European Commission

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

Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV)

Product data: SPEXIT

Volume 3 – Annex B.2 Physical and chemical properties

Rapporteur Member State: Spain

April 2020

Version History

When	What
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Table of contents

INTRODUCTION 3
B.2.1 APPEARANCE 6
B.2.2 STORAGE STABILITY AND SHELF-LIFE 6
B.2.2.2 Effect of exposure to air, packaging etc. on the product stability 10
B.2.3 EXPLOSIVITY AND OXIDISING PROPERTIES 12
B 2.3.1 Explosivity and oxidizing properties 13
B.2.4 FLASH POINT AND OTHER INDICATIONS OF FLAMMABILITY OR SPONTANEOUS IGNITION 13
B 2.4.1 Flash point and other indications of flammability or spontaneous ignition 13
B.2.5 ACIDITY, ALKALINITY AND IF NECESSARY PH VALUE 13
B 2.5.1 Acidity, alkalinity and if necessary pH value 14
B.2.6 VISCOSITY AND SURFACE TENSION 14
B 2.6.1 Viscosity and surface tension 14
B.2.7 TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT 15
B 2.7.1 Wettability 15
B 2.7.2 Persistent foaming 15
B.2.7.3 Suspensibility, suspension stability 16
B.2.7.4 Dry sieve test and wet sieve test 17
B.2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules) 17
B.2.7.6 Emulsifiability, re-emulsifiability, emulsion stability 17
B.2.7.7 Flowability, pourability (rinsability), dustability 18
B.2.8 PHYSICAL, CHEMICAL AND BIOLOGICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED 18
B.2.8.1 Physical compatibility 18
B.2.8.2 Chemical compatibility 18
B.2.8.3 Biological compatibility 19
B.2.9 ADHERENCE AND DISTRIBUTION TO SEEDS 19
B.2.9 Adherence and distribution to seeds 19
B 2.10 SUMMARY AND EVALUATION OF DATA PRESENTED UNDER POINTS 2.1 TO 2.9 1
B.2.11 REFERENCES RELIED ON 1

INTRODUCTION

The company Suisse AG (new Swiss subsidiary of Andermatt Biocontrol AG) 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 1107/2009[1]. Data requirements for the registration of BVs as an active substance and their products are laid down in part B of the regulation documents 283/2013 [2]and 284/2013 [3]and the principles for evaluation and authorization of plant protection products contained microorganism according to regulation 546/2011[4].

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 2008[6], 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, 2007[7] were *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.

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[1]*Regulation (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.

[3]*Commission 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.*

[4]*Commission 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.*

[5]*SANCO/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.*

[6]*Ehlers 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.*

[7]*Review 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.*

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.
- 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/EEC[8]. The active substance SeMNPV was under programme of renewal Regulation EU 686/2012 (AIR-III programme[9]). According to draft working document AIR III renewal programme SANCO/2012/11284[10], *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 844/2012[11] 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* multicapside nucleopopyhedrovirus (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* multipolyhedrivirus (SeMNPV) genotype pool BV-0004 and the microbial product SPEXIT.

[8] *Council 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.*

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

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

[11] *Commission 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.*

[12] *Submission 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.*

PPP (product name/code):	SPEXIT	Formulation type:	SC
Active Substance: (SeMNPV)	*Spodoptera exigua* multicapsid nucleopolyhedrovirus	Conc. of a.s.:	3.75×10^{12} OBs/L
Applicant:	Andermatt Biocontrol GmbH	professional use	☒
Zone(s):	EU	nonprofessional use	☒
Safener:	n.a.	Conc. of safener:	n.a.
Synergist:	n.a.	Conc. of synergist:	n.a.
Verified by RMS:	yes		

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks:**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season**	**L product / ha** **a) Max. Rate per appl.** **b) Max. total rate per crop/season**	**OBs/ha** **a) Max. Rate per appl.** **b) Max. total rate per crop/season**	**Water L/ha** **min / max**		**e.g. g safener/synergist per ha**
1	EU	Pepper (CPSAN)	F/G	*S. exigua* (LAPHEG)	Spray	At infestation (preferably on early larva instar: L1 and L2). First treatment just before hatching)	a) 18 (6) b) 18 (6)	a) 0.2 b) 3.6	a) 7.5×10^{11} b) 1.35×10^{13}	200 / 1600	-	- 2 to 3 applications per pest generation, up to 6 generations (i.e. max. of 18 app.). -Interval between applications: min. of 6 sunny days; 2 partially sunny days = 1 sunny day
2	EU	Leafy vegetables (lettuce crops) (3LETC)	F/G	*S. exigua* (LAPHEG)	Spray	At infestation (preferably on early larva instar: L1 and L2). First treatment just before hatching)	a) 18 (6) b) 18 (6)	a) 0.2 b) 3.6	a) 7.5×10^{11} b) 1.35×10^{13}	200 / 1600	-	- 2 to 3 applications per pest generation, up to 6 generations. -Interval between applications: min. of 6 sunny days; 2 partially sunny days = 1 sunny day

Table MP B.2-1 Summary of critical Good Agricultural Praxis for SPEXIT

n.a. Not applicable

B.2.1 APPEARANCE

B. 2.1 Appearance (colour and odour)	Visual and olfactory assessment	**SPEXIT** (3.75×10^{12} granules SeMNPV/L, SC)	• **Colour**: Grey-brown • **Odour:** Characteristic of aromatic compounds • **Physical state:** Viscous liquid, single phase, no clumping	The typical characteristics of the test item SPEXIT did not change during the test period. Colour and odour of the test item were stable throughout the entire test period of 12 months at a temperature of 5ºC. The product remained a flowable single-phase liquid. Clumps and other particles outside specification of the product were not detected. The physical state of the test product can therefore be considered as stable at a temperature of 5ºC for one year.	N	Konrad, R. (2014)
		HELICOVEX (>7.5 x 10^{12} granules HearNPV/L, SC)	• **Colour**: Grey-brown • **Odour:** Organic odour • **Physical state:** Liquid		Y	Walter, D (2011)
		LITTOVIR (≥ 5 x 10^{11} NPV / L, SC)	• **Colour:** Grey-brown • **Odour:** Typical organic odour **Physical state:** Liquid		Y	Walter et al. (2018)

B.2.2 STORAGE STABILITY AND SHELF-LIFE

Test or study & Data point	**Guideline and method**	**Test material purity and specification**	**Used methods and Results**	**Comments (Acceptable / Non-acceptable)**	**GLP Y/N**	**Reference**
B.2.2.1.1Physical and	Storage stability and	SPEXIT	Results after storage at 5 °C for 12 months: No change to the container shape or size was	**Acceptable biological activity after storage (figure MP 2.2.1.1-1)**	N	Konrad, R.

Test or study & Data point	Guideline and method	Test material purity and specification	Used methods and Results	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
biological stability at the recommended storage temperature, including information on growth of contaminating micro-organisms	shelf life	(3.75×10^{12} granules SeMNPV/L, SC)	observed over the entire test period of 12 months at a temperature of 5°C. The LD_{50} of the test item was not significantly lower than that of the reference standard.	It is noted that the biological activity of the microorganisms in the formulated product no decreased (maximum limit according to the draft guideline for physical and chemical properties of PPP by the Health and Safety Executive (UK) **No information on growth of contaminating microorganisms. DATA GAP** There is no information of contaminants for bacteria and fungi (maximum according to SANCO/12116/2012 rev. 0).The test items was not investigated for contaminants and pathogens before and after storage. RMS considers the lack of data as a data gap for SPEXIT		(2014)

<table>
<tr><th>Test or study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods and Results</th><th>Comments (Acceptable / Non-acceptable)</th><th>GLP Y/N</th><th>Reference</th></tr>
<tr><td></td><td></td><td>HELICOVEX
(>7.5 x 10^{12} granules Hear NPV/L, SC)</td><td>The test item is considered to be stable when stored for 36 months at 5 °C.</td><td></td><td>Y</td><td>Walter, D. (2011)</td></tr>
<tr><td></td><td></td><td>LITTOVIR
(≥ 5 x 10^{11} NPV / L, SC)</td><td>Results after storage at 5 °C for 24 months No damage of the test item containers was observed. No significant loss in weight was founded after storage. The LD_{50} of the test item was not significantly lower than that of the reference standard.</td><td></td><td>Y</td><td>Walter et al. (2018)</td></tr>
<tr><td></td><td>Storage stability</td><td>SPEXIT
(3.75 × 10^{12} granules SeMNPV/L, SC)</td><td><table><tr><th>Test method</th><th>Results before storage</th><th>Results after storage for 12 months at 5°C</th></tr><tr><td>Stability of the original test item container (visual)</td><td colspan="2">The test item was given in Pharma bottles. No damage of the test item containers was observed.</td></tr><tr><td>Activity of active ingredient</td><td colspan="2">LD_{50} of the test item was not significantly lower than that of the reference item (figure MP 2.2.1.1-1)</td></tr></table>Before and after storage the LD_{50} of the test item is not significantly lower than that of the reference item. Therefore, the test item is considered to be stable when stored for 12 months at 5°C.</td><td></td><td>N</td><td>Konrad, R. (2014)</td></tr>
<tr><td></td><td></td><td>MADEX
(3 x 10^{13} granules CpGV/L, SC)</td><td>The formulation does not show any significant changes in the measured parameters (appearance, colour, odour, suspensibility, wet sieving and packaging stability) during storage of seven days at 0 °C.</td><td></td><td>N</td><td>Fanger, U. (2007)</td></tr>
<tr><td></td><td>CIPAC MT 39.3</td><td>HELICOVEX
Batch No. 008
(>7.5 x 10^{12}</td><td><table><tr><th>Test method</th><th>Results before</th><th>Results after storage for</th></tr></table></td><td></td><td>Y</td><td>Walter, D. (2011)</td></tr>
</table>

<table>
<tr><th>Test or study & Data point</th><th>Guideline and method</th><th>Test material purity and specification</th><th>Used methods and Results</th><th>Comments (Acceptable / Non-acceptable)</th><th>GLP Y/N</th><th>Reference</th></tr>
<tr><td></td><td></td><td>granules Hear NPV/L, SC)</td><td>
<table>
<tr><td></td><td>storage</td><td>42 months at 5°C</td></tr>
<tr><td>Stability of the original test item container (visual)</td><td colspan="2">Before: the containers, screw capped 200 mL PET bottles, tightly closed with no damage observed.
After: the containers, screw capped 200 mL PET bottles, tightly closed with no damage or deterioration observed.</td></tr>
<tr><td>Weight change of the test item Container</td><td>-</td><td>No significant changes (<0.1 %) of the weights of the containers were found after storage.</td></tr>
<tr><td>Activity of active ingredient</td><td colspan="2">The LD50 of the test item was not significantly higher (relative potency ≥ 0.55) than that of the reference item.</td></tr>
</table>
Before and after storage the LD_{50} of the test item is not significantly lower than that of the reference item. Therefore, the test item is considered to be stable when stored for 36 months at 5°C.
</td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td>LITTOVIR
(≥ 5 x 10^{11} NPV / L, SC)</td><td>
<table>
<tr><td>Test method</td><td>Results before storage</td><td>Results after storage for 42 months at 5°C</td></tr>
<tr><td>Stability of the original test item container (visual)</td><td colspan="2">The containers (100 mL PET flasks, screw cap of HDPE with LDPE stopper) shut tightly. No damage to the container shape or size was observed.</td></tr>
<tr><td>Weight change of the test item Container</td><td>-</td><td>No significant loss in weight was found after storage.</td></tr>
<tr><td>Activity of active</td><td colspan="2">LD_{50} of the test item was not significantly</td></tr>
</table>
</td><td></td><td>Y</td><td>Walter, D. (2018)</td></tr>
</table>

Test or study & Data point	Guideline and method	Test material purity and specification	Used methods and Results	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
			ingredient lower than that of the reference item Before and after storage the LD_{50} of the test item is not significantly lower than that of the reference item. Therefore, the test item is considered to be stable when stored for 42 months at 5°C.			
B.2.2.1.2 For liquid preparations: Effects of low temperature on physical stability		SPEXIT (3.75×10^{12} granules SeMNPV/L, SC)	No information available	SPEXIT is a liquid formulation and therefore the effect of low temperature of physical stability is requested **Statement of the RMS:** **For liquid preparations a study on the effects of low temperature on physical stability was not conducted and is not considered to be necessary as baculovirus would hasn´t been seen to harmed by freezing no significant effect of freezing was seen in the reference product stored at -20ºC..**	N	Konrad, R. (2014)
B.2.2.1.3 Shelf life of the preparation at the recommended storage temperature	-	-	-		N	Konrad, R. (2014)
B.2.2.2 Effect of exposure to air, packaging etc. on the product stability	-	-		**Experience in the use of SPEXIT shows that the properties of the MP are not expected to be affected by humidity and temperature. In addition, stability studies have been conducted at 5 °C to assess the effect of temperature. The effects of light are not applicable as the product is packaged in opaque**	N	Konrad, R. (2014)

Test or study & Data point	Guideline and method	Test material purity and specification	Used methods and Results	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
				material.		

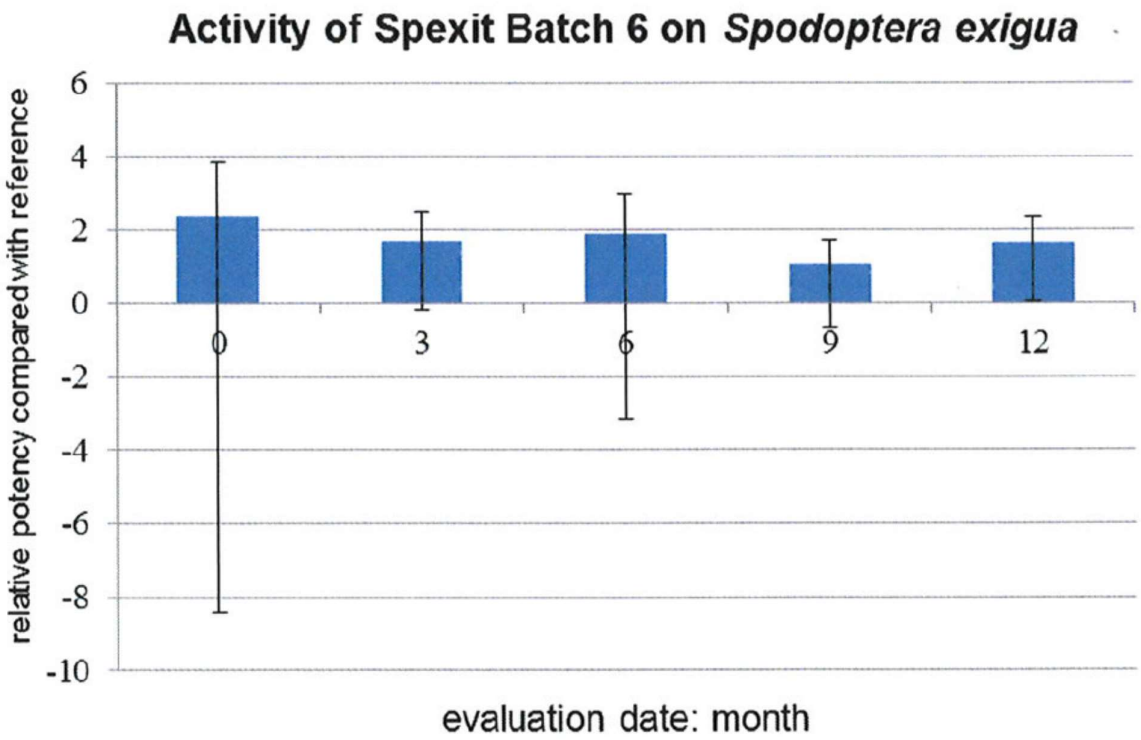

Figure MP B.2.2.1.1-1 Activity of Spexit Batch #6 during storage for l2 months at 5ºC, Konrad, R. (2014). The biological activity of SeMNVP was determined in a bioassay test. The dose-dependent mortality was calculated by profit analysis.

B.2.3 EXPLOSIVITY AND OXIDISING PROPERTIES

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B 2.3.1 Explosivity and oxidizing properties	EC Method A.14 and Guideline OPPTS 830.6316 EC Method A. 21	CpGV, batch no. 472 (3×10^{13} granules/L) (technical material)	The technical product is water based and does not have explosive or oxidizing properties as demonstrated in the two studies. No explosive or oxidising properties are expected for the formulation as all other product components do not have explosive or oxidising properties and no reactivity will occur between product components.	Acceptable for SPEXIT	Y	Ahrens, A. (2011)

B.2.4 FLASH POINT AND OTHER INDICATIONS OF FLAMMABILITY OR SPONTANEOUS IGNITION

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B 2.4.1 Flash point and other indications of flammability or spontaneous ignition	EC Method A.9	HELICOVEX Batch 002 (>7.5 x 10^{12} NPV/liter)	The technical product is water based and is not flammable at all. No flash point under atmospheric conditions (1013 kPa) was observed up to 101 °C. No flash point under atmospheric conditions is expected for the formulation as all other product components are inert and not flammable.	Acceptable for SPEXIT	Y	Messerschmidt, S. (2006a)

B.2.5 ACIDITY, ALKALINITY AND IF NECESSARY PH VALUE

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B 2.5.1 Acidity, alkalinity and if necessary pH value	CIPAC MT 75.3 OPPTS 830.7000	SPEXIT (3.75×10^{12} granules SeMNPV/L, SC)	pH of a 1 % dispersion: 6.35 (23.1 °C) / 6.84 (24.1 °C) Acidity/alkalinity: Not determined	Acceptable	Y	Aversa, S. (2013a)
	CIPAC MT 75.3 OPPTS 830.7000	HELICOVEX; active ingredient: *Helicoverpa armigera* nucleopolyhedrovirus (HearNPV), 7.5×10^9 NPV/mL; Batch No. 024	pH of 1% aqueous solution: 6.43 - 6.92 (23.4-24.1 °C) Acidity / Alkalinity was not determined because it is not required when the pH value is > 4 and < 10.		Y	Aversa, S. (2013b)
	CIPAC MT 75.3	LITTOVIR ($\geq 5 \times 10^{11}$ NPV / L, SC)	pH of a 1 % dispersion: 6.31 Acidity/alkalinity: Not determined because the pH was > 4 and < 10		Y	Walter et al. (2018)

B.2.6 VISCOSITY AND SURFACE TENSION

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B 2.6.1 Viscosity and surface tension	OECD 114 OPPTS 830.7100	SPEXIT (3.75×10^{12} granules SeMNPV/L, SC)	mPa s (RPM 2.5-50) 3120.4 - 610.4 T [°C] 203027.2 - 410.3 T [°C] 40	Acceptable	N	Aversa, S. (2013a)
	EEC A.5	MADEX (3×10^{13} granules CpGV/L, SC)	Surface tension 39.9 mN/m at 20°C (0.1 % aqueous solution)		Y	Walter, D. (2004)

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
	OECD 114 OPPTS 830.7100	HELICOVEX Batch no. 024	mPa s (RPM 2.5-50) 690.1-2863.7 T [°C] 20 405-1490.3 T [°C] 40		Y	Aversa, S. (2013b)
	EEC A.5, OECD 115	HELICOVEX Batch no. 002	52.5 mN/m at 20.1°C (1.0 g/L test dilution) Surface active as < 60 mN/m		Y	Messerschmidt, S. (2006b)

B.2.7 TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B 2.7.1 Wettability			Only required for solid preparations.			
B 2.7.2 Persistent foaming	CIPAC MT 47	MADEX (3 x 10^{13} granules CpGV/L, SC)	50 µL MADEX in 200 mL water Standing time / Foam volume [mL] 10 s 0 1 min 0 3 min 0 12 min 0		N	Fanger, U. (2005a)

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
	CIPAC MT 47.2	HELICOVEX; active ingredient: Helicoverpa armigera nucleopolyhedrovirus (HearNPV), 7.5 × 10^9 NPV/mL; Batch No. 008	Item: 0.1 % (w/v) dispersion in water After (mL) — Foam volume [mL] 10 s — 0 1 min — 0 3 min — 0 12 min — 0		Y	Walter, D. (2011)
	CIPAC MT 47.3	LITTOVIR ($\geq$ 5 x 10^{11} NPV / L, SC)	50 µL LITTOVIR in 200 mL water Standing time — Foam volume [mL] 10 s — 0 1 min — 0 3 min — 0 12 min — 0		Y	Walter, D. (2018)
B.2.7.3 Suspensibility, suspension stability	CIPAC MT 161 MT 160	MADEX (3 x 10^{13} granules CpGV/L, SC)	Suspensibility after 30 min of standing (0.25 mL/L): 89.4 % Spontaneity of dispersion after 5 min. of standing: 96.73 %		N N	Fanger, U. (2005b) Fanger, U. (2005c)
	CIPAC MT 184 CIPAC MT 160	HELICOVEX; active ingredient: Helicoverpa armigera nucleopolyhedrovirus (HearNPV), 7.5 × 10^9 NPV/mL; Batch No. 008	After 30 minutes of standing highest spray concentration 0.1% (v/v): 96.7%. After inversion of the cylinder, the test item was left standing for 5 minutes and the calculated spontaneity of dispersion was 96.7%.		Y	Walter, D. (2011)
	CIPAC MT 184 MT 160	LITTOVIR ($\geq$ 5 x 10^{11} NPV / L, SC)	Suspensibility after 30 min of standing (0.2 % (v/v)): 102.0 % Spontaneity of dispersion after 5 min. of standing: 99.9 %		Y Y	Walter, D. (2018)

Test or study & Data point		Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B.2.7.4	Dry sieve test and wet sieve test	CIPAC MT 59.3	MADEX (3×10^{13} granules CpGV/L, SC)	Wet sieving: 75 µm 2.5 % residues 100 µm 1.6 % residues 125 µm 1.2 % residues 140 µm 1.1 % residues		N	Fanger, U. (2005d)
		CIPAC MT 185	HELICOVEX; active ingredient: Helicoverpa armigera nucleopolyhedrovirus (HearNPV), 7.5×10^9 NPV/mL; Batch No. 008	Wet sieving: 75 µm 1.1 % residues		Y	Walter, D. (2011)
		CIPAC MT 185	LITTOVIR ($\geq 5 \times 10^{11}$ NPV / L, SC)	Wet sieving: 75 µm 0.8 % residues		Y	Walter, D. (2018)
B.2.7.5	Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)			Only required for granular preparations			
B.2.7.6	Emulsifiability, re-emulsifiability, emulsion stability			Not applicable			

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B.2.7.7 Flowability, pourability (rinsability), dustability	CIPAC MT 148	MADEX (3×10^{13} granules CpGV/L, SC)	Flowability: Not applicable Pourability: Residue: 1.05 % Rinsed residue: 0.16 % Dustability: Not applicable		N	Fanger, U. (2006)
	CIPAC MT 148	HELICOVEX; active ingredient: Helicoverpa armigera nucleopolyhedrovirus (HearNPV), 7.5×10^9 NPV/mL; Batch No. 008	Residue: 9.3% Rinsed residue: 0.3%		Y	Walter, D. (2011)
	CIPAC MT 148	LITTOVIR ($\geq 5 \times 10^{11}$ NPV / L, SC)	Flowability: Not applicable Pourability: Residue: 2.35 % Rinsed residue: 0.16 % Dustability: Not applicable		Y	Walter et al. (2018)

B.2.8 PHYSICAL, CHEMICAL AND BIOLOGICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B.2.8.1 Physical compatibility			Not applicable			
B.2.8.2 Chemical compatibility			Not applicable			

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Comments (Acceptable / Non-acceptable)	GLP Y/N	Reference
B.2.8.3 Biological compatibility			Not applicable			

B.2.9 ADHERENCE AND DISTRIBUTION TO SEEDS

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	GLP Y/N	Reference
B.2.9 Adherence and distribution to seeds	Statement		No preparation for seed treatment.		

RMS comment and conclusion on volume 3, B2 MP

The examination above is only valid if SPEXIT identical to MADEX AND HELICOVEX, which is stated by the applicant. The information of the composition of SPEXIT, MADEX AND HELICOVEX is in confidential document volume V4- Appendix 3 Composition of SPEXIT, MADEX, HELICOVEX and LITTOVIR. The equivalence composition of the additives was confirmed by RMS.

B 2.10 SUMMARY AND EVALUATION OF DATA PRESENTED UNDER POINTS 2.1 TO 2.9

SPEXIT, MADEX, HELICOVEX and LITTOVIR are grey-brown and odourless suspension concentrates which are not explosive, oxidizing or flammable. Their pH is within the neutral range. No loss of efficacy is noted when SPEXIT, MADEX, HELICOVEX and LITTOVIR are stored at – 18 °C for two years (for SPEXIT the storage stability study was only conducted for a year, but a GLP storage stability study will be launched in autumn 2018). The technical properties of SPEXIT, MADEX, HELICOVEX and LITTOVIR indicate that no particular problems are to be expected when they are used as recommended.

B.2.11 REFERENCES RELIED ON

A literature search according to EFSA (2011)[13] was conducted to identify relevant recent published peer reviewed references covering the last 10 years (Gueli Alletti, 2018). The literature research was conducted on the search-engine ProQuest Dialog™. The data requirement "Biological properties of the micro-organism" was covered using a focused search encompassing BVs in general but focused on specific search terms related to biological properties. This focused search retrieved a large number of references (240) which were sorted manually for relevance for the data requirements. After a first check for relevance, 22 references were submitted to full text analysis. According to the full text analysis 17 references were regarded relevant for M-MA Section 1, Section 2 and Section 3 of this dossier. For all details on the selection process, please refer to the literature review report submitted in KMA 1.3/01.

From peer reviewed open literature, no essential new findings on the SeMNPV description or strain characterisation were identified by the applicant. Instead, a reference describing the SeMNPV structure in more details was found.

RMS comments:

- RMS has considered all document as new information on the current Draft Assessment Report for the new microbial pest control agent SeMNPV.
- In the opinion of the RMS, the literature research made by the applicant according to EFSA 2011 guidance covered the most relevant news for SeMNPV. The RMS has included the missing references along the document and in the reference section B.1.5

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 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

[13] Guidance of EFSA: Submission 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

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 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
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 Biotecnologie 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 claimed 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 Biotecnologie 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
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

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 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