European Commission

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

Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV)

List of Endpoints

Rapporteur Member State: Spain

April 2020

Version History

When	What
18/09/2018	Completeness check report of the dossier submitted by the notifier
December 2019	DAR submitted to the Notifier for commenting
February 2020	DAR updated with notifier comments
April 2020	DAR updated after EFSA completeness check

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FORMAT FOR THE LISTING OF END POINTS FOR A MICROBIAL OR VIRAL PEST CONTROL AGENT (MPCA) USED IN PLANT PROTECTION

The company Andermatt Biocontrol Suisse AG (new Swiss subsidiary of Andermatt Biocontrol AG) submits submits data on *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) and the formulated product SPEXIT to the European authorities for the evaluation of the microbial pest control agent under Regulation (EC) 1107/2009. SPEXIT is a biological insecticide formulated as suspension concentrate, containing 3.75×10^{12} occlusion bodies (OB) of SeMNPV in 1 L product.

Spodoptera exigua multicapsid nucleopolyhedrovirus belongs to the family of baculoviruses. The inclusion of other baculovirus results in this dossier is justifiable due to this family relationship. This virus acts specific against larvae of the Beet armyworm, *Spodoptera exigua*, and is not supposed to have any harmful effects on organisms not belonging to the genus *Spodoptera*. With regard to safety problems, it is important to note that SeMNPV and the whole group of baculoviruses are naturally present in the environment. The experience that baculoviruses present no risk to mammals and men has been confirmed by numerous studies. Their application in pest control means only a fluctuation of the virus titre in the biotope of the pest insect.

Studies performed with the products Granupom and MADEX, both containing *Cydia pomonella* granulovirus (CpGV) are considered applicable and relevant also with regard to the evaluation of the formulated product SPEXIT.

General remark:
Testing of microorganisms will often be made using specifically tailored studies. Therefore, e. g. toxicity/effects endpoints may differ from case to case. This endpoint list can therefore be seen as indicative only, to be adapted in order to fit individual cases.

APPENDIX II: LIST OF ENDPOINTS

Appendix II.1: Chapter 1 (identity, biological properties, details of uses, further information and proposed classification and labelling)

Identity, Biological properties, Details of uses, further information, and Proposed Classification and Labelling

Active microorganism	*Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) isolate Bv-0004
Function	Control of *Spodoptera exigua*, Bioinsecticide

Rapporteur Member State:	Spain
Co-rapporteur Member State	

Identity of the Microbial Pest control Agent / Active substance (OECD data point IIM 1)

Name of the organism	The valid name of the baculovirus that is subject of this dossier is *Spodoptera exigua* multiple nucleopolyhedrovirus or multicapsid nucleopolyhedrovirus (SeMNPV).In the literature, and previous submitted dossier the term *Spodoptera exigua* nucleopolyhedrovirus (SeNPV) is also used and refers to the same species.
Taxonomy	Domain: Virus Order: *Unassigned* Family: *Baculoviridae* Genus: *Alfabaculovirus* Specie: *Spodoptera exigua multiple nucleopolyhedrovirus* Strain: *Reference number: BV-0004*
Species, subspecies, strain	Strain: *Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate Bv-0004
Identification detection	Genotypic identification: Restriction fragment analysis. Strain specific method submitted is not fully acceptable. Phenotypic identification: Biotest
Culture collection	*Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) pool of isolates Bv-0004 is deposited in the German Collection of Micro-organisms and Cell Cultures Leibniz-Institute (DSMZ) GmbH, with reference number: - Bv-0004 (SeMNPV)
Minimum and maximum concentration of the MPCA used for manufacture of the formulated product	Confidential information, please refer to Volume 4. The occlusion body's count of the technical material seems to be approximately 3.75x 10^{13} OB/mL. A study has been submitted, however there are uncertainties regarding the relevance of the material tested. The content of MPCA in the TGAI is therefore considered to be a data gap.- SPEXIT end use product contains a min of 3.75x 10^{13} OB/mL of SeMNPV A min of 3.75x 10^{13} OB/mL copies/L up to a maximum of 3.75x 10^{13} OB/mL. **(Need to be clarified)**
Identity and content of relevant impurities, additives, contaminating organisms in the technical grade of MPCA:	BVs are rod-shaped and enveloped and contain a circular double-stranded DNA genome Confidential information, please refer to Volume 4.

	No information in relevant impurities have been submitted. The content of impurities in MPCA in the TGAI is therefore considered to be a data gap. -The content of insect debris or nutrients for the insect used were not determine. • No metabolites are produced by SeMNPV • Contaminating microorganisms are determined by ISO standard methods.
Is the MCPA genetically modified; if so provide type of modification	*Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate pool Bv-0004 is natural wild type microorganisms.

Biological properties of the microorganism (OECD data point IIM 2)

Origin and natural occurrence	*Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV), isolate pool Bv-0004 has been isolated from *S. exigua* larvae in nature in China in 2001. There is no confirmed information on the origin of the isolate, considered to be a data gap. The isolate was characterised and its biological properties further studied.
Background level	Background levels are not known, but the virus replicates in *Spodoptera exigua* lepidoptera insects and can survive for short times on the environment (soil, air or water). Varies depending on presence of the host. Not reported. considered to be a data gap.-
Target organism(s)	Restricted to *Spodoptera exigua (armyworm)* insects belongs to the lepidopteran family. There is no specific studios with the isolate SeMNPV-Bv0004 on the effect in non-target related arthropods (S. *litura, Agrotis ipsilon, A. segetum, Bombyx mori, Hyphantria cunea, or Stilpnotia salicis).* There is no scientific evidences confirmed SeMNPV-Bv-0004 only infects the larvae of *S. exigua.* It cannot be confirmed the high host specificity of SeMNPV-Bv0004**. A data gap is therefore identified.**
Mode of action	Following ingestion the virus multiplies inside the insect's body leading to death.
Host specificity	Restricted to arthropod belongs to the lepidopteran family.
Life cycle	The virus is ingested by the feeding larva and the protective virus protein matrix is dissolved in the insect's midgut, releasing the virus particles still enclosed in their protein coats. These pass through the peritrophic membrane and invade midgut cells by fusion with the microvilli. The virus particles invade the cell nuclei where they are uncoated and replicated. Initial replication produces non-occluded virus particles to hasten the invasion of the host insect. Later the virus particles are produced with protein matrices and remain infective when released from the dead insects.
Infectivity, dispersal and colonization ability	Not related to any plant or human pathogen, all baculoviruses are specific for arthropods. SeMNPV is not able to infect any organism except few species of the genus *Spodoptera*. Multiplication only occurs in the species *S. exigua*. SeMNPV is highly specific to *S. exigua* larvae in lepidopteran family. SeMNPV might survive or replicate also other genera arthropod from same family without causing adverse effects. Data unknown. Infectivity: The presence or absence of specific virulence factors are not indicated. It is clearly established baculovirus can NOT cause food poisoning in humans or animals. SeMNPV is not able to infect any organism except few species of the genus Spodoptera. Multiplication only occurs in the species *S. exigua.* Dispersal: SeMNPV OB are suggested to be rather immobile after their introduction into the environment. It is unclear whether or not the OB and virions can multiply in the target organism, and hence be a potential source of dispersal. No information concerning optimum environmental conditions for SeMNPV, e.g. temperature range at which the microorganism grows, pH, nutrient requirements

	etc. OB of SeMNPV are significantly more resistant to UV-B than OB of other baculovirus. Colonisation ability: Information on colonisation ability is scarce. According to two studies (presented in Vol 3, B.8), SeMNPV is not found in out of the target organisms for extended periods of time. **The specific mechanism of virus transmission in SeMNPV isolate Bv-0004 is unknown. Considered to be a data gap.**
Pathogenicity:	There are indications that OB proliferation into the haemocoel of the target organisms may result in septicaemia, contributing to mortality of the insect larvae.
Genetic stability	Stability during the production process, the stored period and under application conditions is not reported. There is no information whether or not genetic transfer may occur in soil, however this cannot be excluded under favourable environmental conditions, since is a virus. **Considered to be a data gap.-**
Information on the production of relevant metabolites (especially toxins)	Viruses do not produce metabolites, as they do not have metabolism of their own. The SeMNPV complete viral genome sequence of other isolate is known and the encoded typical proteins are well understood. None of these proteins shows any homology to known human or animal toxins. It can therefore be stated with certainty that SeMNPV does not produce toxins, not even after infecting the insect host cell. SeMNPV does not have the potential to form toxins or metabolites of human health or environmental concern after release into the environment.
Resistance/sensitivity to antibiotics/ antimicrobial agents used in human or veterinary medicine	Not relevant for baculovirus. Viruses are not metabolically active and cannot produce antimicrobial substances; they are not sensitive to antibiotics and therefore cannot become resistant to these substances or spread resistance.

Classification and proposed labelling (Symbol, Indication of danger, Risk phrases, Safety phrases)

with regard to physical/chemical data:	Not relevant
with regard to toxicological data:	Not relevant. Following Regulation (EC) 283/2013, all microorganisms should be considered potential sensitizers.
with regard to fate and behavior:	Not relevant
with regard to ecotoxicological data:	Not relevant

Appendix II.2: Chapter 2 (Methods of analysis)

Analytical methods for the microorganism (OECD data point IIM 4.2, 4.3 and IIIM 5.3)

Manufactured microorganism (principle of method)	The content of SeMNPV TCA is determined in a biotest. There are several scientifically validated method to identify and quantify baculoviruses such as: Nucleotide sequencing Molecular hybridization RT-qPCR Bioassay **The method to identify and fully discriminate SeMNPV at strain level needs to be verified by testing variants of SeMNPV as well as other viruses, viroid, bacterium, fungi and oomycetes.**
Impurities and contaminating microorganism in manufactured material (principle of method)	- Mutants or genetic modifications are verified by REA analysis of viral DNA. Spontaneous changes would be reflected in changes of infectivity, thus modifications are verified by bioassay test.

	- Microbial contaminants and pathogens: **ISO guidelines methods** ISO 4833, ISO 7932, ISO 6888-2, ISO 16649-2, ISO 6579 - The virus does not produce metabolites. - Rest of insect and insect feed materials are not evaluated. - Other microorganism contaminates (viruses, viroids, bacteria and fungi) need to be determine by molecular hybridization or PCR test.
Microbial pest control product (principle of method)	Scientifically validated and published methods are used, such as: RT-qPCR Molecular hybridization Bioassay **The method to identify and fully discriminate SeMNPV strain level need to be verified by testing variants of SeMNPV as well as other viruses, viroid, bacterium, fungi and oomycetes.**

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms (OECD data point IIM 4.5)

Of the active microorganism (principle of method)	Not necessary
Of relevant impurities (principle of method)	Not necessary (no metabolites) Rest of insect and insect feed materials are not evaluated.

Appendix II.3: Chapter 3 (Further information, Efficacy)

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Effectiveness	Biological insecticide for the control of the Lepidoptera *S. exigua* in horticulture crops products based on *S. exigua* multipolyhedrovirus.
Mode of action	Efficacy data provided by the applicant covers the use in green house for pepper with 3 assays in greenhouse, documents MP3/10.3-01, MP3/10.3-02 and MP3/10.3-03. For open field uses the applicant have included one assay in lettuce, document MP3/10.3-04. SPEXIT is applied by foliar spraying: tractor drawn motor sprayers and knapsack sprayer.
Target insect	Application of SeMNPV should be timed at hatching of larvae so that early-instar larvae come in contact with the virus. The early instar larval stages of the insect life cycle are the most susceptible to infection with SeMNPV. SeMNPV is a baculovirus: SeMNPV is ingested by feeding larvae. OB dissolve in the alkaline midgut and after infection of the midgut epithelium, other tissues are invaded, e.g. fat body, epidermis, and tracheal matrix as well as the Malpighian tubules. Rapid virus multiplication within the host cells finally results in cell destruction and at the end leads to lysis of the whole organism. The intended target insect is exclusively the beet armyworm *Spodoptera exigua... S. exigua* is a polyphagous pest feeding on over 200 different crops amongst which there are: sugar beet, cabbage, lettuce, soybeans, cotton, maize, tomato, potato, legumes, citrus, strawberry, melon, leek, garlic, onion, rice, flax, and tobacco.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

Adverse effects on field crops	No adverse effects on field crops have been observed. SPEXIT risk of phytotoxicity is considered as negligible for lettuces and peppers at these doses, number of applications and interval between applications. To date, no resistance development against Bv have been found. Because of the long existence of the disease-viruses relation, the probability of resistance appearance or development is considered as low. A resistance management strategy is not considered necessary.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

Observations on other undesirable or unintended side effects	-Non target organisms: see Ecotoxicology Section.

Impact on Human and Animal Health (Regulation (EU) N° 283/2013, Annex Part B, point 5 and Regulation (EU) N° 284/2013, Annex Part B, point 7)

Medical data: (including medical surveillance on manufacturing plant personnel) (MA 5.1.1)	SeMNPV does not affect any organism except moth larvae of the genus Spodoptera. No replication in mammalian cell lines takes place. A toxin is not produced. Toxic metabolism or degradation products do not occur. Medical surveillance reports from baculovirus (including SeMNPV) production sites confirm that no adverse effects on the health of manufacturing plant personnel exist.
Sensitisation: (MA 5.2.1 & MP 7.2.3)	No indications on sensitisation by baculovirus agents/products were observed at manufacturing personnel or field operators, workers, bystanders, or consumers. Following Regulation (EC) 283/2013, all microorganisms should be considered potential sensitizers.
Acute oral infectivity, toxicity and pathogenicity: (MA 5.2.2.1 & MP 7.1.1)	LD_{50} oral rat > 3×10^9 PIB *Prodenia litura* NPV /kg bw LD_{50} oral rat > 5×10^9 PIB *Autographa californica* NPV /kg bw
Acute intratracheal/inhalation infectivity, toxicity and pathogenicity: (MA 5.2.2.2 & MP 7.1.2)	These studies are not adequate for the evaluation of acute inhalation toxicity because the doses tested are lower than the limit test dose level and very short times of exposure (5-15 min) were performed. This should be considered a DATA GAP. Therefore, no LC50 for acute inhalation toxicity can be derived.
Acute intravenous/intraperitoneal infectivity: (MA 5.2.2.3)	I.p. injection NOAEL, mice > 1×10^{11} granules/animal of CpGV > 5×10^8 PIB/animal of *M. brassicae* > 1.5×10^9 PIB/kg b.w. of *Orgyia pseudotsugata* NPV S.c. injection NOAEL, rhesus monkeys > 1.2×10^8 PIB/kg b.w. of *H. zea* NPV

Genotoxicity: (MA 5.2.3, MA 5.2.4)	Baculoviruses, based on numerous cell culture studies, do not replicate in mammalian cell lines. All *in vitro* and *in vivo* studies with other baculoviruses resulted in negative reactions. Bacterial reverse mutation test was not carried out. This should be considered a DATA GAP.
Information on short-term toxicity and pathogenicity: (MA 5.2.5)	All short-term toxicity results indicate that baculoviruses applied by oral, subcutaneous or inhalative administration over a period up to 180 days were not toxic to mammals (rats, mice, guinea pigs, dogs, rhesus monkeys), e.g. LOAEL, mice: > 34 doses, each 1.5 x 10^{10} granules CpGV applied as nutrient baits in 3 days intervals for a period of 99 days.
Dermal toxicity: (MP 7.1.3)	No dermal studies conducted. However, 10 succeeding intracutaneous injections of undiluted Hoe 08 3311 (equivalent to the product Granupom containing CpGV) did not produce systemic toxicity. This indicates that less severe dermal applications similarly are without systemic toxicity. Skin irritation of Granupom: not irritating Eye irritation of Granupom: not irritating
Specific toxicity, pathogenicity and infectivity: (MA 5.3)	Not carcinogenic (*H. zea* NPV and *L. dispar* NPV) Not teratogenic (*H. zea* NPV)
Genotoxicity – *in vivo* studies in germ cells: (MA 5.5)	No indication of genotoxicity were obtained from in vitro studies (MA 5.2.3) and in vivo studies in somatic cells (MA 5.4). Therefore, studies in germ cells are not considered necessary.

Reference values

AOEL:	Not applicable
ADI:	Not applicable
ARfD:	Not applicable

Exposure (operator, workers, bystander, consumer): (MA 6.1 & MP 7.3, 8.0)	ADI, ARfD and AOEL are not necessary (and not possible to be derived based on the available data) due to the low toxicological concern related to baculoviruses, so the risk assessment has not been performed.

Appendix II.4: Chapter 4 (Residues)

Residues in or on treated products, food and feed (Annex IIM 6; IIIM 8)

Viable residues	No risk for consumer is expected since baculovirus are ubiquitous in insects and there are no documented causes of harmful effects in humans. Viruses are not able to produce metabolites. SeMNPV is of natural origin and not toxic to man or domestic animals. Furthermore, SeMNPV is unable to enter plant tissue or to infest it and is rapidly inactivated by UV light. Thus, residue data are not required.

Non-viable residues	-Non target organisms: see Ecotoxicology Section. -SeMNPV is not a new microbial active ingredients. SPEXIT is a highly selective biological insecticide used as spray treatment against larvae of the beet armyworm *S. exigua* since 2006 (SeMNPV isolate Bv-0004 since 2010) in Europe. It was authorised in any member state since it was firstly included in 2007. Under the proposed directions of use of the GAP, there is not risk of SeMNPV infection to succeeding crops. There are no indications that the plant protection product could affect other plants, including adjacent crops. Impact on treated plants or plant products to be used for propagation is not relevant. There are not effects on the incident of other non-target organisms or environmental effects have been observed. SeMNPV is of natural origin and not toxic to man or domestic animals. Furthermore, SeMNPV is unable to enter plant tissue or to infest it and is rapidly inactivated by UV light. Thus, residue data are not required.

Appendix II.5: Chapter 5: Fate and behavior in the environment (Regulation (EU) N° 283/2013, Annex Part B, point 7 and Regulation (EU) N° 284/2013, Annex Part B, point 9)

Persistence and multiplication (competitiveness) in soil, water and air	Baculoviruses are rapidly broken down by UV light, pH and bacteria in the environment. The initial PEC for SPEXIT is 5.57 mg/kg dry weight in soil, corresponding to 1.8 x 10^7 OB/kg dry weight soil; and 87.14 µg/L (2.83 x 10^5 OB/L) in a water depth of 30 cm after max. Application of 3.6 L SPEXIT /ha (0.2 L/ha field dose rate, 18 applications, assuming no degradation between applications as a worst case). Air contamination can be excluded.
Mobility	High absorptiveness in the top organic soil layers and very little capacity to leach to lower layers.

PEC soil

Microorganism Method of calculation	• Guidance document on Persistance in soil (9188/VI/97 rev 8) EU Commission (2000) • Soil persistence models and EU registration (FOCUS, 1997)

Application data	Crop interception 0% Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: no crop interception Number of applications: 18 Interval (d): 3 Application rate(s): 1.675 kg cry protein/ha (based on a crystalline protein content of 13.6%) DT_{50}: 1000 days (default)

PECsoil (mg/kg; CFU/kg)	Multiple application Actual	Plateau	Accumulation
Initial	**PEC_{soil} =Initial PEC_{soil}5.57 mg/kg soil~1.8 x 10^7 OB/kg dry weight soil ~ 87.14 µg/L (2.83 x 10^5 OB/L)**		

PEC surface water

Microorganism Method of calculation	• Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001)
Application rate	1.35 x 10^{13} OB/ha
Initial PECsw (µg/L)	1 m 26.17 30 cm 87.143

Appendix II.6: Chapter 6 (Effects on non-target organisms)

Effects on non-target organisms (Regulation (EU) 283/2013, Annex Part B, point 8 and Regulation (EU) 284/2013 Annex Part B, point 10; OECD IIM point 8 & IIIM point 10)

Effects on birds or other terrestrial invertebrates (MA 8.1 & MP 10.1; OECD IIM 8.1 & IIIM 10.1)
No ecotoxicological data were available for *SeMNPV*. Instead, data for other BVs were used for the ecotoxicological risk assessment. RMS considered that it was reasonable to extrapolate information on toxicity, infectivity and pathogenicity from other BV on the basis that BVs have similar modes of action, and in view of the information given in the OECD consensus document (OECD, 2002).

Effects on birds (MA 8.1 & MP 10.1)

No cases of viral toxicity or pathogenicity were observed in avian species. Birds are not at risk since SeMNPV is highly specific on larvae of the Lepidoperan species *Spodoptera exigua*. Information taken from open literature indicated that BVs will not infect birds and that the virus will pass through birds without causing any infection. Overall, on the basis of the information provided the risk to birds from toxicity, infectivity and pathogenicity of SeMNPV was assessed as low. Information on baculoviruses is applicable with regard to the evaluation of SPEXIT since the ingredients of the formulated preparations are inert (Volume 4).

Effects on other terrestrial vertebrates than birds (MA 8.2 & MP 10.2)

Information taken from open literature indicated that BVs will not infect terrestrial vertebrates and that the virus will pass through them without causing any infection. Information in the terrestrial vertebrate's assessment indicated absence of toxicity, infectivity and pathogenicity. It was therefore possible to conclude a low risk to wild mammals from SeMNPV.

Effects on aquatic organisms (MA 8.3 & MP 10.3)

Group	Test material	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory tests			
Fish species (specify)			
Oncorhynchus mykiss	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	96-h (static)	LC_{50} > 2.04 x 10^9 OB/L LOEC =100 mg/L NOEC ≥ 10 mg/L

Fresh water Invertebrate species: (specify)			
Daphnia magna	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	48-h (static)	EC_{50} > 2.04 x 10^9 OB/L EC50 >100 mg/L NOEC >100 mg/L with a probability of more than 99.9 %.

Effects on algae: **(species, growth, growth rate, capacity to recover)**			
Scenedesmus subspicatus	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	Time-scale: 72 h	EC50 > 2.04 x 10^9 OB/L NOEC =100 mg/L EC50 > 100 mg/L

Effects on aquatic plants **(species, growth, growth rate, capacity to recover)**			
Lemna gibba	GRANUPON product Granulosevirus CpGV SC 3.4 × 10^{13} OB/L.	7 days	EC50 > 2.04 x 10^9 OB/L NOEC ≥ 10 mg/L

Effects on bees (MA 8.3 & MP 10.3)

Species	Test material	Crop	Route and Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory tests				
Apis mellifera	GRANUPON product Granulosevirus CpGV SC 2.45 × 10^{13} OB/L	Not relevant; laboratory test.	72h	LD50/72h=3.5 x10^7 OB/bee LD50/48h=4.4x10^7 OB/bee

Effects on terrestrial arthropods other than bees (MA 8.4 & MP 10.4)

Species	Stage	Test material	Dose (kg MPCA/ha)	Route and Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)

Aphidius rhopalosiphi	Adult	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	4.18 kg product/ha (1.35 x 10^{13} OB/ha)	48h	NOEC (48 h) > 7.9 x 10^{12} OB/ha (corresponding to 2.43 kg SPEXIT/ha)
Typhlodromus pyri	Protonymphs	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	4.18 kg product/ha (1.35 x 10^{13} OB/ha)	14 days	NOEC (7 d) > 7.9 x 10^{12} OB/ha (corresponding to 2.43 kg SPEXIT /ha)
Poecilus cupreus	6 - 9 weeks old	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	4.18 kg product/ha (1.35 x 10^{13} OB/ha)	7days	NOEC (7 d) > 9.9 x 10^{12} OB/ha (corresponding to 3.06 kg SPEXIT /ha)

Effects on other terrestrial invertebrates (MA 8.5 & MP 10.5)

Species	Test material	Crop	Route and Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory tests				
Eisenia foetida	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	Not relevant; laboratory test.	14 days	LC50 > 1000 mg/Kg soil =1.67x10^{10} LC50 > 3.25 x 10^{9} OB/kg soil (test substance Granupom)

Effects on soil microorganisms (MA 8.6 & MP 10.6)

Species	Test material	Crop	Route and Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory tests				
- carbon producers soil microorganims - Nitrificant soil microorganism	Granulosevirus CpGV SC 2.2 × 10^{13} OB/L.	Not relevant; laboratory test.	28 days	Soil respiration deviation<15% Nitrogen transformation deviation <15% No effect in soil microorganism

Additional studies

No additional studies were submitted

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Analysis of the active microorganism (principle of method)	Bioassay
Analysis of relevant metabolites (principle of method)	No relevant metabolites are produced

Summary of uses supported by available data (Regulation (EU) N° 283/2013, Annex Part B, point 3; MA Section 3)

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	non-professional use	☒
Safener:	n.a.	Conc. of Safeners:	n.a.
Synergist:	n.a.	Conc. of synergist:	n.a.
Verified by RMS:	y/n		

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	*Spodoptera 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	*Spodoptera 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

n.a. Not applicable