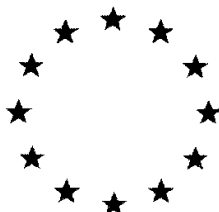


European Commission



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

***Spodoptera exigua* multicapsid nucleopolyhedrovirus (SeMNPV) strain BV-0004**

Active substance data

Volume 3 – Annex B.4 Further Information of the Microorganism

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.4.1 Recommended methods and precautions concerning handling, storage, transport or fire

Handling of SeMNPV does not require special precautionary measures or protective clothing, as indicated in the OECD consensus document (2002) and by the submitted toxicological studies (Volumen 3 Annex B.5 (MA)). Further, Frommer *et al.* (1989) relate the different risk classes according to European classification of micro-organisms to adequate safety precautions for biotechnology. In this review, SeMNPV like other BVs is not listed.

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.

(1) Storage conditions: Store in original package only	
Advises for Storage with other Products	None
Other Information on Storage	<ul style="list-style-type: none"> – 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
(2) There are no restrictions regarding transport on land or sea	
(3) 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):	<ul style="list-style-type: none"> – 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
(4) 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	
(5) 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.	
(6) First aid measures	
General advice	– Change any contaminated or wetted clothing at once. If poisoning occurs contact a doctor
Skin contact	<ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> – 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
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	

B.4.2 Procedures for destruction or decontamination

With regard to destruction and decontamination the following accidental release measures and general information and recommendations are given in the Safety Data Sheet (Anonymous, 2018, Doc KMA 3.7/01):

Decomposition/ persistence	– Decomposition is achieved by thermal combustion at 600 °C without any residues or hazardous products
Special advice for humans and environment	– Keep (remaining) product away from waters – Avoid any contact with the product – Non-hazardous to honeybees due to the selectivity of the product – Non-hazardous to relevant populations of beneficial due to selectivity of the product
Disposal/ Product	– 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
Disposal/ Packages	– Recommendations: add empty packages to local waste disposal or recycling system
Cleaning Agent	– No special cleaning necessary

B.4.3 Measures in case of an accident

Specific measures in case of an accident are not required, since SeMNPV is a common BV, and this family imposes no risk for environment or human health (Volumen 3 Annex B.5 and B8 (MA)).

SeMNPV is highly host-specific and does not cause any harm to organisms other than the target organism *Spodoptera exigua*.

General information

Specific measures in case of an accident are not required, since SeMNPV is a common baculovirus, and this family imposes no risk for environment or health. 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 off in accordance with all

applicable federal, state, and local environmental regulations. No specific treatment after contact with SeMNPV contaminated material is required since this strain is not infective for humans. As a general precautionary measure in case of direct contact to this virus the applicant states the below listed first aid instructions. 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.

First-aid measures	
General advice	<ul style="list-style-type: none"> – Change any contaminated or wetted clothing at once – If poisoning occurs contact a doctor
After eye contact	<ul style="list-style-type: none"> – Rinse thoroughly with plenty of water – Eyelids should be hold away from the eyeball to ensure thorough rinsing – Seek medical advice if irritation develops
After skin contact	<ul style="list-style-type: none"> – Remove contaminated clothing – Seek medical advice if irritation develops – Launder clothes before reuse – After contact with skin, wash immediately with plenty of water
After inhalation	<ul style="list-style-type: none"> – 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
After ingestion	<ul style="list-style-type: none"> – No typical symptoms and affects known
Advice to physician	<ul style="list-style-type: none"> – Symptomatic treatment is advised

B.4.4 References relied on

Literature search:

The literature search carried out by the applicant performed in accordance with the recommendations in the EFSA (2011)¹ 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 DialogTM. The data requirement “Biological properties of the micro-organism” was covered using a focused search encompassing baculoviruses 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 3.3/01.

Regarding Section 3, two references were identified as relevant (in Point MA 3.3, MA 3.6).

From peer reviewed open literature, no fundamental new findings on crops or products protected or treated were identified.

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¹ 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