

Renewal Assessment Report

***Cydia pomonella* GV**

Madex Twin

Volume 3 – B.3 Data on application and efficacy

Rev. 0 – 16 October 2020

Rapporteur Member State: Germany

Co-Rapporteur Member State: The Netherlands

Version history

When	What
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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.3 Data on application and efficacy

B.3.1 Field of use envisaged

MADEX TWIN is an insecticide with activity against the Oriental fruit moth (*Grapholita molesta* Busck) and the Codling moth (*Cydia pomonella* L.) in orchards and in home gardens. No supported uses against *Cydia pomonella* are claimed.

B.3.2 Mode of action

Cydia pomonella Granulovirus isolate V-22 is able to infect the larval stages of the codling moth and the oriental fruit moth. Infection of the larvae starts after oral ingestion of the occlusion bodies of the virus by feeding. The occlusion bodies solubilise in the alkaline pH in the insect's midgut releasing the virions. Virions pass the peritrophic membrane of the midgut and finally fuse with the membrane of the midgut epithelial cells where the virus is able to replicate. After replication, the virus leaves the midgut cells by budding through the cell membrane, forming so-called budded viruses. Budded viruses are able to enter other cells by membrane fusion and spread the infection to other body tissues of the larva. At the late stage of virus infection new occlusion bodies are formed inside the cells. Eventually cells greatly enlarge and burst, releasing new occlusion bodies of the virus. Please refer to Section B.2.2.2 of Volume 3 MA for more detailed information on MoA.

B.3.3 Details of intended use

Please note that the original DAR was restricted to the Mexican isolate, CpGV-M, of *Cydia pomonella* Granulovirus. Hence, Madex Twin was not included in the original authorization process.

Table B.3.3-1: Summary of intended uses of

GAP rev. 1, date: 2021-January-15

Active Substance:

MADEX TWIN *Cydia pomonella* Granulovirus (CpGV-V22)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s. /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		

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Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s. /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Stone fruit (apricot, peach, nectarine, almond, plum)	EU	MADEX TWIN	F	Oriental fruit moth (<i>Grapholitha molesta</i>)	SC	3 × 10 ¹³ GV/L	Foliar spray (tractor drawn)	Before first larvae hatch from eggs (BBCH 71-89)	12	6-8* ²	0.1 l product / ha / application* ³	800	0.3 × 10 ¹³ GV/ha	-	
Stone fruit (apricot, peach, nectarine, almond, plum)	EU	MADEX TWIN	F	Oriental fruit moth (<i>Grapholitha molesta</i>)	SC	3 × 10 ¹³ GV/L	Foliar spray (Knapsack sprayer)	Before first larvae hatch from eggs (BBCH 71-89)	12	6-8* ²	0.1 l product / ha / application* ³	800	0.3 × 10 ¹³ GV/ha	-	Home gardening

*² sunny days, counting 2 partially sunny days as 1 day*³ This application rate of 0.1 L/ha corresponds to 0.0875 L/ha LWA (leaf wall area).

<p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypryr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialicarb-isopropyl).</p> <p>(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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B.3.4 Application rate

Crop	Method of application	Rate of application per unit treated (as preparation)	Rate of application per unit treated (as active substance)
Stone fruit (F)	Foliar spray	0.1 L product / ha (max. rate per appl.) 1.2 L product / ha (max. rate per crop/season)	0.3 x 10 ¹³ GV / ha (max. rate per appl.) 3.6 x 10 ¹³ GV / ha (max. rate per crop/season)
Stone fruit (HG)	Foliar spray	0.1 L product / ha (max. rate per appl.) 1.2 L product / ha (max. rate per crop/season)	0.3 x 10 ¹³ GV / ha (max. rate per appl.) 3.6 x 10 ¹³ GV / ha (max. rate per crop/season)

B.3.5 Content of micro-organism in material used (e.g., in the diluted spray, baits or treated seed)

Crop	Method of application	Material used (e.g. diluted spray, baits, treated seed)	Content of microorganism in material used
Stone fruit (F)	Foliar spray	Water dispersion	0.3 x 10 ¹³ GV / ha (max. rate per appl.) 3.6 x 10 ¹³ GV / ha (max. rate per crop/season)
Stone fruit (HG)	Foliar spray	Water dispersion	0.3 x 10 ¹³ GV / ha (max. rate per appl.) 3.6 x 10 ¹³ GV / ha (max. rate per crop/season)

B.3.6 Method of application

Crop	Method of application	Type of equipment used	Type and volume of diluent per unit of area or volume
Stone fruit (F)	Foliar spray	Tractor drawn	Suspension concentrate, 800 L/ha
Stone fruit (HG)	Foliar spray	Knapsack sprayer	Suspension concentrate, 800 L/ha

B.3.7 Number and timing of applications

Crop	Method of application	Maximum number of applications	Timing of application
Stone fruit (F)	Foliar spray	12	6-8 days

Stone fruit (HG)	Foliar spray	12	6-8 days
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B.3.8 Necessary waiting periods or other precautions to avoid phytopathogenic effects on succeeding crops

Crop	Method of application	Duration of protection afforded by each application
Stone fruit (F)	Foliar spray	Before first larvae hatch from eggs
Stone fruit (HG)	Foliar spray	Before first larvae hatch from eggs

B.3.8.1 Proposed instructions for use

Provided, see document C.

B.3.9 Efficacy data / Effectiveness

MADEX TWIN is a biological insecticide formulated as a suspension concentrate (SC). It contains the active substance *Cydia pomonella* Granulovirus (CpGV) isolate CpGV-V22. MADEX TWIN is to be applied at dose rates of 0.1 L/ha against the Oriental fruit moth (*Grapholita molesta* Busck) in stone fruit and pome fruit and against the Codling moth (*Cydia pomonella* L.) in pome fruits and walnut. This application rate of 0.1 L/ha corresponds to 0.0875 L/ha LWA (leaf wall area).

According to SANCO/12545/2014 rev. 2, efficacy data, i.e., Document M MP 6, is not required for renewal of active substances. The product MADEX TWIN is registered in the EU for the representative uses considered in this dossier. Therefore, it was already evaluated according to Uniform Principles (Regulation (EC) No 546/2011) and all relevant data have been evaluated at zonal and Member State level.

For a summary of current uses of MADEX TWIN, please refer to document D-2.

B.3.9.1 Preliminary tests

see explanation under B.3

B.3.9.2 Testing effectiveness

see explanation under B.3

B.3.10 Information on the development of resistance

MADEX TWIN contains *Cydia pomonella* granulovirus isolate V22 (CpGV-V22). Genetically, CpGV-V22 is closely related to CpGV-M and belongs to the same genome type A as CpGV-M (please refer to Doc MMA, Section 1, Point 1.3). In contrast to CpGV-M and other CpGV isolates, CpGV-V22 is infective to larvae of the oriental fruit moth, *Grapholita molesta* (Tortricidae). Up to date no

resistant *Grapholita molesta* populations have been reported. However, due to the high similarity between the two isolates CpGV-V22 and CpGV-M, it is assumed that similar resistance mechanisms could occur. For instance, cross resistance to different CpGV isolates, e.g. CpGV-M and CpGV-S, was found for resistance type II (Sauer et al. 2017). Therefore, it is recommended that the use of MADEX TWIN should be implemented in avoidance strategies against resistance development. To counteract the resistance, overuse of a single isolate must be avoided and the use of various virus isolates applied. For further details on resistance development, please refer to MMA part B 3.5. The risk of development of resistance is classified as moderate.

B.3.11 Adverse effects on treated crops

B.3.11.1 Effects on the yield of plants or plant products in terms of quantity and/or quality

see explanation under B.3

B.3.11.2 Effects on the quality of plants or plant products

see explanation under B.3

B.3.11.3 Effects on the transformation process

see explanation under B.3

B.3.11.4 Effects on the yield of treated plants or plant products

see explanation under B.3

B.3.11.5 Phytotoxicity to target plants (including different cultivars), or to target plant products

see explanation under B.3

B.3.12 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms, on succeeding crops, other plants or plants used for propagating purposes (e.g. seeds, cuttings, runners)

B.3.12.1 Impact on succeeding crops

see explanation under B.3

B.3.12.2 Impact on other plants, including adjacent crops

see explanation under B.3

B.3.12.3 Impact on treated plants or plant products to be used for propagation

see explanation under B.3

B.3.12.4 Effects on beneficial and other non-target organisms

see explanation under B.3

B.3.13 Other/special studies

see explanation under B.3

B.3.14 Summary and evaluation of efficacy data (3.2)

see explanation under B.3

B.3.15 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 sub- mitted Y/N* If Y => old data point
KMP 3.10	Sauer AJ, Fritsch E, Undorf-Spahn K, Nguyen P, Marec F, Heckel DG, Jehle JA	2017	Novel resistance to Cydia pomonella granulo- virus (CpGV) in codling moth shows autoso- mal and dominant inheritance and confers cross-resistance to different CpGV genome groups, not applicable not applicable, PLoS ONE GLP/GEP: no Published: yes	no	no	not protected		N