Renewal Assessment Report

Cydia pomonella GV

Volume 3 – B.8 Fate and behavior in the environment

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The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS.

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B.8 Fate and behavior in the environment

Introduction

The companies Andermatt Biocontrol GmbH, Arysta Life Science S.A.S. and Serbios srl have agreed on the formation of a Task Force in order to submit a dossier for the renewal of approval of the micro-organism *Cydia pomonella* Granulovirus (CpGV) as an active substance in compliance with Regulation (EU) No 844/2012 and Regulation (EC) No 1107/2009.
The initial dossiers for inclusion of *Cydia pomonella* Granulovirus into Annex I of Commission Directive 91/414 were submitted to the authorities of Germany as rapporteur member state in November 2005. Andermatt Biocontrol GmbH and Probis GmbH together as a Task Force, Arysta LifeSience S.A.S. and Sipcam S.p.A were the notifiers in the initial evaluation of approval of CpGV as active substance. Serbios srl has acquired all data and registrations concerning CpGV and formulated products from Sipcam S.p.A..
Inclusion of the first isolate of *Cydia pomonella* Granulovirus (Mexican isolate) into Annex I (now list of approved active substances) entered into force on 01 May 2009 (Commission Directive 2008/113/EC[1]). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) 540/2011 of 25 May 2011 and Commission Implementation Regulation (EU) No 880/2014 amending Commission Implementation Regulation (EU) No 540/2011. Further isolates were added to Annex I following evaluation according to the "Guidance Document SANCO/0253/2008 rev. 2 on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414" in May 2011, when the SCFCAH took note of the amended review report of 5 May 2011.
The dossier comprised the following isolates: the Mexican isolate CpGV-M, CpGV-15, CpGV-22, CpGV-V03, CpGV-V01 and CpGV-R5.
Cydia pomonella Granulovirus (CpGV) belongs to the group of baculoviruses. The inclusion of data from other baculoviruses is deemed justified due to this group relationship and close similarity of all baculoviruses in terms of their biology. Baculoviruses and CpGV in particular have been used for decades as plant protection products to control diverse pest insects. CpGV acts highly specific against larvae of the codling moth, *Cydia pomonella* and some isolates can infest the Oriental fruit moth *Grapholita molesta* or the plum fruit moth *Grapholita funebrana.* The mode of action of CpGV is a bi-phasic infection process of the larval stages of the above cited hosts. After oral ingestion of viral occlusion bodies, the virus replicates in the midgut cells (primary infection) and then infection is spread via non-occluded viruses to other body tissues (secondary infection) leading to the insect's death. CpGV is not supposed to have any harmful effects on organisms not belonging to the family of Tortricidae. With regard to environmental safety it is important to note that CpGV and the whole group of baculoviruses are naturally present in the environment. The experience that baculoviruses present no risk to mammals and men has been confirmed by numerous studies. The family of baculoviruses is regarded to be safe for humans and vertebrates confirmed by the inclusion of this virus family in the list of "Qualified Presumption of Safety" published by EFSA[2]. Therefore, their application in pest control means only a fluctuation of the virus titre in the biotope of the pest insect. CpGV and the whole family of baculoviruses are not related to any animal or plant pathogen and it does not produce any metabolite. For these reasons, no harmful effects from CpGV on humans, other vertebrates, other non-target organisms or the environment are expected. According to Commission Regulation (EU) 2016/439[3] *Cydia pomonella* Granulovirus is included into Annex IV of Regulation (EC) No 396/2005[4]. This means that no residue definition applies to the microorganism and no MRL is set for any of the existing or intended uses.

[1] OJL 330, 09.12.2007, p.6
[2] EFSA Journal 2015; 13(12):4331
[3] OJL 78, 23.03.2016, p. 31-33
[4] OJL 70, 23.02.2005, p.1-16

According to the GAP tables for the individual formulated products (see LoEP), *Cydia pomonella* granulovirus is used in pome fruit (apple, pear, quince, nashi, *Mespilus*), stone fruit (peach, apricot, nectarine, almond, plum) and walnut against the codling moth (*Cydia pomonella*) and the oriental Fruit moth (*Grapholita molesta*).

In the following, for ease of information, full study summaries/sections taken from the original DAR are included if they are considered relevant for renewal of CpGV. In order to facilitate discrimination between new data and data already evaluated during the first approval process, the headline "New information 2016" begins the section with data, which has previously not been submitted or evaluated. Data and their evaluations from the original DAR and addenda to the DAR are highlighted grey.

New information 2016
A literature search according to EFSA (2011)[5] was conducted covering the last 10 years. The literature research was conducted on the Scopus database (for further details, please refer to chapter B.8.4). Five separate literature searches were conducted using different search terms. A first search focused on the term *Cydia pomonella* Granulovirus and its synonyms including names of commercial products. A second search focused on baculoviruses in general but excluded search terms related to the use of these viruses for the production of recombinant proteins. In addition, some terms (Net present value, Predictive value and related terms) were excluded to limit background noise generated by the search term "NPV", abbreviation of "nucleopolyhedrovirus". Last, three searches were conducted on baculoviruses in general but focusing on specific search terms related to toxicology, ecotoxicology and fate and behaviour in the environment. From a total of 4069 references (after removal of duplicates), 15 references, potentially relevant for fate and behaviour of CpGV in the environment, were subjected to full text analysis. Of those, 10 reports were identified as non-relevant, five reports were identified as relevant for the information on environmental fate and behaviour of CpGV in the environment.

B.8.1 Persistence and multiplication

B.8.1.1 Soil

The following information is derived from the Draft Assessment Report Volume 3, Annex B-8, point B.8.1.1. In the original dossier this information was submitted in Annex II, Doc IIM, Section 5, Point IIM 7.1.1.

Annex Point:	IIM 7.1.1 / MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/01
Author:	Kienzle, J., Schulz, C, Zebitz, C.P.W., Huber, J.
Title:	Persistence of the biological effect of codling moth granulovirus in the orchard – preliminary field trials
Date:	2003
Doc ID:	Papierok, B. & J. Huber (eds.) Entomopathogens and insect parasitic nematodes, Bulletin OILB srop, 26 (1) pp 245-248 BVL-No.: BOD2006-238 (3683014)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	CpGV as MADEX 3, Andermatt Biocontrol
Test concentration:	100 mL/ha
Test system:	Orchard of 0.3-0.4 ha
Temperature:	Not given

[5] 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

Sampling time points:	Application: 23.5.2000 and 30.5.2001 sampling: 26.7.2000 and 31.7.2001 3.8.2000 and 16.8.2001 23.8.2000 and 29.8.2001 23.9.2000 and 27.9.2001
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/02, ALS: IIM 7.1/02
Author:	Young, S
Title:	Persistence of viruses in the environment
Date:	-
Doc ID:	http://www.agctr.lsu.edu/s265/young.htm BVL-No.: BOD2006-239 (3683094)
Guideline:	None
GLP:	Yes
Validity:	Not applicable, review article

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/03
Author:	Jaques, R.P.; Harcourt, D.G.
Title:	Viruses of *Trichoplusia ni* (Lepidoptera: Noctuidae) and *Pieris rapae* (Lepidoptera: Pieridae) in soil in fields of crucifers in southern Ontario
Date:	1971
Doc ID:	The Canadian Entomologist 103, 1285-1290 BVL-No.: BOD2003-234 (3683087)
Guideline:	None
GLP:	No
Validity:	Not applicable, publication
Material and methods:	
Test material:	*Trichoplusia ni* (Lepidoptera: Noctuidae) and *Pieris rapae* (Lepidoptera: Pieridae)
Test concentration:	Not given
Test system:	Field crops in 14 counties in Ontario
Temperature:	Not given
Sampling time points:	Period of 2 years
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/04
Author:	Thomas E.D., Reichelderfer C.F., Heimpel A.M.
Title:	The effect of soil pH on the persistence of cabbage looper nuclear polyhedrosis virus in soil
Date:	1973
Doc ID:	Journal of Invertebrate Pathology 21, 21-25 BVL-No.: BOD2003-235 (3683018)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	Cabbage Looper Nuclear Polyhedrosis Virus
Test concentration:	0 to 400 PIBs/g
Test system:	Loamy sand
Temperature:	30 °C
Sampling time points:	Not given
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/05
Author:	Evans, H.F.; Harrap, K.A.
Title:	Persistence of insect viruses
Date:	March 1982
Doc ID:	Virus Persistence, ed.: Mahy, B.W., Minson, A.C. Darby, G.K., Cambridge University Press, pp. 57-96 BVL-No.: BOD2003-236 (3683022)
Guideline:	None
GLP:	None
Validity:	Not applicable, review article

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/06
Author:	Ogaard, L., Williams, C.F., Payne, C.C., Zethner, O.
Title:	Activity persistence of granulosis viruses (Baculoviridae) in soils in United Kingdom and Denmark
Date:	1988
Doc ID:	Entomophaga 33, pp. 73-80 BVL-no.: BOD2005-293 (3683088)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	Granulosis viruses (Baculoviridae)
Test concentration:	5 mL containing 1011 capsules PbGV and 1010 capsules AsGV
Test system:	Well drained and stoneless soil types
Temperature:	Not given
Sampling time points:	1 h , 2 weeks, 4 weeks, 6 weeks, 13 weeks, 26 weeks, 52 weeks
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/07
Author:	Jaques, R.P.
Title:	Occurrence and accumulation of viruses of Trichoplusia ni in treated field plots
Date:	1974
Doc ID:	Journal of Invertebrate Pathology 23, 140-152 BVL-No.: BOD2003-237 (3683089)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	Trichoplusia ni
Test concentration:	Not given
Test system:	Field plots with a sandy loam soil (pH 5.0 - 6.1)
Temperature:	Not given
Sampling time points:	Various sampling points over the year
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/08
Author:	Jaques, R.P.
Title:	Occurrence and accumulation of the granulovirus of Pieris rapae in treated field plots
Date:	1974
Doc ID:	Journal of Invertebrate Pathology 23, 351-359 BVL-No.: BOD2003-238 (3683090)

Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	Granulovirus of Pieris rapae
Test concentration:	Not given
Test system:	Field plots with a sandy loam soil (pH 5.0 - 6.1)
Temperature:	Not given
Sampling time points:	Various sampling points over the year
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/09
Author:	Tanada, Y; Omi, E.M.
Title:	Persistence of insect viruses in field populations of alfalfa insects
Date:	1974
Doc ID:	Journal of Invertebrate Pathology 23, 360-365 BVL-No.: BOD2003-239 (3682711)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	Granulovirus (GV), Cytoplasmic-polyhedrovirus (CPV), Nuclear-polyhedrovirus (NPV)
Test concentration:	Not given
Test system:	Field populations of alfalfa insects
Temperature:	Not given
Sampling time points:	Various sampling points over the year
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/10
Author:	Jaques, R.P.
Title:	Stability of entomopathogenic viruses
Date:	1977
Doc ID:	Miscellaneous Publications of the Entomological Society of America, 10 (3), pp. 99-116 BVL-No.: BOD2003-240 (3682725)
Guideline:	None
GLP:	None
Validity:	Not applicable, review article

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/11
Author:	David, W.A.L.; Gardiner, B.O.C.
Title:	The persistence of a granulovirus of *Pieris brassicae* in soil and in sand
Date:	1967
Doc ID:	Journal of Invertebrate Pathology 9, 342-347 BVL-No.: BOD2003-241 (3683041)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	Granulovirus from Pieris brassicae
Test concentration:	Not given
Test system:	Garden soil and sand (approximately 800 g)
Temperature:	20 °C

Sampling time points:	2, 6, 12, 18, 24 month
Method of analysis:	Mortality of test larvae

Annex Point:	IIM 7.1.1/MA 7.1.1
Submitted by:	SIP, PKA: IIM 7.1.1/12 listed under IIM 7/01
Author:	OECD
Title:	Consensus document on information used in the assessment of environmental applications involving baculovirus
Date:	2002
Doc ID:	ENV-JM-MONO (2002)1 BVL-No.: BOD2006-255 (3683011)
Guideline:	None
GLP:	None
Validity:	Not applicable, guidance document

Results

The inclusion of other baculoviruses results on persistence and mobility in soil is justifiable due to their close family relationship resulting in many synergisms. As a matter of fact the results of all investigations stated below confirm that the family of Baculoviridae does not reveal deleterious effects to soil. Their application in pest control means only a temporal fluctuation of the virus titre in soil.

Experimental studies have demonstrated the high sensitivity of CpGV to UV light, with 98% inactivation in 2 days (Kienzle 2003, BVL no 3683014). According to Young (2003, BVL no 3683094) the total group of baculoviruses even has a half-life of only a few hours under field conditions and little activity remains after a few days because of inactivation by the UV spectrum of sunlight.

The survey by Jaques & Harcourt (1971, BVL no 3683087) showed that viruses of *Trichoplusia ni* (Lepidoptera: Noctuidae) and *Pieris rapae* (Lepidoptera: Pieridae) occur naturally in non-treated soil of Ontario fields. The occurrence of viruses in soil was influenced by the density of the population of the host insect. The viruses appeared to accumulate in soil during the growing season, presumably due to degradation of host larvae killed by virus. Detectable residues of both viruses were found more frequently in soil sampled late in the season than in soil sampled early in the year.

Thomas et al. (1973, BVL no 3683018) showed a correlation between pH and virus activity: the lower the pH, the more rapidly the virus was inactivated. Soils with pH near neutral have less free carbonate present and more viruses can survive. Hukuhara & Wada (1972) cited by Evans & Harrap (1982, BVL no 3683022) studying CPV of Bombyx mori showed that more polyhedra adsorbed to soil at acid pH values (pH 4.9 - 5.6) than at higher values. These apparently contradictory findings highlight the difficulty of comparing physical presence of virus inclusion bodies in soil and their infectivity in, probably, greatly different soils.

Øgaard et al. (1988, BVL no 3683088) showed that about 99 % of the original virus infectivity was lost during one year. Together with other investigations this result indicates that leaching, passive lateral movements and degradation accounts for the main part of the loss.

Jaques (1974 a/b, BVL no 3683089 / 3683090) showed that *T. ni* NPV, *T. ni* GV remained in the soil following application to soil and accumulated in soil following foliar application of the viruses to cabbage plots. However, within a year after application concentrations in the non-treated plots had increased to equal those in virus-treated plots by accumulation of viruses produced in natural epizootics.

Tanada & Omi (1974, BVL no 3682711) showed that the granulovirus (GV), the cytoplasmic-polyhedrovirus(CPV), and nuclear-polyhedrovirus(NPV) persisted in the soil even during the winter months when no foliage remained on the plants. The authors concluded that the viruses had accumulated from epizootics of the diseases.

Jaques (1977, BVL no 3682725) concluded that virus persisting in soil following treatments or natural epizootics provides a reservoir for initiation of epizootics in succeeding generations of host insects and is a mechanism by which a long-term effect of virus introductions may be attained.

David & Gardiner (1967, BVL no 3683041) found that a granulovirus of *Pieris brassicae* larvae was very stable in garden soil and sand and showed little deterioration after 2 years. The results suggest that the virus is unlikely to be destroyed by organisms or other conditions operating in typical soil and that in the absence of other destructive factors (heat or strong light) it would easily persist from one year to

the next.
In soil, which can be a potential reservoir of baculoviruses, the inactivation rate not only depends on soil type and pH but also on microbial activity (Thompson & Scott 1979, Ignoffo & Garcia 1966, Jaques & Huston 1969, Undorf 1991 all cited by OECD 2002, BVL no 3683011).
David & Gardiner (1967, BVL no 3683041) found that when water equivalent to up to 48 inches (122 cm) of rain was passed through the samples much of *Pieris brassicae* GV remained in the top layer though some was carried away in the percolating water. It seems therefore that much of the virus will persist in the upper layers, where it will be fairly easily accessible, and capable of reinfecting larvae.
Viral inclusion bodies appear to be adsorbed quite firmly onto soil particles (Hukahara 1972, Hukahara & Namura 1971, Hukahara & Wada 1972, all cited by Jaques 1977, BVL no 3682725) and are not leached through the soil by rain. In a field study, Jaques (1969) cited by Jaques (1977) treated surface soil with *T. ni* NPV and found that most viral activity remained in the top 0 - 2.5 cm of the undisturbed soil in the 223 weeks of observation.
Harcourt & Cass (1968) cited by Evans & Harrap (1982, BVL no 3683022) showed that soil disturbed by cultivation retained less virus as a result of mixing of surface with deeper soil, although discing of soil had little effect on retention of *T. ni* NPV and P. rapae GV in the upper layer of soil (Jaques, 1970 cited by Evans & Harrap 1982). *Mamestra brassicae* NPV accumulates in the top 10 cm of soil directly below cabbage plants carrying infected larvae and up to 90 % of the virus produced can be accounted for by this route (H.F. Evans, unpublished information cited by Evans & Harrap 1982).
According to Lopez-Pila (1988, BVL no 3683092) granuloviruses showed stronger adsorption in the presence of waste water than during leaching with deionised water. Regardless of the exact mechanism by which GV adsorb to sand particles, it may safely be assumed that the outer shell, i.e. granulin, plays an important part in the adsorption process.

Further information from the literature
It is assumed that the most important pool of CpGV is soil. In soil the virus is protected against inactivating UV-illumination (Thompson et al., 1981), but there is no direct transport from soil to the larvae in the trees. The stages of the larvae living in soil have no uptake of food in this compartment. Therefore, a transport to susceptible larvae living in the trees by the larvae is unlikely. Transport might occur via birds and beetles.
By the application of molecular methods Eastwell el al. (1999) determined a natural occurrence of about 23 % in five different populations of *Cydia pomonella*.

Conclusion DAR (2007):
Cydia pomonella GV protected from UV light and high surface temperature in deeper soil layers can be persistent and accumulative after both natural epizootics of disease and anthropogenic application. The multiplication of *Cydia pomonella* GV always depends on the presence and the population density of their specific hosts, since viruses have no own metabolic activity and are not able to proliferate themselves.
As very small amounts of viruses suffice to infect many larvae, multiplication and accumulation can restart every time when permissive hosts appear.
The possible loss of *Cydia pomonella* GV activity in soil between two epizootics described in some publications is rather attributed to the disappearance of intact OBs by leaching, lateral movements, denaturation than by the inactivation of OBs.
Microbial activity as the only reason for the loss of virus concentration described in the supplied literature is questionable due to the lack of further information about this way of degradation. Mineralisation is not proven.
Hints by literature about an influence of tillage operations and agricultural procedures like crop rotation on persistence or degradation are not consistent.
So in each case *Cydia pomonella* GV is to be considered as persistent in soil.
Further literature cited:
Eastwell, K. C., Cossentine, J. E. & Bernardy, M. G. (1999). Characterisation of *Cydia pomonella* granulovirus from codling moths in a laboratory colony and in orchards of British Colombia. Annals of Applied Biology 134, 285-291.
Thompson, C. G., Scott, D.W. & Wickman, B. E. (1981). Long-term persistence of nuclear polyhedrosis

virus of the Douglas–fir tussock moth, *Orgyia pseudotsugata* (Lepidoptera: Lymantriidae) in forest soil. Environmental Entomology 10, 254-255.

New data 2016
No new data has been submitted under this point.
Previously submitted information is considered to be acceptable to cover current requirements.
From peer-reviewed open literature two additional references were identified to be relevant for fate and behaviour of *Cydia pomonella* Granulovirus in soil. Please refer to the literature search presented in chapter B.8.4.

Christian et al. (2006, BVL no 3306485) demonstrated in a study conducted with one occluded and two non-occluded viruses, *Helicoverpa armigera single nucleopolyhedrovirus* (HaSNPV) (*Baculoviridae*), *Cricket paralysis virus* (CrPV) (*Disistroviridae*), and *Invertebrate iridescent virus 6* (IIv-6) (*Iridoviridae*), that viruses may be adsorbed to soil-forming minerals. For the occluded viruses, represented by HaSNPV, it was shown that relative activity of the virus was reduced in the presence of the minerals bentonite and kaolinite, indicating an inhibition of HaSPNV activity. By adsorption studies the remaining virus activity ranged from 0.12 to 1.83, indicating that more than 98% of the virus was adsorbed by all tested minerals: aluminium hydroxide, attapulgite, bentonites, ferric oxides, illite, kaolinites, talc. Therefore, activity of occluded viruses in soil may be strongly influenced by soil type or minerals, respectively.

Transportation of CpGV via birds or insects was stated already previously. In the recent literature search one article was identified, reporting on infectivity of the *Spodoptera litura* multiple nucleopolyhedrovirus after the passage through the gut of the predatory stink bug (Gupta et al, 2014, BVL no 3306486). Therefore, possible transportation of CpGV via insects is confirmed.

Cited references:

Report:	MA 7.1.1/01 - Christian P. D., Richards A. R. and Williams T. (2006)
Title:	Differential adsorption of occluded and non-occluded insect-pathogenic viruses to soil-forming minerals Applied and Environmental Microbiology 72 (7): 4648-4652 BVL no 3306485
Abstract:	Soil represents the principal environmental reservoir of many insect-pathogenic viruses. We compared the adsorption and infectivity of one occluded and two nonoccluded viruses, *Helicoverpa armigera single nucleopolyhedrovirus* (HaSNPV) (*Baculoviridae*), *Cricket paralysis virus* (CrPV) (*Dicistroviridae*), and *Invertebrate iridescent virus* 6 (IIV-6) (*Iridoviridae*), respectively, in mixtures with a selection of soil-forming minerals. The relative infective titers of HaSNPV and CrPV were unchanged or slightly reduced in the presence of different minerals compared to their titers in the absence of the mineral. In contrast, the infective titer of IIV-6 varied according to the mineral being tested. In adsorption studies, over 98% of HaSNPV occlusion bodies were adsorbed by all the minerals, and a particularly high affinity was observed with ferric oxide, attapulgite, and kaolinite. In contrast, the adsorption of CrPV and IIV-6 differed markedly with mineral type, with low affinity to bentonites and high affinity to ferric oxide and kaolinite. We conclude that interactions between soil-forming minerals and insect viruses appear to be most important in nucleopolyhedroviruses, followed by invertebrate iridescent viruses, and least important in CrPV, which may reflect the ecology of these pathogens. Moreover, soils with a high content of iron oxides or kaolinite would likely represent highly effective reservoirs for insect-pathogenic viruses.
Submitted for purpose of renewal. **Evaluation by RMS:** The study demonstrated strong adsorption of HaSNPV occlusion bodies to	

soil-forming minerals. Soils with a high content of iron oxides or kaolinite (which act as UV protectant) represent highly effective reservoirs for insect-pathogenic viruses. Relevant and reliable.

Report:	MA 7.1.1/02 - Gupta, R.K., Gani, M., Jasrotia, P., Srivastava, K. and Kaul, V. (2014)
Title:	A comparison of infectivity between polyhedra of the *Spodoptera litura* multiple nucleopolyhedrovirus before and after passage through the gut of the stink bug, *Eocanthecona furcellata* Journal of Insect Science,14, Article 96 BVL no 3306486
Abstract:	Infectivity of polyhedra of *Spodoptera litura* multiple nucleopolyhedrovirus before and after passage through the gut of the predatory stink bug, *Eocanthecona furcellata* Wolff (Hemiptera: Pentatomidae) was compared through field bioassay studies. Three sets of *E. furcellata* were used for bioassays and these were allowed to feed on a single meal of five third instar Oriental leaf worm, *Spodoptera litura* (Fabricius) (Lepidoptera: Noctuidae), that were infected with polyhedra before passage, after passage, and healthy (control) larvae 1 day prior to the trial. The predators were subsequently released on cabbage plants that were infested with 100 healthy *S. litura* larvae. The median lethal dose (LD_{50}) and survival time (ST50) values before and after passage through the gut were not significantly different. Additional mortality due to virus infection increased 13- 17% before and after treatments but within these treatments the mortality did not vary significantly. It was concluded that *E. furcellata* disseminated the virus through their feces into the ecosystem and infectivity of the SpltMNPV was not altered after passage through the gut of the predator.
Submitted for purpose of renewal. **Evaluation by RMS:** The study findings confirmed infectivity of *Spodoptera litura* MNPV after the passage through the gut of the predatory stink bug, *Eocanthecona furcellata,* and dissemination of baculoviruses via predatory stink bugs. Relevant and reliable.	

B.8.1.2 Water

The following information is derived from the Draft Assessment Report Volume 3, Annex B-8, point B.8.1.2. In the original dossier this information was submitted in Annex II, Doc IIM, Section 5, Point IIM 7.1.2.

Annex Point:	IIM 7.1.2/MA 7.1.2
Submitted by:	SIP, PKA: IIM 7.1.2/01 und ALS: 7.1/02
Author:	Jaques, R.P.
Title:	Stability of entomopathogenic viruses
Date:	1977
Doc ID:	Miscellaneous Publications of the Entomological Society of America, 10 (3), pp. 99-116 BVL-No.: WAS2003-156 (3683032)
Guideline:	None
GLP:	None
Validity:	Not applicable, review article

It is known that most viruses in intact inclusion bodies are reasonably stable in aqueous suspension (Jaques, 1977, BVL no 3683032). It is apparent that the pH and salt concentration of water influences stability. There are no risks of pollution of surface or groundwater expected, due to the high level of

retention of the viral particles by the ground. In any case, once introduced into a water body, the viral particles tend to deposit and are absorbed by sediments. Furthermore there is evidence of deactivation/destruction by UV light in surface water.
Conclusion:
Granuloviruses given into an aquatic system precipitate quickly at similar rates as soil particles. According to the given information an activity in sediment remaining for a length of time similarly as in soil cannot be excluded.
Mineralisation could be hampered by the resistance of inclusion bodies to environmental conditions.

New data 2016
No new data has been submitted under this point.
Previously submitted information is considered to be acceptable to cover current requirements.
From peer-reviewed open literature one additional reference was identified to be relevant for fate and behaviour of *Cydia pomonella* Granulovirus in water. Please refer to the literature search presented in chapter B.8.4.

Holmes et al. (2008, BVL no 3306487) conducted a study to assess the persistence of a genetically modified and a naturally occurring baculovirus in an aquatic microcosm. Microcosms at a size of 165 cm diameter at the to, 135 cm diameter at the bottom and 86 cm deep, were installed in a mixed forest. The microcosms were buried to a depth of > 60 cm in the soil and covered either with insect netting, or with wooden lids in winter. Baculoviruses were applied to microcosms at a rate corresponding to a worst-case scenario, assuming accumulated virus rates from 7.8×10^2 budworm (4.0×10^{10} OBs) in one pond.
This accumulated virus rate per pond is based on the following assumptions:

- a heavy budworm infestation of 3.64×10^6 budworm/ha or 3.64×10^2 budworm/m^2
- production of 5.1×10^7 CfMNPV OBs per larva, corresponding to about 1.86×10^{10} OBs/m^2
- pond surface area of 2.14 m^2
- 7.8×10^2 budworm/pond = $2.14 \times 3.64 \times 10^2$ budworm/pond
- 4.0×10^{10} OBs/pond = 5.1×10^7 CfMNPV OBs $\times 7.8 \times 10^2$ budworm/pond

The basic assumptions given above were seen by the study authors as a simplification of what may occur in nature (e.g. 100% of the virus moved down from the trees to the pond, no lateral movement of virus from adjacent areas). During the experimental phase four (40 mL) samples were collected form each microcosm on each collection day: 1 day before treatment, 3 hours, 1 week, 2 weeks, 4 weeks, 3 months and one year after treatment. Samples were collected at 19, 15, 9 and 4 cm above the sediment layer. Although number of baculoviruses was decreased rapidly by UV radiation, both viruses remain viable for at least one year after inoculation. Therefore, these findings confirm previously submitted information that baculoviruses can persist in the flocculent layer of natural ponds.

Cited references:

Report:	MA 7.1.2/01 - Holmes S. B., Fick W. E., Kreutzweiser D. P., Ebling P. M., England L. S. and Trevors J. T. (2008)
Title:	Persistence of naturally occurring and genetically modified *Choristoneura fumiferana nucleopolyhedroviruses* in outdoor aquatic microcosms Pest Management Science 64 (10): 1015-1023 BVL no 3306487
Abstract:	BACKGROUND: To assess the persistence of genetically modified and naturally occurring baculoviruses in an aquatic environment, replicate (three) outdoor, aquatic microcosms were spiked with spruce budworm viruses [Ireland strain of *Choristoneura fumiferana* multiple nucleopolyhedrovirus (CfMNPV) and the recombinant CfMNPVegt(-)/lacZ(+)] at a rate of 1.86×10^{10} occlusion bodies (OBs) m^{-2} of surface area. The presence of virus in water samples collected at

	various times after inoculation was determined by PCR amplification of baculoviral DNA extracted from OBs. RESULTS: Although UV radiation rapidly degrades baculoviruses under natural conditions, both viruses persisted above the level of detection (>100 OBs 450 microL(-1) of natural pond water) for at least 1 year post-inoculation, with little difference between the viruses in their patterns of persistence. CONCLUSION: The present microcosm study suggests that occlusion bodies of baculoviruses can persist in the flocculent layer of natural ponds. On disturbance, OBs could re-enter the main water column and thus be available for transport to new locations. Implications for environmental risk assessment are discussed.
Submitted for purpose of renewal. **Evaluation by RMS:** The study showed that baculoviruses can, under certain conditions, persist for a relatively long period of time in an aquatic reservoir, specifically the flocculent layer of still water ponds. According to the study authors, this floc layer at the water/sediment interface could be an important reservoir for baculovirus occlusion bodies, since these viruses are known to strongly adhere to both biotic and abiotic substrates. Furthermore, aquatic sediments could provide protection to NPVs from harmful UV-B radiation in a manner similar to litter or soil. Relevant and reliable.	

B.8.1.3 Air

The following information is derived from the Draft Assessment Report Volume 3, Annex B-8, point B.8.1.3. In the original dossier this information was submitted in Annex II, Doc IIM, Section 5, Point IIM 7.1.3.

Annex Point:	IIM 7.1.3/MA 7.1.3
Submitted by:	SIP, PKA: IIM 7.1.3/01
Author:	Krieg, A.; Gröner, A.; Huber, J. und Zimmermann, G.
Title:	Inactivation of certain insect pathogens by ultraviolet radiation [in German]
Date:	1981
Doc ID:	Zeitschrift für Pflanzenkrankheiten und Pflanzenschutz 88 (1), 1981, 38-48 BVL No.: LUF2005-48 (3683044)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication
Material and methods:	
Test material:	Two baculoviruses (Granuloviruses, Nuclear polyhedroviruses) and two entomopathogenic microorganisms (*Bacillus thuringiensis*, *Beauveria bassiana*)
Test concentration:	0.1 mL of 108 granules / mL suspension dried out on Petri dishes
Test system:	Sterilising lamp UV-B and UV-A (285 – 3800 nm) dry samples
Temperature:	33 °C
Sampling time points:	-
Method of analysis:	0.5 mL of re-suspended samples into 100 mL codling moth culture medium 50 codling moth egg-larva tested pupation rate as measure of mortality

Results:
This study investigates for four micro-organisms the UV-sensitivity by radiation tests. Only the results for granuloviruses and only for near UV (285 – 380 nm) are of relevance. The authors use a solarium lamp (Ultra-Vitalux, Osram) with 100 mW cm-2 in 50 cm distance. The illumination rate is quoted as 0.5 mW cm-2 at 285 – 315 nm and 2.5 mW cm-2 at 315 – 380 nm for the samples. The room temperature is determined with 20 °C, the temperature of the lamp with 180 °C, and the temperature of the sample with 33 °C.

CpGV were prepared as 0.1 mL of a suspension of 108 granules mL-1 and were placed in a dry petri dish. After complete drying they were illuminated for unknown hours. After resuspension they were mixed with culture medium and feed to the larvae. Pupation rate was used for inactivation calculation. The inactivation time was estimated for 99.0 % with 6.3 min and for 99.9 % with 20.5 min.

Annex Point:	IIM 7.1.3/MA 7.1.3
Submitted by:	ALS: IIM 7.1/03
Author:	Steineke, S. B.
Title:	Populationsdynamik des *Cydia pomonnella* granulovirus
Date:	2004
Doc ID:	Dissertation Gutenberg Uni. Mainz BVL No.:BOD2006-369 (2390213)
Guideline:	None
GLP:	None
Validity:	Not applicable, publication

Results
Cydia pomonella infected, CpGV treated apples were exposed to sunlight for various times.
The activity of CpGV after a single application (usual or topical) was measured in two treated groups and one standard group of 50 apples.
The mortality rate being around 80 % just after application decreased rapidly to reach almost none mortality after 300 hours of sunlight (more than 12 days). The decrease of activity after a normal application could be described by a first order equation:
The calculated half-life time (DT50) by photolysis rests with 52.2 hours.

Conclusion DAR (2007):
Both studies do not follow any guidelines and admit in the discussion that it is not possible to compare the results of these studies with results of other investigations. Consequently, it is difficult to evaluate the results of these studies.
It is not possible to transfer the experimental conditions of the study performed by Krieg, A. et al. (1981, BVL no 3683044) to a typical European radiation situation caused by natural sunlight in the field. Additionally, the experimental conditions of 33 °C are not environmental relevant conditions. Consequently, the study is not considered applicable for accessing the effect of ultraviolet radiation on granuloviruses under field-relevant conditions.
Steineke (2004, BVL no 2390213) showed that the virus is inactivated by sun light. A half-life of 52 hours was determined in that study.

New data 2016
No new data has been submitted under this point.
Previously submitted information is considered to be acceptable to cover current requirements.
From peer-reviewed open literature two additional references were identified to be relevant for fate and behaviour of *Cydia pomonella* Granulovirus in air. Please refer to the literature search presented in chapter B.8.4.

Arthurs et al. (2006, BVL no 3306488) tested different lignin-based formulations and adjuvants to evaluate the persistence of CpGV under UV radiation. Studies were conducted with the commercial preparation of CpGV "Cyd-X®" administered with or without different formulations and applied to apples. Studies under laboratory conditions were surface sterilized and the cut surface immediately heat-treated and sealed with wax and foil. Fruits were than sprayed with the experimental treatments and dried fruits immediately infested with five neonates (< 2 hours old). Apples were irradiated for 4 hours at 765 W/m², corresponding to 9.36×10^6 joules/m². Samples were incubated at 25 °C for 10 days and evaluated for fruit damage, larval survivorship and the proportion of "deep" larval entries (≥6 mm). It became clear, that Cyd-X alone showed significant less larval mortality and significant less deep larval entries, in comparison to experimental formulations when applied at high doses of 3×10^{10} OB/L.
Results from Arthurs et al. (2006) were later confirmed by a study conducted with a field isolate of

CpGV (ZY), originated form Gansu, China (Wu et al., 2015, BVL no 3306489). This strain was used to evaluate protective effects of zinc oxide and titanium dioxide against UV radiation. However, studies were conducted in Petri dishes only, for both, laboratory and field trials. Nevertheless, the authors found the highest survival rate in the samples without any protective formulants.
Both studies confirmed the high influence of UV radiation on the reduction of survival rates or a higher inactivation of CpGV in air.

Cited references:

Report:	MA 7.1.3/01 - Arthurs S. P., Lacey L. A. and Behle R. W. (2006)
Title:	Evaluation of spray-dried lignin-based formulations and adjuvants as solar protectants for the granulovirus of the codling moth, *Cydia pomonella* (L). Journal of Invertebrate Pathology 93 (2): 88-95 BVL no 3306488
Abstract:	Commercial formulations of the codling moth, *Cydia pomonella* L., granulovirus (CpGV) are limited by their short residual activity under orchard conditions in the Pacific Northwest. We evaluated spray-dried lignin-encapsulated formulations of CpGV for improved solar stability based on laboratory bioassays with a solar simulator and in field tests in an infested apple orchard. In laboratory tests, aqueous lignin formulations containing a high dosage of 3×10^{10} occlusion bodies (OB)/L, with and without the additives titanium dioxide (TiO2) and sugar, provided significant solar protection of virus, i.e., mortality of codling moth exposed to lignin formulations that had been irradiated with 9.36×10^{6} joules/m2 was 92–94%, compared with 66–67% from a glycerin-stabilized product (Cyd-X®) or suspension of pure unformulated virus at the same rates. By comparison, a lower dosage of the lignin formulation (3×10^{8} OB/L) did not provide significant solar protection. Equivalent dosage-dependent patterns in solar protection were observed in further tests with the lignin formulation, when an intermediate (3×10^{9} OB/L) as well as the low dosage provided no solar protection. Equivalent rates of a blank lignin formulation (containing no virus) did not affect larval mortality, suggesting a protective effect of the lignin on the virus at the high rate. The use of several spray adjuvants, 'NuFilm-17®' and 'Organic Biolink®' (sticker-spreaders at 0.06% v/v), 'Raynox®' (sunburn protectant at 5% v/v), and 'Trilogy®'(neem oil at 1% v/v) did not provide solar protection of a commercial CpGV preparation in laboratory tests. In season long orchard tests (Golden Delicious), the lignin formulation of CpGV applied at 6.57×10^{12} OB/ha did not significantly improve control of codling moth or protection of fruit compared with Cyd-X at equivalent rates. Our studies show that lignin-based CpGV formulations provided solar protection at relatively high virus dosages. The testing of lignin formulations containing reduced virus concentrations may allow virus solar protection to be achieved at more economical rates.
Submitted for purpose of renewal. **Evaluation by RMS:** The study showed that radiation protectants such as lignin-encapsulation provides significant protection from destructive UV-radiation and thus extend persistence of CpGV formulations. The information can be regarded as supplementary.	

Report:	MA 7.1.3/02 - Wu Z. W., Fan J. B., Yu H., Wang D. and Zhang Y. L. (2015):
Title:	Ultraviolet protection of the *Cydia pomonella* Granulovirus using zinc oxide and titanium dioxide. Biocontrol Science and Technology 25 (1): 97-107 BVL no 3306489
Abstract:	*Cydia pomonella* Granulovirus (CpGV) is a specific pathogen of codling moth, the most serious pest of apple worldwide and has recently been isolated in China. However, its use for codling moth control is limited by ultraviolet (UV) solar radiation, which is a major factor affecting the field persistence of this virus. The

	virion is occluded in the granulin matrix of occlusion bodies. Many substances have been tested as sunscreen agents, but little has been published on the use of reflectors with the occluded bodies (OBs) of CpGV. This work investigates the susceptibility of a native GV, CpGV-ZY, to UVB radiation over different time periods and evaluates the protective effect of two sunscreen agents, zinc oxide (ZnO) and titanium dioxide (TiO_2). Laboratory tests showed 104 OB/ml of CpGV-ZY exposed to UVB light (3.5 W/m2) for 3.75 h caused 50% inactivity. At 15 mg/ml ZnO and 10 mg/ml TiO_2, the mortality was highest after 4-h exposure to UVB light. Semi-field tests indicated both compounds are effective as UV protectants at low concentrations. These are the first results confirming that ZnO and TiO_2 hold promise as UV protectants for this CpGV-ZY isolate. Moreover, it is apparently safe and effective to use within the range of concentrations needed for codling moth control.
Submitted for purpose of renewal. **Evaluation by RMS:** The study showed that ZnO and TiO_2 additives can significantly protect CpGV from UV irradiation in terms of increasing infection rate, shortening lethal time when compared with non-irradiated controls. The information can be regarded as supplementary.	

B.8.2 Mobility

The following information is derived from the Draft Assessment Report Volume 3, Annex B-8, point B.8.2. In the original dossier this information was submitted in Annex II, Doc IIM, Section 5, Point IIM 7.1.1 and DoC IIIM, Section 5, Point IIIM 9.

Annex Point:	IIM 7.1.1/MA 7.2
Submitted by:	PKA: IIM 7.1.1/13
Author:	Krieg, A.
Title:	Testing of a nuclear polyhedrosis preparation MbNPV (unformulated) for leaching behaviour
Date:	14 May 1983
Doc ID:	A55489, CpGV 22; BVL No.: BOD2006-240 (3683091)
Guideline:	BBA Guidelines No. 37
GLP:	None
Validity:	Not applicable, but can be used as additional information
Material and methods:	
Test material:	Nuclear polyhedrovirus preparation MbNPV (unformulated)
Test concentration:	virus suspension was applied: 2.8 x 1010 cleared polyhedra/3 mL
Test system:	Soil columns 30 cm high were placed in laboratory lysimeters 50 mm in diameter; Sp 239: loamy sand with high humus content. pH 5.6; organic carbon = 2.5°f°; particle sizes: 34.5 % > 0.2 mm; 51.6 % :- 0.002 to 0.2 mm; 4.9 % < 0.002 mm) Sp 118: sand with low humus content: pH 7.0; organic carbon = 0.7 %; particle sizes: 61.5 % > 0.2 mm; 33.5 % = 0.042 to 0.2 mm; 5.0 % < 0.002 mm)
Temperature:	Unknown
Sampling time points:	A) 2 lysimeter soil columns were "irrigated" with 786 mL water over a period of 4 days. B) 2 lysimeter soil columns were "irrigated" with 393 mL water over a period of 2 days. The upper 15 cm of each column were divided into 1.5 cm layers, and the lower 15 cm into 3 cm layers Testing of a total of 9 samples per column was carried out by mixing 6.25 g of the pooled soil of the layer in question
Method of analysis:	For each titration point 2 x 50 larvae of Mamestra brarssicae (2nd stage) were used. Evaluation was based on terminal mortality.

Findings
The leaching trial was conducted with loamy sand (pH 5.6, 2.5 % o.c., 34.5 % sand, 4.9 % clay) and

sand (pH 7.0, 0.7 % o.c., 61.5 % sand, 5 % clay). The soil columns were 30 cm high and 5 cm in diameter. The virus suspension contained was applied with 2.8 x 10^{10} cleared polyhedra of *Mamestra brassicae* nuclear polyhedrosis virus (MbNPV) in 3 mL water per column. Two irrigation variants applied (A) 786 mL water over a period of 4 days and (B) 393 mL water over a period of 2 days.

The accumulated virus-related mortality was measured for 9 samples per column on larvae of *Mamestra brassicae*.

Virus activity was still detectable in the bioassay down to a depth of 15 cm for the loamy sand and down to 30 cm in the sand. However, an exponential decrease of activity was documented.
Conclusion:
The study investigates the content of active viruses in different layers of the soil column and does not investigate the leachate itself. No information is provided about the amount of eluate and about the amount of viruses in the eluate. No information is given about the temperature during the experiment.

This study was not conducted with granuloviruses. However, the results may be generalised and show that viruses have the ability to leach through a soil column, but that the risk of reaching deeper soil layers is small.

Annex Point:	IIM 7.1.1/MA 7.2
Submitted by:	SIP: IIM 7.1.1/13, PKA: IIM 7.1.1/14
Author:	Lopez-Pila, J.M.
Title:	Effect of Baculoviren on groundwater and drinking water
Date:	1988
Doc ID:	A55603, A 55604, CpGV 67 a; BVL No.: BOD2003-244 (3683092)
Guideline:	BBA guideline No. 37, but different soil, shorter column length and larger amount of irrigation
GLP:	None
Validity:	Plausible
Material and methods (laboratory lysimeter):	
Test material:	Polio 3 (attenuated strain) f2-bacteriophages
Test concentration:	-
Test system:	Column: 4,8 cm diameter and 20 cm length Filling: (1) sand; (2) organically contaminated soil Irrigated by 2400 mL: (1) deionised water; (2) buffered water, pH 5.1 (3) buffered water, pH 7.4 (4) groundwater; (5) waste water (raw); (6) waste water (biol. purified)
Temperature:	Unknown
Sampling time points:	Unknown number of samples / time periode unknown
Method of analysis:	Not described in detail
Material and methods (field lysimeter):	
Test material:	1014 granules suspended in 20 L tap water
Test concentration:	Unknown
Test system:	Undisturbed unknown soil size unknown cover crop unknown amount of natural rainfall unknown
Temperature:	Location of lysimeter and weather conditions unknown
Sampling time points:	Every 14 days number of samples / time periode unknown
Method of analysis:	Only one pooled sample

Findings
This column leaching investigation used a sand and organic contaminated soil as substrate. The amount of irrigation was 2400 mL. The authors used different types of irrigation water including deionised water, ground water, buffer and waste water. They applied four different bacteria and viruses including granuloviruses. The column fillings were 48 mm diameter and 200 mm length.

The authors leave several experimental conditions unmentioned, e.g. the amount of viruses applied to the columns, duration of the experiment and the method of virus detection in the eluate.

For granuloviruses the study shows that a low percentage of up to 4 % reach the eluate for all types of waters in the sand experiments. For the organic contaminated soil experiment up to 24 % of the granuloviruses for the deionised water and the buffer and up to 4 % for the ground water and the waste water reaches the eluate.
The author mentions a field lysimeter experiment which was conducted 1987 in Marienfelde for 7 month. After application of the granuloviruses the leachate was collected at 14 - day intervals and quantified in pooled samples. The lysimeter was not actively irrigated but provided with natural rainfall. No information is given about the amount of granuloviruses applied, the type of soil, the amount of rainfall, the amount of leachate, and the number of investigated samples. During the 7 month investigation period none of the samples contained viruses.
Conclusion:
Although the study has many deficiencies, it shows the ability of granuloviruses to leach through a column of soil, but also the low risk of reaching the ground water.
The good retention of these viruses by soil is probably attributed to the particular protein envelope of the virus particles consisting of granulin.

New data 2016
No new data has been submitted under this point.
Previously submitted information is considered to be acceptable to cover current requirements.
From peer-reviewed open literature no additional references were identified to be relevant for mobility of *Cydia pomonella* Granulovirus. Please refer to the literature search presented in chapter B.8.4.

B.8.3 Effects of the micro-organism on drinking water analysis

No new data has been submitted under this point.

B.8.4 References relied on

Microbial pest control agent (MPCA)

Reference:	Anonymous (2016): Literature Review Report on *Cydia pomonella* Granulovirus - Fate and behaviour in the environment; unpublished report. BVL no 3306484
Guideline:	European Food Safety Authority; Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092
GLP:	No

The data requirement “Fate and behaviour in the environment” was covered using a focused literature search. The notifier used the ‘Scopus’ database considering that:

- this database is known for being one the of the most comprehensive in the field
- an important number of references were retrieved even after removing duplicates (i.e. 4069 references)
- manual sorting of the obtained references limited the risk of excluding relevant studies.

Five separate literature searches were conducted using different search terms. A first search focused on the term *Cydia pomonella* Granulovirus and its synonyms including names of commercial products. A

second search focused on baculoviruses in general but excluded search terms related to the use of these viruses for the production of recombinant proteins. In addition, some terms (Net present value, Predictive value and related terms) were excluded to limit background noise generated by the search term "NPV", abbreviation of "nucleopolyhedrovirus". Last, three searches were conducted on baculoviruses in general but focusing on specific search terms related to toxicology, ecotoxicology and fate and behaviour in the environment. Details on the used search queries are presented in Table B.8.4 2. This strategy was used in order to avoid any bias that might result from the selection of search terms. The vast majority of relevant references were retrieved in at least two searches showing the overlapping strategy was efficient in limiting bias of search terms. The obtained references were sorted manually for relevance for the data requirements based on the criteria described below.

Table B.8.4-1: Relevance criteria for each data requirement

Data requirements according to Regulation 283/2013 part B	Criteria for relevance
"Fate and behaviour in the environment" (MMA Section 7)	Summary and full text assessment: 1.The article concerns a baculovirus (other viruses are not included) which has not been genetically modified 2. The article concerns the data requirement "Fate and behaviour in the environment" (e.g. natural occurrence of baculoviruses, effects of UV on the persistence of the virus etc.) No additional criteria were used for this data requirement considering the limited number of obtained references.

Table B.8.4-2: Search process for peer-reviewed open literature in bibliographic databases

	Fate and behaviour in the environment linked to *Cydia pomonella* Granulovirus - Details of the searches
Database:	**Scopus**
Justification for choosing the source:	Scopus is the largest abstract and citation database of peer-reviewed literature. Scopus delivers the most comprehensive overview of the world's research output in the fields of science, technology, medicine, social sciences and arts and humanities. Updated daily, Scopus contains more than 57 million records including: • Over 21,000 peer-reviewed journals • Articles-in-press (i.e., articles that have been accepted for publication) from more than 5000 international publishers • 100,000 books • 520 book series • 360 trade publications
Date of the search:	30/05/16
Date span of the search:	01/01/2005 to 30/05/16
Date of the latest database update included in the search:	30/05/16
Search strategies used for the data requirement:	
search term 1:	(TITLE-ABS-KEY (cydia AND pomonella AND granulovirus) OR TITLE-ABS-KEY (cydia AND pomonella AND gv) OR TITLE-ABS-KEY (cpgv) OR TITLE-ABS-KEY (cydia AND pomonella AND granulosis virus) OR TITLE-ABS-KEY (carpovirusine) OR TITLE-ABS-KEY (virosoft) OR

	TITLE-ABS-KEY (granusal) OR TITLE-ABS-KEY (madex) OR TITLE-ABS-KEY (virin) OR TITLE-ABS-KEY (cyap) OR TITLE-ABS-KEY (carpovirus AND plus) OR TITLE-ABS-KEY (cyd-x) OR TITLE-ABS-KEY (carpostop) OR TITLE-ABS-KEY ("Evo 2") OR TITLE-ABS-KEY (carpo 600) OR TITLE-ABS-KEY (virgo AND *virus)) AND PUBYEAR > 2005
search term 2:	(TITLE-ABS-KEY (baculovirus) OR TITLE-ABS-KEY (Baculoviridae) OR TITLE-ABS-KEY (nucleopolyhedrovirus) OR TITLE-ABS-KEY (nuclear AND polyhedrosis AND virus) OR TITLE-ABS-KEY (npv) OR TITLE-ABS-KEY (granulovirus) OR TITLE-ABS-KEY (Betabaculovirus) AND NOT (TITLE-ABS-KEY (Net present value) OR TITLE-ABS-KEY (Protein expression) OR TITLE-ABS-KEY (Diagnostic test accuracy study) OR TITLE-ABS-KEY (Recombinant Proteins) OR TITLE-ABS-KEY (Baculovirus expression system) OR TITLE-ABS-KEY (Gene expression) OR TITLE-ABS-KEY (Predictive value) OR TITLE-ABS-KEY (Predictive value) OR TITLE-ABS-KEY (Predictive Value of Tests) OR TITLE-ABS-KEY (Diagnostic accuracy) OR TITLE-ABS-KEY ("Diagnostic value")))AND PUBYEAR > 2005
search term 3:	(TITLE-ABS-KEY (baculovirus) OR TITLE-ABS-KEY (Baculoviridae) OR TITLE-ABS-KEY (nucleopolyhedrovirus) OR TITLE-ABS-KEY (nuclear AND polyhedrosis AND virus) OR TITLE-ABS-KEY (npv) OR TITLE-ABS-KEY (granulovirus) OR TITLE-ABS-KEY (Betabaculovirus) AND NOT (TITLE-ABS-KEY (Net present value)))AND PUBYEAR > 2005 AND (TITLE-ABS-KEY (beneficial) OR TITLE-ABS-KEY (non target) OR TITLE-ABS-KEY (predator) OR TITLE-ABS-KEY (parasitoid) OR TITLE-ABS-KEY (pollinator))
search term 4:	(TITLE-ABS-KEY (baculovirus) OR TITLE-ABS-KEY (Baculoviridae) OR TITLE-ABS-KEY (nucleopolyhedrovirus) OR TITLE-ABS-KEY (nuclear AND polyhedrosis AND virus) OR TITLE-ABS-KEY (npv) OR TITLE-ABS-KEY (granulovirus) OR TITLE-ABS-KEY (Betabaculovirus) AND NOT (TITLE-ABS-KEY (Net present value)))AND PUBYEAR > 2005 AND (TITLE-ABS-KEY (toxicity) OR TITLE-ABS-KEY (mammals) OR TITLE-ABS-KEY (rat) OR TITLE-ABS-KEY (pathogenicity) OR TITLE-ABS-KEY (infectivity))
search term 5:	(TITLE-ABS-KEY (baculovirus) OR TITLE-ABS-KEY (baculoviridae) OR TITLE-ABS-KEY (nucleopolyhedrovirus) OR TITLE-ABS-KEY (nuclear AND polyhedrosis AND virus) OR TITLE-ABS-KEY (npv) OR TITLE-ABS-KEY (granulovirus) OR TITLE-ABS-KEY (betabaculovirus)) AND PUBYEAR > 2005 AND (TITLE-ABS-KEY (persistence) OR TITLE-ABS-KEY (soil) OR TITLE-ABS-KEY (water) OR TITLE-ABS-KEY (uv) OR TITLE-ABS-KEY (transport)) AND NOT (TITLE-ABS-KEY (net present value))
Total number of summary records retrieved:	5078
Total number of summary records retrieved after removing duplicates	4069

A very broad literature search was conducted in the “Scopus” database based on five separate literature searches using different search terms. This resulted in a high number of references. A total of 4069 reference was retrieved for all data requirements. However, many of these references do not concern the data requirements. After manual sorting of the references, based on the criteria presented in Table 8.4

1, a total of 41 references was selected for full text assessment for Effects on human health (14), Fate and behaviour in the environment (15) and Effects on non-target organisms (12). Based on full text evaluation a total of 31 studies was considered irrelevant for Effects on human health, Fate and behaviour in the environment and Effects on non-target organisms.

Table B.8.4-3: Results of the study selection process

Data requirement captured in the search (as indicated in Table 8.4 2)	**n**
Total number of summary records retrieved after all searches of peer-reviewed literature (excluding duplicates)	4069
Number of summary records excluded from search results after rapid assessment of relevance	4028
Total number of full-text documents assessed in detail (in total for Effects on human health, Fate and behaviour in the enviruonment and Effects on non-target organisms)	41
Number of studies excluded from further consideration after detailed assessment of relevance	31
Number of studies not excluded from further consideration after detailed assessment of relevance (i.e. relevant studies and studies of unclear relevance) in total for Effects on human health, Fate and behaviour in the enviruonment and Effects on non-target organisms	10
Number of studies not excluded from further consideration after detailed assessment of relevance (i.e. relevant studies and studies of unclear relevance) for the data requirement "**Environmental Fate and Behaviour**"	5

Table B.8.4-4: Studies excluded from the risk assessment after detailed assessment of full-text documents

Author	**Year**	**Title**	**Source**	**Reason(s) for not including this study in the dossier**
Eberle K. E., Sayed S., Rezapanah M., Shojai-Estabragh S. and Jehle J. A.	2009	Diversity and evolution of the *Cydia pomonella* granulovirus	Journal of General Virology 90 (3): 662-671	The report is regarded not relevant for the following reasons: This report is focused on the genetic diversity of CpGV isolates from different origins. It only refers to other reports for information where these isolates were sampled: Rezapanah 2008, Harvey and Volkman, 1983, Crook et al., 1985, Tanada, 1964. These reports are cited either elsewhere in this dossier or are regarded as relevant for Biological properties.
Myers J. H. and Cory J. S.	2016	Ecology and evolution of pathogens in natural populations of Lepidoptera	Evolutionary Applications 9 (1): 231-247	This report was regarded not relevant as it does not give information on the persistence of CpGV in field. Results from this report concerning persitance of baculoviruses cannot be transferred to CpGV because environmental conditions as well as the host insect are too different.
Zimmermann G., Huger A. M. and Kleespies R. G.	2013	Occurrence and prevalence of insect pathogens in populations of the codling moth, *Cydia pomone*lla	Microbial Ecology 62 (1): 48-57	This report is regarded not relevant as it does not provide information on the natural occurrence of CpGV, because *C. pomonella* larve sampled were derived from fiels where CpGV

		L.: A long-term diagnostic survey		was applied as biological control measure.
Hewson I., Brown J. M., Gitlin S. A. and Doud D. F.	2011	Nucleopolyhedrovirus Detection and Distribution in Terrestrial, Freshwater, and Marine Habitats of Appledore Island, Gulf of Maine	Microbial Ecology 62 (1): 48-57	This report is regarded not relevant as the authors have detected the polH gene only and did noch check whether viable viruses are present in the environmental compartments. Furthermore the study was performed in Appledore Island, Gulf of Maine (USA). Climatic conditions cannot be transferred to European conditions.
Jeyarani S., Sathiah N. and Karuppuchamy P.	2013	An in vitro method for increasing UV-tolerance in a strain of Helicoverpa armigera (Lepidoptera: Noctuidae) nucleopolyhedrovirus	Biocontrol Science and Technology 23 (3): 305-316	This article was regarded not relevant as it does not provide new information on degradation of CpGV due to UV radiation. It shows that sensitivity of a baculovirus (HearNPV.) can be reduced by selection methods in vitro. This does not provide relevant information on the fate and behaviour of baculoviruses in the environment.
Pessoa V., Cunha F., Bueno A. F., Bortolotto O. C., Monteiro T. and Ramos V. M.	2014	Velvet-bean nucleopolyhedrovirus persistence after different rainfall intensities	Ciencia Rural 44 (1): 5-10	This report is regarded not relevant for the following reasons: The study is focussed on whether the efficacy of baculovirus (AgMNPV) application on soybean plants is impaired by rainfall. The experiment took place under greenhouse conditions It does not provide information on fate and behaviour of baculoviruses in the environment.
Sood P., Mehta P. K. and Prabhakar C. S.	2013	Effect of UV protectants on the efficacy of Pieris brassicae granulovirus	Biological Agriculture and Horticulture 29 (2): 69-81	This report is regarded not relevant for the following reasons: The study was performed in India under field condition and can therefore not be transferred to European conditions. Furthermore it provides only data on the efficacy of baculovirus application with and without different UV protectants. The study provides only information that efficacy of PbGV is impaired by UV light. However, on this topic CpGV specific data is available.
Mehrvar A.	2009	Persistence of different geographical isolates of Helicoverpa armigera nucleopolyhedrovirus in two types of soils under different	Journal of Biological Sciences 9 (3): 264-267	This report is regarded not relevant for the following reasons: The study was performed outside the EU (India) where completely different climate conditions and soil types are present. The baculovirus observed in this sudy was HearNPV which is a Nucleoplyhedrovirus. Therefore results cannot be fully transferred

		conditions		to persistence of CpGV in European orchard soils.The conclusion ofthis study is that HearNPV is able to persist in soil for at least 6 months. This is no new information and does not alter the conclusions drawn in the DAR of first evaluation of CpGV as active substance.
Villamizar L., Espinel C. and Cotes A. M.	2009	Effect of ultraviolet radiation on the insecticidal activity of a *Spodoptera frugiperda* (Lepidoptera: Noctuidae) nucleopolyhedrovirus	Revista Colombiana de Entomologia 35 (2): 116-121	This report is regarded not relevant as thestudy was done outside the EU. Climatic contitions cannot be transferred. Furthermore this study was performed with *Spodoptera frugiperda*NPV and not CpGV. As there is CpGV specific data on UV inactivation available, results from other baculoviruses are not relevant in this case.
Sajap A. S., Bakir M. A., Kadir H. A. and Samad N. A.	2007	Effect of pH, rearing temperature and sunlight on infectivity of Malaysian isolate of nucleopolyhedrovirus to larvae of Spodoptera litura (Lepidoptera: Noctuidae)	International Journal of Tropical Insect Science 27 (2): 108-113	This report is regarded not relevant as thestudy was done outside the EU. Climatic contitions cannot be transferred. Furthermore this study was performed with *Spodoptera litura*NPV and not CpGV. As there is CpGV specific data on UV inactivation available, results from other baculoviruses are not relevant in this case.

Table B.8.4-5: Relevant studies subjected to a detailed assessment of full-text documents (n = 5) by data requirement

Data requirement (numbered according to Regulation 283/2013 part B)	Author(s)	Year	Title	Source
7. FATE AND BEHAVIOUR IN THE ENVIRONMENT				
7.1. Persistence and multiplication				
MA 7.1.3	Arthurs S. P., Lacey L. A. and Behle R. W.	2006	Evaluation of spray-dried lignin-based formulations and adjuvants as solar protectants for the granulovirus of the codling moth, *Cydia pomonella* (L)	Journal of Invertebrate Pathology 93 (2): 88-95
MA 7.1.3	Wu Z. W., Fan J. B., Yu H., Wang D. and Zhang Y. L.	2015	Ultraviolet protection of the *Cydia pomonella* granulovirus using zinc oxide and titanium dioxide	Biocontrol Science and Technology 25 (1): 97-107
7.1.1 Soil				
MA 7.1.1	Christian P. D., Richards A. R. and Williams T.	2006	Differential adsorption of occluded and nonoccluded insect-pathogenic viruses to soil-forming minerals	Applied and Environmental Microbiology 72 (7): 4648-4652
MA 7.1.1	Gupta, R.K., Gani, M., Jasrotia, P., Srivastava,	2014	A comparison of infectivity between polyhedra of the *Spodoptera litura* multiple nucleopolyhedrovirus before and after passage through the gut of the	Journal of Insect Science,14

	K. and Kaul, V.		stink bug, *Eocanthecona furcellata*	
7.1.2 Water				
MA 7.1.2	Holmes S. B., Fick W. E., Kreutzweiser D. P., Ebling P. M., England L. S. and Trevors J. T.	2008	Persistence of naturally occurring and genetically modified *Choristoneura fumiferana* nucleopolyhedroviruses in outdoor aquatic microcosms	Pest Management Science 64 (10): 1015-1023

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not** **BVL registration number**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previously submitted Y/N*** **If Y => old data point**
KMA 7/01	Anonymous	2016	LITERATURE REVIEW REPORT ON CYDIA POMONELLA GRANULOVIRUS - FATE AND BEHAVIOUR IN THE ENVIRONMENT Arysta LifeScience S.A.S., not applicable Arysta Lifescience, France GLP/GEP: no Published: no 3306484	no	yes	New data for active ingredient, not previously submitted nor evaluated	ALS	N
KMA 7.1.1	Kienzle, J., Schulz, C, Zebitz, C.P.W., Huber, J.	2003	PERSISTENCE OF THE BIOLOGICAL EFFECT OF CODLING MOTH GRANULOVIRUS IN THE ORCHARD -PRELIMINARY FIELD TRIALS not available, not applicable Insect Pathogens and Insect Parasitic Nematodes, IOBC wprs Bulletin, 26 (1), 245-248 GLP/GEP: no Published: yes 3683014	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Young, S.	2003	PERSISTENCE OF VIRUSES IN THE ENVIRONMENT not available, not applicable http://www.lsuagcenter.com/s265/young.htm GLP/GEP: no Published: yes 3683094	no	no	not protected	-	Y KIIM 7.1.1

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N* If Y => old data point
KMA 7.1.1	Jaques, R.P., Harcourt, D.G.	1971	VIRUSES OF TRICHOPLUSIA NI (LEPIDOPTERA: NOCTUIDAE) AND PIERIS RAPAE (LEPIDOPTERA: PIERIDAE) IN SOIL IN FIELDS OF CRUCIFERS IN SOUTHERN ONTARIO not available, not applicable The Canadian Entomologist, Journal, 103, 1285-1290 GLP/GEP: no Published: yes 3683087	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Thomas, E.D., Reichelderfer, C.F., Heimpel, A.M.	1973	THE EFFECT OF SOIL PH ON THE PERSISTENCE OF CABBAGE LOOPER NUCLEAR POLYHEDROSIS VIRUS IN SOIL not available, not applicable Journal of invertebrate Pathology, 21, 21-25 GLP/GEP: no Published: yes 3683018	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Evans, H.F., Harrap, K.A.	1982	PERSISTENCE OF INSECT VIRUSES not available, not applicable Virus Persistence, Publisher: Cambridge University Press, 58-96 GLP/GEP: no Published: yes 3683022	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Ogaard, L., Williams, C.F., Payne, C.C., Zethner, O.	1988	ACTIVITY PERSISTENCE OF GRANULOSIS VIRUSES (BACULOVIRIDAE) IN SOILS IN UNITED KINGDOM AND DENMARK not available, not applicable Entomophaga, 33 (1), 73-80 GLP/GEP: no Published: yes 3683088	no	no	not protected	-	Y KIIM 7.1.1

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Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N* If Y => old data point
KMA 7.1.1	Jaques, R.P.	1974a	OCCURRENCE AND ACCUMULATION OF VIRUSES OF TRICHOPLUSIA NI IN TREATED FIELD PLOTS not available, not applicable Journal of invertebrate Pathology, 23, 140-152 GLP/GEP: no Published: yes 3683089	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Jaques, R.P.	1974b	OCCURRENCE AND ACCUMULATION OF THE GRANULOSIS VIRUS OF PIERIS RAPAE IN TREATED FIELD PLOTS not available, not applicable Journal of invertebrate Pathology, 23, 351-359 GLP/GEP: no Published: yes 3683090	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Tanada, Y., Omi, E.M.	1974	PERSISTENCE OF INSECT VIRUSES IN FIELD POPULATIONS OF ALFALFA INSECTS not available, not applicable Journal of Invertebrate Pathology 23, 360-365 GLP/GEP: no Published: yes 3682711	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Jaques, R.A.	1977	STABILITY OF ENTOMOPATHOGENIC VIRUSES not available, not applicable Miscellaneous Publication of the Entomological Society of America, 10 (3), 99 - 116 GLP/GEP: no Published: yes 3682725	no	no	not protected	-	Y KIIM 7.1.1

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not BVL registration number	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N* If Y => old data point
KMA 7.1.1	David, W.A.L., Gardiner, B.O.C.	1967	THE PERSISTENCE OF A GRANULOSIS VIRUS OF PIERIS BRASSICAE IN SOIL AND IN SAND not available, not applicable Journal of Invertebrate Pathology 9, 342-347 GLP/GEP: no Published: yes 3683041	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Anonymous	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 3683011	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1	Thompson, C. G., Scott, D.W. & Wickman, B. E.	1981	LONG-TERM PERSISTENCE OF NUCLEAR POLYHEDROSIS VIRUS OF THE DOUGLAS-FIR TUSSOCK MOTH, ORGYIA PSEUDOTSUGATA (LEPIDOPTERA: LYMANTRIIDAE) IN FOREST SOIL not available, not applicable Environ Entomol, 10, 254-255 GLP/GEP: no Published: yes	no	no	not protected	-	Y Report included in DAR by RMS
KMA 7.1.1	Eastwell, K. C., Cossentine, J. E. & Bernardy, M. G.	1999	CHARACTERISATION OF CYDIA POMONELLA GANULOVIRUS FROM CODLING MOTHS IN A LABORATORY COLONY AND IN ORCHARDS OF BRITISH COLOMBIA not available, not applicable Annals of Applied Biology, 134, 285-291 GLP/GEP: no Published: yes	no	no	not protected	-	Y Report included in DAR by RMS

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not** **BVL registration number**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previously submitted Y/N*** **If Y => old data point**
KMA 7.1.1	Lopez-Pila, J.M.	1988	EFFECT OF BACULOVIRUSES ON GROUNDWATER AND DRINKING WATER (GERMAN ORIGINAL) not available, not applicable In: Mitteilung aus der Biol. Bundesanstalt, 246, p 178-203 GLP/GEP: no Published: yes 3683092	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.1.1/01	Christian, P.D., Richards, A.R., Williams, T.	2006	DIFFERENTIAL ADSORPTION OF OCCLUDED AND NONOCCLUDED INSECT-PATHOGENIC VIRUSES TO SOIL-FORMING MINERALS not available, not applicable Applied and Environmental Microbiology, 72, 4648-4652 GLP/GEP: no Published: yes 3306485	no	no	not protected	-	N
KMA 7.1.1/02	Gupta, R.K., Gani, M., Jasrotia, P., Srivastava, K., Kaul, V.	2014	A COMPARISON OF INFECTIVITY BETWEEN POLYHEDRA OF THE SPODOPTERA LITURA MULTIPLE NUCLEOPOLYHEDROVIRUS BEFORE AND AFTER PASSAGE THROUGH THE GUT OF THE STINK BUG, EOCANTHECONA FURCELLATA not available, not applicable Journal of Insect Science, 14, 1-8 GLP/GEP: no Published: yes 3306486	no	no	not protected	-	N

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not** **BVL registration number**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previously submitted Y/N*** **If Y => old data point**
KMA 7.1.2	Jaques, R.A.	1977	STABILITY OF ENTOMOPATHOGENIC VIRUSES not available, not applicable Miscellaneous Publication of the Entomological Society of America, 10 (3), 99 - 116 GLP/GEP: no Published: yes **Submitted in: KMA 7.1.1** 3683032	no	no	not protected	-	Y KIIM 7.1.2
KMA 7.1.2/01	Holmes, S.B., Fick, W.E., Kreutzweiser, D., Ebeling, P.M., England, L.S., Trevors, J.T.	2008	PERSISTENCE OF NATURALLY OCCURRING AND GENETICALLY MODIFIED CHORISTONEURA FUMIFERANA NUCLEOPOLYHEDROVIRUSES IN OUTDOOR AQUATIC MICROCOSMS not available, not applicable Pest Management Science, 64, 1015 - 1023 GLP/GEP: no Published: yes 3306487	no	no	not protected	-	N
KMA 7.1.3	Krieg, A., Gröner, A., Huber, J., Zimmermann, G.	1981	INACTIVATION OF CERTAIN INSECT PATHOGENS BY ULTRAVIOLET RADIATION not available, not applicable Journal of Plant Diseases and Protection, 88 (1), 38-48 GLP/GEP: no Published: yes 3683044	no	no	not protected	-	Y KIIM 7.1.3

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not** **BVL registration number**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previously submitted Y/N*** **If Y => old data point**
KMA 7.1.3	Steineke, S.B.	2004	POPULATIONSDYNAMIK DES CYDIA POMONELLA GRANULOVIRUS not available, not stated Johannes Gutenberg-Universität, Fachbereich Biologie, Mainz GLP/GEP: no Published: no 2390213	no	no	not protected		Y KIIM 7.1
KMA 7.1.3/01	Arthurs, S.P., Lacey, L.A., Behle, R.W.	2006	EVALUATION OF SPRAY-DRIED LIGNIN-BASED FORMULATIONS AND ADJUVANTS AS SOLAR PROTECTANTS FOR THE GRANULOVIRUS OF THE COLDING MOTH, CYDIA POMONELLA (L) not available, not applicable Journal of Invertebrate Pathology, 93, 88-95 GLP/GEP: no Published: yes 3306488	no	no	not protected	-	N
KMA 7.1.3/02	Wu, Z.W., Fan, J.B., Yu, H., Wang, D., Zhang, Y.L.	2015	ULTRAVIOLET PROTECTION OF THE CYDIA POMONELLA GRANULOVIRUS USING ZINC OXIDE AND TITANIUM DIOXIDE not available, not applicable Biocontrol Science and Technology, 25, 97-107 GLP/GEP: no Published: yes 3306489	no	no	not protected	-	N

Data point	**Author(s)**	**Year**	**Title** **Owner, Report No.** **Source (where different from owner)** **GLP or GEP status** **Published or not** **BVL registration number**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**	**Previously submitted Y/N*** **If Y => old data point**
KMA 7.2	Krieg, A.	1983	TESTING OF A NUCLEAR POLYHEDROSIS PREPARATION MBNPV (UNFORMULATED) FOR LEACHING BEHAVIOUR (GERMAN ORIGINAL) Andermatt Biocontrol GmbH / Probis GmbH, A55490 BBA, Darmstadt, Germany GLP/GEP: no Published: no 3683091	no	no	not protected	PKA	Y KIIM 7.1.1
KMA 7.2	Lopez-Pila, J.M.	1988	EFFECT OF BACULOVIRUSES ON GROUNDWATER AND DRINKING WATER (GERMAN ORIGINAL) not available, not applicable In: Mitteilung aus der Biol. Bundesanstalt, 246, p 178-203 GLP/GEP: no Published: yes **Submitted in: KMA 7.1.1** 3683092	no	no	not protected	-	Y KIIM 7.1.1
KMA 7.2	Steineke, S.B.	2004	POPULATIONSDYNAMIK DES CYDIA POMONELLA GRANULOVIRUS not available, not stated Johannes Gutenberg-Universität, Fachbereich Biologie, Mainz GLP/GEP: no Published: no **Submitted in: KMA 7.1.3** 2390213	no	no	not protected		Y KIIM 7.1