Renewal
Assessment Report

Cydia pomonella GV

Volume 3 – B.7 Residues in or on treated products, food and feed

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Rapporteur Member State: Germany

Co-Rapporteur Member State: The Netherlands

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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 Summary of the data and information

B.7 Residues in or on treated products, food and feed

Introduction

Cydia pomonella Granulovirus (CpGV) belongs to the group of baculoviruses. General information on baculoviruses such as organism characteristics, behavior in the environment, their history of use and interactions, as well as environmental safety considerations are summarised in an OECD publication (2002, TOX2006-1036).

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 affect any organism except codling moth larvae from the *Tortricidae* family.

Baculoviruses are part of our natural environment and have been successfully used for biological insect control for many decades. According to Krieg (1976, RIP2006-1339, BWS2003-90), the application of baculoviruses in pest control means only a fluctuation of the virus titre in the biotope of the pest insect.

The general safety of baculoviruses for vertebrates including humans was emphasised by OECD (2002, TOX2006-1036). The EFSA's biohazard panel also regards the family of baculoviruses as safe for humans and vertebrates by the inclusion of this virus family in the list of "Qualified Presumption of Safety"[1], which means that this virus family is regarded as safe for humans and vertebrates. As presented in section B.6., no scientific evidence indicated that baculoviruses have any negative effects on animals and humans to date.

According to Commission Regulation (EU) 2016/439[2] CpGV is included into Annex IV of Regulation (EC) No 396/2005. Consequently, no maximum residue levels are set in food and feed and no residue definition is applicable for *Cydia pomonella* GV.

A literature search was performed according to the guidance of EFSA[3] both by the applicants and by the RMS. Relevant articles regarding residue assessment were not identified. Summary of literature research method and of the results is presented in paragraph B.7.4.

[1] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci A, Allende A, Bolton D, Chemaly M, Davies R, Girones R, Herman L, Koutsoumanis K, Lindqvist R, Nørrung B, Robertson L, Ru G, Sanaa M, Simmons M, Skandamis P, Snary E, Speybroeck N, Ter Kuile B, Threlfall J, Wahlstrom H, Coconcelli PS, Klein G (deceased), Prieto Maradona M, Querol A, Peixe L, Suarez JE, Sundh I, Vlak JM, Aguilera-Gomez M, Barizzone F, Brozzi R, Correia S, Heng L, Istace F, Lythgo C and Fernandez Escamez PS, 2017. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. EFSA Journal 2017;15(3):4664, 178 pp. doi:10.2903/j.efsa.2017.4664

[2] COMMISSION REGULATION (EU) 2016/439 of 23 March 2016 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Cydia pomonella Granulovirus (CpGV), calcium carbide, potassium iodide, sodium hydrogen carbonate, rescalure and Beauveria bassiana strain ATCC 74040 and Beauveria bassiana strain GHA

[3] EFSA. 2011. 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.

B.7.1 Persistence and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs

In general, baculoviruses are unable to enter plant tissues or to multiply on plant surfaces. The occurrence of *Cydia pomonella* Granulovirus is strictly dependent on the presence of its host. Replication of CpGV does only happen inside the larval stages of the target insect species *Cydia pomonella* or for some isolates also in *Grapholita molesta* or *Grapholita funebrana*. CpGV is rapidly degraded by UV light; therefore persistence in nature is very limited. Therefore, it is unlikely that CpGV occurs on treated food/feed stuffs in concentrations considerably higher than under natural conditions.

B.7.2 Further Information required - Exposure to consumers

B.7.2.1 Non-viable residues

Cydia pomonella Granuloviruses as well as any other baculovirus have no metabolism of their own and are therefore not able to produce any toxin. Likewise, non-viable residues (toxic metabolites or degradation products) do not occur.

B.7.2.2 Viable residues

Viruses like CpGV are ubiquitous in plant and fruits, and as a consequence they are continuously consumed by people. With reference to the B.6 section (Effects on human health) cases of baculoviruses causing diseases in humans have never been documented.

Bacterial contamination
The applicant provided the following information:
As baculoviruses need to be produced in vivo using insect larvae, sterile conditions in the production process are not possible. The insect's natural intestinal microflora, including *Bacillus cereus*, cannot be separated in the production process. Therefore, CpGV preparations naturally contain B. *cereus*.

According to SANCO Working document on Microbial Contaminant Limits for Microbial Pest Control Products (SANCO/12116/2012-rev.0 ASB2019-4942) and to OECD issue paper on microbial contaminant limits for microbial pest control products (ENV/JM/MONO(2011)43, Series on Pesticides No. 65, ASB2019-4945)) the limit level for *B. cereus* in the formulated products is 10^7 CFU per g or mL. The contamination by microorganisms is checked in batch analyses. Adequate analyses (see Vol. 4) show that the CFU threshold limit is not exceeded in all of the formulated products. Accordingly, the content of *B. cereus* in the formulated products can be regarded as acceptable.

B.7.3 Summary and evaluation of residue behaviour

Metabolism studies on plants or livestock animals, residue studies or a residue definition for the active substance *Cydia pomonella* Granulovirus (CpGV) are not considered necessary. It does not affect any vertebrate organisms. A toxin is not produced. Toxic metabolism or degradation products do not occur. A risk to consumers arising from CpGV was not identified.

The contamination with *Bacillus cereus* should be controlled at a level that the final contamination with *B. cereus* in the formulated product does not exceed 10^7 CFU/g or mL.

B.7.4 Literature search

A literature search was performed according to the guidance of EFSA both by the applicants and by the RMS.

The applicant's search with regard to human health is described in a KII document provided by Arysta Life Science SAS (Anon., 2016, ASB2017-11932). The aim of this report was to provide a global overview of peer-reviewed literature concerning side effects of the active substance *Cydia pomonella* Granulovirus. The literature search was only conducted in the "Scopus" database. Taking into account the nature of the active ingredient as a virus, this approach is considered acceptable by the RMS. The time span considered was from 01 January 2005 to 9 August 2016 which is also acceptable. The search aimed to find articles concerning baculoviruses (only when not genetically modified) in relation to the data requirement "Residues in or on treated products, food and feed".

Keywords used by applicants:
((((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 (granulovirus) OR TITLE-ABS-KEY (betabaculovirus))) OR ((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) AND (TITLE-ABS-KEY(multiplicat* OR coloni* OR residue*) AND TITLE-ABS-KEY (crop* OR feed* OR food* OR consumer*))

In total, 36 records (excluding duplicates) of which one reference was considered relevant for residue aspects following *rapid assessment of relevance*. Unfortunately, relevance criteria applied were not given and cannot be assessed by the RMS, therefore, and the outcome must be simply described here only. The remaining document was evaluated on full text basis and was considered relevant after *detailed assessment of relevance*.

Several literature searches for the data requirements "Effects on non-target organisms", "Fate and behaviour in the environment", "Effects on human health" and "Biological properties of the micro-organism" were also conducted by the applicant. As the requirement for providing information on residues is partially covered by the section "Fate and behaviour in the environment" the references obtained by this particular search were also screened for relevance (for details see E-fate section B.8). In total, 4069 references for the "E-fate" requirements (excluding duplicates) were retrieved of which the vast majority (4063) was immediately excluded, following *rapid assessment of relevance* for the residue requirements. Of the six references submitted to *full text analysis*, two were finally considered relevant and implemented in the dossier.

Collectively, both searches yielded three articles relevant to the data requirement "Residues in or on treated products, food and feed". These references were implemented in the dossier by the applicant. Article summaries and conclusion by the RMS are reported below.

Report KMA 6.1/02 – Jeyarani, S., Sathiah, N., Karrupuchamy, P., 2013. An in vitro method for increasing UV-tolerance in a strain of Helicoverpa armigera (Lepidoptera: Noctuidae) nucleopolyhedrovirus. Published report. Biocontrol Science and Technology, 23(3): 305-316, ASB2017-11931

Abstract:

A method for increasing tolerance to ultraviolet (UV) radiation in a strain of nucleopolyhedrovirus of

cotton bollworm, Helicoverpa armigera (Hübner) (HearNPV) using a solar simulator is described. The Coimbatore isolate (CBE I) of HearNPV was subjected to a five-step sequence of selection to increase its UV tolerance. Each step consisted of irradiation of wet deposits of the virus to near UV (at energy level of 300W/m^2), bioassay against second instar H. armigera larvae and propagation in early fifth instar larvae. Selection steps carried out at 15, 30, 60 and 90 minutes of exposure revealed that the continuous exposure of HearNPV-CBE I at low doses of UV irradiation (270–540 KJ/m^2) did not significantly affect the virus activity as measured by its biological activity against second instar larvae. Selection at higher doses (1620 KJ/m^2) led to loss of viral activity in the first two exposure cycles; however, there was retention of virulence coupled with increased tolerance to UV doses from third cycle onwards. Further, studies on the persistence of UV tolerant strain of HearNPV-CBE I in comparison with original strain showed that the tolerant strain had more persistence even after 7 days of weathering both under exposed (18% original activity remaining) and shaded (26% original activity remaining) condition on potted cotton plant.

Conclusion by the RMS (2019):

Article contains information on UV-sensitivity of baculoviruses and focuses especially on the development of an in vitro method for increasing the UV-tolerance in a strain of Helicoverpa armigera nucleopolyhedrovirus (HearNPV). Not relevant for the data point "residues".

Report KMA 6.1/03 – Prater, C.A., Redmond, C.T., Barney, W., Bonning, B.C., Potter, D.A., 2006. Microbial Control of black cutworm (Lepidoptera: Noctuidae) in turfgrass using *Agrotis ipsilon* multiple mucleopolyhedrovirus. Published report. J Econ Entomol., 99(4):1129-1137. ASB2017-11933

Abstract:

Agrotis ipsilon multiple nucleopolyhedrovirus (family Baculoviridae, genus Nucleopolyhedrovirus, AgipMNPV), a naturally occurring baculovirus, was found infecting black cutworm, Agrotis ipsilon (Hufnagel) (Lepidoptera: Noctuidae), on central Kentucky golf courses. Laboratory, greenhouse, and field studies investigated the potential of AgipMNPV for managing black cutworms in turfgrass. The virus was highly active against first instars (LC50 = 73 occlusion bodies [OBs] per microl with 2-microl dose; 95% confidence intervals, 55-98). First instars that ingested a high lethal dose stopped feeding and died in 3-6 d as early second instars, whereas lethally infected fourth instars continued to feed and grow for 4-9 d until death. Sublethal doses consumed by third or fifth instars had little or no effect on subsequent developmental rate or pupal weight. Horizontal transmission of AgipMNPV in turfgrass plots was shown. Sprayed suspensions of AgipMNPV (5 × 108 - 6 × 109 OBs/m2) resulted in 75 to > 93% lethal infection of third or fourth instars in field plots of fairway-height creeping bentgrass, Agrotis stolonifera (Huds.), and on a golf course putting green collar. Virus spray residues (7 × 109 OBs/m2) allowed to weather on mowed and irrigated creeping bentgrass field plots significantly increased lethal infection of implanted larvae for at least 4 wk. This study, the first to evaluate a virus against a pest in turfgrass, suggests that AgipMNPV has potential as a preventive bioinsecticide targeting early instar black cutworms. Establishing a virus reservoir in the thatch and soil could suppress successive generations of that key pest on golf courses and sport fields.

Conclusion by the RMS (2019):

Article contains information on the efficacy of an Agrotis ipsilon Multiple Nucleopolyhedrovirus (AgripMNPV) for control of the pest in turf. Not relevant for the data point "residues".

Report KMA 6.1/04 – Pessoa, V., Cunha, F., de Freitas Bueno, A., Ceolin Bortolotto, O., Monteiro, T., Ramos, V.M. Velvet-bean nucleopolyhedrovirus persistence after different rainfall intensities, Published report. Ciencia Rural, 44(1):5-10, ASB2017-11934

Abstract:

The persistence of the velvet-bean nucleopolyhedrovirus (AgMNPV) produced raw (macerated caterpillars) and lyophilized (commercial product) was evaluated after spraying in soybean plants followed by different simulated rainfall rates (0; 10; 20; 30mm) at 30mm hour-1 rate. Rainfall was simulated in greenhouse through micro sprinkler irrigation. After simulated rainfall, soybean leaves were offered to caterpillar in laboratory conditions at zero, three, six and nine days after spraying (DAS). Soybean plants were kept in greenhouse protected from rainfall. Trial was carried out in complete randomized design, under controlled conditions (RH 70%±10%, 25±2°C, 14h photophase) in a factorial 4 (rainfall rates) ×2 (formulations, raw and lyophilized) with four replicates of 30 caterpillars. Results indicate that rainfall rates up to 30mm, in 60 minutes, do not decrease caterpillar mortality caused by AgMNPV regarding to both tested baculovirus formulations, raw and lyophilized virus, when leaves were offered to caterpillars at zero DAS. However, virus production (raw or lyophilized) impacted its persistence. Six DAS, mortality rate was higher than 90% when the virus was applied raw and lower than 50% when it was applied lyophilized. These results suggest that both raw and lyophilized AgMNPV efficacy is not impaired by 30-mm rainfalls at 30mm hour rate. However, raw virus was more efficient in a long term evaluation since it had longer persistence on soybean leaves after being water washed.

Conclusion by the RMS (2019):

Article contains information on the persistence of the velvet-bean nucleopolyhedrovirus (AgMNPV) after spraying in soybean plants under different simulated rainfall rates. Not relevant for the data point "residues".

The literature search by the RMS was conducted in two databases (Scopus, and Web of Science) while the keywords were slightly adapted. Thus, the approach was different from that one taken by the applicant. 45 (Scopus) and 35 (Web of Sciences) articles were found (see Table B.7.4-1). The total number of 80 was reduced to 56 when duplicates were deleted. They were subjected to a *rapid assessment* based on title and abstract. One article (Kalawate, 2014, ASB2017-16166) was considered relevant by the RMS in relation to human health aspects (B.6). Thorough review by RMS reviewers left no publication for full text evaluation since none of the screened articles was potentially related to residue aspects.

Keywords used by RMS:
((TS=(baculovirus) OR TS=(baculoviridae) OR TS=(nucleopolyhedrovirus) OR (TS=(nuclear) AND TS=(polyhedrosis) AND TS=(virus)) OR TS=(granulovirus) OR TS=(betabaculovirus)) OR ((TS=(cydia) AND TS=(pomonella) AND TS=(granulovirus)) OR (TS=(cydia) AND TS=(pomonella) AND TS=(gv)) OR (TS=(cpgv) OR (TS=(cydia) AND TS=(pomonella) AND TS=(granulosis) AND TS=(virus)) OR TS=(carpovirusine) OR TS=(virosoft) OR TS=(granusal) OR TS=(madex) OR TS=(virin) OR TS=(cyap) OR TS=(carpovirus) AND TS=(plus)) OR TS=(cydx) OR TS=(carpostop) OR TS=("Evo 2") OR TS=(carpo 600) OR (TS=(virgo) AND TS=(*virus)))) AND (TS=(multiplicat*) OR TS= (coloni*) OR TS=(residue*)) AND (TS=(crop*) OR TS=(feed*) OR TS=(food*) OR TS=(consumer*)) Indexes=SCI-EXPANDED, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, CCR-EXPANDED, IC

Table B.7.4-1: Results of literature search conducted by RMS

Year	Author	Title	Journal
2010	Abd-Alla, A.M.M. et al.	Dynamics of the salivary gland hypertrophy virus in laboratory colonies of Glossina pallidipes (Diptera: Glossinidae)	Virus Research, 150 1-2, 103-110
2010	Akbulult, A.	Techno-economic analysis of electricity and heat generation from farm-scale biogas plant:	Energy, 44 1, 381-390

Year	Author	Title	Journal
		Çiçekdağicase study	
2013	Ansari, M.S. et al.	Microbial insecticides: Food security and human health	Management of Microbial Resources in the Environment, 9789400759312 341-360
2014	Ardisson-Araújo, D.M.P. et al.	Genome sequence of erinnyis ello granulovirus (ErelGV), a natural cassava hornworm pesticide and the first sequenced sphingid-infecting betabaculovirus	BMC Genomics, 15 1
2016	Arrizubieta, M. et al.	Insecticidal efficacy and persistence of a co-occluded binary mixture of Helicoverpa armigera nucleopolyhedrovirus (HearNPV) variants in protected and field-grown tomato crops on the Iberian Peninsula	Pest Management Science, 72 4, 660-670
2014	Bindhu, F. et al.	Influence of Agathi grandiflora active principles inhibit viral multiplication and stimulate immune system in Indian white shrimp Fenneropenaeus indicus against white spot syndrome virus infection	Fish & Shellfish Immunology, 41 2, 482-492
2012	Bixby-Brosi, A. J. et al.	Can a chitin-synthesis-inhibiting turfgrass fungicide enhance black cutworm susceptibility to a baculovirus?	Pest Management Science, 68 3, 324-329
2016	Blackburn, D. et al.	Biological control and nutrition: Food for thought	Biological Control, 97 131-138
2005	Byeon, G. M. et al.	A digestive beta-glucosidase from the silkworm, Bombyx mori: cDNA cloning, expression and enzymatic characterization	Comparative Biochemistry and Physiology B-Biochemistry & Molecular Biology, 141 4, 418-427
2010	Cao, X. et al.	Developing a MODIS-based index to discriminate dead fuel from photosynthetic vegetation and soil background in the Asian steppe area	International Journal of Remote Sensing, 31 6, 1589-1604
2017	Carballo, A. et al.	Co-infection with iflaviruses influences the insecticidal properties of Spodoptera exigua multiple nucleopolyhedrovirus occlusion bodies: Implications for the production and biosecurity of baculovirus insecticides	PLoS ONE, 12 5
2009	Chau, J. et al.	Techno-economic analysis of wood biomass boilers for the greenhouse industry	Applied Energy, 86 3, 364-371
2013	Dalla S., et al.	Amino acid substitutions of Na,K-ATPase conferring decreased sensitivity to cardenolides in insects compared to mammals	Insect Biochemistry and Molecular Biology, 43 12, 1109-1115
2011	Delivand, M.K. et al.	Economic feasibility assessment of rice straw utilization for electricity generating through combustion in Thailand	Applied Energy, 88 11, 3651-3658
2010	Espinel-Correal, C. et al.	Genetic and biological analysis of colombian phthorimaea operculella granulovirus isolated from tecia solanivora (Lepidoptera: Gelechiidae)	Applied and Environmental Microbiology, 76 22, 7617-7625
2010	Gomez, D. L. M. et al.	Effects of Fetal Bovine Serum deprivation in cell cultures on the production of Anticarsia gemmatalis Multinucleopolyhedrovirus	BMC Biotechnology, 10
2011	Gómez-Bonilla, Y. et al.	Characterization of a costa rican granulovirus strain highly pathogenic against its indigenous hosts, phthorimaea operculella and tecia solanivora	Entomologia Experimentalis et Applicata, 140 3, 238-246
2015	Gosens, J.	Biopower from direct firing of crop and forestry residues in China: A review of developments and investment outlook	Biomass and Bioenergy, 73 110-123

Year	Author	Title	Journal
2016	Hekmatnejad, M. et al.	Insights into kinetic mechanism of Janus kinase 3 and its inhibition by tofacitinib	Archives of Biochemistry and Biophysics, 612 22-34
2007	Hur, Y.J. et al.	A phosphate starvation-induced acid phosphatase from Oryza sativa: Phosphate regulation and transgenic expression	Biotechnology Letters, 29 5, 829-835
2014	Kalawate, A.S.	Microbial viral insecticides	Basic and Applied Aspects of Biopesticides, 47-68
2015	Kale, V. et al.	Chondroitin Lyase from a Marine Arthrobacter sp MAT3885 for the Production of Chondroitin Sulfate Disaccharides	Marine Biotechnology, 17 4, 479-492
2016	Kim, J.H. et al.	Improved insecticidal activities of Novel Bacillus thuringiensis Cry1-type genes	Journal of Asia-Pacific Entomology, 19 1, 145-151
2008	Kim, Y.S. et al.	Mutagenesis of Bacillus thuringiensis cry1Ac gene and its insecticidal activity against Plutella xylostella and Ostrinia furnacalis	Biological Control, 47 2, 222-227
2015	Lacey, L.A. et al.	Insect pathogens as biological control agents: Back to the future	Journal of Invertebrate Pathology, 132 1-41
2016	Leland L. et al.	Microbial Control of Insect and Mite Pests of Cotton	Microbial Control of Insect and Mite Pests: From Theory to Practice, 185-197
2016	Liao, Z.H. et al.	Effect of juvenile hormone and pyriproxyfen treatments on the production of Spodoptera litura nuclear polyhedrosis virus	Entomologia Experimentalis et Applicata, 161 2, 112-120
2018	Liu, Z.H. et al.	A small heat shock protein 21 (sHSP21) mediates immune responses in Chinese oak silkworm Antheraea pernyi	International Journal of Biological Macromolecules, 111 1027-1031
2016	Mei H.Z. et al.	Molecular cloning, expression, purification and characterization of a novel cellulase gene (Bh-EGaseI) in the beetle Batocera horsfieldi	Gene, 576 1, 45-51
2010	Mengual Gómez, D. L. et al.	Effects of Fetal Bovine Serum deprivation in cell cultures on the production of Anticarsia gemmatalis Multinucleopolyhedrovirus	BMC Biotechnology, 10
2017	Mohammadi, A. et al.	Biochar addition in rice farming systems: Economic and energy benefits	Energy, 140 415-425
2007	Nicholson, G. M.	Fighting the global pest problem: Preface to the special Toxicon issue on insecticidal toxins and their potential for insect pest control	Toxicon, 49 4, 413-422
2013	Oh., S. et al.	Molecular and immunohistochemical characterization of granulin gene encoded in Pieris rapae granulovirus genome	Journal of Invertebrate Pathology, 113 1, 7-17
2013	Oh., S. et al.	Molecular and immunohistochemical characterization of the chitinase gene from Pieris rapae granulovirus	Archives of Virology, 158 8, 1701-1718
2014	Opoku-Debrah, J. K. et al.	Comparison of the biology of geographically distinct populations of the citrus pest, Thaumatotibia leucotreta (Meyrick) (Lepidoptera: Tortricidae), in South Africa	African Entomology, 22 3, 530-537
2017	Patil, S.B. et al.	Sustainable management of chickpea pod borer. A review	Agronomy for Sustainable Development, 37 3,
2016	Prasad, V. et al.	Insect Viruses	Ecofriendly Pest Management for Food Security, 411-442
2010	Progar, R.A. et al.	Nuclear polyhedrosis virus as a biological control agent for Malacosoma americanum (Lepidoptera: Lasiocampidae)	Journal of Economic Entomology, 99 4, 1129-1137
2006	Rajendra, W. et al.	Functional expression of lepidopteran-selective	Journal of Applied Entomology, 134 8, 641-

Year	Author	Title	Journal
		neurotoxin in baculovirus: Potential for effective pest management	646
2014	Ramanujam, B. et al.	Management of insect pests by microorganisms	Biochimica et Biophysica Acta - General Subjects, 1760 2, 158-163
2009	Ranjit, N. et al.	Proteolytic degradation of hemoglobin in the intestine of the human hookworm necator Americanus	Proceedings of the Indian National Science Academy, 80 2, 455-471
2005	Shao, L. et al.	Identification and characterization of a novel peritrophic matrix protein, Ae-Aper50, and the microvillar membrane protein, AEG12, from the mosquito, Aedes aegypti	Insect Biochemistry and Molecular Biology, 35 9, 947-959
2006	Szewczyk, B. et al.	Baculoviruses - Re-emerging biopesticides	Biotechnology Advances, 24 2, 143-160
2017	Thompson, R.E. et al.	Tyrosine sulfation modulates activity of tick-derived thrombin inhibitors	Nature Chemistry, 9 9, 909-917
2006	Trösken, E.R., et al.	Comparison of lanosterol-14α-demethylase (CYP51) of human and Candida albicans for inhibition by different antifungal azoles	Toxicology, 228 1, 24-32
2013	Walker, J. T. S. et al.	Codling moth (Cydia pomonella) mating disruption outcomes in apple orchards	New Zealand Plant Protection, 66 259-263
2018	Wang, Y. et al.	Genome analysis of a novel Group I alphabaculovirus obtained from Oxyplax ochracea	PLoS ONE, 13 2
2011	Wang, Y. et al.	Genomic sequence analysis of granulovirus isolated from the Tobacco cutworm, spodoptera litura	PLoS ONE, 6 11
2012	Wearing, C. H. et al.	Codling moth, Cydia pomonella L., olonization of a newly-planted organic pome fruit orchard in Central Otago, New Zealand, and methods of pest management over the first ten years	Crop Protection, 40 105-113
2010	Wu, J. et al.	Economic feasibility of a woody biomassbased ethanol plant in central Appalachia	Journal of Agricultural and Resource Economics, 35 3, 522-544
2010	Xiang, Y., et al.	Comparative analysis of the composition of dominant intestinal microflora in silkworm reared with different forages	Shengtai Xuebao/ Acta Ecologica Sinica, 30 14, 3875-3882
2008	Yamaji, H. et al.	Production of functional antibody Fab fragment by recombinant insect cells	Biochemical Engineering Journal, 41 3, 203-209
2005	Young, V.L. et al.	Characterization of an exochitinase from Epiphyas postvittana nucleopolyhedrovirus (family Baculoviridae)	Journal of General Virology, 86 3253-3261
2017	Zamora-Avilès, N. et al.	Genetic and Biological Characterization of Four Nucleopolyhedrovirus Isolates Collected in Mexico for the Control of Spodoptera exigua (Lepidoptera: Noctuidae)	Journal of Economic Entomology, 110 4, 1465-1475
2015	Zhang, H. et al.	Functional analysis of a novel cysteine-rich antimicrobial peptide from the salivary glands of the tick Rhipicephalus haemaphysaloides	Parasitology Research, 114 10, 3855-3863

B.7.5 References relied on

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	Previously submitted Y/N* If Y => old data point
KMA 6.1	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 BVL-3415107, BVL-3538405, RIP2006-1339, BWS2003-90	no	no	not protected	-	Y KIIM 6.1
KMA 6.1/01	Anonymous	2016	LITERATURE REVIEW REPORT ON CYDIA POMONELLA GRANULOVIRUS - RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED Arysta LifeScience S.A.S., not applicable Arysta Lifescience, France GLP/GEP: no Published: no BVL-3306480, ASB2017-11932	no	yes	New data for existing formulation, not previously submitted nor evaluated	ALS	N
KMA 6.1/02	Jeyarani, S., Sathiah, N., Karuppuchamy, P.	2013	AN IN VITRO METHOD FOR INCREASING UV-TOLERANCE IN A STRAIN OF HELICOVERPA ARMIGERA (LEPIDOPTERA: NOCTUIDAE) NUCLEOPOLYHEDROVIRUS not available, not applicable Biocontrol Science and Technology, 23, 305-316 GLP/GEP: no Published: yes BVL-3306481, ASB2017-11931	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	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 6.1/03	Prater, C.A., Redmond, C.T., Barney, W., Bonning, B.C., Potter, D.A.	2006	MICROBIAL CONTROL OF BLACK CUTWORM (LEPIDOPTERA: NOCTUIDAE) IN TURFGRASS USING AGROTIS IPSILON MULTIPLE NUCLEOPOLYHEDROVIRUS not available, not applicable Journal of Economic Entomology, 99, 1129-1137 GLP/GEP: no Published: yes BVL-3306482, ASB2017-11933	no	no	not protected	-	N
KMA 6.1/04	Pessoa, V., Cunha, F., de Freitas Bueno, A., Ceolin Bortolotto, O., Monteiro, T., Ramos, V.M.	2014	VELVET-BEAN NUCLEOPOLYHEDROVIRUS PERSISTENCE AFTER DIFFERENT RAINFALL INTENSITIES not available, not applicable Ciencia Rural, 44, 5-10 GLP/GEP: no Published: yes BVL-3306483, ASB2017-11934	no	no	not protected	-	N