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Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV)

Active substance data

Volume 3 – Annex B.9 Effects on non-target organisms

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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 the SeNPV-BV0004, approved in 2010. Conversely, the current dossier was based on the data already assessed by the MS and EU authorities:

[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 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.*

B.9 EFFECTS ON NON-TARGET ORGANISMS

SeMNPV belongs to the genera alphabaculovirus and 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. In accordance with host specify, the occurrence of SeMNPV is linked to the presence of the host, *S. exigua*. Therefore, their application in pest control means only a fluctuation of the virus titre in the biotope of the pest insect. Effect on non-target organism and environment behaviour of SeMNPV would considered similar to related BV CpGV and the ecotoxicological studios on CpGV SC appropriate to assess whether risk might be caused by application of SeMNPV in a plant protection product.

RMS comments:

NONE of the ecotoxicological studies presented in this section have been conducted with the target organism ***S.exigua*multicapsid nucleopolyhedrovirus (SeMNPV) isolate Bv-0004, or any other SeMNPV isolate, or BVs belong to the genera *alphabaculovirus*. All studios were performed with BVs *Cydia pomonella* granulovirus (CpGV SC) belongs to the genera *betabaculovirus*.**

The studios provided by the applicant have performed between 1998 and 2002, before the isolate SeMNPV Bv-0004 was deposited at the German Collection of Microorganism and Cell Cultures in 2004.

Even the biology of all BVs is very similar, there are slight morphologic differences between *alphabaculoviruses* and *betabaculoviruses*. Furthermore, it has to be kept in mind that SeMNPV is highly specific and has an effect exclusively in beet armywarm (*Spodoptera exigua)* inside the family *Noctuidae* (Lepidoptera), since the target organism in CpGV SC is the codling moth (*Cydia pomonella*) inside the family *tortrichidae* (Lepidoptera).

Differences between the granulovirus CPGV SC presented in this document as representative of BVs behaviour, and SeMNPV have been fully explained by the RMS, together with an evaluation of the impact of the change on the ecotoxicological properties.

No ecotoxicological data were available for SeMNPV. Instead, data for other BVs (CpGV SC), was used for the ecotoxicological risk assessment. The issue of using data for other BVs was discussed by EFSA experts in 2012 (Pesticides Peer Review Meeting M05; EFSA, 2012a). The experts considered that it was reasonable to extrapolate information on toxicity, infectivity and pathogenicity from other BVs, on the basis that BV have similar modes of action, and in view of the information given in the OECD consensus document (OECD, 2002). Nevertheless, in order to considered SeMNPV isolate Bv0004 as a low risk microorganism according to Commission regulation EU 2017/1432, "*Baculoviruses shall be considered as being of low risk unless at strain level they have demonstrated adverse effects on non-target insects*" the effect of non-target insect have to be evaluated in SeMNPV isolate Bv0004.

B.9.1 EFFECTS ON BIRDS

Due to the high host specify of BVs and the similarity within the group, no study is submitted for determination of effects of SeMNPV on birds. Abundant data on analyses of effects on BVs are available from the literature. The following information for species related to SeMNPV regarding effects on birds can be derived from literature:

No cases of viral toxicity or pathogenicity were observed in studies specifically designed to include pathology in avian species (chicken, turkey, pheasant, dove, mallard, sparrow and quail) using different BVs (Ignoffo, 1975). At least four species of birds (quail, chicken, sparrow, and mallard) were exposed to heavy doses of *Heliothis* sp. NPV without any adverse reactions (Burges *et al*., 1980). No adverse effects were reported when English sparrows were fed 8 x 10^9 polyhedra inclusion bodies (PIB)/kg.

Lautenschlager *et al.* (1979) studied the response of birds to aerial application of *Lymantria dispar* MNPV (LdMNPV). No changes in population of the wild birds were detected that could be attributed to the treatment. No significant differences, or differences in trends, were revealed for any species in organ weights or necropsy and histopathological ranking of the condition of organs and tissues between treated and control birds. It was concluded that the aerial application of NPV had no short-term adverse effect on birds, neither directly nor secondarily by feeding on NPV-infected gypsy moth larvae or on other NPV-contaminated food sources. Lewis and Podgwaite (1981) reported that bobwhite quail and mallard ducks were challenged with 100 times the field dose of LdMNPV. No effect was apparent in either species with regard to toxicity, behaviour, or mortality due to the oral administration of LdMNPV. LdMNPV was fed to *Parus atricapillus* and to *Passer domesticus* as NPV-infected *L. dispar* larvae (Lewis and Podgwaite, 1981). Analyses of bodyweights and histopathological examination of organs from NPV-treated birds indicated that LdMNPV had no apparent short-term effects on these two avian predators of the insects. These studies have shown that LdMNPV has no apparent adverse effects on those birds that may utilize *L. dispar* as a food source, or on those birds that may contact the virus from NPV spray, spray residue, or NPV-infected larvae (Lewis and Podgwaite, 1981). After aerial application of LdMNPV, data from 23 caged quails and 53 free-living birds showed no differences for any species between NPV-treated and control birds as judged by organ weights or necropsy and histopathological rankings of the conditions of organs and tissues (summarized by Gröner, 1986). After a naturally occuring epizootic among *Lymantria dispar* caused by LdMNPV, intestinal contents of wildlife birds were analysed for presence of LdMNPV. Infective LdMNPV was found in *Cyanocitta cristata* (blue jay) and *Pipilo erythrophthalmus* (towhee). No signs of pathogenicity or disease symptoms were reported (Lautenschlager *et al*., 1980). This observation demonstrates that birds as well as mammals, especially insect feeding animals, but also other species, are constantly exposed to BV without showing any disease symptom.

After ingesting inclusion bodies of a *Mamestra brassicae* NPV virus by chickens, the faeces of these test animals showed virus activity caused by unaltered inclusion bodies (Gröner and Döller, 1982). The treatment of the chicken faeces with chloroform had no deleterious effect on the virus activity in the faeces. Therefore, the polyhedra were presumably not solubilised in the alimentary canal of the chickens. An interpretation of the different behaviour of polyhedra between the alimentary tracts of birds and mammals could be based on the results of previous studies which indicated that polyhedra were not attacked by trypsin (at pH 9.2) within 18 h unless they were pretreated with HCl at pH 1 for 2 h. The low acidity in the stomach of birds may result in an insufficient pre-treatment of the polyhedra which would leave them resistant to the intestinal alkaline protease.

None of four avian species (mallard duck, ring-necked pheasants, house sparrows, mule deer) tested with *Orgyia pseudotsugata* MNPV showed symptoms or signs of systemic toxicity-pathogenicity, except for minor temporary weakness in some of the test subjects (Martignoni, 1978). Similarly, no deleterious effects on small forest songbirds were attributed to an aerial application of OpMNPV.

To test the safety to vertebrates of *Pieris rapae* GV in China, the virus was administered at 50 mg/kg body weight as a single oral dose to birds. None showed ill effects and growth was normal during the 2-3 months that followed the administration. No cytopathogenicity or virus replication was observed after administration of *Pieris rapae* GV to an embryonic chicken cell culture (Xuebao, 1982).

No ill effects were observed in acute oral toxicity tests with NeleNPV in chicken and turkey. Reproduction of NeleNPV in avian cell cultures was not detected. In the course of field trials, pre-spray and post-spray counts were made of birds. No ill effects were noted. There was no evidence of NeleNPV having any harmful effects in acute oral tests on mallard ducks and bobwhite quail (summarized by Cunningham and Entwistle, 1981).

Entwistle *et al*. (1978) studied the passage of *Gilpinia hercyniae* NPV through the gut of passerine birds (*Sturnus vulgaris*, *Parus major*, *P. ater*, *P. caerulus*) during cage tests. Following feeding infected *G. hercyniae* larvae, polyhedral inclusion bodies of the virus could be detected in bird faeces within 0.5 h. Peak passage of polyhedra occurred in less than 1 h and none were detected after 2.5 h. The faeces of all birds remained infective in bioassay tests using first instar *Gilpinia hercyniae* larvae to the end of the day of infection while those of nine birds remained infective to the next day and of six birds to the third day. One bird was infective up to day 7. The infectivity of NPV in faeces stored for 2 years at ±3°C declined by half. The comparatively long retention and passage of infective virus suggests birds may be effective in short- and long-distance transport of BV. Polyhedral inclusion bodies of BV pass undegraded through the alimentary tract of all bird species so far tested, indicating that an acidic milieu apparently has no effect on PIBs or on the virions they contain. The protein matrix of PIBs is dissolved in mildly alkaline conditions and when the polyhedral membrane is destroyed proteolytic digestion of the matrix may occur. Gröner (1986) summarized that birds have the potential for transporting NPVs within "contaminated" ecosystems and even for passing faeces containing infective *Gilpinia hercyniae* NPV throughout the nonlarval winter period as a result of their feeding on the cadavers of NPV-killed larvae adhering to trees.

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 AQUATIC ORGANISMS

B.9.2.1 Effects on fish

A study on the effects of the formulated product Granupom, containing *Cydia pomonella* GV on rainbow trout is submitted in Volume 3 MP B 10, Point B10.2.2

Furthermore, for SeMNPV related species the following information regarding effects on fish can be derived from literature:

Gröner *et al*. (1981) summarized that lepidopteran and hymenopteran BV have a narrow host range, confined to few species of the same genus. Moth caterpillars are not a principal source of food for fish. The authors have found no indications of hazard to at least 12 fish species and at least six fish cell lines by entomopathogenic viruses in the published literature. Moreover high virus titres can also occur naturally during mass reproduction of moth and sawfly larvae. This means that aquatic organisms have always been confronted by considerable numbers of BV under natural conditions without any observable damage. Burges *et al*. (1980) and Gröner (1986) summarized that heavy doses of *Heliothis zea* NPV and other NPVs had been tested on at least seven different fish species and no negative effects were reported in the published literature.

240 juvenile bluegills and 240 juvenile brown trouts were exposed to *Lymantria dispar* MNPV in 69 h static exposure tests (Lewis and Podgwaite, 1981). LdMNPV had no demonstrable effect on survival and histopathology of either species at doses approximately 100 times the field application dose.

Banowetz *et al*. (1976) showed that the application of *Orgyia pseudotsugata* NPV had no deleterious effects on chinook salmon, coho salmon, or steelhead trout which reside in waters adjacent to treated forests. Coho salmon seem reluctant to eat *O. pseudotsugata* larvae. Fingerlings (average weight 0.5 g) of the three species and coho salmon smolts (average weight 20 g) were exposed to virus by intraperitoneal injection, by feeding, and in the water. The virus caused no pathological changes. Bioassay of tissue homogenates from kidney, liver, spleen, and digestive tract of coho salmon smolts showed that the virus was cleared or inactivated rapidly (within 24 h after exposure). All attempts to feed tussock moth larvae to coho salmon smolts failed. The fish, even when deprived of food for 5 d, rejected the larvae (including larvae coated with serum albumin), but they did not reject earthworms cut to the size of larvae. Cell lines derived from chinook salmon embryos and steelhead trout embryos were refractory to non-occluded virions and no cytopathology was observed by light and electron microscopy.

To test the safety of *Pieris rapae* GV in China, the virus was administered at 50 mg/kg body weight as a single oral dose to fish (Xuebao 1982). None showed ill effects and growth was normal during the 2-3 months that followed the administration.

Bluegill sunfish and rainbow trout were exposed to *Neodiprion sertifer* NPV in aquaria and rainbow trouts were exposed to *Neodiprion lecontei* NPV by intubation and topical application (Hicks *et al*., 1981; Cunningham and Entwistle 1981). There was no evidence of the viral preparation having any harmful effects.

B.9.2.2 Effects on freshwater invertebrates

A study on the effects of the formulated product Granupom, containing *C. pomonella* GV, on *Daphnia magna* is submitted in Volumen 3 MP, B 10, Point B10.2.3

The following information regarding effects of SeMNPV and related BVs on freshwater invertebrates can be derived from the literature:

Gröner *et al.* (1981) summarized possible effects on aquatic organisms and pointed out that no hazard occurs for aquatic invertebrates from the application of BVs. The BVs that occur endemically in shrimps in USA are not related to lepidopteran BVs and no cross infections are known to occur.

Ignoffo (1975) reported negative results in tests using *Heliothis* sp. NPV on brown shrimp and water fleas, and also on oysters. Gröner (1986) reported that the application of *Heliothis zea* NPV to Daphnia resulted in no adverse effects.

Lewis and Podgwaite (1981) also reported that survival, development time of the immatures, and subsequent reproduction of the treated adults of *Daphnia magna*, *Notonecta undulata*, and *Chironomus thummi* was unaffected by exposure to LdMNPV during their development from first instar to adult.

In a study conducted by Hicks *et al.* (1981) no ill-effects were detected in *Daphnia pulex* when *Neodiprion lecontei* NPV was added to their culture. No significant differences ($p < 0.05$) were noted in brood size or fecundity in individual daphnids between treated and control groups. A total of 60 daphnids was assessed histologically and no lesions or abnormalities were noted in any of the tissues examined. The alimentary canals frequently contained ingesta suggestive of algae and fragmented material resembling that found in the uninfected and NPV-infected larval preparation. Water fleas were not susceptible to 10^6 to 10^9 polyhedral inclusion bodies per animal (Burges *et al*., 1980).

B.9.2.3 Effects on algae growth

A study on the effects of the formulated product Granupom, containing *C. pomonella* GV, on *Scenedesmus subspicatus* is **submitted in MP, B 10, Point 10.2/03**. Based on the observation made during this test, the NOEC was 100 mg/L, the EC50 was determined to be 100 mg/L Granulosevirus CpGV.

A study on the effects of the formulated product Granupom, containing *C. pomonella* GV on *Lemna gibba* is submitted in MP, B 10, Point 10.2/04. In this study, no effects were determined at 100 mg/L. No LOEC and EC_{50} could be determined for any growth parameter; the NOEC was 100 mg/L.

Due to the close relationship between all lepidoptera BVs and since SeMNPV containing formulation SPEXIT does not contain any ingredients of toxicological concern (see confidential data on Volume 4), information obtained for Granupom (CpGV) is also valid for SPEXIT (SeMNPV).

B.9.2.4 Effects on plants other than algae

No member of the Baculoviridae family is known to infect plants (OECD, 2002). Thus it is assumed highly unlikely that SeMNPV would be phytotoxic or phytopathogenic.

B.9.3 EFFECTS ON BEES

A study on the effects of the formulated product Granupom, containing *C. pomonella* GV on *Apis mellifera* is submitted in Volume 3MP, B 10, Point B10.2.7.

According to the results of this study it can be assumed that the oral LD50/72 h is above 3.5 x 10^7 granula/bee (> 20300 µg/bee) and the contact LD50/48 h of Granupom is above 4.4 x 10^7 granula/bee (> 25500 µg/bee).

Due to the close relationship between all lepidopteran BVs and since SeMNPV containing formulation SPEXIT does not contain any ingredients of toxicological concern (see confidential data on Volume 4), information obtained for Granupom (CpGV) is also valid for SPEXIT (SeMNPV).

The following information regarding effects of SeMNPV and related BVs on bees can be derived from published literature.

Gröner (1990) reported that no deleterious effects of various BVs (2 GV and 11 NPV including *Heliothis zea* NPV) on honeybees have ever been found. Treatments of whole colonies have never revealed any abnormalities in egg production, brood rearing, worker and queen mortality, and general colony behaviour. Even when hymenopteran specific NPV as NeseNPV and NeleNPV were applied to control *Neodiprion sertifer* and *N. lecontei*, respectively, no impact on bee colonies was detected. NeseNPV was applied to bees in a colony without causing harm to bees, showing again the high host specifity of BVs. Similarly, *Galleria mellonella* NPV was used to control *G. mellonella* in bee hives (Krieg 1976).

Suspensions of a technical preparation of OpMNPV were fed to honey bees in sucrose solution (Martignoni, 1978). Each test hive was exposed to 1/10 of the full acre dose. The estimated dose per bee was 10.850 AU_{GL} (which is the activity unit determined in larvae of *O. pseudotsugata*). Observation of the colonies over a period of 4 months failed to show any detrimental effects. Egg laying, brood rearing, and honey production were the same as those of control hives. *Lymantria dispar* NPV was incorporated in sucrose solutions and fed to bee colonies for up to 4 months and no deleterious effects could be attributed to LdMNPV (summarized by Lewis and Podgwaite, 1981).

Inclusion bodies from two BVs, *Mamestra brassicae* MNPV and *Cydia pomonella* GV, were tested on adult bees (*Apis mellifera*; Gröner *et al*., 1978). Pure suspensions of 5 x 10^7 polyhedra/mL or 1 x 10^{10} granula/mL, respectively, as well as a 10 % suspension of formulated wettable powders (with a content of 1.7 x 10^8 polyhedra/g or 1 x 10^{11} granula/g, respectively) induced no harmful effect during the first 3 days after feeding, wetting, contact or exposure to the gas phase. Additional feeding tests were run over a period of 10 days. In one test a dose of 10 µL virus suspension (containing 5 x 10^7 polyhedra/mL or 1 x 10^{10} granula/mL, respectively) was applied once during the experiment. In a second test, the same dose was fed daily (resulting in a tenfold total dose). In both tests, no detrimental or pathogenic effects on bees could be detected. These virus preparations can therefore be regarded as “not harmful for bees”.

RMS conclusion: The experience that BVs present no risk for non-target species has been confirmed by numerous literature studies cited in Annex MA Point 8.1. SeMNPV is highly specific and only has an effect on larvae of *Spodoptera spp.*

Even all considerations mentioned related to the specificity of BV, the RMS consider 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 Andermatt Biocontrol GmbH.

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.9.4 EFFECTS ON ARTHROPODS OTHER THAN BEES

The effects of the formulated product Granupom, containing *C. pomonella* GV, on *Aphidius rhopalosiphi*, *Typhlodromus pyri*, and *Poecilus cupreus* are assessed in studies submitted in Volume 3MP, B10 Point B10.2.9

Furthermore, the following information regarding effects on terrestrial arthropods can be derived from the literature for BVs including SeMNPV.

BVs are characterised by a very high host specify, with host ranges normally comprising only few species within a genus, rarely different genera of one family. In general, the host range never exceeds the order and only rarely the family. Cross-infection of lepidopteran NPVs or GVs to insects other than Lepidoptera has never been observed (Gröner, 1990). This high host specificity allows even the application of *Hyphantria cunea* NPV to control *H. cunea* on mulberry trees without causing harm to silkworms (*Bombyx mori*; Krieg, 1976). Determination of cross-infectivity strongly depends on the purity of the virus that should be tested. If other viruses are present in the test preparation, these may lead to wrong-positive results. Furthermore, if the host population is infected with a latent virus, the latter might be activated by the test virus (or a combination of both) and thus leads to positive effects, which cannot be attributed to the test virus alone (Huber, 1978; Gröner, 1990). *Autographa californica* NPV has the widest known host range among BVs, including 13 moth species, from several different genera and families of Lepidoptera. Some NPV, especially Hymenopteran NPVs, may be specific to a single host species, e.g. the NPV of some sawflies (Burges *et al*., 1980).

There are a number of reports of cross-infectivity studies using oral routes of infection with polyhedra and high doses of virus inoculum that show that most NPVs are not species specific, but have narrow insect host range and are, therefore, optimal candidates for insect pest control (summarized in Gröner, 1986).

SeMNPV differs from other BVs in the fact that it infects only a single insect species and is highly virulent for larvae of the beet armyworm *Spodoptera exigua*. SeMNPV only replicates in *S. exigua* cells. Simon *et al*. (2004) determined the course of infection processes and virus replication in larvae of *S. littoralis*, *S. frugiperda*, and *S. exigua* after oral intake of occlusion bodies or after injection of occlusion-derived virions into the haemocoel. None of these treatments resulted in virus progeny in the heterologous hosts. Block of virus proliferation occurs after the haemocoel transmission stage and the virus was then cleared from larval tissues (Simon *et al*. 2004).

The host range of SeMNPV was determined in cross- infection experiments (summarized by Gröner 1986). Results of experiments to cross-transmit SeMNPV to other lepidopteran species are listed in Table MA 8.8-1.

Species	**Family**	**Result**	**References**
Agrotis segetum	Noctuidae	-	Gröner 1986
Amathes c-nigrum	Noctuidae	-	Gröner 1986
Mamestra brassicae	Noctuidae	-	Gröner 1986
Mamestra oleracea	Noctuidae	-	Gröner 1986
Spodoptera frugiperda	Noctuidae	-	Simon *et al*. 2004
Spodoptera littoralis	Noctuidae	-	Gröner 1986, Simon *et al*. 2004
Plutella xylostella	Plutellidae	-	Gröner 1986
Galleria mellonella	Pyralidae	-	Gröner 1986
Ostrinia nubilalis	Pyralidae	-	Gröner 1986
Adoxophyes orana	Tortricidae	-	Gröner 1986
Cydia pomonella	Tortricidae	-	Gröner 1986

Table MA B.9.8-1. Results of experiments to infect larvae or cell cultures from Lepidopteran species with SeMNPV

Infectivity of different virus species from *Spodoptera* species was analysed in *S. exigua*, *S. littoralis*, and *S. frugiperda*. SeMNPV was fed to 2nd instar larvae or injected into the haemocoel of 4th instar larvae of *S. littoralis* and *S. frugiperda*. No symptoms were observed after feeding or injection into the haemocoel and no virus replication occurred in heterologous species. Initial infection occurred in *S. littoralis* and *S. frugiperda*, but infection stopped and the virus was cleared from larvae (Simon *et al*. 2004). SeMNPV is considered to be the most specific baculovirus as it only infects one single insect species, *S. exigua* (Ijkel *et al*. 1999). This extremely high host-specificity is especially important for assessing the side-effects on beneficial arthropods and other non-target organisms.

No deleterious effects on beneficial insects resulting from treatment with different NPVs including *H. zea* NPV were found in studies with honeybees, silkworms, entomophagous insects and insect predators. However, there may have been some indirect effects on certain entomophagous insects resulting from the death of the host insect from a virosis before the development of the parasitoid had been completed. On the other hand, individuals of the parasitoid *Hyposoter exiguae* completed their development before their hosts died of virus infection. Interestingly, if the host was exposed to the virus after parasitisation, the parasite larvae spent significantly less time in the infected host. The authors found that the parasitoid, *Apanteles militaris*, was killed or failed to pupate when its armyworm host was infected with the hypertrophic strain of an NPV (summarized by Gröner, 1986).

Gröner (1990) reported that laboratory studies with several predators of lepidopteran larvae (pentatomids, lacewings, ladybirds and scavenger beetles) have established that BVs pose no adverse effect on these species, neither when fed via infected larvae, nor when fed suspended in semisynthetic diets, nor by direct contact. Furthermore, it was demonstrated that predators are potential dispersal agents of BVs. This is due to the fact that they often feed on virus-infected larvae as well as on larvae that have died from the effects of a BV and therefore yield infectious occlusion bodies. Results from field tests suggest that the predator complex enhances the epidemic potential of BVs by contaminating the foliage with occlusion bodies, either directly after individuals clean their mouthparts with the tarsi, or via faeces. Because viral occlusion bodies are retained in the gut of heteropteran nymphs which preyed on virus-diseased hosts until after the final moult, the adults (being strong fliers) appear capable of introducing the viral inoculum to healthy pest populations. Few results of studies of viral impact on adult parasites are available. Gröner (1990) summarised that BVs have a narrow host range and no evidence of direct deleterious effects to parasites has been documented. All lethal and sublethal effects are indirect, being caused by the host's unsuitability due to virus infection.

Jaques *et al*. (1981) found that treatment of apple trees with CpGV substantially reduced damage by longevity of females of the parasitoid *Apanteles melanoscelus*, parasitisation ratio, and sex ratio of emerging offspring were not significantly different between treatment with *Lymantria dispar* NPV and control. Ten lepidopteran, two hymenopteran, one coleopteran, one orthopteran, and one dipteran species were challenged with *L. dispar* NPV at a dose of 1.5 x 108 PIB/mL. Despite the high doses, no apparent effect of these treatments was noted (Lewis and Podgwaite, 1981). *Pieris rapae* GV showed no ill effects on silkworms (*Bombyx* spp.) and growth was normal during the 2-3 months that followed the administration (Xuebao, 1982).

Cydia pomonella larvae were compared between treated and untreated trees. CpGV had little effect on populations of insects predacious on *C. pomonella* (thrips, clerids, pentatomids and mirids). The lack of effect of CpGV on species of insects that prey on eggs and larvae of *C. pomonella* and on the red mite indicated the value of the virus in an integrated pest management system. In long-term field trials set up to study the influence of CpGV on the apple fauna, the parasitization of the codling moth and of apple leafrollers were also kept under observation on experimental fields (Dickler, 1986). By decimating the host population, the CpGV-treatments were seen to have a notable effect on the population of the codling moth parasites.

Studies on the side-effects of *M. brassicae* NPV as well as of *Cydia pomonella* GV were carried out by testing watery suspensions of inclusion bodies and of formulated wettable powder on a parasite, *Trichogramma cacoeciae*, and a predator, *Chrysopa carnea*. A 10-fold concentration of that normally applied in the field was used in the tests (summarized by Gröner, 1978). No detrimental effects with MbMNPV and CpGV were observed on parasitation capacity, fertility, and development of *T. cacoeciae* in the treated generation and its offspring. The feeding capacity of *C. carnea* larvae, fecundity of the adults and viability of eggs were not affected when larvae were treated with the virus.

Long-term field trials were run to investigate the effect of CpGV on the fauna of apple trees (Gröner, 1990). By decimating the host population, the CpGV treatments have a notable effect on the population of codling moth parasites, in contrast to the leafroller parasite species. Because the leafrollers were not infected by CpGV, their population level remained unaltered, so, therefore did that of their parasites, and presumably also, those of other pests (e.g. red mites and aphids) in the virus-treated plots. Due to the narrow host range of this baculovirus (and by skipping chemical insecticides), predators of mites and aphids were not negatively affected and the population of European red mites and woolly apple aphids remained below the economic threshold in the virus-treated plots. Tests in Canadian apple orchards showed little effect of CpGV on populations of insects predaceous on the codling moth (thrips, clerids, pentatomids, and mirids). Numbers of the European red mite averaged around 1% of the number in chemically treated plots, providing further evidence of greater predatory activity in trees treated with CpGV.

Gröner (1990) concluded that since BVs are naturally occurring, beneficial insects have always had contact with these natural regulatory agents. Deleterious effects of BVs to pollinators, predators, and adult parasitoids have never been reported from nature. Atypical development of entomophagous larvae in virus-infected host larvae proved to be entirely due to the unsuitability of the host for the parasitoids in question. Host discrimination on the basis of viral infection has been documented, implying that some parasitoid species do not "waste" eggs on a host which is soon to die. Parasitoids which develop exclusively in eggs or pupae will be unaffected by or after a virus application, because these stages are nearly insensitive to viral infection. The decrease in numbers of beneficial insects after pest control based on BVs is due to the decreased number of hosts. In crops with a complex of pests the selective baculoviral application will allow the survival of all other insects and mites except the target pest. Therefore, alternative hosts for the predators and parasitoids are still available.

The RMS has considered:

1- SeMNPV containing formulation SPEXIT does not contain any ingredients of toxicological concern (see confidential data on Volume 4).
2- SPEXIT and GRANUPOM have the same additive and at the same quantity according with information provided in Volume 4, Appendix 3.
3- Close relationship between all lepidopteran BVs.
4- CpGV and SeMNPV do not belong to the same group of baculoviris family (SeMNPV is an alphabaculovirus and CpGV belongs to betabaculovirus).
5- 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 arthropods other than 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).

The RMS consider that a study need to confirm the reports from literature excluding adverse effects on related lepidoptera.

A data gap is therefore identified.

B.9.5 EFFECTS ON EARTHWORMS

The effects of the formulated product Granupom, containing *C. pomonella* GV, on earthworms are assessed in a study submitted in Volumen 3MP, B9, Point B9.7

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.

Due to the close relationship between all lepidopteran BVs and since SeMNPV containing formulation SPEXIT does not contain any ingredients of toxicological concern (see confidential docment VolumDoc J), information obtained for Granupom (CpGV) is also valid for SPEXIT (SeMNPV).

B.9.6 EFFECTS ON NON-TARGET SOIL MICROORGANISMS

The effects of the formulated product Granupom, containing *C. pomonella* GV, on soil microorganisms are assessed in a study submitted in Volume 3MP, section B 9, Point 9.7.

The impact on soil respiration of soil type 1 and soil type 2 is considered as negligible (< 15 % deviation) even at 5.0 L/ha CpGV SC application rate.

Due to the close relationship between all lepidopteran BVs and since SeMNPV containing formulation SPEXIT does not contain any ingredients of toxicological concern (see confidential data on Volume 4), information obtained for Granupom (CpGV) is also valid for SPEXIT (SeMNPV).

B.9.7 ADDITIONAL STUDIES

Cross-infectivity studies have shown that most BVs have a narrow host range, never exceeding the order and usually not the family of the host from which the virus was originally isolated (Gröner, 1990). Commonly, the host range is restricted to the genus of the competent host. SeMNPV acts highly specific to Noctuidae only. Other terrestrial invertebrates, therefore, are not endangered.

Resident populations of white-footed mice, *Peromyscus leucopus*, red-backed voles, *Clethrionomys gapperi*, opossums, *Didelphis marsupialis*, chipmunks, *Tamias striatus*, and racoons, *Procyon lotor*, were evaluated to detect any short-term effects from aerial applications of *Lymantria dispar* NPV (Lautenschlager *et al*., 1978). NPV in two formulations was sprayed on woodland plots in central Pennsylvania at the rate of 2.5 x 10^{12} polyhedral inclusion bodies (PIB)/ha. Comparisons of pre-spray and post-spray censuses of white-footed mice and red-backed voles in control and treated plots revealed no changes in populations or body weight that could be attributed to NPV treatments. Data from 47 caged and 250 free-living mammals showed no significant differences in organ and tissue weights, haematological values or necropsy and histopathological rankings between control and treated mammals when sample sizes were large and mean total weight between groups similar. It was concluded that aerial applications of NPV at 2.5 x 10^{12} PIB/ha caused no short term adverse effects to those mammals that either contacted NPV during its application or subsequently fed on NPV infected gypsy moths or other NPV-contaminated food sources.

Martignoni (1978) reported that no cytopathic effects were observed in fish and amphibian cell lines exposed to active non-occluded BVs. No changes occurred in growth rate, nor in the cells' response to subculture. No increase in virus titre in culture passages was demonstrable. Exposure of rainbow trout fry cells to BVs failed to interfere with their susceptibility to infectious pancreatic necrosis virus. In conclusion, no evidence was found that BV are capable of entering into or altering the cells used in these studies.

Larvae of the coot clam *Mulinia lateralis* were challenged for 48 h during the straight hinged stage of development with the LdMNPV (*Lymantria dispar* MNPV = multiple nucleocapsids per virion) at a density of 106 occlusion bodies/mL. Mortalities observed were significantly higher than those obtained with a control (OECD, 2002).

Postlarval, early, and late juvenile stages of two species of penaeid shrimp, *Penaeus aztecus* and *P. sertiferus*, were tested for susceptibility to *Autographa californica* NPV (Lightner *et al*., 1973). Shrimps were exposed to the virus by intramuscular inoculation of polyhedral protein-free virus and by feeding a diet containing virus polyhedra. Mortality attributable to viral infection did not occur during the 30-day test period, nor was there histological evidence of viral segment nerve ganglia, or hypodermis.

B.9.8 LITERATURE REVIEW

A literature search according to EFSA guidance (2011)[13] was conducted in January 2018 covering the last 10 years. The literature research was carried out using the search-engine ProQuest Dialog™. After rapid assessment based on title and abstract; no reference was submitted to a detailed assessment of full text documents. For more details please refer to Schöbinger (2018, provided in KMA 8/01).

Cited references

Report KMA 8/01 – Schöbinger (2018), Literature review on *S.exigua* multiple nucleopolyhedrovirus (SeMNPV): Effects on non-target organisms

Not published

Summary: Not applicable

RMS comments:

– RMS has considered all document as new information on the current Draft Assessment Report for the new microbial pest control agent SeMNPV.

[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

– 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**
KMA 8/01	Schöbinger, U.	2018	Literature review on *Spodoptera exigua* multiple nucleopolyhedrovirus (SeMNPV): Effects on non-target organisms Andermatt Biocontrol AG, CH, 159365-MA-08-01 not available GLP/GEP: no Published: no	no	yes		ABA
KMA 8.1/01	Ignoffo, C.M.	1975	Evaluation of in vivo specificity of insect viruses not available, not applicable In: Baculoviruses for insect pest control: Safety considerations ... Publisher: American Society for Microbiology, 52-57 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/02	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/03	Lautenschlager, R.A., Rothenbacher, H., Podgwaite, J.D.	1979	Response of birds to aerial application of the nucleopolyhedrosis virus of the Gypsy Moth, Lymantria dispar not available, not applicable Environ. Entomol. 8, pp. 760-764 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agricultur, 1584, 475-479 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMA 8.1/05	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/06	Lautenschlager, R.A., Podgwaite, J.D., Watson, D.E.	1980	Natural occurrence of the nucleopolyhedrosis virus of the gypsy moth, Lymantria dispar (Lep.: Lymantriidae) in wild birds and mammals not available, not applicable Entomophaga, 25 (3), 261-267 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/07	Gröner, A., Döller, G.	1982	Passage of infectious nuclear polyhedrosis virus by mice and chickens not available, not applicable Entomophagna 27 (2), 155-157 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/08	Martignoni, M.E.	1978	The douglas-fir tussock moth: A synthesis not available, not applicable Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W. GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/09	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly Pieris rapae larvae not available, not applicable RAE Serie A, 70 (4), 2368 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.1/10	Cunningham, J.C., Entwistle, P.F.	1981	Microbial control of pests and plant diseases 1970-1980 not available, not applicable Microbial control of pests and plant diseases, 391-393 GLP/GEP: no Published: yes	no	no	not protected	-

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**
KMA 8.1/11	Entwistle, P.F., Adams, P.H.W., Evans, H.F.	1978	Epizootiology of a nuclear polyhedrosis virus in european spruce sawfly (Gilpinia hercyniae): The rate of passage of infective virus through the gut of birds during cage tests not available, not applicable Journal of Invertebrate Pathology 31, 307-312, 1978 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/01	Gröner, A., Huber, J., Krieg, A.	1981	Use of Baculoviruses in crop protection: safety to aquatic organisms (German original) not available, not applicable Zeitschrift für Binnenfischerei, 31 (4), 25-27 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/02	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes Submitted in: KMA 8.1/02	no	no	not protected	-
KMA 8.2.1/03	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes Submitted in: KMA 8.1/05	no	no	not protected	-
KMA 8.2.1/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agricultur, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-

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KMA 8.2.1/05	Banowetz, G.M., Fryer, J.L., Iwai P.J., Martignoni, M.E.	1976	Effects of the douglas-fir tussock moth nucleopolyhedrosis virus (baculovirus) on three species of salmonid fish not available, not applicable USDA Forest Service Research Paper-PNW 214 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/06	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly Pieris rapae larvae not available, not applicable RAE Serie A, 70 (4), 2368 GLP/GEP: no Published: yes Submitted in: KMA 8.1/09	no	no	not protected	-
KMA 8.2.1/07	Hicks, B.D., Geraci, J.R., Cunningham, J.C., Arif, B.M.	1981	Effects of red-headed pine sawfly, Neodiprion lecontei, nuclear polyhedrosis virus on rainbow trout, Salmo gairdneri and Daphnia pulex not available, not applicable J. Environ. SCI. Health, B16 (4), pp. 493-509 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.2.1/08	Cunningham, J.C., Entwistle, P.F.	1981	Microbial control of pests and plant diseases 1970-1980 not available, not applicable Microbial control of pests and plant diseases, 391-393 GLP/GEP: no Published: yes Submitted in: KMA 8.1/10	no	no	not protected	-
KMA 8.2.2/01	Gröner, A., Huber, J., Krieg, A.	1981	Use of Baculoviruses in crop protection: safety to aquatic organisms (German original) not available, not applicable Zeitschrift für Binnenfischerei, 31 (4), 25-27 GLP/GEP: no Published: yes Submitted in: KMA 8.2.1/01	no	no	not protected	-
KMA 8.2.2/02	Ignoffo, C.M.	1975	Evaluation of in vivo specificity of insect viruses not available, not applicable In: Baculoviruses for insect pest control: Safety considerations ... Publisher: American Society for Microbiology, 52-57 GLP/GEP: no Published: yes Submitted in: KMA 8.1/01	no	no	not protected	-

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KMA 8.2.2/03	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes Submitted in: KMA 8.1/05	no	no	not protected	-
KMA 8.2.2/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agricultur, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-
KMA 8.2.2/05	Hicks, B.D., Geraci, J.R., Cunningham, J.C., Arif, B.M.	1981	Effects of red-headed pine sawfly, Neodiprion lecontei, nuclear polyhedrosis virus on rainbow trout, Salmo gairdneri and Daphnia pulex not available, not applicable J. Environ. SCI. Health, B16 (4), pp. 493-509 GLP/GEP: no Published: yes Submitted in: KMA 8.2.1/07	no	no	not protected	-
KMA 8.2.2/06	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes Submitted in: KMA 8.1/02	no	no	not protected	-
KMA 8.2.4/01	OECD	2002	Consensus document on information used in the assessment of environmental applications involving baculovirus not available, not applicable ENV/JM/MONO, 1, 1-90 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMA 8.3/01	Gröner, A.	1990	Safety to nontarget invertebrates of baculoviruses not available, not applicable Safety of microbial insecticides, Laird M., Lacey L.A., Davidson E.W., Chapter 10, 135-147 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.3/02	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application not available, not applicable Z Angew Entomol, 82, 129-134 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.3/03	Martignoni, M.E.	1978	The douglas-fir tussock moth: A synthesis not available, not applicable Forest Ser. Tech. Bulletin 1585. U.S. Dep. of Agriculture, ed. by: Brookes, M.H., Stark, R.W., Campell, R.W. GLP/GEP: no Published: yes Submitted in: KMA 8.1/08	no	no	not protected	-
KMA 8.3/04	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agricultur, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-
KMA 8.3/05	Gröner, A., Huber, J., Krieg, A., Pinsdorf, W.	1978	Testing of two baculovirus preparations on honey-bees (German original) not available, not applicable Nachrichtenblatt des Deutschen Pflanzenschutzdienstes, 30, 39-41 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/01	Gröner, A.	1990	Safety to nontarget invertebrates of baculoviruses not available, not applicable Safety of microbial insecticides, Laird M., Lacey L.A., Davidson E.W., Chapter 10, 135-147 GLP/GEP: no Published: yes Submitted in: KMA 8.3/01	no	no	not protected	-

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
KMA 8.4/02	Krieg, A.	1976	Granulosis and nuclear polyhedrosis viruses: safety aspects concerning their production and application not available, not applicable Z Angew Entomol, 82, 129-134 GLP/GEP: no Published: yes Submitted in: KMA 8.3/02	no	no	not protected	-
KMA 8.4/03	Huber, J.	1978	About the host spectrum of the codling moth granulosis virus not available, not applicable Safety aspects of baculoviruses as Biological Insecticides, 75-85 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/04	Burges, H.D., Croizier, G., Huber, J.	1980	A review of safety tests on baculoviruses not available, not applicable Entomophaga, 329-339 GLP/GEP: no Published: yes Submitted in: KMA 8.1/02	no	no	not protected	-
KMA 8.4/05	Gröner, A.	1986	Specificity and Safety of Baculoviruses not available, not applicable The Biology of Baculoviruses, Volume I, Biological Properties and Molecular Biologie, Chapter 9, 177-201 GLP/GEP: no Published: yes Submitted in: KMA 8.1/05	no	no	not protected	-
KMA 8.4/06	Simón, O., Williams, T., López-Ferber, M., Caballero, P.	2004	Virus entry or the primary infection cycle are not the principal determinants of host specificity of Spodoptera spp. nucleopolyhedroviruses not available, not applicable Journal of General Virology, 85, 2845 - 2855 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/07	Ijkel, W.F.J., van Strien, E., Heldens, J.G.M., Broer, R., Zuidema, D., Goldbach, R.W., Vlak, J.M.	1999	Sequence and organisation of the Spodoptora exigua multicapsid nucleopolyhedrovirus genome not available, not applicable Journal of General Virology, 80, 3289 - 3304 GLP/GEP: no Published: yes	no	no	not protected	-

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
KMA 8.4/08	Jaques, R.P., Laing, J.E., MacLellan, C.R.,Proverbs, M.D., Sanford, K.H., Trottier, R.	1981	Apple orchard tests on the efficacy of the granulosis virus of the codling moth, Laspeyresia pomonella [Lep.: Olethreutidae] not available, not applicable Entomophaga 26 (2), pp. 111-118 GLP/GEP: no Published: yes	no	no	not protected	-
KMA 8.4/09	Lewis, F.B., Podgwaite, J.D.	1981	The Gypsy Moth: Research Toward Integrated Pest Management - Safety Evaluations not available, not applicable Technical Bulletin, U.S. Department of Agricultur, 1584, 475-479 GLP/GEP: no Published: yes Submitted in: KMA 8.1/04	no	no	not protected	-
KMA 8.4/10	Xuebao, W.	1982	Safety tests of a GV insecticide against cabbage butterfly Pieris rapae larvae not available, not applicable RAE Serie A, 70 (4), 2368 GLP/GEP: no Published: yes Submitted in: KMA 8.1/09	no	no	not protected	-
KMA 8.4/11	Dickler, E.	1986	Einfluss von Behandlungen mit Apfelwickler-Granulosevirus (CpGV) und breitenwirksamen chemischen Insektiziden auf Parasiten des Apfelwicklers und Parasiten von Schalenwicklerarten not available, not applicable Biologische Bundesanstalt, Inst. f. Pflanzenschutz im Obstbau, Dossenheim, 90-97 GLP/GEP: no Published: yes	no	no	not protected	-
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