados and B.A. Federici (eds.). The Biology of Baculoviruses, Vol. 2, Practical Applications for Insect Control. pp. 181–202. CRC Press, Boca Raton, FL.	N	N	Open literature	

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 Y/N	Justification if data protection is claimed	Owner
MA B.2.1/04	Wallace and Cunningham	1995	Wallace, D.R. and J.C. Cunningham. 1995. Diprionid sawflies. In J.A.Armstrong and W.G.H. Ives (eds.). Forest Pest Insects in Canada. pp. 193–232. Natural Resources Canada, Ottawa, ON.	N	N	Open literature	
KMA 2.1.1/02 MA B.2.1/05	Mazid, S., Kalita, J.C., Rajkhowa, R.C.	2011	A REVIEW ON THE USE OF BIOPESTICIDES IN INSECT PEST MANAGEMENT not available, not available International Journal of Science and Advanced Technology, 1, 169 - 178 GLP/GEP: no Published: yes	N	N	Open literature	
MA B.2.1/07 MA B.2.2.3/01	Cory J.S	2015	Insect virus transmission: different routes to persistence. Curr Opin Insect Sci 8:1-6	N	N	Open literature	
KMA 2.2.2/08 MA B.2.1/08 MA B.2.2.3/05	Virto, C., Navarro, D., del Mar Tellez, M., Williams, T., Murillo, R., Caballero, P.	2016	Mixtures of vertically and horizontally transmitted variants of <i>Spodoptera exigua</i> multiple nucleopolyhedroviruses (SeMNPV) as the basis for biological insecticides not available, not applicable IOBC/wprs Bulletin, 113, 131-135 GLP/GEP: no Published: yes	N	N	Open literature	
MA B.2.1/09	Arrizubieta, M., Simón O., Williams T., Caballero, P	2015	A novel binary mixture of <i>Helicoverpa armigera</i> single nucleopolyhedrovirus (HearSNPV) genotypic variants has improved insecticidal characteristics for control of cotton bollworms. Appl. Environ Microbiol 81:3984-3993	N	N	Open literature	
MA B.2.1/10	Bernal A., Simon O., Williams T., Muñoz D., Caballero P.	2013	<i>A. Chrysodeixis chalcites</i> single-nucleocapsid nucleopolyhedrovirus population from the Canary islands is genetically structured to maximize survival. Appl Environ Microbiol 79:7709-7718	N	N	not protected	

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 on claimed Y/N	Justification if data protection is claimed	Owner
KMA 2.1.2/02 MA B.2.1/11 MA B.2.5/01	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application not available, not applicable Z Angew Entomol, 82, 129-134 GLP/GEP: no Published: yes	N	N	not protected	-
MA B2.1.1/01	Smits, P.H.	1987	Smits, P.H., 1987. Nuclear polyhedrosis virus as biological control agent of <i>Spodoptera exigua</i> . PhD Thesis, Wageningen Agricultural University, Wageningen, The Netherlands	N	N	not protected	
MA B2.1.1/02	Gelernter W.D. and Federici B.A.	1986	Isolation, identification and determination of virulence of a nuclear polyhedrosis virus from the beet armyworm, <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae) Environ. Entomol., vol. 15, pp. 240-245, Apr. 1986	N	N	not protected	
MA B2.1.1/03	Caballero P., Aldebis H. K., Vargas-Osuna E., and Santiago-Alvarez C.	1992	Epizootics caused by a nuclear polyhedrosis virus in populations of <i>Spodoptera exigua</i> in southern Spain. Biocontrol Sci. Technol., vol. 2, pp. 35-38	N	N	not protected	
KMA 2.3/04 MA B2.1.1/04 MA B.2.3/05	Ijkel, W.F.J., van Strien, E., Heldens, J.G.M., Broer, R., Zuidema, D., Goldbach, R.W., Vlak, J.M.	1999	Sequence and organisation of the <i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus genome not available, not applicable Journal of General Virology, 80, 3289 - 3304 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.1.1/07 MA B2.1.1/05	Smits P.H., Vlak, J.M.	1994	Registration of the first viral insecticide in the Netherlands: The development of Spod-X, based on <i>Spodoptera exigua</i> nuclear polyhedrosis virus not available, not applicable Med Fac Landbouww Univ Gent, 59/2a, 385-392 GLP/GEP: no Published: yes	N	N	not protected	-

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 on claimed Y/N	Justification if data protection is claimed	Owner
MA B2.1.1/06	Kolodny-Hirsch, D. M., T. Sitchawat, T. Jansiri, A. Chenrchaivachirakul, and U. Ketunuti	1997	Field evaluation of a commercial formulation of the <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae) nuclear polyhedrosis virus for control of beet armyworm on vegetable crops in Thailand. <i>Biocontrol Sci. Technol.</i> 7: 475–488.	N	N	not protected	
MA B2.1.1/07 MA B.2.2.1/04	Bianchi, F. J., J. M. Vlak, R. Rabbinge, and W. Van der Werf.	2002	Biological control of beet armyworm, <i>Spodoptera exigua</i> , with baculoviruses in greenhouses: development of a comprehensive process-based model. <i>Biol. Control</i> 23: 35–46.	N	N	not protected	
MA B2.1.1/08	Lasa, R., I. Pagola, I. Ibañez, J. E. Belda, T. Williams, and P. Caballero	1997	Efficacy of <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus (SeMNPV) as a biological insecticide for beet armyworm in greenhouse of southern Spain. <i>Biocontrol Sci. Technol.</i> 17: 221–232.	N	N	not protected	
MA B2.1.1/09	Virto, C., Navarro, D., Tellez, M.M., Herrero, S., Williams, T., Murillo, R., Caballero, P	2014	Natural populations of <i>Spodoptera exigua</i> are infected by multiple viruses that are transmitted to their offspring. <i>J. Invertebr. Pathol.</i> 122, 22–27.	N	N	not protected	
MA B2.1.1/10	Steinhaus, E.A	1949	Nomenclature and classification of insect viruses. <i>Bacteriol. Rev.</i> 13, 203–223.	N	N	not protected	
MA B2.1.1/11 MA B.2.3/07	Vlak, J.M., Van Frankenhuyzen, K., Peters, D., Gröner, A	1981	Identification of a new nuclear polyhedrosis virus from <i>Spodoptera exigua</i> . <i>J. Invertebr. Pathol.</i> 38, 297–298.	N	N		
MA B2.1.1/12 MA B.2.3/08	Gelernter, W.D., Federici, B.A.,	1986	Isolation, identification, and determination of virulence of a nuclear polyhedrosis virus from the beet armyworm, <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae). <i>Environ. Entomol.</i> 15, 24–245.	N	N	not protected	
MA B2.1.1/13	Caballero, P., Zuidema, D., Santiago-Alvarez, C., Vlak, J.M.,	1992	Biochemical and biological characterization of four isolates of <i>Spodoptera exigua</i> nuclear polyhedrosis virus. <i>Biocontrol Sci. Technol.</i> 2, 145–157.	N	N	not protected	

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MA B2.1.1/14	Kolodny-Hirsch	1993	D. M. Kolodny-Hirsch, D. L. Warkentin, B. Alvarado-Rodriguez, and R. Kirkland, "Spodoptera exigua nuclear polyhedrosis virus as a candidate viral insecticide for the beet armyworm (Lepidoptera: Noctuidae)," J. Econ. Entomol., vol. 86, pp. 314-321, Apr. 1993.	N	N	not protected	
MA B2.1.1/15	A. Kondo, M. Yamamoto, S. Takashi, and S. Maeda,	1994.	"Isolation and characterization of nuclear polyhedrosis viruses from the beet armyworm Spodoptera exigua (Lepidoptera: Noctuidae) found in Shiga, Japan," Appl. Entomol. Zool., vol. 29, pp. 105-111, Jan.	N	N	not protected	
MA B2.1.1/16	K. Hara, M. Funakoshi, and T. Kawarabata	1995	, "In vivo and in vitro characterization of several isolates of Spodoptera exigua nuclear polyhedrosis virus," Acta Virol., vol. 39, pp. 215-222	N	N	not protected	
MA B2.1.1/17	H. F. Guo, J. C. Fang, W. F. Zhong, and B. S. Liu	2013	, Interactions between Meteorus pulchricornis and Spodoptera exigua multiple nucleopolyhedrovirus," Insect Sci., vol. 13, pp. 1-12	N	N	not protected	
MA B2.1.1/18 MA B.2.2.1/9	Zamora-Avilés N. Zamora-Avilés, R. Murillo, R. Lasa, S. Pineda, J. I. Figueroa, A. Bravo-Patiño, O. Díaz, J. L. Corrales, and A. M. Martínez	2017	Genetic and biological characterization of four nucleopolyhedrovirus isolates collected in Mexico for the control of Spodoptera exigua (Lepidoptera: Noctuidae)," J. Econ. Entomol., vol. 110, pp. 1465-1475				
KMA 2.1.1/08 MA B2.1.1/19 MA B.2.2.4/01 MA B.2.7/01 MA B.2.7.3/02	Muñoz, D., Castillejo, J.I., Caballero, P	1998	Naturally Occurring Deletion Mutans are Parasitic Genotypes in a wild-type Nucleopolyhedrovirus Population of Spodoptera exigua not available, not applicable Applied and Environmental Microbiology, 64, No. 11, 4372-4377 GLP/GEP: no Published: yes	N	N	not protected	

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MA B2.1.1/20	Murillo, R., D. Muñoz, C. Ruiz-Portero, D. M. Alcazar, E. J. Belda, T. Williams, and P. Caballero.	2007	Abundance and genetic structure of nucleopolyhedrovirus populations in greenhouse substrate reservoirs. Biol. Control 42: 216–225.	N	N	not protected	
KMA2.1.1/04 MA B2.1.1/21	Jianfeng, Z.	2005	The identity of <i>Spodoptera exigua</i> Nuclear Polyhedrosis Virus (SeNPV) strain Andermatt Biocontrol AG, CH, not applicable not available GLP/GEP: no Published: no	N	N		ABA
MA B.2.2.1/01	Smagghe, G., Pineda, S., Carton, B., Del Estal, P., Budia, F., Viñiela, E.	2003	Toxicity and kinetics of methoxyfenozide in greenhouse-selected <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae). Pest Manag. Sci. 59, 1203–1209	N	N	not protected	-
MA B.2.2.1/02	Su, R., Zheng, G.L., Wan, F.H., Li, C.Y.	2016	Establishment and characterization of three embryonic cell lines of beet armyworm, <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae). Cytotechnology 68, 1223–1232.	N	N	not protected	
MA b.2.2.1/03	Osorio, A., Martinez, A.M., Schneider, M.I., Diaz, O., Corrales, L.J., Aviles, C.M., Pineda, S.	2008	Monitoring of beet armyworm resistance to spinosad and methoxyfenozide in Mexico. Pest Manag. Sci. 64, 1001–1007.	N	N	not protected	
MA B.2.2.1/05	Saeed, S., Sayyed, A.H., Ahmad, I.	2010	Effect of host plants on life-history traits of <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae). J. Pest. Sci. 83, 165–172.	N	N	not protected	
MA B.2.2.1/06	Underwood, N	2011	Density dependence in insect performance within individual plants: induced resistance to <i>Spodoptera exigua</i> in tomato. Oikos 119, 1993–1999	N	N	not protected	
MA B.2.2.1/07	Zheng et al Zheng, X.L., Cong, P.X., Wang, P.X., Lei, L.C.	2011	A review of geographic distribution, overwintering and migration in <i>Spodoptera exigua</i> Hübner (Lepidoptera: Noctuidae). J. Entomol. Res. Soc. 13, 39–48.	N	N	not protected	

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MA B.2.2.1/08	Sayyed, H.A., Naveed, M., Rafique, M., Arif, M.J.	2012	Detection of insecticides resistance in <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae) depends upon insect collection methods. Pakistan Entomol. 34, 7–15.	N	N	not protected	
KMA 2.2.1/01 MA B.2.2.1/10	Hill, D.S.	1983	Agricultural insect pests of the tropics and their control not available, not available Cambridge University Press, 376 GLP/GEP: no Published: yes no not protected	N	N	not protected	
KMA 2.2.1/02 MA B.2.2.1/11	Moulton, J.K., Pepper, D.A., Dennehy, T.J.	2000	Beet armyworm (<i>Spodoptera exigua</i>) resistance to spinosad not available, not applicable Pest Management Science, 56, 842-848 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.1/03 MA B.2.2.1/12	Wang, W., Mo, J., Cheng, J. Zhunang, P., Tang, Z.	2006	Selection and characterization of spinosad resistance in <i>Spodoptera exigua</i> (hübner) (Lepidoptera: Noctuidae) not available, not available Pesticide Biochemistry and Physiology, 84, 180-187 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.2/01 MA B.2.2.2/01	Evans, H.F., Harrap, K.A.	1982	Persistence of insect viruses not available, not applicable Virus Persistence, Publisher: Cambridge University Press, 58-96 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.2/02 MA B.2.2.2/02	Martins, T., Montiel, R., Medeiros, J., Oliveira, L., Simones, N.	2005	Occurrence and characterization of a nucleopolyhedrovirus from <i>Spodoptera littoralis</i> (Lepidoptera: Noctuidae) isolated in the Azores not available, not applicable Journal of Invertebrate Pathology, 89, 185-192 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.2.2.3/02 MA B.2.4.1/01 MA B.2.8.4/01	Williams T, Virto C, Murillo R and Caballero P	2017	Covert Infection of Insects by Baculoviruses. Front. Microbiol. 8:1337. doi: 10.3389/fmicb.2017.01337	N	N	not protected	

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KMA 2.2.2/06 MA B.2.2.3/03	Cabodevilla, O., Villar, E., Virto, C., Murillo, R., Williams, T., Caballero, P.	2011a	Intra- and intergenerational persistence of an insect nucleopolyhedrovirus: adverse effects of sublethal disease on host development, reproduction, and susceptibility to superinfection not available, not applicable Applied and Environmental Microbiology, 77(9), 2954-2960 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.2/07 MA B.2.2.3/04	Cabodevilla, O., Ibañez, I., Simón, O., Murillo, R., Caballero, P., Williams, T.	2011b	Occlusion body pathogenicity, virulence and productivity traits vary with transmission strategy in a nucleopolyhedrovirus not available, not applicable Biological Control, 56, 184-192 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.2.2.3/6 MA B.2.8.4/03 MA B.2.8.4/07	Virto, C., Williams, T., Navarro, D., Tellez, M. M., Murillo, R., and Caballero, P.	2017	Can mixtures of horizontally and vertically transmitted nucleopolyhedrovirus genotypes be effective for biological control of <i>Spodoptera exigua</i> ? J. Pest Sci. 90, 331–343. doi: 10.1007/s10340-016-0743-x	N	N	not protected	-
KMA 2.2.2/10 MA B.2.2.3/07 MA B.2.2.4/05	Caballero, P., Murillo, R., Munoz, D., Williams, T.	2009	El nucleopoliedrovirus de <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae) como bioplaguicida: análisis de avances recientes en España not available, not applicable Revista Colombiana de Entomología, 35(2), 105-115 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.2/13 MA B.2.2.3/08 MA B.2.2.5/03	van Houte, S., van Oers, M.M., Han, Y., Vlak, J.M., Ros, V.I.D.	2015	Baculovirus infection triggers a positive phototactic response in caterpillars: a response to Dobson et al. (2015) not available, not applicable Biology Letters, 11, 1-4 GLP/GEP: no Published: yes	N	N	not protected	-

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KMA 2.2.2/11 KMA 7.2/07 MA B.2.2.3/09 MA B.2.2.5/01	van Houte, S., Ros, V. I. D., van Oers, M. M.	2014	Hyperactivity and tree-top disease induced by the baculovirus AcMNPV in <i>Spodoptera exigua</i> larvae are governed by independent mechanisms not available, not available Naturwissenschaften, 101, 347-350 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.2/14 MA B.2.2.3/10 MA B.2.2.5/04	Rebolledo, D. Lasa, R., Guevara, R., Murillo, R., Williams, T.	2015	Baculovirus-Induced Climbing Behavior Favors Intraspecific Necrophagy and Efficient Disease Transmission in <i>Spodoptera exigua</i> not available, not applicable PloS ONE, 1-16 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.2/12 MA B.2.2.3/11 MA B.2.2.5/02	Dobson, A.D.M., Auld, S.K.J.R., Tinsley, M.C.	2015	Insufficient evidence of infection-induced phototactic behaviour in <i>Spodoptera exigua</i> : a comment on van Houte et al. (2014) not available, not applicable Biology Letters, 11, 1-3 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.2/15 MA B.2.2.3/12 MA B.2.2.6/04	Wan, N.-F., Jiang, J.-X., Li, B.	2016	Effect of host plants on the infectivity of nucleopolyhedrovirus to <i>Spodoptera exigua</i> larvae not available, not applicable Journal of Applied Entomology, 140, 636-644 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.2.2.4/02 MA B.2.7.3/01	Muñoz, D., J. M. Vlak, and P. Caballero	1997	In vivo recombination between two strains of the genus Nucleopolyhedrovirus in its natural host, <i>Spodoptera exigua</i> . Appl. Environ. Microbiol. 63:3025–3031.	N	N	not protected	

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KMA 2.7/06 MA B.2.2.4/03	Serrano, A., Pijlman, G.P., Vlak, J.M., Muñoz, D., Williams, T., Caballero, P.	2015	Identification of <i>Spodoptera exigua</i> nucleopolyhedrovirus genes involved in pathogenicity and virulence not available, not applicable Journal of Invertebrate Pathology, 126, 43-50 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.2.1/04 MA B.2.2.4/04 MA B.2.4.1/02	Pascual, L., Jakubowska, A.K., Blanca, J.M., Cañizares, J., Ferré, J., Gloeckner, G., Vogel, H., Herrero, S.	2012	The transcriptome of <i>Spodoptera exigua</i> larvae exposed to different types of microbes not available, not applicable Insect Biochem Molec Biol, 42, 557-570 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.2.2.6/01	Hoover, K., Washburn J.O., Volkman L.E.	2000	Midgut-based resistance of <i>Heliothis virescens</i> to baculovirus infection mediated by phytochemicals in cotton. J. Insect Physiol., 46,999-1007	N	N	not protected	
MA B.2.2.6/02	Ali M.I., Young S.Y., McNew R.C.	2004	Host plant influence on activity of <i>Bacillus thuringiensis</i> Berliner against lepidopterus pests of crops. J. Entomol Sci, 39	N	N	not protected	
MA B.2.2.6/03	Shikano I., Ericsson J.D., Cory J.S., Myers J.H.,	2010	Indirect Plant-mediated effects on insect immunity and disease resistance in a tritrophic system. Basic Appl Ecol, 11,15-22	N	N	not protected	
KMA 2.3/01 MA B.2.3/01/01	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 2.3/02 MA B.2.3/01/02	Simón, O., Williams, T., López-Ferber, M., Caballero, P.	2004	Virus entry or the primary infection cycle are not the principal determinants of host specificity of <i>Spodoptera</i> spp. nucleopolyhedroviruses not available, not applicable Journal of General Virology, 85, 2845 - 2855 GLP/GEP: no Published: yes	N	N	not protected	-

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MA B.2.3/01/06	Chen Y., Qia B., Zheng G., Zhang Y., Deng F., Wan, F., Li C.	2019	Identification and genomic sequence analysis of a new <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus, SeMNPV-QD, isolated from Qingdao, China. Journal of Invertebrate Pathology 160 (2019) 8–17.	N	N	not protected	-
KMA 2.4/02 MA B.2.4/02	Entwistle, P.F., Adams, P.H.W., Evans, H.F.	1978	Epizootiology of a nuclear polyhedrosis virus in european spruce sawfly (<i>Gilpinia hercyniae</i>): The rate of passage of infective virus through the gut of birds during cage tests not available, not applicable Journal of Invertebrate Pathology 31, 307-312, 1978 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.2.2.5.1/02	Monteiro, F., Carinhas, N., Carrondo, M. J., Bernal, V., and Alves, P. M.	2012	Toward system-level understanding of baculovirus-host cell interactions: from molecular fundamental studies to large-scale proteomics approaches. Front. Microbiol. 3:391. doi: 10.3389/fmicb.2012.00391	N	N	not protected	
MA B.2.7.1/01	Lua, L. H. L., Pedrini, M. R. S., Reid, S., Robertson, A., Tribe, D.E.	2002	Phenotypic and genotypic analysis of <i>Helicoverpa armigera</i> nucleopolyhedrovirus serially passed in cell culture. Journal of General Virology, 83: 945-955	N	N	not protected	
MA B.2.7.1/02	Heldens, J. G., Broer, R., Zuidema, D., Goldbach, R. W. & Vlak, J. M	1997	Identification and functional analysis of a non-hr origin of DNA replication in the genome of <i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus. J Gen Virol 78, 1497–1506.	N	N	not protected	
MA B.2.7.1/03	Chaeychomsri S.	2018	Replication and Occlusion Body Formation of <i>Spodoptera exigua</i> Multicapsid Nucleopolyhedrovirus in a Homologous Cell Line Journal of Advanced Agricultural Technologies doi: 10.18178/joaat.5.3.236-244	N	N	not protected	
MA B.2.7.1/04	Liu, S., Chen, Y., and Bonning, B. C.	2015	RNA virus discovery in insects. Curr. Opin. Insect Sci. 8, 54–61. doi: 10.1016/j.cois.2014.12.005	N	N	not protected	

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MA B.2.7.1/05	Airenne KJ, Makkonen KE, Mähönen AJ and Ylä-Herttuala S.	2010	Baculoviruses Mediate Efficient Gene Expression in a Wide Range of Vertebrate Cells. In: Merten OW and Al-Rubeai M. (eds.), Viral Vectors for Gene Therapy: Methods and Protocols, Methods in Molecular Biology, 737, 279-303.	N	N	not protected	
MA B.2.7.1/06	Condreay JP, Witherspoon SM, Clay WC and Kost TA.	1999	Transient and stable gene expression in mammalian cells transduced with a recombinant baculovirus vector. Proc. Natl. Acad. Sci. USA, 96, 127-132.	N	N	not protected	
MA B.2.7.1/07	Hu, YC.	2008	Baculoviral vectors for gene delivery : a review. Current Genetic Therapy, 8, 54-65.	N	N	not protected	
MA B.2.7.1/08	Cheng T, Xu CY, Wang YB, Chen M, Wu T, Zhang J and Xia NS.	2004	A rapid and efficient method to express target genes in mammalian cells by baculovirus. World J Gastroenterol., 10, 1612-1618.	N	N	not protected	
MA B.2.7.1/09	Airenne KJ, Hu YC, Kost TA, Smith RH and Kotin RM.	2013	Baculovirus: an insect-derived vector for diverse gene transfer applications. Mol Ther, 21, 739-49.	N	N	not protected	
MA B.2.7.1/10	Sun XC, Cheng GY, Zhou MZ, Hu ZH and Sun XL.	2005	Transfer of the AaIT Gene of a Recombinant <i>Helicoverpa armigera</i> Nucleopolyhedrovirus to its Surrounding Organisms. Virologica Sinica, 20, 420-423.	N	N	not protected	
MA B.2.7.1/11	Arends	2005	http://vir.sgmjournals.org/content/86/10/2731.full - aff-1 HM, Winstanley D and Jehle JA. Virulence and co-mutagenesis of <i>Cydia pomonella</i> granulovirus mutants: parameters that do not match. J Gen Virol, 86, 2731-2738.	N	N	not protected	
MA B.2.7.1/12	Kang WK, Tristem M, Maeda S, Crook NE and O'Reilly DR.	1998	Identification and characterization of the <i>Cydia pomonella</i> granulovirus cathepsin and chitinase genes. Journal of General Virology, 79, 2283-2292.	N	N	not protected	

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MA B.2.7.1/13	Lauzon HAM, Garcia-Maruniak A, Zannotto PMA, Clemente JC, Herniou EA, Lucarotti CJ, Arif BM and Maruniak JE.	2006	Genomic coMAarison of <i>Neodiprion sertifer</i> and <i>Neodiprion lecontei</i> nucleopolyhedroviruses and identification of potential hymenopteran baculovirus-specific open reading frames. J Gen Virol, 87, 1477-1489.	N	N	not protect ed	
MA B.2.7.1/14	Rohrmann G	2011	Introduction to the baculoviruses, their taxonomy, and evolution. in: Baculovirus Molecular Biology: Second Edition.	N	N	not protect ed	
MA B.2.7.2/02	Thézé, J., Cabodevilla, O., Palma, L., Williams, T., Caballero, P., and Herniou, E. A.	2014	Genomic diversity in European <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus isolates. J. Gen. Virol. 95, 2297–2309. doi: 10.1099/vir.0.064766-0	N	N	not protect ed	
KMA 2.5/01 MA B2.8/01 MA B2.8.3/01	Jaques, R.A.	1977	Stability of entomopathogenic viruses not available, not applicable Misc Publ Entomological Soc America, 10(3), 99-119 GLP/GEP: no Published: yes	N	N	not protect ed	-
KMA 2.5/02 MA B2.8/02	Krieg, A., Gröner, A., Huber, J., Zimmermann, G.	1981	Inactivation of certain Insect Pathogens by Ultraviolet Radiation not available, not applicable Journal of Plant Diseases and Protection, 88 (1), 38-48 GLP/GEP: no Published: yes	N	N	not protect ed	-
KMA 2.5/03 MA B2.8/03 MA B2.8.3/02	Evans, H.F., Harrap, K.A.	1982	Persistence of insect viruses not available, not applicable Virus Persistence, Publisher: Cambridge University Press, 58-96 GLP/GEP: no Published: yes Submitted in: KMA 2.2.2/01	N	N	not protect ed	-
KMA 2.5/04 MA B2.8/04	Thomas, E.D., Reichelderfer, C.F., HeiMAel, A.M.	1973	The effect of soil pH on the persistence of cabbage looper nuclear polyhedrosis virus in soil not available, not applicable Journal of invertebrate Pathology, 21, 21-25 GLP/GEP: no Published: yes	N	N	not protect ed	-

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MA B2.8.4/03	Ebert, D.	2013	The epidemiology and evolution of symbionts with mixed-mode transmission. <i>Annu. Rev. Ecol. Evol. Syst.</i> 44, 623–643. doi: 10.1146/annurevcolsys-032513-100555	N	N	not protected	
MA B2.8/0	Ignoffo Ignoffo, C. M	1992	Environmental factors affecting persistence of entomopathogens. <i>Fla. Entomol.</i> 75: 516-525.	N	N	not protected	
MA B2.8.4/04	Cooper, D., Cory, J. S., Theilmann, D. A., and Myers, J. H.	2003	Nucleopolyhedroviruses of forest and western tent caterpillars: cross-infectivity and evidence for activation of latent virus in high-density field populations. <i>Ecol. Entomol.</i> 28, 41–50. doi: 10.1046/j.1365-2311.2003.00474.x	N	N	not protected	
MA B2.8.4/06	Hostetter, D. L., and Bell, M. R.	1985	“Natural dispersal of baculoviruses in the environment,” in <i>Viral Insecticides for Biological Control</i> , eds K. Maramorosch and K. E. Sherman (Orlando, FL: Academic Press), 249–284. doi: 10.1016/B978-0-12-470295-0.50014-8	N	N	not protected	
MA B2.8.4/07	Burden, J. P., Griffiths, C. M., Cory, J. S., Smith, P., and Sait, S. M	2003	Vertical transmission of sublethal granulovirus infection in the Indian meal moth, <i>Plodia interpunctella</i> . <i>Mol. Ecol.</i> 11, 547-555.	N	N	not protected	
MA B2.8.4/08	Vilaplana, L., Wilson, K., Redman, E., and Cory, J.	2010	Pathogen persistence in migratory insects: high levels of vertically-transmitted virus infection in field populations of the African armyworm. <i>Evol. Ecol.</i> 24, 147-160.	N	N	not protected	
MA B2.8.4/09	Jones, E. O., White, A., and Boots, M.	2011	The evolution of host protection by vertically transmitted parasites. <i>Proc. R. Soc. B</i> 278, 863–870. doi: 10.1098/rspb.2010.1397	N	N	not protected	
MA B2.8.4/10	Hedges, L. M., Brownlie, J. C., O'Neill, S. L., and Johnson, K. N	2008	Wolbachia and virus protection in insects. <i>Science</i> 322:702. doi: 10.1126/science.1162418	N	N	not protected	

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 on claimed Y/N	Justification if data protection is claimed	Owner
MA B2.8.4/11	Xu, P., Liu, Y., Graham, R. I., Wilson, K., and Wu, K	2013	Densovirus is a mutualistic symbiont of a global crop pest (<i>Helicoverpa armigera</i>) and protects against a baculovirus and Bt biopesticide. PLoS Pathog. 10:e1004490. doi: 10.1371/journal.ppat.1004490	N	N	not protected	
MA B.2.8/12	Graham, R.I., Grzywacz, D., Mushobozi, W.L., Wilson, K.	2012	Wolbachia in a major 522 African crop pest increases susceptibility to viral disease rather than protects. 523 Ecol. Lett. 15, 993–1000.	N	N	not protected	
MA B.2.8/14	Bonsall, M. B., Sait, S. M., and Hails, R. S.B	2005	Invasion and dynamics of covert infection strategies in structured insect–pathogen populations.	N	N	not protected	
MA B.2.8/15	Sorrell, I., White, A., Pedersen, A. B., Hails, R. S., and Boots, M.	2009	The evolution of covert, silent infection as a parasite strategy. Proc. R. Soc. B 276, 2217–2226. doi: 10.1098/rspb.2008.1915	N	N	not protected	
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 on claimed Y/N	Justification if data protection is claimed	Owner
KMP 2.1/01 KMP 2.2.1/01	Konrad, R.	2014	SPEXIT ONE YEAR STORAGE STABILITY AND CORROSION CHARACTERISTICS AT 5 °C Andermatt Biocontrol AG, CH, not available Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA

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 on claimed Y/N	Justification if data protection is claimed	Owner
KMP 2.1/02 KMP 2.2.1/02 KMP 2.7.2/02 KMP 2.7.3/03 KMP 2.7.4/02 KMP 2.7.7/02	Walter, D.	2011	3 Year Storage Stability of the Formulation Helicovex at 5 °C Andermatt Biocontrol AG, CH, 20061550/01-PCTY Eurofins Agroscience Services GmbH GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 2.1/03 KMP 2.2.1/03 KMP 2.5/03 KMP 2.7.2/03 KMP 2.7.3/04 KMP 2.7.4/03 KMP 2.7.7/03	Walter, D.	2018	Physico-chemical Properties of the Formulation Littovir over 2 Years at 5 °C Andermatt Biocontrol AG, CH, S14-03255 Eurofins Agroscience Services EcoChem GmbH / Eurofins Agroscience Services Ecotox GmbH GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 2.2.1/04	Fanger, U.	2007	7 day storage stability of MADEX at 0 °C Andermatt Biocontrol AG, CH, not applicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA

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 on claimed Y/N	Justification if data protection is claimed	Owner
KMP 2.3/01	Ahrens, A.	2011	Explosive Properties A.14. (OPPTS 830.6316) Andermatt Biocontrol AG, CH, 20100409.02 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 2.4/01	Messerschmidt, S.	2006a	Flash Point of HELICOVEX Andermatt Biocontrol AG, CH, 20061440/01-PCFB eurofins-GAB GmbH, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 2.5/01 KMP 2.6/01	Aversa, S.	2013	Physical-chemical Properties: pH, Viscosity and Relative Density of test item Spexit Andermatt Biocontrol AG, CH, BT110/13 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA

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 Y/N	Justification if data protection is claimed	Owner
KMP 2.5/02 KMP 2.6/03	Aversa, S.		Physical-chemical Properties: pH, Viscosity and Relative Density of test item Helicovex Andermatt Biocontrol AG, CH, BT109/13 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 2.6/02	Walter, D.	2004	Surface tension of the formulation Madex Andermatt Biocontrol AG, CH, 20041161/01-PCST GAB Biotechn. GmbH & GAB Analytik GmbH, Niefern-Öschelbronn GLP: yes Published: no	no	no	not protected	ABA
KMP 2.6/04	Messerschmidt, S.	2006b	SURFACE TENSION OF HELICOVEX Andermatt Biocontrol AG, CH, 20061440/01-PCST not available GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 2.7.2/01	Fanger, U.	2005a	Persistent foam (CIPAC MT47.1) foaming of suspension concentrates (CIPAC MT47.2) of Madex Capex Cryptex Andermatt Biocontrol GmbH, CIPAC MT 47 Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA

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 on claimed Y/N	Justification if data protection is claimed	Owner
KMP 2.7.3/01	Fanger, U.	2005b	Suspensibility (CIPAC MT 161) of Madex Andermatt Biocontrol AG, CH, not applicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no	no	no	not protected	ABA
KMP 2.7.3/02	Fanger, U.	2005c	Spontaneity of dispersion (CIPAC MT 160) of Madex Andermatt Biocontrol AG, CH, not applicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no	no	yes	protected	ABA
KMP 2.7.4/01	Fanger, U.	2005d	Sieve analysis (CIPAC MT59) of Madex Capex Cryptex Andermatt Biocontrol GmbH, not applicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 2.7.7/01	Fanger, U.	2005e	Pourability (CIPAC MT 148) of Madex Capex Cryptex Andermatt Biocontrol GmbH, not applicable Andermatt Biocontrol GmbH, Germany GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	ABA

A.3 FURTHER INFORMATION OF THE MICROORGANISMS

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
KMA 3.2/01 MA B.3.1/01 MA B.3.2/01	Anonymous	2018a	SPEXIT Insecticide for the biological control of the beet armyworm (<i>Spodoptera exigua</i>) Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y		ABA
KMA 3.3/02 MA B.3.3/01	Wan, N.-F., Jiang, J.-X., Li, B.	2016	Effect of host plants on the infectivity of nucleopolyhedrovirus to <i>Spodoptera exigua</i> larvae not available, not applicable Journal of Applied Entomology, 140, 636-644 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 3.5/01 MA B.3.5/01	Roush, R.T.	1998	Strategies for Resistance Management not available, not applicable GLP/GEP: no Published: yes	N	N	not protected	-
KMA 3.5/02 MA B.3.5/02	Fritsch, E., Undorf-Spahn, K., Kienzle, J., Zebitz, C.P.W., Huber, J.	2005	Apfelwickler-Granulosevirus: Erste Hinweise auf Unterschiede in der Empfindlichkeit lokaler Apfelwickler-Populationen not available, not applicable Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 57, 29-34 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 3.5/03 MA B.3.5/03	Vijaykumar, K.B.K., Fakrudin, B.	2003a	Effectiveness of <i>Helicoverpa armigera</i> Nuclear Polyhedrosis Virus Against Insecticide Resistant Strains of <i>Helicoverpa armigera</i> (Hubner) (Lepidoptera: Noctuidae) not available, not applicable Resistant Pest Management Newsletter, 13, 27-28 GLP/GEP: no Published: yes	N	N	not protected	-

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
KMA 3.5/04 MA B.3.5/04	Vijaykumar, K.B.K., Fakrudin, B.	2003b	Effect of Nuclear Polyhedrosis Virus Infection on the Insecticide Susceptibility of <i>Heliothis armigera</i> Larvae not available, not applicable Resistant Pest Management Newsletter, 13, 28-30 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.3.5/05	Asser-kaiser asser-kaiser, s., fritsch, e., undorf-spahn, k., kienzle, j., eberle, k.e., gund, n.a., reineke, a., zebitz, c. P. W., heckel, d.g., huberjehle, j. A.,	2007	Rapid Emergence of Baculovirus Resistance in Codling Moth Due to Dominant, Sex-Linked Inheritance. Science, 317, 1916-1918	N	N	not protected	-
MA B.3.5/06	Clem, R. J., and A. L. Passarelli	2013	BACULOVIRUSES: SOPHISTICATED PATHOGENS OF INSECTS. PloS Pathogens 9:e1003729	N	N	not protected	-
MA B.3.5/07	Virto, C., Navarro, D., del Mar Tellez, M., Williams, T., Murillo, R., Caballero, P.	2016	Mixtures of vertically and horizontally transmitted variants of <i>Spodoptera exigua</i> multiple nucleopolyhedroviruses (SeMNPV) as the basis for biological insecticides not available, not applicable IOBC/wprs Bulletin, 113, 131-135 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.3.5/08	Virto, C., Williams, T., Navarro, D., Tellez, M. M., Murillo, R., and Caballero, P.	2017	Can mixtures of horizontally and vertically transmitted nucleopolyhedrovirus genotypes be effective for biological control of <i>Spodoptera exigua</i> ? J. Pest Sci. 90, 331–343. doi: 10.1007/s10340-016-0743-x	N	N	not protected	-

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
MA B.3.5/09	Caballero, P., Murillo, R., Munoz, D., Williams, T.	2009	El nucleopoliedrovirus de <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae) como bioplaguicida: análisis de avances recientes en España not available, not applicable REvista Colombiana de Entomología, 35(2), 105-115 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.3.5/10	Cabodevilla, O., Villar, E., Virto, C., Murillo, R., Williams, T., and Caballero, P.	2011a	Intra- and intergenerational persistence of an insect nucleopolyhedrovirus: Adverse effects of sublethal disease on host development, reproduction, and susceptibility to superinfection. Applied and Environmental Microbiology, 77(9), 2954–2960. GLP/GEP: no Published: yes	N	N	not protected	-
MA B.3.5/11	Cabodevilla, O., Ibañez, I., Simón, O., Murillo, R., Caballero, P., Williams, T.	2011b	Occlusion body pathogenicity, virulence and productivity traits vary with transmission strategy in a nucleopolyhedrovirus not available, not applicable Biological Control, 56, 184-192 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 3.6/01 MA B.3.6/01	Lasa, R., Williams, T., Caballero, P.	2008	Insecticidal Properties and Microbial Contaminants in a <i>Spodoptera exigua</i> Multiple Nucleopolyhedrovirus (Baculoviridae) Formulation Stored at Different Temperatures not available, not applicable Journal of Economic Entomology, 101(1), 42-49 GLP/GEP: no Published: yes	N	N	not protected	-

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
MA B.3.6/02	Podgwaite, J.D., Dubois, N.R., Reardon, R.C. and, Witcosky, J	1993	Retarding outbreak of low-density gypsy moth (Lepidoptera: Lymantriidae) populations with aerial applications of Gypchek and <i>Bacillus thuringiensis</i> . Journal of Economic Entomology 86, 730-734.	N	N	not protected	-
MA B.3.6/03	Garcia-Lara, J., A. J. Needham, and S. J. Foster	2005	Invertebrates as animal models for <i>Staphylococcus aureus</i> pathogenesis: a window into host-pathogen interaction. FEMS Immunol. Med. Microbiol. 43: 311D323.	N	N	not protected	-
KMA 3.7/01 MA B.3.7/01	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus not available, not applicable ENV/JM/MONO, 1, 1-90 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 3.7/02 MA B.3.7/02	Frommer, W., Ager, B., Archer, G., Collins, C.H., Donikian, R., Frontali, C., Hamp, S., Houwink, E.H., Küenzi, M.T., Krämer, P., Lagast, H., Lund, S., Mahler, J.L., Normand-Plessier, F., Sargeant, K., Tuijnenburg Muijs, G., Vranich, S.P., Werner, R.G.	1989	Safety precautions for handling microorganisms of different risk classes not available, not applicable Applied Microbiology and Biotechnology, 30, 541-552 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 3.7/03 MA B.3.8/01	Anonymous	2018b	Safety Data Sheet SPEXIT Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y		ABA

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
KMA 3.3/01	Gueli Alletti, G.	2018	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus (SeMNPV): Biological properties Andermatt Biocontrol AG, CH, 356159-MA-02-01 GAB Consulting GmbH, Heidelberg, Germany GLP/GEP: no Published: no	N	Y		ABA

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
KMP 3/01 B.3.10.2	Hill, D.S.	1983	AGRICULTURAL INSECT PESTS OF THE TROPICS AND THEIR CONTROL not available, not available Cambridge University Press, 376 GLP/GEP: no Published: yes	N	N	not protected	-
KMP 3/02 B.3.16	Simon, O., Williams, T., Lopez-Ferber, M., Caballero, P.	2004	Virus entry or the primary infection cycle are not the principal determinants of host specificity of <i>Spodoptera</i> spp. nucleopolyhedroviruses not available, not applicable Journal of General Virology, 85, 2845-2855 GLP/GEP: no Published: yes	N	N	not protected	-

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
B.3.1.5	Frommer, W., Ager, B., Archer, G., Collins, C.H., Donikian, R., Frontali, C., Hamp, S., Houwink, E.H., Küenzi, M.T., Krämer, P., Lagast, H., Lund, S., Mahler, J.L., Normand-Plessier, F., Sargeant, K., Tuijnenburg Muijs, G., Vranck, S.P., Werner, R.G	1989	Safety precautions for handling microorganisms of different risk classes not applicable Appl Microbiol Biotechnol, 30, 541-552	N	N	not protected	
B.3.2	Evans, H.F., Harrap, K.A.	1982	Persistence of insect viruses	N	N	not protected	
B.3.2	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus not applicable ENV/JM/MONO, 1, 1-90 Report-no. not applicable GLP/GEP: no Published: yes	N	N	not protected	
B.3.2	Muñoz, D., Vlak, J.M., Caballero, P.	1998	Naturally Occurring Deletion Mutants are Parasitic Genotypes in a wild-type Nucleopolyhedrovirus Population of <i>S. exigua</i> Appl Environ Microbiol, 64, No. 11, 4372-4377 Report-no. not applicable GLP/GEP: no Published: yes	N	N	not protected	
B.3.2	Martins, T., Montiel, R., Medeiros, J., Oliveira, L., Simones, N.	2005	Occurrence and characterization of a nucleopolyhedrovirus from <i>Spodoptera littoralis</i> (Lepidoptera: Noctuidae) isolated in the azores not applicable J Invertebr Pathol, 89, 185-192 Report-no. not applicable GLP/GEP: no Published: yes	N	N	not protected	

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
B.3.2	Muñoz, D., Vlask, J.M., Caballero, P.	1997	In vivo Recombination between Two Strains of the Genus Nucleopolyhedrovirus in Its Natural Host <i>S. exigua</i> Appl Environ Microbiol, 63, No. 8, 3025-3031 Report-no. not applicable GLP/GEP: no Published: yes	N	N	not protected	
KMP 3.9/01	Anonymous	2018	SPEXIT INSECTICIDE FOR THE BIOLOGICAL CONTROL OF THE BEET ARMYWORM (<i>S. exigua</i>) Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y		ABA
B.3.10.1 B.3.11	Luna-Espino, J.C., Castrejón-Gómez, V.R., Pineda, S., Figueroa, J.I., and Martínez, A.M.	2018	Effect of Four Multiple Nucleopolyhedrovirus Isolates on the Larval Mortality and Development of <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae): Determination of Virus Production and Mean Time to Death Florida Entomologist, 101(2):153-159 Report-no. not applicable GLP/GEP: no Published: yes	N	N	not protected	
KMP 3.10/01 B.3.10 B.3.12 B.3.13	Mayoral Domínguez, F	2006	SPEXIT efficacy evaluation study 1bl06 GLP/GEP: yes Published: no	N	Y		ABA
KMP 3.10/02 B.3.10 B.3.12	Mayoral Domínguez, F	2006	SPEXIT efficacy evaluation study 2bl06 GLP/GEP: yes Published: no	N	Y		ABA
KMP 3.10/03 B.3.10 B.3.12 B.3.13	Mayoral Domínguez, F	2007	SPEXIT efficacy evaluation study 7bl07 GLP/GEP: yes Published: no	N	Y		ABA
KMP 3.10/04 B.3.10 B.3.12 B.3.13	Mayoral Domínguez, F	2007	SPEXIT efficacy evaluation study 1cl07 GLP/GEP: yes Published: no	N	Y		ABA

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
B.3.10.1 MA B.1.3.3/9	Zamora-Avilés, N., Murillo, R., Lasa, R., Pineda, S., Figueroa, J.I., Bravo-Patiño, A., Díaz, O., Corrales, J.L. and Martínez, A.M.,	2017	Genetic and biological characterization of four nucleopolyhedrovirus isolates collected in Mexico for the control Report-no. not applicable GLP/GEP: no Published: yes	N	N	not protected	
B.3.10.1	Rebolledo, D., Lasa, R., Roger Guevaral, R., Murillo, R., and Williams, T.	2015	Baculovirus-Induced Climbing Behavior Favors Intraspecific Necrophagy and Efficient Disease Transmission in <i>Spodoptera exigua</i> . PLOS ONE DOI:10.1371/journal.pone.0136742 GLP/GEP: no Published: yes	N	N	not protected	
B.3.10.1	Elvira, M. S., Ibargutxi, A., Gorria, N., Muñoz, D., Caballero, P., and Williams, T.	2013	Insecticidal Characteristics of Two Commercial <i>Spodoptera exigua</i> Nucleopolyhedrovirus Strains Produced on Different Host Colonies. J. Econ. Entomol. 106(1): 50-56 GLP/GEP: no Published: yes	N	N	not protected	
B.3.10.1 B.3.11	Cabodevilla, O., Villar, E., Virto, C., Murillo, R., Williams, T., and Caballero, P.	2011	Intra- and intergenerational persistence of an insect nucleopolyhedrovirus: Adverse effects of sublethal disease on host development, reproduction, and susceptibility to superinfection. Applied and Environmental Microbiology, 77(9), 2954–2960. GLP/GEP: no Published: yes	N	N	not protected	
B.3.10.1	Belda, J. E., Mirasol, E., Escribano, A. Rapallo, S. and P. Caballero,	2000	Eficacia de nucleopoliedrovirus (VPNSe) en el control de <i>Spodoptera exigua</i> (Hübner, 1808) (Lepidoptera: Noctuidae) en pimiento de invernadero. Bol. San. Veg. Plagas, 26: 619-628, 2000.	N	N	not protected	
B.3.10.1	Murillo, R., Muñoz, D., Ruiz-Portero, M. C., Alcazar, M. D., Belda, J. E., Williams, T. & Caballero, P.	2007	Abundance and genetic structure of nucleopolyhedrovirus populations in greenhouse substrate reservoirs. Biol Control 42, 216–225.	N	N	not protected	

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
B.3.10.1	Munñoz, D., Castillejo, J. I. and Caballero, P	1998	Naturally occurring deletion mutants are parasitic genotypes in a wild-type nucleopolyhedrovirus population of <i>Spodoptera exigua</i> . Appl Environ Microbiol 64, 4372–4377.	N	N	not protected	
B.3.10.1	Escribano A, Williams T, Goulson D, Cave RD, Chapman JW, Caballero P.	1999	Selection of a nucleopolyhedrovirus for control of <i>Spodoptera frugiperda</i> (Lepidoptera: Noctuidae): structural, genetic, and biological comparison of four isolates from the Americas. Journal of Economic Entomology 92: 1079–1085.	N	N	not protected	
B.3.10.1	Rios-Velasco C, Gallegos-Morales G, Berlanga-Reyes D, Cambero-Campos J, Romo-Chacón A	2012	Mortality and production of occlusion bodies in <i>Spodoptera frugiperda</i> larvae (Lepidoptera: Noctuidae) treated with nucleopolyhedrovirus. Florida Entomologist 95: 752–757.	N	N	not protected	
B.3.10.1	Smith PH and Vlak JM.	1988	Biological activity of <i>Spodoptera exigua</i> nuclear polyhedrosis virus against <i>S. exigua</i> larvae. Journal of Invertebrate Pathology 51: 107–114.	N	N	not protected	
B.3.10.1	Cooper D, Cory JS, Myers JH	2003	Hierarchical spatial structure of genetically variable nucleopolyhedroviruses infecting cyclic populations of western tent caterpillars. Molecular Ecology 12: 881–890.	N	N	not protected	
B.3.10.1	Serrano A, Pijlman PG, Vlak MJ, Muñoz D, Williams T	2015	Identification of <i>Spodoptera exigua</i> nucleopolyhedrovirus genes involved in pathogenicity	N	N	not protected	
B.3.11	Andermatt and Andermatt	2015	Product Portfolio. Andermatt Biocontrol AG, Stahlermatten 6, 6146 Grossdietwil, Switzerland.	N	N	not protected	
B.3.11	Serrano , L.	2017	Analysis of genes potentially involved in Vertical Transmission of <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus. Grado en ingeniería agroalimentaria y del medio rural Gradua nekazaritzako elikagaien eta landa ingurunearen ingeniariartzan	N	N	not protected	

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
B.3.11	Myers, J. H., and Cory, J. S.	2016	Transmission of NPV is largely horizontal although low levels of vertical transmission occur, Ecology and evolution of pathogens in natural populations of Lepidoptera. Evolutionary Applications 231–247.	N	N	not protected	
B.3.11	Clem, R. J., and A. L. Passarelli	2013.	Baculoviruses: sophisticated pathogens of insects. PloS Pathogens 9:e1003729.	N	N	not protected	
B.3.11	Cory, J. S., and M. T. Franklin	2012	Evolution and the microbial control of insects. Evolutionary Applications 5:455–469.	N	N	not protected	
KMP 3/03 B.3.16	Ijkel, W.F.J., van Strien, E., Heldens, J.G.M., Broer, R., Zuidema, D., Goldbach, R.W., Vlak, J.M.	1999	Sequence and organisation of the <i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus genome not available, not applicable Journal of General Virology, 80, 3289 - 3304 GLP/GEP: no Published: yes	N	N	not protected	-
KMP 3/04 B.3.16	Roush, R.T.	1998	Strategies for Resistance Management not available, not applicable GLP/GEP: no Published: yes	N	N	not protected	-
KMP 3/05	Vijaykumar, K.B.K., Fakrudin, B.	2003a	Effectiveness of Helicoverpa armigera Nuclear Polyhedrosis Virus Against Insecticide Resistant Strains of <i>Helicoverpa armigera</i> (Hubner) (Lepidoptera: Noctuidae) not available, not applicable Resistant Pest Management Newsletter, 13, 27-28 GLP/GEP: no Published: yes	N	N	not protected	-
KMP 3/06	Vijaykumar, K.B.K., Fakrudin, B.	2003b	Effect of Nuclear Polyhedrosis Virus Infection on the Insecticide Susceptibility of <i>Heliothis armigera</i> Larvae not available, not applicable Resistant Pest Management Newsletter, 13, 28-30 GLP/GEP: no Published: yes	N	N	not protected	-

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
KMP 3.9/01 B.3.1 B.3.9	Anonymous	2018	SPEXIT Insecticide for the biological control of the beet armyworm (<i>Spodoptera exigua</i>) Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y		ABA

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
KMP 4.1/01	Anonymous	2005	Regulation Information Sheet. VORIDIAN PET 9921W Andermatt Biocontrol AG, CH, not applicable not applicable GLP/GEP: no Published: no	no	no	not protected	ABA
KMP 4.1/02	Anonymous	2009a	PRODUCT SPECIFICATION 100 ML Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.1/03	Anonymous	2009b	PRODUCT SPECIFICATION 200 ML Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.1/04	Anonymous	2009c	PRODUCT SPECIFICATION 500 ML Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.1/05	Anonymous	2009d	PRODUCT SPECIFICATION 1 L not available, not available not available GLP/GEP: no Published: no	no	yes		ABA

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
KMP 4.1/06	Anonymous	2009e	PRODUCT SPECIFICATION 5 L Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.4/01	Anonymous	2018	Safety Data Sheet SPEXIT Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA

A.4 ANALITICAL 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
MA B.4.1.1/01	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculoviruses not available, not applicable OECD Organisation for Economic Co-operation and Development, 2002 Not available; Not applicable. GLP/GEP: no Published: yes	N	N	not protected	
MA B.4.1.1/02	Yingjian Chen, Benxiang Qia, Guiling Zheng, Yuan Zhang, Fei Deng, Fanghao Wan, Changyou Li	2019	Identification and genomic sequence analysis of a new <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus, SeMNPV-QD, isolated from Qingdao, China. Journal of Invertebrate Pathology 160 (2019) 8–17.	N	N	not protected	-
MA B.4.1.1/03	Toprak, U., Ş. Bayram, and M.O. Gürkan,	2005	Gross pathology of SpliNPVs and alterations in <i>Spodoptera littoralis</i> Boisd. (Lepidoptera: Noctuidae) morphology due to baculoviral infection. J. Agric. Sci., 11 (1): 65-71.				
MA B.4.1.1/04 MA B.4.1.2/01	Zamora-Avilés N. Zamora-Avilés, R. Murillo, R. Lasa, S. Pineda, J. I. Figueroa, A. Bravo-Patiño, O. Díaz, J. L. Corrales, and A. M. Martínez	2017	Genetic and biological characterization of four nucleopolyhedrovirus isolates collected in Mexico for the control of <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae),” J. Econ. Entomol., vol. 110, pp. 1465-1475				

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
MA B.4.1.1/05	Murillo, R., Munˆoz, D., Ruiz-Portero, M. C., Alcazar, M. D., Belda, J. E., Williams, T. & Caballero, P.	2007	Abundance and genetic structure of nucleopolyhedrovirus populations in greenhouse substrate reservoirs. Biol Control 42, 216–225.	N	N	not protected	
MA B.4.1.1/06	Chaufaux, J., and P. Ferron.	1986	Sensibilite´ differente de deux populations de Spodoptera exigua Hub. (Lep., Noctuidae) aux baculovirus et aux pyrethroodes de synthese. Agronomie 6: 99–104.				
KMA 4.2/01 MA B.4.2/01	Richards, A.R., Christian, P.D.	1999	A rapid bioassay screen for quantifying nucleopolyhedroviruses (Baculoviridae) in the environment. not available, not applicable Journal of Virological Methods, 82, 63-75 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 4.2/02 MA B.4.2/02	De Moraes, R.R., Maruniak, J.E., Funderburk, J.E.	1999	Methods for Detection of Anticarsia gemmatilis Nucleopolyhedrovirus DNA in Soil not available, not applicable Applied and Environmental Microbiology, 65, 2307-2311 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 4.2/03 MA B.4.2/03	Jehle, J.	2004	Validation of an analytical method for the determination of Cydia pomonella granulovirus in surface water Andermatt Biocontrol GmbH, CPGV/2004-01 DLR-Rheinfalz, Neustadt, Germany GLP/GEP: no Published: no	N	N	not protected	ABA

No references cited.

A.5 EFFECT OF HUMAN HEALTH

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B6.1.1/01	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus ENV/JM/MONO, 1, 1-90 No GLP Published	N	N		-
B6.1.1/02	Jehle, J.A., et al.	2006	Molecular identification and phylogenetic analysis of baculoviruses from Lepidoptera Virology, 346, 180-193 No GLP Published	N	N		-
B6.1.1/03	Rohrmann, G.F.	2013	Chapter 1: Introduction to the baculoviruses, their taxonomy and evolution Baculovirus Molecular Biology, 3rd edition, 1-24 No GLP Published	N	N		-
B6.1.1/04	Lung, O.	2002	Pseudotyping <i>Autographa californica</i> Multicapsid Nucleopolyhedrovirus (AcMNPV): F Proteins from Group II NPVs Are Functionally Analogous to AcMNPV GP64 Virology, 346, 180-193 No GLP Published	N	N		-
B6.1.1/05	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: Safety aspects concerning their production and application Z Angew Entomol, 82, 129- 134 No GLP Published	N	N		-
B6.1.1/06	Sechase, S.	2018	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus (SeMNPV) toxicology Andermatt Biocontrol AG, CH, 159365-MA-05-01 No GLP Unpublished	N	Y	Proprietary information	ABA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B6.1.1.1/01	Gronowski, A.M., et al	1999	Baculovirus stimulates antiviral effects in mammalian cells Journal of Virology, 73, 9944-9951 No GLP Published	N	N		-
B6.1.1.1/02	Ignoffo, C.M.	1973	Effects of entomopathogens on vertebrates Annals of the New York Academy of Sciences, 217, 141-172 No GLP Published	Y	N		-
B6.1.1.1/03	Burges, H.D.; et al	1980	A review of safety tests on baculoviruses Entomophaga, 25 (4), 329-339 No GLP Published	N	N		-
B6.1.1.1/04	Gröner, A.	1986	Specificity and safety of baculoviruses The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 No GLP Published	N	N		-
B6.1.1.2	Zingg, D.	2018	Occupational health statement Andermatt Biocontrol AG, CH, No GLP Unpublished	N	Y	Proprietary information	ABA
B6.1.1.3/01	Andermatt, M.	2006a	Declaration Andermatt Biocontrol AG, CH, Andermatt Biocontrol AG, Grossdietwil, Switzerland No GLP Unpublished	N	N		ABA
B6.1.1.3/02	Andermatt, M.	2006b	Statement on the production of baculovirus products of Andermatt Biocontrol AG and on its workers exposure taking account of potential risks of inhalation toxicity Andermatt Biocontrol AG, Grossdietwil, Switzerland No GLP Unpublished	N	N		ABA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B6.1.1.3/03	Zingg, D.	2018	Occupational health statement Andermatt Biocontrol AG, CH, No GLP Unpublished	N	Y	Proprietary information	ABA
B6.1.1.3/04	Seehase, S.	2018	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus (SEMNPV) toxicology Andermatt Biocontrol AG, CH, 159365-MA-05-01 No GLP Unpublished	N	Y	Proprietary information	ABA
B6.1.1.4	Heimpel, A.M., Buchanan, L.K.	1967	Human feeding tests using a nuclear-polyhedrosis virus of <i>Heliothis Zea</i> Journal of Invertebrate Pathology, 9, 55-57 No GLP Published	N	N		-
B6.1.2.1/01	██████████	1976a	Testing for sensitising properties of nuclear polyhedrosis virus (NPV) in guinea pigs by the method of LANDSTEINER Andermatt Biocontrol GmbH, Report No.148/76, A55527 ████████████████████ No GLP Unpublished	Y	N		ABA
B6.1.2.1/02	██████████	1986	HOE 083311 OI LC08 A101 Testing for sensitising properties of on Pirbright White guinea pigs by the method of LANDSTEINER Andermatt Biocontrol GmbH, 861169, 86.1373 ████████████████████ GLP Unpublished	Y	N		ABA
B6.1.2.1/03	██████████	1992	Hoe 083311; Water miscible suspension concentrate: 2.2*10 exp. 13 vir./1 (code: Hoe 083311 00 SC13 A102) Testing for respiratory sensitization in the male and	Y	N		ABA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			female Pirbright White guinea pig. Report No. 91.1096 Andermatt Biocontrol GmbH, [REDACTED] GLP Unpublished				
B6.1.2.1/04	Hackl et al.	2015	Literature search and data collection on risk assessment for human health for microorganisms used as plant protection products reference. EFSA supporting publication 2015:en-801. 173 pp				
B6.1.2.1/05	Martel et al.	(2010)	Bibliographic review on the potential of microorganisms, microbial products and enzymes to induce respiratory sensitization. EFSA supporting publication 2010 volume 7, issue 9, 95pp				
B6.1.2.2.1/01	[REDACTED]	1976b	Tolerance testing with nuclear polyhedrosis virus after single oral or intravenous administration to male and female rats Report No. 488/76 Andermatt Biocontrol GmbH, [REDACTED] No GLP Unpublished	Y	N		ABA
B6.1.2.2.1/02	[REDACTED]	1980	Tolerance testing of (AcNPV) nuclear polyhedrosis virus following single-dose administration to SPF wistar rats Andermatt Biocontrol GmbH, 595, 234/80 [REDACTED] GLP Unpublished	Y	N		ABA
B6.1.2.2.1/03	Martignoni, M.E.	1978	The Douglas-fir tussock moth: a synthesis Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W.	N	N		-

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			No GLP Published				
B6.1.2.2.1/04	Cunningham , J.C., Entwistle, P.F.	1981	Control of sawflies by baculovirus. IV Characterization and safety testing. Microbial control of pests and plant diseases, 392-393 No GLP Published	N	N		-
B6.1.2.2.1/05	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly <i>Pieris rapae</i> larvae RAE Serie A, 70 (4), 2368 No GLP Published	N	N		-
B.6.1.2.2.2/01		1992	Hoe 083311; water miscible suspension concentrate: 2.2*10 exp. 13 vir./1 (code: Hoe 083311 00 SC13 A102) Testing for respiratory sensitization in the male and female Pirbright White guinea pig. Report No. 91.1096 Andermatt Biocontrol GmbH, GLP Unpublished	Y	N		ABA
B.6.1.2.2.2/02	Gröner, Aet al	1978	Investigations with baculoviruses in mammals Zeitschrift für angewandte Zoologie, 65, 69-80 No GLP Published	Y	N		-
B.6.1.2.2.2/03	Ignoffo, C.M., et al .	1975	Insusceptibility of the Rhesus Monkey, <i>Macaca mulatta</i> , to an insect virus, <i>Baculovirus heliothis</i> Environ Entomol, 4, 569-573 No GLP Published	Y	N		-
B.6.1.2.2.2/04	Martignoni, M.E.	1978	The Douglas-fir tussock moth: a synthesis Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W. No GLP	N	N		

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published				
B.6.1.2.2.2/05	Lewis, F.B., Podgwaite, J.D.	1981	The gypsy moth: research toward integrated pest management - safety evaluations Technical Bulletin, U.S. Department of Agriculture, 1584, 475-479 No GLP Published	N	N		-
B.6.1.2.2.2/06	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application Z Angew Entomol, 82, 129- 134 No GLP Published	N	N		-
B.6.1.2.2.2/07	Cunningham , J.C., Entwistle, P.F.	1981	Control of sawflies by baculovirus. iv characterization and safety testing. Microbial control of pests and plant diseases, 392-393 No GLP Published	N	N		-
B.6.1.2.2.3/01	[REDACTED]	1976b	Tolerance testing with nuclear polyhedrosis virus after single oral or intravenous administration to male and female rats Report No. 488/76 Andermatt Biocontrol GmbH, [REDACTED] No GLP Unpublished	Y	N		ABA
B.6.1.2.2.3/02	Gröner, A., et. al.	1978	Investigations with baculoviruses in mammals Zeitschrift für angewandte Zoologie, 65, 69-80 No GLP Published	Y	N		-
B.6.1.2.2.3/03	Ignoffo, C.M. et al.	1975	Insusceptibility of the Rhesus Monkey, <i>Macaca mulatta</i> , to an insect virus, Baculovirus <i>heliothis</i> Environ Entomol, 4, 569-573 No GLP Published	Y	N		-

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.1.2.3.1/01	Reimann, R., Miltenburger , H.G.	1983	Cytogenetic studies in mammalian cells after treatment with insect pathogenic viruses [baculoviridae]. II In vitro studies with mammalian cell lines Entomophaga, IOBC journal, 28, 33-44 No GLP Published	N	N		-
B.6.1.2.3.1/02	Gröner, A.	1986	Specificity and safety of baculoviruses The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 No GLP Published	N	N		-
B.6.1.2.3.1/03	Reimann, R.K.H.	1984	Cytogenetic investigations of the effect of viral insect pathogens (baculoviruses) on mammalian cells in vivo and in vitro (german original) Dissertation Technische Hochschule Darmstadt No GLP Published	Y	N		-
B.6.1.2.3.1/04	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application [german original] Zeitschrift für angewandte Entomologie, 82, 129-134 No GLP Published	N	N		-
B.6.1.2.4/01	Ignoffo, C.M., Rafajko, R.R.	1972	In vitro attempts to infect primate cells with the nucleopolydrosis virus of <i>heliothis</i> Journal of Invertebrate Pathology, 20, 321-325 No GLP Published	N	N		-
B.6.1.2.4/02	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly <i>Pieris rapae</i> larvae RAE Serie A, 70 (4), 2368 No GLP Published	N	N		-

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.1.2.4/03	Martignoni, M.E.	1978	The Douglas-fir tussock moth: a synthesis Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W. No GLP Published	N	N		-
B.6.1.2.4/04	Tjia, S., et al.	1983	<i>Autographa californica</i> nuclear polyhedrosis virus (ACNPV) DNA does not persist in mass cultures of mammalian cells Virology 125, pp 107-117 No GLP Published	N	N		-
B.6.1.2.4/05	Gröner, A., et al.	1984	Interaction of <i>Autographa californica</i> nuclear polyhedrosis virus with two nonpermissive cell lines Intervirology 21: pp. 203-209 (1984) No GLP Published	N	N		-
B.6.1.2.4/06	Röder, A., Pünter, J.	1977	Interactions between nuclear polyhedrosis viruses and vertebrate cells Zentralblatt für Bakteriologie und Hygiene I Abteilung Original, A 239, 459-464 No GLP Published	N	N		-
B.6.1.2.4/07	Schmidt, J., Erfle, V.	1982	Studies on the retrovirus- activating potential of nuclear polyhedrosis viruses in mammalian cell cultures Zbl. Bakt. Hyg., I. Abt. Orig. A 252, pp. 438-455 GLP/GEP: no Published: yes	N	N		-
B.6.1.2.4/08	Gröner, A.	1990	<i>Cydia pomonella granulosus</i> virus (CPGV) HOE 083311 summary and conclusions on the toxicity Andermatt Biocontrol GmbH, AgrEvo, Hoechst and Schering, Marburg, Germany No GLP Unpublished	N	N		ABA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.1.2.4/9	Döller, G., Gröner, A.	1981a	Safety test for the control of virus replication of nuclear polyhedrosis virus from <i>Mamestra brassicae</i> in vertebrates (german original) Z Angew Entomol, 92, 99-105 No GLP Published	N	N		-
B.6.1.2.4/10	Döller, G. et al	1983a	Safety evaluation of nuclear polyhedrosis virus replication in pigs Applied and Environmental Microbiology 45 (4): pp. 1229-1233 No GLP Published	N	N		-
B.6.1.2.4/11	Döller, G.	1981b	Unspecific interaction between granulosis virus and mammalian immunoglobulins Naturwissenschaften, 68, 1-2 No GLP Published	N	N		-
B.6.1.2.4/12	Döller, G., Huber, J.	1983b	Safety test for the control of virus replication of granulosis virus form <i>Laspeyresia pomonella</i> in mammals (german original) Z Angew Entomol, 95, 64-69 No GLP Published	N	N		-
B.6.1.2.4/13	Bailey, M.J. et al	1987	Specific immunological response against the granulosis virus of the codling moth (<i>Cydia pomonella</i>) in woodmice (<i>Apodemus sylvaticus</i>): field observations Annals of Applied Biology, 111, 649-660 No GLP Published	N	N		-
B.6.1.2.5/01	Lewis, F.B., Podgwaite, J.D.	1981	The gypsy moth: research toward integrated pest management - safety evaluations Technical Bulletin, U.S. Department of Agriculture, 1584, 475-479 No GLP Published	N	N		-

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.1.2.5/02	Gröner, A.etal	1978	Investigations with baculoviruses in mammals Zeitschrift für angewandte Zoologie, 65, 69-80 No GLP Published	Y	N		-
B.6.1.2.5/03	Ignoffo, C.M.etal .	1975	Insusceptibility of the Rhesus Monkey, <i>Macaca mulatta</i> , to an insect virus, Baculovirus <i>heliothis</i> Environ Entomol, 4, 569-573 No GLP Published	Y	N		-
B.6.1.2.5/04	Cunningham , J.C., Entwistle, P.F.	1981	Control of sawflies by baculovirus. iv characterization and safety testing. Microbial control of pests and plant diseases, 392-393 No GLP Published	N	N		-
B.6.1.2.5.1	Ignoffo, C.M.etal	1975	Insusceptibility of the Rhesus Monkey, <i>Macaca mulatta</i> , to an insect virus, Baculovirus <i>heliothis</i> Environ Entomol, 4, 569-573 No GLP Published	Y	N		-
B.6.2.1/01	Krieg, A.	1976a	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application Z Angew Entomol, 82, 129-134 No GLP Published	N	N		-
B.6.2.1/02	Lewis, F.B., Podgwaite, J.D.	1981	The gypsy moth: research toward integrated pest management - safety evaluations Technical Bulletin, U.S. Department of Agricultur, 1584, 475-479 No GLP Published	N	N		-
B.6.2.1/03	Ignoffo, C.M.etal	1973	Teratogenic potential in rats fed the nuclear polyhedrosis virus of <i>heliothis</i> Environ Entomol, 2, 337-338 No GLP Published	Y	N		-

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.2.1/04	Döller, G., Huber, J.	1983	Safety test for the control of virus replication of granulosis virus form <i>Laspeyresia</i> <i>pomonella</i> in mammals (german original) Z Angew Entomol, 95, 64-69 No GLP Published	Y	N		-
B.6.2.1/05	Ignoffo, C.M.et al	1975	Insusceptibility of the Rhesus Monkey, <i>Macaca mulatta</i> , to an insect virus, Baculovirus <i>heliothis</i> Environ Entomol, 4, 569-573 No GLP Published	Y	N		-
B.6.2.2/01	Reimann, R.K.H.	1984	Cytogenetic investigations of the effect of viral insect pathogens (baculoviruses) on mammalian cells in vivo and in vitro (german original) Dissertation Technische Hochschule Darmstadt No GLP Published	N	N		-
B.6.2.2/02	Gröner, A.et al	1978	Investigations with baculoviruses in mammals Zeitschrift für angewandte Zoologie, 65, 69-80 No GLP Published	Y	N		-

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.1/01	Gröner, A.	1986	Specifity and safety of baculoviruses. The Biology of Baculoviruses, Biological Properties and Molecular Biology, Publisher: CRC Press, 9, 177 - 201 No GLP Published	N	N		-

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.1/02	Gröner, A.	1990	Cydia pomonella granulosus virus (CpGv) Hoe 083311 Summary and conclusions on the toxicity Andermatt Biocontrol AG, CH, AgrEvo, Hoechst and Schering, Marburg, Germany No GLP Not Published	N	N	Proprietary information	ABA
B.6.2.1/01	[REDACTED]	1998	Acute dermal irritation /corrosion Granumpom SC (CpGv). Report 98 10 42 829 Andermatt Biocontrol GmbH, [REDACTED] [REDACTED] GLP Not Published	Y	N	Proprietary information	ABA
B.6.2.1/02	Ignoffo, C.M., et al	1975	Insusceptibility of the Rhesus Monkey, <i>Macaca mulatta</i> , to an Insect Virus <i>Baculovirus heliothis</i> Environ Entomol, 4, 569 - 573 No GLP Not Published	Y	N		-
B.6.2.2/01	[REDACTED]	1993	Hoe083311 Watermiscible suspension concentrate 2.2*10 exp13Vir/ml (Code Hoe 083311 00 SC13 A401) Testing for primary eye irritation in the rabbit. Report No. 93.0567, Study No. 93.0485 Andermatt Biocontrol AG, CH, [REDACTED] [REDACTED] GLP Not Published	Y	N	Proprietary information	ABA
B.6.2.3/01	Hack, E et al..	2015	Literature search and data collection on risk assessment for human health for microorganisms used as plant protection products reference. EFSA supporting publication 2015:EN-801. 173 pp.	N	N		
B.6.2.3/02	Martel et al	2010	Bibliographic review on the potential of microorganisms, microbial products and enzymes to induce respiratory sensitization EFSA supporting publication 2010 volume 7, Issue 9, 95pp Published	N	N		

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B.6.3/01	Andermatt, M.	2006	Statement on the production of baculovirus products of Andermatt Biocontrol AG and on its workers exposure taking account of potential risks of inhalation toxicity Andermatt Biocontrol AG, CH, No GLP Not Published	N	Y	Proprietary information	ABA
B6.6/01	[REDACTED]	1980	Tolerance testing of AcNPV nuclear polyhedrosis virus following single- dose administration to SPF Wistar rats, Report No. 234/80 Andermatt Biocontrol AG, CH, [REDACTED] GLP Not Published	N	N	Proprietary information	ABA
B6.6/02	Ignoffo, C.M., et al	1975	Insusceptibility of the Rhesus Monkey, <i>Macaca mulatta</i> , to an insect virus, <i>Baculovirus heliothis</i> Environ Entomol, 4, 569 - 573 Not GLP Published	Y	N		-
B6.6/03	[REDACTED]	1992	Hoe 083311; water miscible suspension concentrate: 2.2*10 exp. 13 vir./1 (code: Hoe 083311 00 SC13 A102) testing for respiratory sensitization in the male and female Pirbright White guinea pig, Report No. 91.1096 Andermatt Biocontrol AG, CH, [REDACTED] GLP Not Published	Y	N	Proprietary information	ABA
B.6.6/04	[REDACTED]	1998	Acute dermal irritation/corrosion Granupom SC (CpGv) Report 98 10 42 829 Andermatt Biocontrol AG, CH, [REDACTED] GLP Not Published	N	N	Proprietary information	ABA
B6.6/05	[REDACTED]	1993	Hoe 083311; water miscible suspension concentrate; 2.2*10 exp. 13 vir./ml (code: Hoe 083311 00 SC13 A401) Testing for primary eye irritation in the rabbit Report No.: 93.0485, 93.0567 Andermatt Biocontrol AG, CH, [REDACTED] GLP Not Published	Y	N	Proprietary information	ABA

Data Point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
B6.6/06	██████████ ██████████	1986	Hoe 083311 OILC08 A101 Testing for sensitising properties of Pirbright-White guinea pigs by the method of LANDSTEINER, Report No. 86.1373 Andermatt Biocontrol AG, CH, ██████████ ██████████████████████████████████████ GLP Not Published	N	N	Proprietary information	ABA

A.6 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

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
KMA 6/01 MP B.6.1/01	Jakubowska, A.	2017	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus and its metabolites: Residues in or on treated products, food and feed Andermatt Biocontrol AG, CH, 356159-MA-06-01 not available GLP/GEP: no Published: no	N	Y		ABA
KMA 6.1/01 MP B.6.1/01	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus not available, not applicable ENV/JM/MONO, 1, 1-90 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 6.1/02 MP B.6.1/02	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application not available, not applicable Z Angew Entomol, 82, 129-134 GLP/GEP: no Published: yes	N	N	not protected	-

A.7 FATE AND BEHAVIOUR IN THE ENVIRONMENT

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
KMA 7/01	Gueli Alletti, G.	2018	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus (SeMNPV): Fate and behaviour in the environment Andermatt Biocontrol AG, CH, 356159-MA-07-01 GAB Consulting GmbH, Heidelberg, Germany GLP/GEP: no Published: no	N	Y		ABA
KMA 7.1/01 B.7.1.1/01	Arrizubieta, M., Simon, O., Torres-Vila, L.M., Figueiredo, E., Mendiola, J., Mexia, A., Caballero, P., Williams, T.	2016	Insecticidal efficacy and persistence of a co-occluded binary mixture of <i>Helicoverpa armigera</i> nucleopolyhedrovirus (HearNPV) variants in protected and field-grown tomato crops on the Iberian Peninsula not available, not applicable Pest Management Science, 72, 660-670 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/02 MA B.7.1/01	Caballero, P., Murillo, R., Munoz, D., Williams, T.	2009	El nucleopoliedrovirus de <i>Spodoptera exigua</i> (Lepidoptera: Noctuidae) como bioplaguicida: análisis de avances recientes en España not available, not applicable REvista Colombiana de Entomología, 35(2), 105-115 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/03 MA B.7.1/02 MA B.7.2/01	Cabodevilla, O., Villar, E., Virto, C., Murillo, R., Williams, T., Caballero, P.	2011	Intra- and Intergenerational Persistence of an Insect Nucleopolyhedrovirus: Adverse Effects of Sublethal Disease on Host Development, Reproduction, and Susceptibility to Superinfection not available, not applicable Applied and Environmental Microbiology, 77(9), 2954-2960 GLP/GEP: no Published: yes	N	N	not protected	-
MA B.7.2/02	Bianchi, F. J., J. M. Vlak, R. Rabbinge, and W. Van der Werf.	2002	Biological control of beet armyworm, <i>Spodoptera exigua</i> , with baculoviruses in greenhouses: development of a coMAREhensive process-based model. Biol. Control 23: 35–46.	N	N	not protected	
MA B.7.2/04	Murillo, R., D. Muñoz, C. Ruiz-Portero, D. M. Alcazar, E. J. Belda, T. Williams, and P. Caballero.	2007	Abundance and genetic structure of nucleopolyhedrovirus populations in greenhouse substrate reservoirs. Biol. Control 42: 216–225.				

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
KMA 7.1/04 MA B.7.1/03	Virto, C., Navarro, D., Tellez, M.M., Herrero, S., Williams, T., Murillo, R., Caballero, P.	2014	Natural populations of <i>Spodoptera exigua</i> are infected by multiple viruses that are transmitted to their offspring not available, not applicable Journal of Invertebrate Pathology, 122, 22-27 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/05 MA B.7.1/04 MA B.7.2.2/01	Han, Y., van Houte, S., Drees, G.F., van Oers, M.M., Ros, V.I.D.	2015	Parasitic Manipulation of Host Behaviour: Baculovirus SeMNPV EGT Facilitates Tree-Top Disease in <i>Spodoptera exigua</i> Larvae by Extending the Time to Death not available, not applicable insects, 6, 716-731 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/06 MA B.7.1/05 MA B.7.2.2/02	Han, Y., van Houte, S., van Oers, M.M., Ros, V.I.D.	2017	Timely trigger of caterpillar zombie behaviour: temporal requirements for light in baculovirus-induced tree-top disease not available, not applicable Parasitology, 1-6 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/07 MA B.7.1/06 MA B.7.2.2/03	Myers, J.H., Cory, J.S.	2016	Ecology and evolution of pathogens in natural populations of Lepidoptera not available, not available Evolutionary Applications, 9(1), 231-247 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/08 MA B.7.1.1/02 MA B.7.1.4/04 MA B.7.2.2/03	Shapiro, M., El Salamouny, S., Jackson, D. M., Shepard, B. M.	2012	Field Evaluation of a Kudzu/Cottonseed Oil Formulation on the Persistence of the Beet Armyworm nucleopolyhedrovirus not available, not available Journal of Entomological Science, 47(3), 197-207 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/09 MA B.7.1.1/03 MA B.7.1.4/03	Salamouny, S., Shapiro, M., Ling, K. S., Shepard, B. M.	2009	Black Tea and Lignin as Ultraviolet Protectants for the Beet Armyworm Nucleopolyhedrovirus not available, not available Journal of Entomological Science, 44(1), 50-58 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1/10 MA B.7.1.1/04 MA B.7.1.4/02	Shapiro, M., El Salamouny, S., Shepard, B. M.	2008	Green tea extracts as ultraviolet protectants for the beet armyworm, <i>Spodoptera exigua</i> , nucleopolyhedrovirus not available, not available Biocontrol Science and Technology, 18(6), 591-603 GLP/GEP: no Published: yes	N	N	not protected	-

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
KMA 7.1/11 MA B.7.1/07 MA B.7.2/04	Virto C., Zárate, C. A., López-Ferber, M., Murillo, R., Caballero, P., Williams, T.	2013	Gender-Mediated Differences in Vertical Transmission of a Nucleopolyhedrovirus not available, not available PloS ONE, 8, e70932 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/01 MA B.7.1.1/05	Jehle, J.A., Lange, M., Wang, H., Hu, Z., Wang, Y., Hauschild, R.	2006	Molecular identification and phylogenetic analysis of baculoviruses from Lepidoptera not available, not applicable Virology, 346, 180-193 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/02 MA B.7.1.1/06 MA B.7.1.2/01 MA B.7.3.1/03	Young, S.	2005	Persistence of viruses in the environment not available, not applicable http://www.lsuagcenter.com/s265/young.htm GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/03 MA B.7.1.1/07 MA B.7.1.3/02 MA B.7.3.2/02	Ignoffo, C.M.	1992	Environmental factors affecting persistence of entomopathogens not available, not applicable Fla Entomol, 75, 516-525 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/04 MA B.7.1.1/08	Chakraborty, S., Monsour, C., Teakle, R., Reid, S.	1999	Yield, biological activity, and field performance of a wild-type <i>Helicoverpa</i> nucleopolyhedrovirus produced in <i>H. zea</i> cell cultures not available, not applicable Journal of invertebrate Pathology, 73, 199-205 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/05 MA B.7.1.2/02	Evans, H.F., Harrap, K.A.	1982	Persistence of insect viruses not available, not applicable Virus Persistence, Publisher: Cambridge University Press, 58-96 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/06 MA B.7.1.2/03 MA B.7.1.3/01 MA B.7.3.2/01	Jaques, R.A.	1977	Stability of entomopathogenic viruses not available, not applicable Misc Publ Entomological Soc America, 10(3), 99-119 GLP/GEP: no Published: yes	N	N	not protected	-

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
KMA 7.1.1/07 MA B.7.1.2/04 MA B.7.1.4/01 MA B.7.3.1/02	Krieg, A.	1983	Testing of a nuclear polyhedrosis preparation MbNPV (unformulated) for leaching behaviour (German Original) Andermatt Biocontrol GmbH, A55490 BBA, Darmstadt, Germany GLP/GEP: no Published: no	N	N	not protected	ABA
KMA 7.1.1/08 MA B.7.1.2/05 MA B.7.3.1/01	Lopez-Pila, J.M.	1988	Effect of Baculoviruses on Groundwater and Drinking water (German Original) not available, not applicable In: Mitteilung aus der Biol. Bundesanstalt, 246, p 178-203 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/09 MA B.7.1.2/06	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculoviruses not available, not applicable OECD Organisation for Economic Co-operation and Development, 2002 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/10 MA B.7.1.2/07	Jaques, R.P., Harcourt, D.G.	1971	Viruses of <i>Trichoplusia ni</i> (lepidoptera: Noctuidae) and <i>pieris rapae</i> (lepidoptera: pieridae) in soil in fields of crucifers in southern Ontario not available, not applicable The Canadian Entomologist, Journal, 103, 1285-1290 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/11 MA B.7.1.2/08	Thomas, E.D., Reichelderfer, C.F., Heimpel, A.M.	1973	The effect of soil pH on the persistence of cabbage looper nuclear polyhedrosis virus in soil not available, not applicable Journal of invertebrate Pathology, 21, 21-25 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/12 MA B.7.1.2/09	Jaques, R.P.	1974a	Occurrence and accumulation of viruses of <i>Trichoplusia ni</i> in treated field plots not available, not applicable Journal of invertebrate Pathology, 23, 140-152 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.1.1/13 MA B.7.1.2/10	Jaques, R.P.	1974b	Occurrence and accumulation of the granulosis virus of <i>Pieris rapae</i> in treated field plots not available, not applicable Journal of invertebrate Pathology, 23, 351-359 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.2/03 MA B.7.3.1/04	van Houte, S., van Oers, M.M., Han, Y., Vlak, J.M., Ros, V.I.D.	2014a	Baculovirus infection triggers a positive phototactic response in caterpillars to induce tree-top disease not available, not applicable Biology Letters, 10, 1-4 GLP/GEP: no Published: yes	N	N	not protected	-

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
KMA 7.2/04 MA B.7.3.1/05	van Houte, S., van Oers, M.M., Han, Y., Vlak, J.M., Ros, V.I.D.	2015	Baculovirus infection triggers a positive phototactic response in caterpillars: a response to Dobson et al. (2015) not available, not applicable Biology Letters, 11, 1-4 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.2/05 MA B.7.3.1/06	Dobson, A.D.M., Auld, S.K.J.R., Tinsley, M.C.	2015	Insufficient evidence of infection-induced phototactic behaviour in <i>Spodoptera exigua</i> : a comment on van Houte et al. (2014) not available, not applicable Biology Letters, 11, 1-3 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.2/06 MA B.7.3.1/07	Rebolledo, D. Lasa, R., Guevara, R., Murillo, R., Williams, T.	2015	Baculovirus-Induced Climbing Behavior Favors Intraspecific Necrophagy and Efficient Disease Transmission in <i>Spodoptera exigua</i> not available, not applicable PloS ONE, 1-16 GLP/GEP: no Published: yes	N	N	not protected	-
KMA 7.2/07 MA B.7.3.1/08	van Houte, S., Ros, V. I. D., van Oers, M. M.	2014b	Hyperactivity and tree-top disease induced by the baculovirus AcMNPV in <i>Spodoptera exigua</i> larvae are governed by independent mechanisms not available, not available Naturwissenschaften, 101, 347-350 GLP/GEP: no Published: yes	N	N	not protected	-

No references cited.

A.8 EFFECTS ON NON-TARGET ORGANISMS

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
KMA 8/01	Schöbinger, U.	2018	Literature review on <i>Spodoptera exigua</i> multiple nucleopolyhedrovirus (SeMNPV): Effects on non-target organisms Andermatt Biocontrol AG, CH, 159365-MA-08-01 not available GLP/GEP: no Published: no	no	yes		ABA
KMA 8.1/01	Ignoffo, C.M.	1975	Evaluation of in vivo specificity of insect viruses not available, not applicable In: Baculoviruses for insect pest control: Safety considerations ... Publisher: American Society for Microbiology, 52-57 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/02	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/03	Lautenschlager, R.A., Rothenbacher, H., Podgwaite, J.D.	1979	Response of birds to aerial application of the nucleopolyhedrosis virus of the Gypsy Moth, <i>Lymantria dispar</i> not available, not applicable Environ. Entomol. 8, pp. 760-764 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agriculture, 1584, 475-479 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMA 8.1/05	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/06	Lautenschlager, R.A., Podgwaite, J.D., Watson, D.E.	1980	Natural occurrence of the nucleopolyhedrosis virus of the gypsy moth, <i>Lymantria dispar</i> (Lep.: Lymantriidae) in wild birds and mammals not available, not applicable Entomophaga, 25 (3), 261-267 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/07	Gröner, A., Döller, G.	1982	Passage of infectious nuclear polyhedrosis virus by mice and chickens not available, not applicable Entomophaga 27 (2), 155-157 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/08	Martignoni, M.E.	1978	The douglas-fir tussock moth: A synthesis not available, not applicable Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W. GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/09	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly <i>Pieris rapae</i> larvae not available, not applicable RAE Serie A, 70 (4), 2368 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/10	Cunningham, J.C., Entwistle, P.F.	1981	Microbial control of pests and plant diseases 1970-1980 not available, not applicable Microbial control of pests and plant diseases, 391-393 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMA 8.1/11	Entwistle, P.F., Adams, P.H.W., Evans, H.F.	1978	Epizootiology of a nuclear polyhedrosis virus in european spruce sawfly (<i>Gilpinia hercyniae</i>): The rate of passage of infective virus through the gut of birds during cage tests not available, not applicable Journal of Invertebrate Pathology 31, 307-312, 1978 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/01	Gröner, A., Huber, J., Krieg, A.	1981	Use of Baculoviruses in crop protection: safety to aquatic organisms (German original) not available, not applicable Zeitschrift für Binnenfischerei, 31 (4), 25-27 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/02	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes Submitted in: KMA 8.1/02	no	no	not protected	-
KMA 8.2.1/03	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes Submitted in: KMA 8.1/05	no	no	not protected	-
KMA 8.2.1/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agriculture, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-

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
KMA 8.2.1/05	Banowetz, G.M., Fryer, J.L., Iwai P.J., Martignoni, M.E.	1976	Effects of the douglas-fir tussock moth nucleopolyhedrosis virus (baculovirus) on three species of salmonid fish not available, not applicable USDA Forest Service Research Paper-PNW 214 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/06	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly <i>Pieris rapae</i> larvae not available, not applicable RAE Serie A, 70 (4), 2368 GLP/GEP: no Published: yes Submitted in: KMA 8.1/09	no	no	not protected	-
KMA 8.2.1/07	Hicks, B.D., Geraci, J.R., Cunningham, J.C., Arif, B.M.	1981	Effects of red-headed pine sawfly, <i>Neodiprion lecontei</i> , nuclear polyhedrosis virus on rainbow trout, <i>Salmo gairdneri</i> and <i>Daphnia pulex</i> not available, not applicable J. Environ. SCI. Health, B16 (4), pp. 493-509 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/08	Cunningham, J.C., Entwistle, P.F.	1981	Microbial control of pests and plant diseases 1970-1980 not available, not applicable Microbial control of pests and plant diseases, 391-393 GLP/GEP: no Published: yes Submitted in: KMA 8.1/10	no	no	not protected	-
KMA 8.2.2/01	Gröner, A., Huber, J., Krieg, A.	1981	Use of Baculoviruses in crop protection: safety to aquatic organisms (German original) not available, not applicable Zeitschrift für Binnenfischerei, 31 (4), 25-27 GLP/GEP: no Published: yes Submitted in: KMA 8.2.1/01	no	no	not protected	-

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
KMA 8.2.2/02	Ignoffo, C.M.	1975	Evaluation of in vivo specificity of insect viruses not available, not applicable In: Baculoviruses for insect pest control: Safety considerations ... Publisher: American Society for Microbiology, 52-57 GLP/GEP: no Published: yes Submitted in: KMA 8.1/01	no	no	not protected	-
KMA 8.2.2/03	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes Submitted in: KMA 8.1/05	no	no	not protected	-
KMA 8.2.2/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agriculture, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-
KMA 8.2.2/05	Hicks, B.D., Geraci, J.R., Cunningham, J.C., Arif, B.M.	1981	Effects of red-headed pine sawfly, Neodiprion lecontei, nuclear polyhedrosis virus on rainbow trout, <i>Salmo gairdneri</i> and <i>Daphnia pulex</i> not available, not applicable J. Environ. SCI. Health, B16 (4), pp. 493-509 GLP/GEP: no Published: yes Submitted in: KMA 8.2.1/07	no	no	not protected	-
KMA 8.2.2/06	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes Submitted in: KMA 8.1/02	no	no	not protected	-

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
KMA 8.2.4/01	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus not available, not applicable ENV/JM/MONO, 1, 1-90 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.3/01	Gröner, A.	1990	Safety to nontarget invertebrates of baculoviruses not available, not applicable Safety of microbial insecticides, Laird M., Lacey L.A., Davidson E.W., Chapter 10, 135-147 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.3/02	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application not available, not applicable Z Angew Entomol, 82, 129-134 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.3/03	Martignoni, M.E.	1978	The douglas-fir tussock moth: A synthesis not available, not applicable Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W. GLP/GEP: no Published: yes Submitted in: KMA 8.1/08	no	no	not protected	-
KMA 8.3/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agriculture, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-

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
KMA 8.3/05	Gröner, A., Huber, J., Krieg, A., Pinsdorf, W.	1978	Testing of two baculovirus preparations on honey-bees (German original) not available, not applicable Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 30, 39-41 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/01	Gröner, A.	1990	Safety to nontarget invertebrates of baculoviruses not available, not applicable Safety of microbial insecticides, Laird M., Lacey L.A., Davidson E.W., Chapter 10, 135-147 GLP/GEP: no Published: yes Submitted in: KMA 8.3/01	no	no	not protected	-
KMA 8.4/02	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application not available, not applicable Z Angew Entomol, 82, 129-134 GLP/GEP: no Published: yes Submitted in: KMA 8.3/02	no	no	not protected	-
KMA 8.4/03	Huber, J.	1978	About the host spectrum of the codling moth granulosis virus not available, not applicable Safety aspects of baculoviruses as Biological Insecticides, 75-85 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/04	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes Submitted in: KMA 8.1/02	no	no	not protected	-

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
KMA 8.4/05	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes Submitted in: KMA 8.1/05	no	no	not protected	-
KMA 8.4/06	Simón, O., Williams, T., López-Ferber, M., Caballero, P.	2004	Virus entry or the primary infection cycle are not the principal determinants of host specificity of <i>Spodoptera</i> spp. nucleopolyhedroviruses not available, not applicable Journal of General Virology, 85, 2845 - 2855 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/07	Ijkel, W.F.J., van Strien, E., Heldens, J.G.M., Broer, R., Zuidema, D., Goldbach, R.W., Vlak, J.M.	1999	Sequence and organisation of the <i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus genome not available, not applicable Journal of General Virology, 80, 3289 - 3304 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/08	Jaques, R.P., Laing, J.E., MacLellan, C.R., Proverbs, M.D., Sanford, K.H., Trottier, R.	1981	Apple orchard tests on the efficacy of the granulosis virus of the codling moth, <i>Laspeyresia pomonella</i> [Lep.: Olethreutidae] not available, not applicable Entomophaga 26 (2), pp. 111-118 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/09	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agriculture, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-

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
KMA 8.4/10	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly <i>Pieris rapae</i> larvae not available, not applicable RAE Serie A, 70 (4), 2368 GLP/GEP: no Published: yes Submitted in: KMA 8.1/09	no	no	not protected	-
KMA 8.4/11	Dickler, E.	1986	Einfluss von Behandlungen mit Apfelwickler-Granulosevirus (CpGV) und breitenwirksamen chemischen Insektiziden auf Parasiten des Apfelwicklers und Parasiten von Schalenwicklerarten not available, not applicable Biologische Bundesanstalt, Inst. f. Pflanzenschutz im Obstbau, Dossenheim, 90-97 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/12	Gröner, A.	1978	Studies on the specificity of the nuclear polyhedrosis virus of <i>Mamestra brassicae</i> (L.) (Lep.: Noctuidae) not available, not applicable Safety aspects of baculoviruses as biological insecticides, Symposium 13.-15 Nov 1978, BMFT, Bonn, p. 265-271 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.7/01	Gröner, A.	1990	Safety to nontarget invertebrates of baculoviruses not available, not applicable Safety of microbial insecticides, Laird M., Lacey L.A., Davidson E.W., Chapter 10, 135-147 GLP/GEP: no Published: yes Submitted in: KMA 8.3/01	no	no	not protected	-
KMA 8.7/02	Lautenschlager, R.A., Rothenbacher, H., Podgwaite, J.D.	1978	Response of small mammals to aerial applications of the nucleopolyhedrosis virus of the gypsy moth, <i>Lymantria dispar</i> not available, not applicable Environ Entomol, 7, 676-683 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMA 8.7/03	Martignoni, M.E.	1978	The douglas-fir tussock moth: A synthesis not available, not applicable Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W. GLP/GEP: no Published: yes Submitted in: KMA 8.1/08	no	no	not protected	-
KMA 8.7/04	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus not available, not applicable ENV/JM/MONO, 1, 1-90 GLP/GEP: no Published: yes Submitted in: KMA 8.2.4/01	no	no	not protected	-
KMA 8.7/05	Lightner, D.V., Proctor, R.R., Sparks, A.K., Adams, J.R., Heimpel, A.M.	1973	Testing penaeid shrimp for susceptibility to an insect nuclear polyhedrosis virus not available, not applicable Environm. Entomol., 2, p. 611-613 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMP 7.1/01 MPB.9.1.1	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Biological Properties and Molecular Biology, Publisher: CRC Press, 9, 177 - 201 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMP 7.1/02 MPB.9.1.2	Gröner, A.	1990	Cydia pomonella granulosis virus (CpGV) HOE 083311 summary and conclusions on the toxicity Andermatt Biocontrol AG, CH, not applicable AgrEvo, Hoechst and Schering, Marburg, Germany GLP/GEP: no Published: no	no	no	not protected	
KMP 10.2/01 MPB.9.3.1.1		1998a	Acute toxicity testing of granulosevirus CpGV SC in rainbow trout (<i>Oncorhynchus mykiss</i>) (Teleostei, Salmonidae) Andermatt Biocontrol AG, CH, 96272/01-AAOm GLP: yes Published: no	no	no	not protected	
MPB.9.3.2.1	Gröner, A., Döller, G.	1982	Passage of infectious nuclear polyhedrosis virus by mice and chickens not applicable Entomophagna 27 (2), 155-157 Report-no. not applicable GLP: no Published: yes	no	-	IIM 8.1/07	
KMP 10.2/02 MPB.9.3.2.1		1998b	Acute toxicity testing of granulosevirus CpGV SC on <i>Daphnia magna</i> using the 48 h acute immobilisation test Andermatt Biocontrol AG, CH, 96272/01-AADm GLP: yes Published: no	no	no	not protected	ABA

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
KMP 10.2/03 MPB.9.3.4	Dengler, D.	1998	Testing of toxic effects of granulosevirus CpGV SC on the single cell green alga <i>Scenedesmus subspicatus</i> Andermatt Biocontrol AG, CH, 96272/01-AASs ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA
KMP 10.2/04 MPB.9.3.4	Dengler, D.	2002	Assessment of toxic effects of Granupom on aquatic plants using the duckweed <i>Lemna gibba</i> Andermatt Biocontrol AG, CH, 20011323/01-AALg ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA
KMP 10.3/01 MPB.9.4.1	Kling, A.	2002	Assessment of side effects of Granupom to the honey bee, <i>Apis mellifera</i> L. in the laboratory Andermatt Biocontrol AG, CH, 20011323/01-BLEU ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA
KMP 10.4/01	Kühner, C.	1998	Granulosevirus CpGV SC: Acute toxicity to the predatory mite, <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory Andermatt Biocontrol AG, CH, 96272/01-NLTp ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA

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
KMP 10.4/02 MPB.9.5	Kühner, C.	2001	Granulosevirus CpGV SC: Acute toxicity to the aphid parasitoid, <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) in the laboratory Andermatt Biocontrol AG, CH, 96272/01-NLAp ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA
KMP 10.4/03 MPB.9.5	Kühner, C.	1997	Granulosevirus CpGV SC: Acute toxicity to the ground beetle, <i>Poecilus cuperus</i> L. (Coleoptera, Carabidae) in the laboratory Andermatt Biocontrol AG, CH, 96272/01-NLPc ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA
KMP 10.5/01 MPB.9.6	Wachter, S.	1998a	Acute toxicity of CpGV SC on earthworms, <i>Eisenia foetida</i> using an artificial soil test Andermatt Biocontrol AG, CH, 96272/01-NLEf ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA
KMP 10.6/01 MPB.9.7	Wachter, S.	1998b	Assessment of the side effects of CpGV SC on the activity of the soil microflora Andermatt Biocontrol AG, CH, 96272/01-ABMF ArGe GAB Biotech/IFU, Niefern-Öschelbronn, Germany GLP: yes Published: no	no	no	not protected	ABA

A.9 SUMMARY AND EVALUATION OF ENVIRONMENTAL IMPACT

Please note that all submitted studies on effects on non-target organisms were evaluated under the active substance since none of them concerned the representative formulation. Hence there is no differentiation between studies submitted as KMA or KMP in this section.

A.10 CONFIDENTIAL 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
KMA 1.3/04 C1.2.1	Schoenfelder, M.	2006	THE BACULOVIRUS PREPARATION SENPV Andermatt Biocontrol AG, CH, not applicable not available GLP/GEP: no Published: no	N	N	not protected	ABA
KMA 1.4.1/02 C1.2.2.1	Fenfen, F.	2017	SPECIFICATION SHEET Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y	New data for active ingredient, not previously submitted nor evaluated	ABA
KMP 5.1/01	Bachmann, F., Zügler, M.	2017	CERTIFICATION OF ANALYSIS Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	ABA
KMA 1.4.1/03	Kessler, P.-a	2018a	METHOD OF ANALYSIS Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	Y	New data for active ingredient, not previously submitted nor evaluated	ABA
KMA 1.4.2/01	Kessler, P.-b	2018b	SPEXIT QUALITY CONTROL: ANALYSIS OF THE ACTIVE INGREDIENT Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	Y	New data for active ingredient, not previously submitted nor evaluated	ABA

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
Confidential Annex I C1.2.2.1	Bollhalder	2019	Confidential information. Annex I Correction of the formulation declaration for the microbial plant protection product SPEXIT and other baculovirus products mentioned in the SeMNPV active substance dossier	N	Y		ABA
KMA 3.4/01	Kessler, P.-c	2018c	PRODUCTION OF <i>S. exigua</i> NUCLEOPOLYHEDROVIRUS Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	Y	New data for active ingredient, not previously submitted nor evaluated	ABA
KMA 1.4.1/01 KMP 1.4/02 C1.2.2.1	Bachmann, F.	2018	DECLARATION ON COMPOSITION OF PRODUCT SPEXIT Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y	New data for active ingredient, not previously submitted nor evaluated	ABA
KMP 1.4/03	Anonymous	2018	SAFETY DATA SHEET SPEXIT Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	ABA
KMP 5.1/02	Pfefferkorn, A.	2006	CONFIRMATION OF MICROBIAL EXAMINATION METHOD Andermatt Biocontrol AG, CH, not applicable not applicable GLP/GEP: no Published: no	N	Y	protected	ABA
KMP 1.4/04	Anonymous		SAFETY DATA SHEET GLYCERIN 1.26 (MIN. 99.5%) PH.EUR Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	N	Y	New data for existing formulation, not previously submitted nor evaluated	ABA