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.8 Fate and behavior in the environment

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

Table of contents

B.8 ..... INTRODUCTION

The company Andermatt Biocontrol GmbH 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 according to the Regulation (EC) 1107/2009. SPEXIT is a microbial pest control product formulated as a suspension concentrate and containing 3.75 x 10^{12} occlusion bodies (OB) of SeMNPV in 1.0 L product.

The intended target insect is the beet army *Spodoptera exigua* in pepper and leafy vegetables (lettuce crops). For more details, please refer to **Table MP B. 8-1**.

*Se*MNPV belongs to the family of baculoviruses. The use of other BV species data in this dossier is justifiable due to this family relationship. This virus acts highly specific and exclusively against larvae of the beet armyworm, *S. exigua* and is not supposed to have any harmful effects on organisms not belonging to the family of Noctuidae. With regard to safety considerations, it is important to note that SeMNPV and the whole group of baculoviruses are naturally present in the environment. The experience that BVs present no risk to mammals, including humans 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.

In the evaluation of the documents it was taken in consideration that a previous *Spodoptera exigua* nuclueopolyedrovirus isolate, Florida isolate (SENPV-F1), deposited at the American Type Collection, with ATCC number SD-5339, was submitted and approved as a microbial agent in 2007, until the end of the approval period in 2017. According to the Guidance Document SANCO/0253/2008 rev.2 for the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC, two other isolates were further approved: in 2008 isolate SEMNPV-SP2, deposited at the Collection Nationale De cultures De microorganisms, Institut Pasteur (contained the genotypes ALPst0935 (CNCM I-3572), ALPst1400 (CNCM I-357) and ALPst1033 (CNCM I-357)) and its microbial product VIR-EX and in 2010 the isolate SeMNPV-BV0004, deposited at the German Collection of Microorganism and Cell Cultures, with the reference number BV-0004 and its microbial product SPEXIT.

The representative product SPEXIT and its microbial agent *Spodoptera exigua* nuclueopolyedrovirus isolate BV0004, have been authorised at Member State level since 2010 until the end of the approval period in 2016 and have therefore been assessed in line with Uniform Principles".

It is referred to the information submitted for the microbial pest control agent, *Spodoptera exigua* MNPV and for baculoviruses in general in MA 7. The ingredients of the preparation SPEXIT formulated as SC are inert and no hazards to the environment are expected (see Volumen 4 confidential information). Therefore, studies and information on SeMNPV are considered applicable and relevant with regard to the evaluation of the formulated product.

The predicted environmental concentrations in soil and water are presented in VOLUMENN 3 SECTION MP B.11.

Table MP B.8-1 Summary of critical Good Agricultural Praxis for SPEXIT

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:	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

B.8.1 Persistence and multiplication

B.8.1.1 Soil

The predicted environmental concentrations in soil and water are presented in VOLUMENN 3 SECTION MP B.8.

B.8.1.2 Water

The predicted environmental concentrations in soil and water are presented in VOLUMENN 3 SECTION MP B.8.

B.8.1.3 Air

The predicted environmental concentrations in soil and water are presented in VOLUMENN 3 SECTION MP B.8.

B.8.2 Mobility

Evaluation is presented in VOLUMENN 3 SECTION MP B.8.

B.8.3 References relied