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.4 Further Information of the Plant Protection Product

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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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. Two new more isolates were further applied for at Member State level: the SeMNPV-SP2, approved in 2008 and

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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.*

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.4.1. Summary of critical Good Agricultural Praxis for SPEXIT

n.a. Not applicable

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks: e.g. g safener/synergist per ha**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**L product / ha a) max. rate per appl. b) max. total rate per crop/season**	**OBs/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**		
1	EU	Pepper (CPSAN)	F/G	*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

B.4.1 PACKAGING AND COMPATIBILITY OF THE PREPARATION WITH PROPOSED PACKAGING MATERIALS

Packaging description:

SPEXIT is sold in 100 mL, 200 mL, 500 mL and 1 L flasks and 5 L canisters.

100mL amber polyethylene flasks (Anonymous, 2009a)

Bottle dimensions: 95x48mm (height x diameter)

Diameter bottleneck: 22mm

Materials: polyethylene

Cap height: 24mm

Cap diameter: 32mm

200mL amber polyethylene flasks (Anonymous, 2009b)

Bottle dimensions: 116 x 60mm (height x diameter)

Diameter bottleneck: 22 mm

Materials: polyethylene

Cap height: 24 mm

Cap diameter: 32 mm

500mL amber polyethylene flasks (Anonymous, 2009c)

Bottle dimensions: 153x78mm (height x diameter)

Diameter bottleneck: 22mm

Materials: polyethylene

Cap height: 24mm

Cap diameter: 32mm

1 L HDPE flasks (Anonymous, 2009d)

Bottle dimensions: 219x88mm (height x diameter)

Diameter bottleneck: 46mm

Materials: HDPE

Cap height: 29mm

Cap diameter: 55mm

5 L HDPE flasks (Anonymous, 2018)

Bottle dimensions: 145x190 x 235mm (width x length x height)

Diameter bottleneck: 41mm

Materials: HDPE

Cap height: 20mm

Cap diameter: 59mm

Specifications of packaging and measures of its suitability:

Taking into account the composition of the product and its physical and toxicological properties, SPEXIT is characterized as non-reactive and non-hazardous. The specification sheets are describing the features of the bottles in detail (Anonymous, 2005a; Anonymous, 2009a, Anonymous, 2009b, Anonymous, 2009c, Anonymous, 2009d, Anonymous, 2018).

B.4.2 PROCEDURES FOR CLEANING APPLICATION EQUIPMENT

Rinse application equipment thoroughly with water and spray over already treated area.
Use pressure rinsing devices or triple rinsing with water to reduce any product residues in the container. Do not dispose product or containers on ponds, rivers or ditches. Do not re-use containers for other purposes. Waste disposal and recycling contractors will take cleaned containers.

Waste resulting from the use of the product must be disposed on site or on an approved waste disposal facility. Empty the sprayer out in the field being treated by spraying out on to a relatively pest free part of the field left unsprayed or under-dosed for the purpose. Do not exceed the maximum dose approved for the crop.

Protective clothing shall be washed in the usual way.

B.4.2.1 Effectiveness of the cleaning procedures

B.4.3 RE-ENTRY PERIODS, NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO PROTECT MAN, LIVESTOCK AND THE ENVIRONMENT

No waiting periods are required. SPEXIT does not harm human health, animals including livestock, plants or other non-target organisms.

B.4.3.1 Pre-harvest intervals, re-entry or withholding periods to minimise residues in crops, plants, plant

No information was submitted by the applicant.

B.4.3.2 Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used

No information was submitted by the applicant.

B.4.4 RECOMMENDED METHODS AND PRECAUTIONS CONCERNING: HANDLING, STORAGE, TRANSPORT OR FIRE

Handling of SPEXIT does not require special precautionary measures or protective clothing, as indicated by the technical properties and by the submitted toxicological studies. The following general precautionary measures in handling are stated on the Safety Data Sheet (Safety Data Sheet, see Doc. MA 3.7).

The following general precautionary measures in **handling** are stated on the Safety Data Sheet (Anonymous, 2018).

The usual precautions for handling chemicals should be observed:

- To avoid any direct contact with the product.
- To wash hands after contamination with the product.
- To keep (remaining) product away from waters.

Storage conditions:	Store in original package only.
Advises for Storage with other Products:	None
Other Information on Storage:	To maintain quality: Store below 0 °C. Stored in the refrigerator (< 5 °C) for two years. Stored at -18 °C for years without any loss of activity.

There are no restrictions regarding **transport** on land or sea.

In case of **fire** the following information and instructions are given:

Extinguishing media:	Water mist, alcohol resistant foam, carbon dioxide, dry powder
Measures unsuitable for safety reasons:	Water-jet, foam
Special hazard properties (products or vapours from thermal combustion):	Vapours cause coughing. At elevated temperatures (> 200 °C), there is a risk of exothermic polymerization. At temperatures > 280 °C, acrolein may be formed.
Protective equipment:	No specific recommendations. Use protective clothing.
Cleaning/disposal:	Spray remaining product dispersed in liquid manure. Small amounts can be added to compost.
Other advices:	Avoid contact with oxidizing agents. Cool closed containers with water.

The standard protection measures for workers are adequately protecting their health in case SeMNPV containing material is released or spilled accidentally at the manufacturing facilities.

The contaminated area may be cleaned by sweeping up spill, and spillage can be safely disposed of in accordance with all applicable federal, state, and local environmental regulations.

First aid measures:

General advice:	Change any contaminated or wetted clothing at once. If poisoning occurs contact a doctor.
Skin contact:	Remove contaminated clothing. Seek medical advice if irritation develops. Launder clothes before reuse. After contact with skin, wash immediately with plenty of water.
Eye contact:	Rinse thoroughly with plenty of water. Eyelids should be hold away from the eyeball to ensure thorough rinsing. Seek medical advice if irritation develops.
Ingestion:	No typical symptoms and affects known.
Inhalation:	This is only possible by exposure to HOT product or to spray. Move to fresh air, rest, half upright position, loosen clothing. Oxygen or artificial respiration if there is difficulty in breathing. Seek medical advice after significant exposure. Symptomatic treatment is advised.
Other information:	None
Advice to Physician:	Symptomatic treatment is advised.

In addition, persons who may want to seek medical attention upon accidental contact to SeMNPV, should inform the physician about the identity of the virus on species level, and may show the label of the packaging as supporting information.

SDS (Anonymous, 2018)

1.	Handling:	– The usual precautions for handling chemicals should be observed
2.	Storage:	– Store in original package only. Sealed packages can be stored for at least two years at temperatures of 5 °C.
3.	Transport:	– Inland transport: Not restricted – Sea transport: Not restricted – Air transport: Not restricted
4.	Firefighting measures	– Suitable extinguishing media: Water mist, alcohol resistant foam, carbon dioxide, dry powder – Unsuitable extinguishing media: Water-jet, foam – Special hazards arising from the mixture: Vapours cause coughing. At elevated temperatures (> 200 °C), there is a risk of exothermic polymerization. At temperatures > 280 °C, acrolein may be formed. – Advice for firefighters: Avoid contact with oxidizing agents. Cool closed containers with water.

B.4.5 MEASURES IN CASE OF AN ACCIDENT

1.	Containment of spillages:	– Prevent entry into drains, waters, sewages etc. of the product, contact immediately the municipal technical management if the product enters such bodies. Use adsorbent material to collect spillage (e.g. sawdust, peat, chemical binder). Place contaminated adsorbent in closable containers. Use a damp cloth to clean floors and other objects after removal of contaminated adsorbent. Also place used cleaning materials into closable receptacles.
2.	Decontamination of areas, vehicles and buildings:	– Refer to the above statement on spillages
3.	Disposal of damaged packaging, adsorbents and other materials:	– Refer to the above statement on spillages
4.	Protection of emergency workers:	– Use protective clothing, chemical-resistant gloves and boots. Do not inhale.
5.	First aid measures:	– General notes: Change any contaminated or wetted clothing at once. – No typical symptoms and effects known. In all cases of doubt, seek medical attention. – Inhalation: This is only possible by exposure to HOT product or to spray. Move to fresh air, rest, half upright position, loosen clothing. Oxygen or artificial respiration if there is difficulty in breathing. Seek medical advice after significant exposure. Symptomatic treatment is advised. – Skin: Remove contaminated clothing. Seek medical advice if irritation develops. Launder clothes before reuse. After contact with skin, wash immediately with plenty of water. – Eye: Rinse thoroughly with plenty of water. Eyelids should be hold away from the eyeball to ensure thorough rinsing. Seek medical advice if irritation develops.

	–	Ingestion: No typical symptoms and effects known
6. Further medical treatment:	–	Symptomatic treatment
Cleanup / containment of spillage	–	Use adsorbent material to collect spillage (e.g. sawdust, peat, chemical binder). Place contaminated adsorbent in closable containers. Use a damp cloth to clean floors and other objects after removal of contaminated adsorbent. Also place used cleaning materials into closable receptacles

SDS (Anonymous, 2018)

1. Personal precautions, protective equipment and emergency procedures	–	Use protective clothing. Do not inhale.
2. Environmental precautions	–	Prevent entry into drains, waters, sewages etc. of the product; contact immediately the municipal technical management if the product enters such bodies.
3. Methods and material for containment and cleaning up	–	Use adsorbent material to collect spillage (e.g. sawdust, peat, chemical binder). Place contaminated adsorbent in closable containers. Use a damp cloth to clean floors and other objects after removal of contaminated adsorbent. Also place used cleaning materials into closable receptacles.
4. Exposure controls/personal protection:		
5. Control parameters:	–	The usual precautionary measures for handling chemicals should be observed
6. Eye/face protection	–	No specific recommendations
7. Skin protection	–	Use protective clothing
8. Respiratory protection	–	No specific recommendations
9. Thermal hazards	–	No specific recommendations
10. First aid measures General notes	– –	Change any contaminated or wetted clothing at once. If poisoning occurs contact a physician.
11. Following inhalation	–	Only possible by exposure to HOT product. Move to fresh air, rest, half upright position, loosen clothing. Oxygen or artificial respiration if there is difficulty in breathing. Seek medical advice after significant exposure. Symptomatic treatment is advised.
12. Following skin contact	–	Remove contaminated clothing. Seek medical advice if irritation develops. Launder clothes before reuse. After contact with skin, wash immediately with plenty of water.
13. Following eye contact	–	Rinse thoroughly with plenty of water. Eyelids should be hold away from the eyeball to ensure thorough rinsing. Seek medical advice if irritation develops.
14. Following ingestion	–	No typical symptoms and affects known
15. Advice to physician	–	Symptomatic treatment

B.4.6 PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING

The disposal of product has to be performed in accordance with all applicable federal, state and local environmental regulations. Waste resulting from the use of the product must be disposed on site or on an approved waste disposal facility. Empty the sprayer out in the field being treated by spraying out on to a relatively pest free part of the field left unsprayed or under-dosed for the purpose. Do not exceed the maximum dose approved for the crop.

Totally cleaned packages can be given to the regular waste disposal.

SDS (Anonymous, 2018)

Product/Packaging disposal:

Use pressure rinsing devices or triple rinsing with water to reduce any product residues in the container to insignificant levels. Don't dispose product or containers on ponds, rivers or ditches. Don't re-use containers for other purposes. Waste disposal and recycling contractors will take cleaned containers.

Waste resulting from the use of the product must be disposed on site or on an approved waste disposal facility. Empty the sprayer out in the field being treated by spraying out on to a relatively pest free part of the field left unsprayed or under-dosed for the crop.

B.4.6.1 Controlled incineration

In accordance with local authority regulations, take to special waste incineration plant.

B.4.6.2 Others

Not applicable

B.4.7 REFERENCES RELIED ON

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

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

RMS comments:

- RMS has considered all document as new information on the current Draft Assessment Report for the new microbial pest control agent SeMNPV.
- In the opinion of the RMS, the literature research made by the applicant according to EFSA 2011 guidance covered the most relevant news for SeMNPV. The RMS has 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 4.1/01	Anonymous	2005	Regulation Information Sheet. VORIDIAN PET 9921W Andermatt Biocontrol AG, CH, not applicable not applicable GLP/GEP: no Published: no	no	no	not protected	ABA
KMP 4.1/02	Anonymous	2009a	PRODUCT SPECIFICATION 100 ML Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.1/03	Anonymous	2009b	PRODUCT SPECIFICATION 200 ML Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.1/04	Anonymous	2009c	PRODUCT SPECIFICATION 500 ML Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.1/05	Anonymous	2009d	PRODUCT SPECIFICATION 1 L not available, not available not available GLP/GEP: no Published: no	no	yes		ABA

[13] Guidance of EFSA: Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092

Data point	**Author(s)**	**Year**	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**
KMP 4.1/06	Anonymous	2009e	PRODUCT SPECIFICATION 5 L Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA
KMP 4.4/01	Anonymous	2018	Safety Data Sheet SPEXIT Andermatt Biocontrol AG, CH, not available not available GLP/GEP: no Published: no	no	yes		ABA

ABA – Andermatt Biocontrol AG
References included by the RMS in GREY