

# ***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.1 Identity**

**Rapporteur Member State: Spain**

**April 2020**

**Version History**

<b>When</b>	<b>What</b>
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## INTRODUCTION

The company Andermatt Biocontrol 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<sup>1</sup>. 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<sup>2</sup> and 284/2013<sup>3</sup> and the principles for evaluation and authorization of plant protection products contained microorganism according to regulation 546/2011<sup>4</sup>.

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 necessarily evaluated at strain level (SANCO/0253/2008).<sup>5</sup> 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<sup>6</sup>, 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<sup>7</sup> 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

<sup>1</sup>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.

<sup>2</sup> 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.

<sup>3</sup>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.

<sup>4</sup>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.

<sup>5</sup>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.

<sup>6</sup>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.

<sup>7</sup>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.

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<sup>8</sup>. The active substance SeMNPV was under programmed of renewal Regulation EU 686/2012 (AIR-III program<sup>9</sup>). According to draft working document AIR III renewal program SANCO/2012/11284<sup>10</sup>, *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<sup>11</sup> 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 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)<sup>12</sup> 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.

<sup>8</sup>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.

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

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

<sup>11</sup>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.

<sup>12</sup>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.

**B.1 IDENTITY OF THE PLANT PROTECTION PRODUCT**

PPP (product name/code):	SPEXIT	Formulation type:	SC
Active Substance: (SeMNPV)	<i>Spodoptera exigua</i> multicapsid nucleopolyhedrovirus	Conc. of a.s.:	$3.75 \times 10^{12}$ OBs/L
Applicant:	Andermatt Biocontrol GmbH	professional use	<input checked="" type="checkbox"/>
Zone(s):	EU	nonprofessional use	<input checked="" type="checkbox"/>
Safener:	n.a.	Conc. of Safeners:	n.a.
Synergist:	n.a.	Conc. of synergist:	n.a.
Verified by RMS:	yes		

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

n.a. Not applicable

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:  e.g. g safener/synergist per ha
					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		
1	EU	Pepper (CPSAN)	F/G	<i>S. exigua</i> (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) $7.5 \times 10^{11}$ b) $1.35 \times 10^{13}$	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	<i>S. exigua</i> (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) $7.5 \times 10^{11}$ b) $1.35 \times 10^{13}$	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



**B.1.1 APPLICANT****SPEXIT**

Name	Andermatt Biocontrol Suisse AG (new Swiss subsidiary of Andermatt Biocontrol AG)
Address	Zellerstrasse 9 79618 Rheinfelden Germany
Contact person	██████████
Phone	██████████
Fax	██████████
Email	████████████████████

**B.1.2 MANUFACTURER OF THE PREPARATION AND THE MICROORGANISM(S)**

The manufacturer of the active substance, as well as the formulated product, is Andermatt Biocontrol GmbH. For further information, see confidential information, Volume 4, Annex C.

**B.1.3 TRADE NAME OR PROPOSED TRADE NAME, AND MANUFACTURER'S DEVELOPMENT CODE NUMBER OF THE PREPARATION IF APPROPRIATE**

The trade name is SPEXIT

**B.1.4 DETAILED QUANTITATIVE AND QUALITATIVE INFORMATION ON THE COMPOSITION OF THE PREPARATION**

The identity and content of the composition, co-formulates, impurities and additives is confidential and is presented in Vol 4.

The BV that is subject of this dossier is *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004. The strain is deposited since 2006 in the German Collection of Microorganisms and Cell Cultures (DSMZ), Mascheroder Weg 1b, D-38124 Braunschweig, Germany. The Reference number is BV-0004 (Schönfelder, 2006).

Content of active substance *Spodoptera exigua* multicapsid nucleopolyhedrovirus:  $3.75 \times 10^{12}$  OB/L. The MPCA is a baculovirus without concrete development phases. The product contains occlusion bodies (OBs).

For further information regarding the composition in terms of g/kg or g/L and % w/w of each ingredient in MPCP see Confidential information, Volume 4, Annex C.

The identity and content of the composition, co-formulates, impurities and additives is confidential and is presented in Vol 4.

For further information regarding quality control data (measures of quality criteria) from 3-5 production batches, including product stored for duration of shelf life if it is metabolically active see Confidential information, Volume 4, Annex C and table MP B.1.4-1 for the limits for microbial contaminants in microbial product SPEXIT.

For further information regarding the formation and/or impact of unintentional ingredients, see confidential information, Volume 4, Annex C.

**Table MP B.1.4-1: Limits for microbial contaminants in SPEXIT**

Microbial contaminants and pathogens	Threshold in SANCO/12116/2012 rev.0
Aerobic mesophilic count	Max. 10 <sup>8</sup> CFU/g
<i>Bacillus cereus</i>	< 10 <sup>7</sup> CFU/g
<i>Staphylococcus aureus</i>	Negative in 1g
<i>Escherichia coli</i>	Negative in 1g
<i>Salmonella</i> spp.	Negative in 25g

**Safeners, synergists and co-formulates**

See confidential information, Volume 4, Annex C.

**B.1.5 PHYSICAL STATE AND NATURE OF PREPARATION**

Aqueous suspension concentrate [SC].

**B.1.6 FUNCTION**

Function: SeMNPV acts as insecticide, for biological control of the beet armyworm, *Spodoptera exigua*.

Field of use: Horticulture

### B.1.7 REFERENCES RELIED ON

A literature search according to EFSA (2011)<sup>13</sup> 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.

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

ABA – Andermatt Biocontrol AG

<sup>13</sup>

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