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.9 Effects on non-target organisms

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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B.9 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 1107/2009[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 Netherlans 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	non professional use	☒
Safener:	n.a.	Conc. of safener:	n.a.
Synergist:	n.a.	Conc. of synergist:	n.a.
Verified by RMS:	yes		

Table MP B.9.1. Summary of critical Good Agricultural Praxis for SPEXIT

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. interva 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	*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

n.a. Not applicable

B.9.1 EFFECTS ON BIRDS

It is referred to the information submitted for BVs in Vol3 MA B.10.1. The ingredients of the preparation SPEXIT formulated as SC are inert and no hazards to birds are expected. Therefore, studies and information on the active ingredient, *Spodoptera exigua* SeMNPV, are considered applicable and relevant with regard to the evaluation of effects of the formulated product on birds. SeMNPV is highly specific and only replicates in larvae of *S. exigua*, birds are not at risk and studies are not regarded as necessary

Information taken from open literature indicated that baculoviruses 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 in the mammalian toxicological assessment indicated absence of toxicity, infectivity and pathogenicity. It was therefore possible to conclude a low risk to wild mammals from *S. exigua* MNPV isolate Bv0004 and its product SPEXIT.

B.9.1.1 Toxicity to birds

The active substance is a virus. Viruses have no metabolism of their own and are therefore not able to produce secondary metabolites**:** Due to the physical and biological characteristics of the MPCA SeMNPV refers in volume 3 (B2.8.) there is no production of toxins/metabolites.

RMS comments:
No studies on toxicity of SPEXIT to birds were submitted by the applicant.

B.9.1.2 Infectiveness to birds

The mode of action of BVs is very specific. The replication of BVs in permissive hosts as well as in semi- or non-permissive host cells showed that in case of a non-compatible baculovirus-host cell interaction, the BVs gene expression and replication is blocked at an early stage. This can be explained by a number of BVs genes involved in differential host cell and host larval specificity (OECD Consensus document No. 20).
Gröner, 1986) reported that no member of the BVs family is known to infect vertebrates. The OECD consensus document (OECD 2002) also states that no risk to birds is expected after use of BVs.

RMS comments:
No studies on the infectiveness of SPEXIT to birds were submitted by the applicant.

B.9.1.3 Pathogenicity to birds

Published studies demonstrate that the no degraded and still infective occlusion bodies of different BVs can be found in the faeces of birds fed either with BVs itself or with infected larvae (Gröner 1990). Gröner (1986) has reported that birds have the potential for transporting NPVs within “contaminated” ecosystems and even for passing feces containing infective *Gilpinia hercyniae* NPV throughout the non-larval winter period as a result of their feeding on the cadavers of NPV-killed larvae adhering to trees. Gröner & Döllner 1982 showed that attempts to destruct the inclusion body matrix by the digestion enzyme Trypsin at a pH of 9.2 was unsuccessful for 18 h, unless they were pre-treated with HCl at pH 1 for 2 h. The dissolution of the occlusion body matrix in the host of the BVs is facilitated by an insect derived alkaline protease, which is associated with the occlusion body matrix (OECD Consensus document No. 20). The high pH in the stomach of birds is possibly responsible for the resistance of occlusion bodies to the alkaline proteases within the gut, and BVs non-degraded occlusion bodies are not able to invade the midgut cells of birds.

RMS comments:
No studies on the pathogenicity of SPEXIT to birds were submitted by the applicant.

B.9.1.4 Risk assessment for birds

Reports from literature clearly exclude adverse effects on birds. In general, no member of the Bvs family is known to be infective to vertebrates. No toxicity, no pathogenicity, and no infectivity to birds was ever observed for any BVs previously used as a biological control agent.
Considering all facts, a risk on birds caused by the application of BVs as microbial plant protection products would be remote.

RMS conclusions:
Even all considerations above mentioned, the RMS consider convenient to include at least one specific short-term dietary pathogenicity/toxicity study with the product SPEXIT, due to the insectivorous birds can eat contaminated insects contained the dissolved OB in the active substance treated area (worst-case assumptions). There is no information on the short-term and long-term espouse on the ingestion by the birds of *S. exigua* infected larvae by the virus from SPEXIT spraying. No acute end-points are available and no studies on birds were submitted on infectivity from MPCP Andermatt Biocontrol GmbH.

The RMS consider that a study need to confirm the reports from literature excluding adverse effects on birds. A data gap is therefore identified.

B.9.2 EFFECTS ON TERRESTRIAL VERTEBRATES OTHER THAN BIRDS

In general, no member of the baculovirus family is known to be infective to vertebrates. For the sake of completeness a mammalian risk assessment is conducted according to the Guidance Document SANCO/4145/2000 (2002). Information in the mammalian toxicological assessment indicated absence of toxicity, infectivity and pathogenicity. It was therefore possible to conclude a low risk to wild mammals from *S. exigua* NPV.

B.9.2.1.1 Toxicity to vertebrates others than birds

RMS comments:
No studies on the toxicity of SPEXIT to vertebrates others than birds were submitted by the applicant.

B.9.2.1.2 Infectiveness to vertebrates others than birds

RMS comments:
No studies on the infectiveness of SPEXIT to vertebrates others than birds were submitted by the applicant.

B.9.2.1.3 Pathogenicity to vertebrates others than birds

RMS comments:
No studies on the pathogenicity of SPEXIT to vertebrates others than birds were submitted by the applicant.

B.9.2.1.4 Risk assessment to vertebrates others than birds

No toxicity, no pathogenicity, and no infectivity of SPEXIT to vertebrates others than birds was ever observed for any BVs previously used as a biological control agent.
Considering all facts, a risk to vertebrates others than birds caused by the application of BVs as microbial plant protection products would be remote.

B.9.3 EFFECTS ON AQUATIC ORGANISMS

B.9.3.1 Effects on fish

B.9.3.1.1 Toxicity to fish

The effects on fish were evaluated for the product Granulosevirus CpGV SC, containing *Cydia pomonella* GV. The composition of Granulosevirus CpGV SC is comparable to that of SPEXIT. Therefore, results obtained within those studies are also applicable for SPEXIT.

Reference:	[redacted] **(1998a)** Acute toxicity testing of Granulosevirus CpGV SC in Rainbow Trout (*Oncorhynchus mykiss*) (Teleostei, Salmonidae). No. 96272/01-AAOm , BVL No.: WAT2003-373
Report No.:	**MP 10.2/01**
Guideline:	OECD Guideline 203 and Annex to commission Directive 92/69/F-EC, procedure C.1 Deviations: - A main test was not performed as at the limit concentration of 100 m/L no significant mortality could be observed. On the base of the results a main test below 100 mg/L would not give additional information - The temperature was up to 1°C lower than outlined in the study protocol. But this circumstance did not influence the validity of the test as the control group was not influenced in any way.
GLP:	YES
Summary:	In a 96-h acute toxicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed to Granulosevirs CpGV SC at nominal concentrations between 0.01 and 100 mg/L under static conditions. The 96-h LC_{50} was higher than 100 mg/L. The NOEC value, based on mortality/sublethal effects, was ≥ 10 mg/L; the LOEC was 100 mg/L. No main test neither statistical evaluation were performed because the highest mortality was 10% at the limit concentration of 100 mg/L. At this concentration level all fish showed a change in pigmentation to a darker colour, one of them with problems of maintenance of equilibrium.
M&M	• Microbial contaminants: Aerobic Counts on Microbial Contaminants and microbial analysis. • Physical and molecular stability of OBs: viral DNA and restriction endonuclease analysis. • Eficacy: Bioassays on Insecticidal Activity.
Test substances	• Test item: Granulosevirus CpGV SC 2.2×10^{13} OB/mL. Batch no AE F083311 SC13 A503 • Target organim: Rainbow trout (*Oncorhynchus mykiss*), Forellenhof Fredelsloh, U. Müller, D-37186 Moringen, Weight1 - 2 g, Length4.0 - 6.0 cm. Acclimatisation period 24 h at test conditions without food.

Test conditions	• Temperature: 14.0 - 16.9°C • Photoperiod: 12 - 16 hour photoperiod • Oxygen content: > 60% of the air saturation value. • Hardness: Approx. 20°dH • pH: 7.2 - 7.8 • In-life dates: 27.10.1997 to 13.10.1997 • System: Static • Duration: 96 hours • Test vessel: 25-Litre capacity containers • Concentration: 0, 0.01, 0.1, 1.0, 10 and 100 mg/L (2.210^4, 2.210^5, **$2.2x10^6$**, $2.2x10^7$, and $2.2x10^8$OB/mL).
Study Design and Methods	• Aeration: Continuous aeration of the test tanks with a membrane pump using a Pasteur pipette • Observations: Daily check for mortality, occurrence of sublethal effects (loss of equilibrium, erratic swimming loss of reflex, excitability, discolouration, or change in behaviour), dissolved oxygen, pH and temperature.
Results:	Up to a nominal concentration level of 10 mg/L, one fish died by chance at 0.1 mg/L. At this concentration level no lethal or sublethal effects were observed on the remaining nine organisms. The mortality may be caused by an attack of one of the others. The one dead fish at 100 mg/L represents no significant mortality caused by the test substance but it corresponds to the observed sublethal effects caused by the test substance as outlined below. According to these results, no main test was required because no significant mortality could be expected up to the limit concentration of 100 mg/L (Table MP B.9.2-1). No significant mortality neither sublethal effect was observed at all concentrations below the nominal concentration level of 100 mg/L over 96 h with the exception of a single dead fish at 0.1 mg/L who died by chance. At 100 mg/L all fish showed a change in pigmentation to a dark colour. Therefore, the concentration of 100 mg/L represented the LOEC in this test.
Conclusions:	The acute fish toxicity was determined for the test substance granulosevirus CpGV SC following the OECD guideline 203. The rainbow trout (*Oncorhynchus mykiss*) was used as test organism. The test was performed under static conditions with 5 concentrations of the test substance in a nominal range between 0.01 and 100 mg/L. the serial dilution factor was 10. The test was performed in a limit test design (10 fish per concentration) over a period of 96h. No main test neither statistical evaluation were performed because the highest mortality was 10% at the limit concentration of 100 mg/L. At this concentration level all fish showed a change in pigmentation to a darker colour, one of them with problems of maintenance of equilibrium. **Therefore, the LOEC is 100 mg/L. The NOEC is ≥ 10 mg/L. The LC_{50} value at 96 h was estimated to be > 100 mg/L.**

Table MP 8.3-1: Observation of clinical signs of fish during the main test

	Granulosevirus CpGV SC [mg/L]																							
	Control					0.01					0.1					1.0					10.0					100.0				
Time [h]	**0**	°	*	#	+	**0**	°	#	+	**0**	°	*	#	+	**0**	°	*	#	+	**0**	°	*	#	+	**0**	°	*	#	+
0	10				0	10			0	10				0	10				0	10				0	10				0
3	10				0	10			0	10				0	10				0	10				0	10				0
6	10				0	10			0	10				0	10				0	10				0	10				0
24	10				0	10			0	9			1	0	10				0	10				0	9			1	0
48	10				0	10			0	9			1		10				0	10				0	9			1	0
72	10				0	10			0	9			1		10				0	10				0	8			1	1	0
96	10				0	10			0	9			1		10				0	10				0	8			1		1

O: no clinical signs

: Unusual behaviour (reduced activity and /or orientation to bottom or surface of the vessel)

*: difficulties with maintenance of equilibrium

#: fish upside down with loss of equilibrium, showing only movement of gills as a sign of life

+: no sign of life

RMS comments:

- This study is appropriate for the assessment of the BV SeMNPV in terms of BVs similarities regarding to their host specify.

- Information on the composition of the product contained Granulosevirus CpGV is required. The confirmation of the composition of the product used in the study was provided by the applicant in order to confirm SPEXIT product and the product used with Granulosevirus CpGV SC are comparable.

- The concentration of the active ingredient in SPEXIT product is $3.75x10^{12}$ OB/L, equivalent to $3.75x10^{6}$OB/mg of MPP. According to the granulovirus concentration evaluated, there were 2.210^{4}OB/L for 0.01mg/L; 2.210^{5}OB/L for 0.1mg/L; $2.2x10^{6}$ OB/L for 1mg/L; $2.2x10^{7}$OB/L for 10mg/L and **$2.2x10^{8}$OB/L** for 100mg/L.

- The active ingredient is applied at a maximum dose per ha of 0.2 L/ha and diluted in water with a minimum of 200 L of water per ha and can be applied maximum of 18 times per crop period. There ford, the evaluation should be done with fractions (0.01, 0.1, 1.0, 10 and 100) of the concentration **$6.75x10^{10}$OB/L** This concentration is 3000 times higher that evaluated dose **$2.2x10^{8}$ OB/L.** The RMS considers the active ingredient concentration evaluated low.

(0.2L/ha) x ($3.75x10^{12}$OB/L)/(200Lwater/ha)=$3.75x\ 10^{9}$ OB/Lx18application/crop=$6.75x10^{10}$OB/L

- According to EFSA Panel on Biological Hazards (BIOHAZEFSA) 2012-a, the biological agents from baculoviridae family recommended for the QPS list and proposed as plant protection products (under the Council Directive 91/414/EC (Official Journal, 1991) could be exempted from oral toxicity data requirements.

B.9.3.1.2 Infectiveness to fish

RMS comments:
No studies on the infectiveness of SPEXIT to fish were submitted by the applicant.

B.9.3.1.3 Pathogenicity to fish

RMS comments:
No studies on the pathogenicity of SPEXIT to fish were submitted by the applicant.

B.9.3.1.4 Risk assessment to fish

RMS comments:
No toxicity, no pathogenicity, and no infectivity of SPEXIT to fish was ever observed for any BVs previously used as a biological control agent.
Considering all facts, a risk to fish caused by the application of BVs as microbial plant protection products would be remote.

B.9.3.2 Effects on freshwater invertebrates

B.9.3.2.1 Toxicity

The effects on *Daphnia* were evaluated for the product Granulosevirus CpGV SC, containing *Cydia pomonella* GV. The composition of Granulosevirus CpGV SC is comparable to that of SPEXIT. Therefore, results obtained within those studies are also applicable for SPEXIT.

Reference:	[redacted] **1998b.** Acute toxicity testing of Granulovirus CpGV SC on Daphnia magna using the 48 h acute immobilisation test. Andermatt Biocontrol AG, CH, 96272/01-AADm. Report No. 96272/01-AADm, BVL No.: WAT2003-375
Report No.:	**MP 10.2/02**
Guideline:	- OECD Guideline 202, Part I: Daphnia sp., Acute Immobilisation Test and Reproduction Test and Annex to Commission Directive 92/69/EEC, procedure C.2. Deviations: - As no effects were expected, the concentration level of 0.01 mg/L was not performed in the range-finding test. - A main test was not performed as no observable effects took place during the range-finding test. These deviations were not considered to have affected the outcome or the objectives of the study.
GLP:	YES
Summary:	The acute toxicity on *Daphnia magna* of Granulosevirus CpGV SC was tested in a 48 h static immobilisation test following the OECD guideline 202, Part I and Annex to Commission Directive 92/69/EEC, procedure C.2. The range-finding test was performed in a static design. The test was performed with a serial dilution factor of 10 between 0.1 and 100 mg/L. One control without test substance and two reference groups with potassium dichromate were also tested. No immobilisation was observed at any concentration level. Therefore, the test can be regarded as a limit test. Based on the results of the static range-finding test with a serial dilution factor of 10 between 0.1 and 100 mg/L no main test was performed. The EC_{50} is > 100 mg/L, the NOEC is 100 mg/L with a probability of more than 99.9%.
M&M:	• **Test Item:** Granulosevirus CpGV SC (2.2×10^{13} OB/mL) Brown fluid Batch no. AE F083311

	SC13 A503
Test substances:	• **Target organim:** *Daphnia magna Straus*, clone 5 Control groups: 20, Treated groups: 20, Breeding stock in the laboratory.
Test conditions:	• Temperature:20 ± 1°C • Photoperiod:16hours daily • Oxygen content: >60% air saturation • pH: 6.5-8.5 • In-life dates: 11.12.1997 to 13.12.1997 • System: static
Study Design and Methods	• Duration:48 • Test vessel: 25mm glass test tubes • Concentration: 0.1, 1.0, 10 and 100 mg/L ($2.2x10^5$, $2.2x10^6$, $2.2x10^7$ and $2.2x10^8$OB/mL). • Observation: Daily check for mortality, dissolved oxygen, pH and temperature
Results:	The immobilisation in the range-finding test was 0% up to 100 mg/L after 48 h of test duration (Table MP B.9.2-2)
Conclusions:	The immobilisation test with *Daphnia magna* was carried out at 4 concentrations ranging from 0.1 to 100 mg/L Granulosevirus CpGV SC for a period of 48 h. The test was performed in a static design. One control without test substance and two reference groups with potassium dichromate were also tested. The EC_{50} was greater than 100 mg/L, the NOEC was 100 mg/L with a probability of more than 99.9 %. At 48 h the product Granulosevirus CpGV SC did not show any toxic effect on *Daphnia magna*.

Table MP B.9.2-2: Mortality of *Daphnia magna*

Nominal concentration (mg/L)	Cumulative mortality (%)		
	hours	24 h	48 h
Control	0	0	0
0.1	0	0	0
1.0	0	0	0
10	0	0	0
100	0	0	0

RMS comments:

- This study is appropriate for the assessment of the BV SeMNPV in terms of BVs similarities regarding to their host specifity.

- The concentration of the active ingredient in SPEXIT product is $3.75x10^{12}$ OB/L, equivalent to $3.75x10^6$OB/mg of MPP.

- The active ingredient is applied at a maximum dose per ha of 0.2 L/ha and diluted in water with a minimum of 200 L of water per ha and can be applied maximum of 18 times per crop period. There ford, the evaluation should be done with fractions (0.01, 0.1, 1.0, 10 and 100) of the concentration **$6.75x10^{10}$OB/L** This concentration is 300 times higher than maximum evaluated dose **$2.2x10^8$ OB/L.** The RMS considers the active ingredient concentration evaluated low.

(0.2L/ha) x (3.75x1012OB/L)/(200Lwater/ha)=3.75x 109 OB/Lx18application/crop=6.75x1010OB/L

– According to EFSA Panel on Biological Hazards (BIOHAZEFSA) 2012-a, the biological agents from baculoviridae family recommended for the QPS list and proposed as plant protection products (under the Council Directive 91/414/EC (Official Journal, 1991) could be exempted from oral toxicity data requirements.

B.9.3.3 Effects on algae

The effects on algae were evaluated for the product Granulosevirus CpGV SC, containing *Cydia pomonella* GV. The composition of Granulosevirus CpGV SC is comparable to that of SPEXIT. Therefore, results obtained within those studies are also applicable for SPEXIT.

Reference:	Dengler, D. 1998. Testing of toxic effects of Granulovirus CpGV on the single cell green alga *Scenedesmus subspicatus.* Report No. 96272/01-AASs, BVL No.: WAT2003-374
Report No.:	MP 10.2/03
Guideline:	OECD Guideline 201: Alga, Growth Inhibition Test and EEC Directive C.3, Alga inhibition test.
GLP:	YES
Summary:	The growth inhibition effect of Granulosevirus CpGV SC was tested with the green algae *Scenedesmus subspicatus* following the OECD guideline 201 and EEC-Directive C.3. The cell growth was measured 24, 48 and 72 hours after initiation of the test. Prior to the test, a range-finding test was carried out in single test assays with concentrations of 0, 0.01, 0.1, 11, 10 and 100 mg Granulosevirus CpGV SC/L. No inhibitory effects were detected in the range-finding test at any test concentration. The main test was performed in a limit test design with 6 control vessels and 6 test vessels with the highest concentration of 100 mg/L. No significant effects were detected at 100 mg/L. Therefore, no EC_{50} value at any time could be calculated. The EC_{50} was estimated to be > 100 mg/L with a probability of 95% because no inhibitory effect was observed at this concentration level. On the basis of the observations made during the test, the NOEC was determined to be > 100 mg/L.
M&M: **Test substances:** **Test conditions:** **Study Design & Methods**	• **Test Item**: Granulosevirus CpGV SC (2.2 × 1013 OB/L), Brown fluid, AE F083311 SC13 A503. • **Target organism**: *Scenedesmus subspicatus Chodat*, Strain No. 8681. 104cell/mL • Temperature: 23°C ± 2°C • Photoperiod: Continuous illumination with a light intensity of approx. 8000 Lux • Test units: Erlenmeyer flasks of 500 mL volume with 200 mL test medium. Each test unit was uniquely identified with the study number, treatment and replicate number • pH: pH 8.13 to 8.28 at test start and pH 7.93 to 10.40 at test end • In-life dates: 24.11.1997 to 04.12.1997 • Duration72 hours • Concentration: 0, 0.01, 0.1, 1, 10 and 100 mg Granulosevirus CpGV SC/L (2.2104, 2.2105, 2.2x106, 2.2x107and 2.2x108OB/mL). • Introduction of algae: The test was started (0 hours) by inoculation with cells from semistatic liquid cultures to an initial cell density of 104 cells/mL. • Determination of the algal growth inhibition: The cell density was determined by counting the cells with Neubauer chamber and a microscope.
Results:	Based on the results of the range-finding test, the main test was performed at a limit test design with 6 controls without test substance and 6 concentrations with 100 mg/L Granulosevirus CpGV SC. No inhibitory effects were detected during the 72h incubation period (Table MP B.9.2-3).
Conclusions:	The possible inhibitory effects of Granulosevirus CpGV SC on the unicellular alga *Scenedesmus subspicatus* was tested following the OECD Guideline 201, and EEC-Directive C.3. The test was performed

in a limit test design with 6 controls and 6 assays at the highest concentration of 100 mg/L. The test fulfils the validity criterion, since the factor of biomass, measured in the controls between 0 h and 72 h was found to be 173.7.

No significant inhibitory effects were determined at 100 mg/L. Therefore no EC_{50} value at any time could be calculated for Granulosevirus CpGV SC.

The EC_{50} was estimated to be >100 mg/L with a probability of 95% because no inhibitory effect was observed at this concentration level. On the basis of the observations made during the test, the NOEC was determined to be > 100 mg/L.

Table MP B.9.2-3: Results of the limit test (mean cell numbers)

Time [h]	Cells / mL * 10^{-4} #	
	Control	Granulosevirus CpGV SC
0	1.00	1.00
24	5.73	4.95
48	35.68	45.31
72	173.70	187.30

Algal counts are divided by 1000. At the start, 10000 cells were incubated

RMS comments:

- This study is appropriate for the assessment of the BV SeMNPV in terms of BVs similarities regarding to their host specify.

B.9.3.4 Effects on aquatic plants

The effects on aquatic plants were evaluated for the product Granupom, containing *Cydia pomonella* GV. The composition of Granupom is comparable to that of SPEXIT. Therefore, results obtained within those studies are also applicable for SPEXIT.

Reference:	Dengler, D., 2002. Assessment of toxic effects of Granupom on aquatic plants using the duckweed *Lemna gibba*. Report No. 20011323/01-AALg, BVL No.: WAT2003-372
Report No.:	MP 10.2/04
Guideline:	OECD Guidelines for the Testing of Chemicals: Lemna sp. Growth Inhibition Test, Proposal for a New Guideline 221, October 2000.
GLP:	YES
Summary:	The growth inhibition effect of Granupom to aquatic plans was tested with *Lemna gibba* G3 (Duckweed). Prior to the test, a range-finding test was carried out in single test assays with concentrations of 0, 0.01, 0.1, 11, 10 and 100 mg/L. No inhibitory effects were detected in the range-finding test at any test concentration. The main test was performed in a limit test design with 6 control vessels and 6 test vessels with the highest concentration of 100 mg/L. Fresh test solutions were prepared after three and five days of test duration. After 3, 5 and 7 days fronds were counted for calculation of growth rates and doubling times; additionally, biomass production was determined based on frond dry weight after 7 days. No LOEC and EC_{50} could be determined for any growth parameter; the NOEC can be set to be ≥ 100

mg/L.

M&M:

Test substances:

- **Test Item:** Granupom 3.4 × 10^{13} OB/mL V121401
- **Target organism:** *Lemna gibba* G3 Institut für Pflanzenökologie und Ökotoxikologie at University of Hohenheim, 70599, Germany.

Test conditions:

- Temperature23 - 25°C
- Photoperiod Continuous illumination with a light intensity of approx. 6500 Lux
- Test units100 mL glass beakers each filled with a volume of approx. 500 mL of test solution.
- pH 7.5
- In-life dates13.05.2002 to 07.07.2002.
- Duration7 days
- Concentration0 and 100 mg Granupom/L (0 and 3.4x 10^6OB/mL)

Study Design & Methods

The test was started (0 hours) by inoculation of the test vessels with colonies consisting of 2-5 fronds to a total of 12 fronds per test vessel.

Introduction of algae:

Frond numbers in each test vessel were determined at the start of the test. Frond numbers and the appearance of the colonies were checked at days 3, 5 and 7 as well as any change in plant development, frond size, appearance, necrosis or mortality and additional observations of test media or other abnormalities.

Observations:

The mean initial dry weight of the inoculum plants per test vessel was determined by collecting 3 representative samples at test initiation. The final dry eight of the yield from each test vessel was determined at the end of the test period. Plants in the respective vessels were collected, blotted dry and dried in glass dishes at 60°C to a constant weight. Any root fragments were included.

Growth rate: Means and standard deviations of the frond number for the test assays at each observation time were calculated. The average frond number was plotted against time in a semi-logarithmic graph for each treatment and control to product growth curves.

Evaluation and calculation of the inhibitory effects:

The average specific growth rate (μ) for exponentially growing cultures was calculated as:

$$\mu = \frac{\ln N_n - \ln N_0}{t_n - t_0}$$

- N_n is the avearage number of fronds observed in the test or control vessel after n days;
- N_0 is the average number of fronds observed in the test or control vessel at the beginning of the test;
- t_n is the time at which N fronds are being counted;
- T_0 is the start time

Percent inhibition of growth rate was calculated for each test concentration according to the following formula:

$$\%I_r = \frac{(C_\mu - T_\mu)}{C_\mu} \cdot 100$$

- % I_R : percent inhibition in average specific growth rate
- C_μ: mean value for min the control
- T_μ: mean value for μ in the treatment group

Doubling time: The average doubling time (T_d) of the culture in the control vessel was calculated using the following formula:

$$T_d = \frac{\ln 2}{\mu}$$

$$\% I_b = 100 \cdot \frac{\Delta b_c - \Delta b}{\Delta b_c}$$

Inhibition of biomass increase: The mean percent inhibition (%I_b) of the biomass increase (based on dry weight) was calculated for each test

	concentration as follows: - b_c is the average increase of the biomass for the control vessel; - b is the average increase of the biomass in the respective test concentrations
Results:	Based on the results of the range-finding test, the main test was performed at a limit test design with 6 controls without test substance and 6 concentrations with 100 mg/L Granupom. The test media was freshly prepared at days 0, 3 and 5. No inhibitory effects were detected during the 7 day incubation period (figure MP B.9.2-2) Analytical results: The concentration course of the formulation Granupom was tested in growth medium during the main test by analysing the active ingredient CpGV over the whole test period of 7 days by means of a bioassay. For this purpose the liquids of the replicates were pooled and analysed afterwards. Granupom nominal contains 2.2×10^{10} OB per mL, and 3.4×10^{10} of virus-OB were reanalysed in the certificate of analysis. 100 mg of Granupom per L correspond to 91.7 µl/L containing nominal 2.02×10^{6} OB per mL and analysed 3.12×10^{6} OB per mL. All initial concentrations were found within the limit of 80% of the nominal concentrations. Two of the aged solutions showed reduced values of virus concentration probably due to adhesion of OB at the glass vessel during the test.
Conclusions:	The growth inhibition effect of Granupom to aquatic plants was tested with *Lemna gibba* G3 (Duckweed). In a range-finding test, which preceded the main test (Table MP B.9.2-4), no inhibitory effects of Granupom were detected at any test concentration from 0.01 to 100 mg/L. Therefore, the main test was conducted in a limit test design with 6 control vessels and 6 test vessels with the highest concentration of 100 mg/L **(Table MP B.9.2-10)**. Fresh test solutions were prepared after three and five days of test duration. The growth rate was determined by counting the number of fronds produced for each test concentration and the controls; the effect to biomass production was evaluated by determination of the final dry weights of the plants. The test results can be regarded to be valid, as the doubling time of control frond numbers was calculated at 36.7 h. This is less than demanded in the draft guideline (50 h). The results of the range-finding test could be verified in the main test: No effects were determined at 100 mg/L in frond numbers of *Lemna gibba*. (Tables MP B.9.2-5); in the growth rate of *Lemna gibba* (Tables MP B.9.2-6); in the inhibition growth rate of *Lemna gibba* (Tables MP B.9.2-7); in the double time growth of *Lemna gibba* (Tables MP B.9.2-8) or in the biomass increase of *Lemna gibba* (Tables MP B.9.2-9); Granupom can be classified to be not toxic against *Lemna gibba*. No LOEC and EC_{50} could be determined for any growth parameter; the NOEC can be set to be ≥ 100 mg/L.

Figure MP B.9.2-2

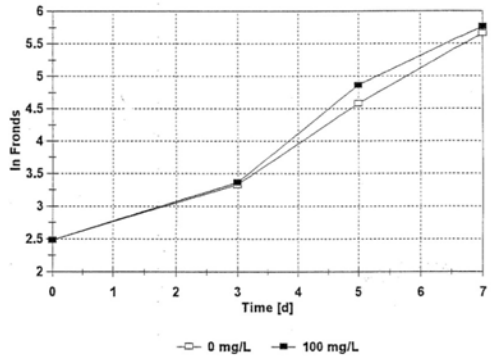


Table MP B.9.2-5 Mean frond numbers

Conc. OB[mg/L]	0 d	3 d		5 d		7 d	
0.00	12	±0.0	28	±2.2	98	±16.4	289	±29.2
100	12	±0.0	29	±2.3	130	±13.2	320	±26.6

Table MP B.9.2-6 Mean growth rates [l/d]

Conc. OB[mg/L]	3 d		5 d		7 d	
0.00	0.2796	±0.0267	0.4165	±0.0346	0.4536	±0.0156
100	0.2971	±0.0250	0.4571	±0.0217	0.4684	±0.0121

Table MP B.9.2-7 Percentage of inhibition of growth rates (%)

Conc. OB [mg/L]	3 d	5 d	7 d
0.00	0.0	0.0	0.0
100	-6.3	-14.0	-3.3

Table MP B.9.2-8 Mean doubling time [T_d]

Conc.OB [mg/L]	3 d	5 d	7 d	
	T_d [days]			T_d [h]
0.00	2.479	1.664	1.528	36.7
100	2.333	1.459	1.480	35.5

Table MP B.9.2-9 Biomass increase per 12 fronds [µg] and % inhibition at the end of the test

Conc.OB [mg/L]	Biomass increase		I_b [%]
	Mean	Std. Dev.	
0.00	28.9	2.3	0.0
100	31.0	2.5	-7.3

Table MP B.9.2-10

Parameter	% inhibition	
	Control	100 mg/L
Frond numbers	0	-11.2
Growth rates [μ]	0	-3.3
Doubling times [T_d]	0	3.3
Biomass production [% I_b)	0	-7.3

RMS comments:

- This study is appropriate for the assessment of the BV SeMNPV in terms of BVs similarities regarding to their host specify.
- However, information on the composition of the Granupom contained Granulosevirus CpGV 3.4×10^{10} OB/L is required. The confirmation of the composition of the product GRANUPOM used in the study was provided by the applicant in order to confirm SPEXIT product and the product used with Granulosevirus CpGV SC are comparable.
- The concentration of the active ingredient in SPEXIT product is $3.4x10^{10}$ OB/L, equivalent to $3.4x10^{4}$OB/mg of MPP. According to the granulovirus product GRANUPOM concentration evaluated, there were $23.4x10^{5}$OB/L for 10mg/L.

B.9.3.5 Effects on freshwater invertebrates

RMS comments:

No data or document was provided by the applicant.

B.9.4 EFFECTS ON BEES

B.9.4.1 Toxicity on bees

The effects on bees were evaluated for the product Granulosevirus CpGV SC, containing *Cydia pomonella* GV. The composition of Granulosevirus CpGV SC is comparable to that of SPEXIT. Therefore, results obtained within those studies might be applicable for SPEXIT.

Reference:	**Kling, A. 2002.** Assessment of Side Effects of Granupom to the Honey Bee, *Apis mellifera* L. in the Laboratory. Project n° 20011323/01-BLEU
Report No.:	**MP 10.3/01**
Guideline:	Guideline on test methods for evaluating the side-effects of plant protection products on honey bees, Bulletin OEPP/EPPO Bulletin 22, 203-215 (1992), No. 170 Deviations: - To guarantee high food uptake of the bees in the oral toxicity test, the starvation phase was prolonged (2 hours 45 minutes instead of 2 hours). - Observations were made under neon light instead of red light due to a better visibility of bees and their behaviour under neon light.
GLP:	YES
Summary:	The oral and contact toxicity of Granupom to the Honey bee (*Apis mellifera* L.) was determined in a limit test according to the EPPO Guideline No. 170 (EPPO, 1992). The bees were exposed to the highest possible dose of 4.4×10^{7} OB per bee of Granupom by feeding and topical application. The concentration of Granupom in the feeding solution was intentionally set 25% higher than needed to achieve the nominal dosage of 4.4×10^{7} OB per bee with the quantity of 250 µL offered per cage to compensate for a potential decrease in food uptake of bees frequently observed in such tests.

	In the oral toxicity test the maximum nominal test lever (4.4×10^7 OB per bee) corresponded to an actual intake of 3.5×10^7 OB per bee. At this concentration a corrected mortality of 18.4% was observed after 72 hours. At the concentration of 4.4×10^7 OB per bee (pure product) which was tested in the contact toxicity test with Granupom no mortality (corrected mortality: -4.2%) occurred after 48 hours. In the control of the oral toxicity test a mortality of 2.0% was observed after 72 hours. A mortality of 4.0% occurred in the control of the contact toxicity test after the 48 hours observation period. Regarding the behaviour, the treated bees did not differ from the control at any time during the test. According to the results of this study it can be assumed that the oral LD_{50}/72 h is above 3.5×10^7 OB per bee and the contact LD_{50}/48 h of Granupom is above 4.4×10^7 OB per bee.
M&M: **Test substances:** **Test conditions:** **Study desing & methods** Experimental treatment:	• **Test Item:** Granulopom 2.45 10^{13} OB/L, V121401, orange to brown liquid • **Target organism:** Honey bee (*Apis mellifera L.)*. Young adult worker bees. honey bee colonies, disease-free and queen-right, bred by Arbeitsgemeinschaft GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, 75223 Niefern-Öschelbronn, Germany • Test duration: 48h (contact toxicity)/72h (oral toxicity) • Temperature: 24-26ºC • Hr: 44-64% • Illumination: darkness • In life date: 11.09.2001 to 14-09-2001 Contact toxicity test:In the contact toxicity test, pure product of Granupom was tested. After the bees had been anaesthetised with carbon dioxide they were treated individually by topical application with a microapplicator. 2 µL of the test substance were applied to the ventral side of the thorax of each bee. After application the bees were returned to their cages and fed with a 50% aqueous sucrose solution ad libitum. Between every application the needle of the microapplicator was cleaned from the outside with a mixture of water and a wetting agent, to make sure that the drop of the test substance solution will spread immediately after the application. Oral toxicity test: For the oral toxicity test, Granupom was directly mixed with a 50% aqueous sucrose solution. The concentration of Granupom in the feeding solution was intentionally set 25% higher as needed to achieve the nominal dose with the quantity of 250 µL offered per cage to compensate for a potential decrease in food uptake of bees. Before the feeding started, the bees starved for 2 hours and 45 minutes. A quantity of 250 µL was offered for approx. 6 hours to each cage of 10 bees to ensure sufficient intake of test substance. The bees in one cage shared the test solution and so received similar doses. After the test substance was taken up, the bees in the test cages were supplied ad libitum with a 50% aqueous sucrose solution without Granupom. • Replicate: 5 • Bee/replicate: 10 Mortality (number of bees dead) and abnormal behaviour (vomiting, apathy, intensive cleaning): after 2 , 4, 24, 48 and 72 hours; the observation period in the oral toxicity test was prolonged up to 72h because the mortality continued to rise between the 24h and the 48h assessment. The average mortality of the five replicates per concentration was calculated after correction for control mortality according to the formula of Schneider-Orelli (1947), Corrected mortality: Observation: $M = \frac{t - c}{100 - c} \times 100$ M = corrected mortality (%) c = Mortality in the control group (%) t = Mortality in the test substance group (%)
Results:	Oral toxicity test: The nominal test concentration of 4.4×10^7 OB per bee corresponded to an actual intake of 3.5×10^7 OB per bee. At this concentration the corrected mortality was

	determined to be 18.4% after 72 hours. 2.0% mortality was observed in the control group after 72 hours. Regarding the behaviour, the treated bees did not differ from the control at any time during the test (table MP B.9.3-1) Contact toxicity test: At the concentration of 4.4 × 107 OB per bee which was tested in the contact toxicity test with Granupom no mortality (corrected mortality: -4.2%) was observed after 48 hours. In the control group a mean mortality of 4.2% occurred after 48 hours. Regarding the behaviour, the treated bees did not differ from the control at any time during the test (table MP B.9.3-2)
Conclusions:	According to the results of this study it can be assumed that the oral LD_{50}/72 h of Granupom is above 3.5×10^7 OB per bee and the contact LD_{50}/48 h is above 4.4×10^7 OB per bee. Regarding the behaviour, the treated bees did not differ from the control at any time during the test.

Table MP B.9.3-1 Corrected average mortality in the oral toxicity test with Granupom as a function of the intake of test substance, the toxic standard and the control

Treatment	Intake of test substance [µg a.i./bee]	Mortality [%]			Mortality [%] (corrected for control)		
		24 h	48 h	72 h	24 h	48 h	72 h
Control	--	2.0	2.0	2.0	-	-	-
Granupom							
4.4×10^7 OB/bee	3.5×10^7	4.0	20.0	20.0	2.0	18.4	18.4
Toxic standard: "Perfekthion"							
0.15 µg a.i./bee	0.18	94.0	96.0	96.0	93.9	95.9	95.9

Table 8.3-2 Corrected average mortality in the contact toxicity test as a function of the concentration of test substance applied to the thorax of the bees

Treatment	Mortality [%]		Mortality [%] (corrected for control)	
	24 h	48 h	24 h	48 h
Control	4.0	4.0	-	-
Test substance: Granupom				
4.4×10^7 OB/bee	0.0	0.0	-4.2	-4.2
Toxic standard: "Perfekthion"				
0.21 µg a.i./bee	72.0	84.0	70.8	83.3

RMS comments:

- No studio in infectiveness or pathogenicity were included by the applicant.
- SeMNPV isolate Bv0004 can be considered as a low risk substance, according to Commission regulation (EU) 2017/1432 if at strain level they have demonstrated NO adverse effects on non-target insects". The RMS consider that at least one specific study with the product SPEXIT need to be included in order to exclude adverse **effects** on bees others than *Spodoptera exigua*.
- There is no information on the short-term and long-term espouse on the ingestion by arthropod of *S. exigua* virus from SPEXIT spraying. No acute end-points are available and no studies on bees were submitted on infectivity from the applicant.

Taking all above mentioned consideration together, the RMS considers the results of the studies with GRANUPOM not applicable for SeMNPV. The RMS would considered convenient to include at least one specific study with bees, due to the relevance of these species, that can be exposure to the dissolved OB in the active substance treated area (worst-case assumptions). There is no information on the short-term and long-term espouse on the ingestion by bees of *S. exigua* virus from SPEXIT spraying. No acute end-points are available and no studies on bees were submitted on infectivity from applicant.

The RMS consider that a study need to confirm the reports from literature excluding adverse effects on bees. A data gap is therefore identified.

B.9.5 EFFECTS ON ARTHROPODS OTHER THAN BEES

The effects on *Aphidius rhopalosiphi*, *Typhlodromus pyri*, and *Poecilus cupreus* were evaluated for the product Granulosevirus CpGV SC, containing *Cydia pomonella* GV. The composition of Granulosevirus CpGV SC is comparable to that of SPEXIT. Therefore, results obtained within those studies are also applicable for SPEXIT.

Reference:	Kühner, C., 2001. Granulovirus CpGV SC: Acute toxicity to the aphid parasitoid: *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) in the laboratory. Report No. 96272/01-NLAp; BVL No.: ANA2003-230
Report No.:	MP 10.4/01
Guideline:	POLGÁR (1988), MEAD-BRIGGS (1992) and Guidance Document for Regulatory Testing Procedures for Pesticide with Non-Target Arthropods (ESCORT 1994)
GLP:	YES
Summary:	Granulosevirus CpGV SC was tested at an application rate corresponding to 360 mL/ha. This corresponds to the 2-fold maximum recommended field application rate, corrected with the factor 0.4 for foliage dwelling organisms. Adults of *Aphidius rhopalosiphi* were exposed to a freshly applied dry layer of the test substance on glass plates. Mortality of the adults was assessed 30 min, 2 h, 24 h, and 48 h after exposure by counting the number of dead and affected test organisms. The reproduction rate of the surviving test organisms was evaluated in a fertility test afterwards. The number of mummies produced within 24 h was counted 12 days after the start of the fertility test. The mean mortality of *Aphidius rhopalosiphi* after 48 h exposure to Granulosevirus CpGV SC treated glass plates was 2.5% compared to 2.5% mortality in the control group. The corrected mortality of Granulosevirus CpGV SC was calculated as 0.0%. The reproduction rate of the control organisms resulted in 13.2 mummies per female. In the Granulosevirus CpGV SC treated group 11.7 mummies were produced. The reduction in reproduction rate was calculated as 11.4%. Thus, the reduction in beneficial capacity of Granulosevirus CpGV SC on *Aphidius rhopalosiphi* was calculated as 11.3%. Based on these results it is assumed that Granulosevirsu CpGV SC will have no effects on *Aphidius rhopalosiphi* under field conditions up to the tested application rate of 360 mL/ha, which is regarded as the worst case exposure situation.
M&M:	
Test substances:	• **Test Item**: Granulosevirus CpGV SC2.2 × 10^{13}OB/L, Bacht # AE F083311 SC13 A503 Brown fluid. • **Target organism**: *Aphidius rhopalosiphi* (Hymenoptera, Braconidae). Adult. Katz Biotech AG, An der Birkenpfuhlheide 10, D-15837 Baruth
Test conditions:	• Test duration: 48 h exposure of adults to treated glass plates, followed by 12 days of fertility test of the female adults • Temperature: 20±3ºC • Hr: 50-85% • Photoperiod: long day conditions (16h light/8h darkness) ~1000lux

Study desing & methods

- In life dates: 09.03.1998 to 23.03.1998

Experimental treatment: For assessment of the mortality of *Aphidius rhopalosiphi* adults less than 48 h old were exposed to glass plates treated with the test substance. The adults were provided with artificial food (honey water solution). The parasitoids were confined for 48 h. After 48 h the surviving females were removed from the cages and the parasitic capacity per female was assessed in a fertility test. The females were offered aphids for oviposition.

Replicates: 4 replicates of 10 individuals (5 males and 5 females) per group

Observations: Mortality of the adults was evaluated after approx. 30min, 2h, 24h and 48h. Counting of the parasitized aphids was carried out 12 days after the start of the fertility test.

Evaluation: Mortality: the percentage of mortality after 48 h was calculated for each replicate from the number of dead parasitoids and the number of released parasitoids. The mean value in the treated group was compared to the mean mortality of the control using the formula of Schneider-Orelli (1947):

$$M = \frac{t - c}{100 - c} \times 100$$

M = corrected mortality (%)
c = Mortality in the control group (%)
t = Mortality in the test substance group (%)

Reproduction rate: the mean number of offspring per female was determined for the treated and control groups by averaging the replicate values. The reduction of reproduction rate in the treated group was calculated using the formula of Abbott (1925):

$$R = \frac{c - t}{c} \times 100$$

R = Reduction in reproduction rate (%)
c = Number of mummies per female in the control group
t = Number of mummies per female in the treated group

Reduction of beneficial capacity: in order to assess the total effect of the test substance on *Aphidius rhopalosiphi* in the treated group in comparison to the control, the data of mortality and reproduction rate were combined in the formula of Overmeer and van Zon (1982):

$$E = 100 - (100 - M) \times r$$

E = Reduction in beneficial capacity (%)
M = Corrected mortality
r = t/c
t = Number of mummies per female in the treated group
c = Number of mummies per female in the control group

Results: Mortality: After 48 h, in each treated group and the control group, 1 adult was dead. The mortality of *Aphidius rhopalosiphi* was calculated as 2.5% in each group.
The corrected mortality (M) of *Aphidius rhopalosiphi* after exposure to Granulosevirus CpGV SC was calculated as 0%.
Fecundity: In the control group 18 females were tested in the fertility test. The total number of mummies developed within 11 days was 237 for the control group which corresponds to 13.2 mummies per female.
In the Granulosevirus CpGV SC group 19 females were tested, which produced 222 mummies. The number of mummies per female was calculated as 11.7.
The reduction in reproduction rate after exposure to Granulosevirus CpGV SC was calculated as 11.4%.

	The average mortality of the test organisms after 48 h exposure to Granulosevirus CpGV SC was 2.5% compared to 2.5% mortality in the control group. The corrected mortality (M) was calculated as 0%. The number of mummies per female during the fertility test was 11.7 in the Granulosevirus CpGV SC group compared to 13.2 mummies per female in the control. The combination of the corrected pre-imaginal mortality (M) of the test organisms with the factor r resulted in a reduction of beneficial capacity of 11.3%.
Conclusions:	Granulosevirus CpGV SC was tested at an application rate corresponding to 360 mL/ha, which is equivalent to the 2-fold maximum recommended field application rate, corrected with the factor 0.4 for foliage dwelling organisms. The corrected mortality of Granulosevirus CpGV SC was calculated as 0.0%. The results of the fertility test showed a reduction in the reproduction rate of 11.4% in the Granulosevirus CpGV SC group. Thus, the reduction in beneficial capacity of Granulosevirus CpGV SC on *Aphidius rhopalosiphi* was calculated as 11.3%. Based on these results it is assumed that Granulosevirsu CpGV SC will have no effects on *Aphidius rhopalosiphi* under field conditions up to the tested application rate of 360 mL/ha, which is regarded as the worst case exposure situation.

RMS comments:

- SeMNPV isolate Bv0004 can be considered as a low risk substance, according to Commission regulation (EU) 2017/1432 if at strain level they have demonstrated NO adverse effects on non-target insects". **The RMS consider that at least one specific study with the product SPEXIT need to be included in order to exclude adverse effects on Arthropoda others than *Spodoptera exigua*.**

Reference:	Kühner, C., 1997- Granulovirus CpGV SC: Acute Toxicity to the Ground Beetle, *Poecilus cupreus* L. (*Coleoptera, Carabidae*) in the laboratory. Report No. 96272801-NLPc; BVL No.: ANA2003-232
Report No.:	MP 10.4/03
Guideline:	BBA Guideline VI 23-2.1.8 (Heimbach 1991) and Guidance Document for Regulatory Testing Procedures for Pesticides with Non-Target Arthropods (ESCORT 1994) Deviations: The minimum temperature was 16°C for short periods; the min/max humidity was 50/90% due to technical reasons
GLP:	YES
Summary:	Beetles were exposed to moist sand treated with the test substance solution at a concentration corresponding to an application rate of 450 mL Granulosevirus CpGV SC per hectare. This is equivalent to twice the maximum recommended field application rate corrected by 0.5 for ground dwelling organisms. Mortality and feeding capacity of the beetles were assessed and compared to those of a water treated control group. In the Granulosevirus CpGV SC group and the control no mortality was observed after 14 days of exposure. The average food consumption during the whole test was 4.23 pupae per beetle in the Granulosevirus CpGV SC group and 5.27 pupae per beetle in the control group. The reduction in feeding capacity in the Granulosevirus CpGV SC treated group compared to the control was calculated as 19.73%. Based on these results it is assumed that Granulosevirus CpGV SC will not affect *Poecilus cupreus* under field conditions up to the tested application rate of 450 mL/ha.
M&M:	
Test substances:	• **Test Item:** Granulosevirus CpGV SC2.2 × 1013/L, batch # AE F083311 SC13 A503, characteristics: Brown fluid • **Target organism**: Poecilus cupreus L. 6-9 week old beetles BTL Bio-Test Labor GmbH Sagerheide Acclimation period 3days under test conditions without food

Test conditions:

- Test duration; 14 days
- Temperature: 25±3ºC
- Hr: 70±15%
- In life dates: 08.09.1997 to 22.09.1997

Study desing & methods

Experimental treatment:

Beetles were exposed on moistened quartz sand. Prior to the application the beetles were introduced to the test vessels, and *Musca* pupae (2 for every beetle) were added as food. In order to simulate field application conditions the test substance solution was applied using an automatic laboratory spraying-cabin.

Replicates:

5 replicates containing 3 pairs of beetles for each variant

Observations:

Mortality: was recorded 2, 4 and 6 hours after application and again on day 2, 3, 5, 8, 12 and 15.
Feeding capacity: the beetles in the test were fed on day 1, 3, 5, 8 and 12. At every feeding session the old pupae were removed. All pupae, eaten completely or gnawed at and all pupae, which could not be found, were recorded as eaten. At the final assessment the sand in the vessels was investigated and buried pupae were recorded.

Evaluation:

Mortality: mortality of each variant was recorded for each day and for each sex separately Mortality was calculated as percentage of the number of beetles put in at the start of the test. A mean mortality was calculated from the 5 replicates. The corrected mortality was obtained by comparing the values observed in the treated series with those in the control series, according to the formula of Schneider-Orelli (1947):

$$M = \frac{t - c}{100 - c} \times 100$$

M = corrected mortality (%)
c = Mortality in the control group (%)
t = Mortality in the test substance group (%)

Feeding capacity: the number of eaten pupae (with respect to the number of living beetles at the date on which pupae were added) per sampling time was calculated for every replicate as an average of eaten pupae per living beetle and summed up over the test period as total value of each replicate. The average food consumption per beetle in each group was calculated. The reduction of feeding capacity in the treated group compared to the control was calculated using the formula of Abbott (1925):

$$R = \frac{c - t}{c} \times 100$$

R = Reduction in feeding capacity (%)
c = average number of eaten pupae per beetle in the control group
t = average number of eaten pupae per beetle in the treated group

Results:

Behaviour of the test organisms: Observation started on the day of application. The beetles in the control and in the Granulosevirus CpGV SC treated group showed normal activity during the entire exposure period.
Mortality: In the Granulosevirus CpGV SC group and the control group no mortality was observed. The corrected mortality (M) for Granulosevirus CpGV SC was calculated at 0.0%.
Feeding capacity: The average number of eaten pupae per beetle (mean value of 5 replicates) was 4.23 in the Granulosevirus CpGV SC group compared to 5.27 pupae in the control. The reduction in feeding capacity of the beetles in the Granulosevirus CpGV SC was calculated as 19.73%.

Conclusions:

Granulosevirus CpGV SC was tested at an application rate corresponding to 450 mL/ha, which is equivalent to the 2-fold maximum recommended field application rate, corrected with the factor 0.5 for foliage dwelling organisms.
No mortality of *Poecilus cupreus* after exposure to Granulosevirus CpGV SC was observed. The

	reduction in feeding capacity compared to the control was calculated as 19.73%. Based on these results it is assumed that Granulosevirus CpGV SC will not affect *Poecilus cupreus* under field conditions up to the tested application rate of 450 mL/ha which is equivalent to the worst-case exposure situation.

RMS comments:

SeMNPV isolate Bv0004 can be considered as a low risk substance, according to Commission regulation (EU) 2017/1432 if at strain level they have demonstrated NO adverse effects on non-target insects". The RMS consider that the study MP3.10-01 contain specific data with the product SPEXIT to exclude adverse effects on arthropods others than *Spodoptera exigua*. The effect on non-target arthropods have been confirmed in document MP3.10-01 (document B3.3) where the efficacy at different doses of SPEXIT have been evaluated on greenhouse experiments. **A data gap is therefore identified.**

B.9.6 EFFECTS ON EARTHWORMS

During the normal agriculture practice the active substance, CpGV SC may come into contact with earth worms. Because of the importance of earthworms in the maintenance of soil structure and fertility it is essential to determine the possible effect of the Bvs on them. The objective of the study is to determine the effect of BVs on *Eisenia foetida* in artificial soil under laboratory conditions. The effects on *Eisenia foetida* were evaluated for the product Granulosevirus CpGV SC, containing *Cydia pomonella* GV.

Reference:	Wachter, S., 1998a.Acute toxicity of CpGV SC on earthworms, *Eisenia foetida* using an artificial soil test. No. 96272/01-NLEf; BVL No.: ARW2003-110
Report No.:	MP 10.5/01
Guideline:	OECD Guideline No. 207
GLP:	YES
Summary:	The acute toxicity of CpGV SC to earthworms (*Eisenia fetida*) during a 14-day exposure period was evaluated under artificial soil substrate. The main test was performed with concentrations of 100, 178, 316, 562 and 1000 mg/kg artificial soil. Adult earthworms were exposed for 14 days to the test substrate at a temperature of 20 ± 2°C under continuous light. Any mortality of the earthworms was recorded after 7 and 14 days of exposure to the test substance. Additionally, the body weight of the earthworms at the beginning of the test and after 14 days of exposure was determined. No mortality was recorded in the control group and in the test concentrations. No statistically significant difference between the body weights compared with the control was recorded. Therefore, no negative effect of CpGV SC could be demonstrated. The LC_{50} is shown to be greater than 1000 mg/kg artificial soil.
M&M:	
Test substances:	• **Test Item:** CpGV SC2.2 × 10^{13} /L AE F083311 SC13 A503 Brown fluid
Test conditions:	• **Target organism**: *Eisenia foetida* (Michaelsen), origen more than 2 months-old with clitellum. Healthy rearing stock at the testing facility.10 per group • **Toxic standard (positive control)**: **2-chloroacetamide 99.2%**
Study desing & methods	• Soil substrate: 10% sphagnum peat;20% kaolinite clay;69% fine sand;Approx. 1% calcium carbonate (pH adjusted to 6.0 ± 0.5) • Temperature:20°C ± 2.0°C • Photoperiod: Continuous light • Light intensity: 400 - 800 lux

Experimental treatment:	• In-life dates: 22.10.1997 to 29.01.1998
Evaluation:	Ten earthworms per group were released in 1-liter test bottles filled with moist artificial soil equivalent to 500 g on oven-dry basis. Delivery of CpGV SC was achieved by diluting the desired amount directly in the volume of water needed to moisten the soil substrate up to about 50% of its water holding capacity. Treatment groups: - negative control treated with water, - toxic standard consisting of 10, 18, 32, 56, 100 mg 2-chloroacetamide/kg artificial soil, - a geometric series of five concentrations of **100, 178, 316, 562, 1000 mg CpGV SC/kg).** For the preliminary study, only one replicate was made for each concentration of the substance in order to have a first estimation of the LC50. For the main study, each treatment group includes four replicates. Mortality was assessed on Days 7 and 14. After identifying the surviving earthworms in each group, they were replaced on the same test substrate surface. The wet weight of surviving earthworms was assessed 14 days after test initiation. The pH value of the substrates was controlled at the end of the test. Mean moisture of the substrate was assessed at the end of the test from 3 samples of the control group after 30-hour oven exposure at 50 ± 2°C. Biomass was evaluated in measuring the earthworms mean weights in each group.
Results:	No mortality was observed in the negative control and at all test concentrations over the test period. The LC_{50} of 2-chloroacetamide was found to be between 18 and 32 mg/kg. The average body weight of the test organisms in the CpGV SC group was between 79.7% and 86.4% from the initial weight. In the control group the average body weight was 82.1% from the initial weight. No significant difference between the body weights compared with the control was recorded at all test concentrations (Dunnett's t-Test).
Conclusions:	No mortality was observed at any Bv concentration evaluated. After 14 days of exposure, the body weight was between 79.7% and 86.4% from initial weight (table MP-B.9.5-1). There were no significant difference between body weights compared to the control at all CpGV SC concentrations. The median lethal concentration LC_{50} of CpGV SC to *Eisenia foetida* determined after 14 days exposure is shown to be greater than 1000 mg/kg of artificial soil, corresponding with 1.67×10^{10} OB/kg artificial soil (assuming a density of 1.2 mg/L). According to the results, it is confirm the innocuous effect of the BV CpGV SC on earthworms.

Treatments		Body weight		Mortality
		[%]	mg	[%]
Control	-	82.1	340	0
CpGV SC (mg/Kg)	100	85.7	335.5	0
	178	86.4	313	0
	316	79.7	304	0
	562	82.6	336	0
	1000	83.2	337.25	0

Table MP-B.9.6-1: Weight (in mg and in % of initial weight) after 14 days exposure to CpGV SC.

RMS comments:

Considering the follow assumption:

- Composition of both BVs product are identical according with provided information (Volume 4 appendix III). If CpGV SC MPCP and SPEXIT have similar composition, then results obtained within this study might also be applicable for SPEXIT.
- SeMNPV containing formulation SPEXIT does not contain any ingredients of toxicological concern (see confidential data on Volume 4).
- Close relationship between all lepidopteran BVs.
- CpGV and SeMNPV do not belong to the same group of baculoviris family (SeMNPV is an alphabaculovirus and CpGV belongs to betabaculovirus).
- CpGV and SeMNPV have different target organisms.

Taking all above mentioned consideration together, the RMS considers the results of the studies with GRANUPOM not applicable for SeMNPV. The RMS would considered convenient to include at least one specific study with beneficial lepidopteran, due to the relevance of these species, that can be exposure to the dissolved OB in the active substance treated area (worst-case assumptions). There is no information on the short-term and long-term espouse on the ingestion by other related lepidopteran of S. exigua virus from SPEXIT spraying. No acute end-points are available and no studies on arthropods other than bees were submitted on infectivity from the applicant.

The RMS consider that a study need to confirm the reports from literature excluding adverse effects on beneficial arthropods other than bees.

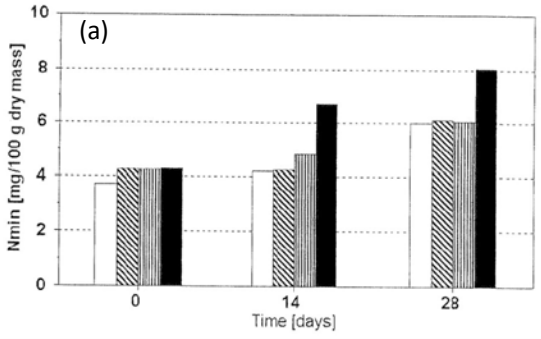
B.9.7 EFFECTS ON NON-TARGET SOIL MICROORGANISMS

The effects on soil microorganisms were evaluated for the product Granulosevirus CpGV SC, containing *Cydia pomonella* GV. The composition of Granulosevirus CpGV SC is comparable to that of SPEXIT. Therefore, results obtained within those studies are also applicable for SPEXIT.

Reference:	Wachter, S., 1998b. Assessment of the side effects of CpGV SC on the activity of the soil microflora. No. 96272/01-ABMF; BVL No.: BMF2003
Report No.:	MP 10.6/01
Guideline:	BBA-Guideline for the official testing of pesticides, part VI, 1-1, 2nd edition, dated March 1990, with a sandy and a sandy loam soil type.
GLP:	YES
Summary:	The possible effects of Bv CpGV SC on the soil microflora were measured in a test on nitrogen turnover after addition of ground Lucerne and on short term respiration after addition of glucose. Two soil types were used, specified as sandy soil and a sandy loam soil type. CpGV SC was incubated over a period of 28 days at 1-x and 10-x dosage rates, referring to 0.5 and 5.0 L/ha,

	respectively. The control consisted of a treatment group with deionised water. A reference group with a formulation of dinoterb was also tested to demonstrate the normal sensitivity of the soil microflora against pesticides. Soils were sampled at the beginning, and then after 14 and 28 days of incubation: The nitrate were extracted, determined and compared. The samples were mixed with glucose in order to measure the glucose induced respiration rate for 12 consecutive hours. Respiration rates were expressed as oxygen consumed (mg oxygen/kg soil/h). The impact on nitrogen transformation and soil respiration of soil type 1 and soil type 2 is considered as negligible (< 15 % deviation) even at the 10-x dosage (5.0 L/ha) of the highest recommended CpGV SC application rate, corresponding with 10×10^{13} OB/ha.
M&M:	
Test substances:	• Test Item: CpGV SC2.2 $\times 10^{13}$OB/L, batch # AE F083311 SC13 A503. Brown fluid • Target organism: *Herbogil liquide* (a.i. dinoterb) • Test soil: two soil types (1) sandy soil and (2) sandy loam soil type
Test conditions:	• Temperature: 20°C ± 2°C • Photoperiod: darkness • In-life dates: 06.11.1997 to 04.12.1997
Study desing & methods	Distinct fractions of dry soil were prepared by adding water so that the moisture was equivalent to 58% of the total water holding capacity. The fractions were then incubated in the dark, at 20°C ± 2°C.
Experimental treatment:	The measurements were performed within 3 hours of addition of pesticide, and then on days 14 and 28 of the incubation period. Nitrate concentration: Nitrate concentration was determined in three replicates per group. Glucose induced respiration: Samples were mixed with a sufficient amount of glucose to elicit an immediate maximum respiratory response. The respiration rate was assessed from the oxygen consumed by the glucose amended soil samples for 12 consecutive hours, using an incubation system combined with a manometric oxygen measurement. The results were expressed as mg oxygen/kg dry weight/h.
Results:	In the treatment groups, the deviation of the nitrate contents of soil type 1 and soil type 2 was less than 15 % from the control group within the 28 days incubation period. The nitrite and ammonium content of both soil types was found to be under the determination limit. The total content of nitrogen (expressed as N_{min}) was in the range of the control group and was not significantly different from the control (Figure MP B.9.6-1). Therefore, the impact on soil nitrogen turnover is considered as negligible even at 10-x dosage rate of CpGV SC. The short term respiration of the soil microflora was not significantly different from the control over a 28 d period after admixture with glucose at 1-x and 10-x dosage. The reference substance inhibited the short term respiration and stimulated the content of nitrogen within the 28 days incubation in the soil type 1 test. In soil type 2 the reference substance stimulated the short term respiration and the content of nitrogen within the 28 days incubation. The deviation from the control was distinctly more than 15% for both soil types.
Conclusions:	The impact on nitrogen transformation and soil respiration of soil type 1 and soil type 2 is considered as negligible (< 15% deviation) even at the 10-x dosage (5.0 L/ha) of the highest recommended CpGV SC application rate, corresponding with 10×10^{13} OB/ha.

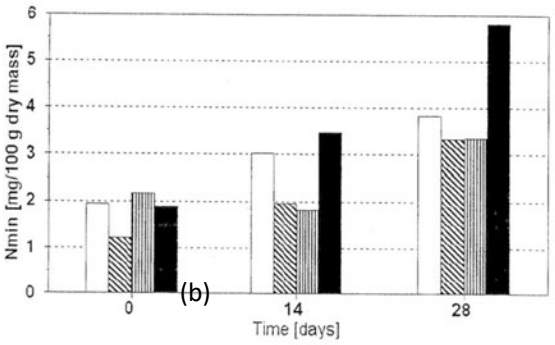
Figure MP B.9.7-1: Total content of nitrogen (expressed as Nmin) in tow different soil types: soil type 1 (a) and soil type 2 (b)

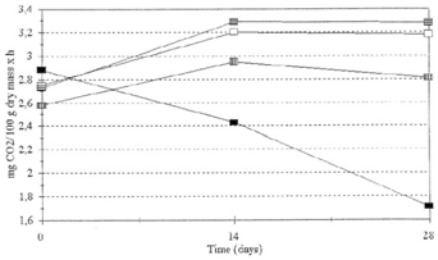


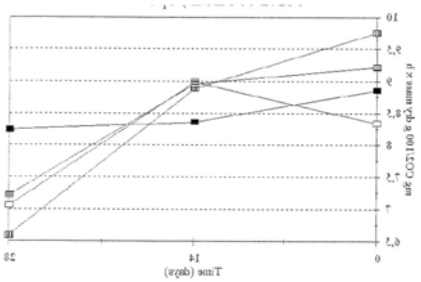
(b)

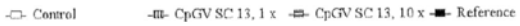
Figure MP B.9.7-2: Soil term respiration of two different soil types, soil 1 (a) and soil 2 (b)

(a)









RMS comments:

Dosage rates evaluated were 0.5-5L/ha at 2.210^{13}OB/L correspond to 1.1-5.5 x 10^{10} OB/m^3 of soil (depth of 10cm) and 1.43-14.3 x 10^{10}OB/g of soil.

B.9.8 REFERENCES RELIED ON

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 also included some new references considered important for the evaluation.

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	-
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	[redacted]	1998a	Acute toxicity testing of granulosevirus CpGV SC in rainbow trout (Oncorhynchus mykiss) (Teleostei, Salmonidae) Andermatt Biocontrol AG, CH, 96272/01-AAOm [redacted] 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	[redacted]	1998b	Acute toxicity testing of granulosevirus CpGV SC on Daphnia magna using the 48 h acute immobilisation test Andermatt Biocontrol AG, CH, 96272/01-AADm [redacted] 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 Scenedesmus subspicatus 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 Lemna gibba 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, Apis mellifera 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, Typhlodromus pyri 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
KMP 10.4/02 MPB.9.5	Kühner, C.	2001	Granulosevirus CpGV SC: Acute toxicity to the aphid parasitoid, Aphidius rhopalosiphi (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, Poecilus cuperus 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

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 10.5/01 MPB.9.6	Wachter, S.	1998a	Acute toxicity of CpGV SC on earthworms, Eisenia foetida 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

ABA- Andermatt Biocontrol