

Renewal Assessment Report

***Cydia pomonella* GV**

Madex

Volume 3 – B.3 Data on application and efficacy

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Version history

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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 is an insecticide with activity against the Codling moth (*Cydia pomonella* L.) in orchards and in home gardens.

B.3.2 Mode of action

Cydia pomonella Granulovirus is able to infect the larval stages of the Codling 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 the MoA.

B.3.3 Details of intended use

Please note that currently authorized uses in the EU have different maximum application rate of active substance per treatment of 3×10^{12} GV/ha, which is lower for a factor of 10. Furthermore, in the original DAR maximum application rate of active substance per treatment were at 0.15×10^{13} GV/ha, which is even more less.

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

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

Active Substance:

MADEX *Cydia pomonella* Granulovirus (CpGV, Mexican isolate)

| 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./ha min-max (l) | Water L/ha min-max | kg a.s./ha min-max (l) | | |
| Pome fruit (apple, pear, quince, nashi, <i>Mespilus</i>) Walnut | EU | MADEx | F | Codling moth (<i>Cydia pomonella</i>) | SC | 3 × 10 ¹³ GV/L product | Foliar spray (tractor drawn) | Before first larvae hatch from eggs* ¹ (BBCH 71-89) | 10 | 6 days* ² | 0.1 l product / ha / application | 400-1200 | 0.3 × 10 ¹³ GV/ha | - | The application rate of 0.1 L/ha corresponds to 0.0875 L/ha LWA (leaf wall area) |
| Pome fruit (apple, pear, quince, nashi) Walnut | EU | MADEx | F n | Codling moth (<i>Cydia pomonella</i>) | SC | 3 × 10 ¹³ GV/L product | Foliar spray (Knapsack sprayer) | Before first larvae hatch from eggs* ¹ (BBCH 71-89) | 10 | 6 days* ² | 0.1 l product / ha / application | 400-1200 | 0.3 × 10 ¹³ GV/ha | - | Home gardening Max. tree height: 2 m The application rate of 0.1 L/ha corresponds to 0.0875 L/ha LWA (leaf wall area) |

*¹First treatment 85 degree days after the first warm evening with flight activity. Zero point of development of the codling moth is 10°C.

*²sunny days, counting 2 partially sunny days as 1 day

| | |
|---|--|
| <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. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-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> |
|---|--|

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) |
|------------------------|-----------------------|--|--|
| Pome fruit, Walnut (F) | Foliar spray | 0.1 L product/ha (max. rate per appl.) 1 L product/ha (max. total rate per crop/season) | 0.3 x 10 ¹³ GV/ha (max. rate per appl.) 3 x 10 ¹³ GV/ha (max. rate per crop/season) |
| Pome fruit, Walnut (F) | Foliar spray | 0.1 L product/ha (max. rate per appl.) 1 L product/ha (max. total rate per crop/season) | 0.3 x 10 ¹³ GV/ha (max. rate per appl.) 3 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 |
|------------------------|-----------------------|---|--|
| Pome fruit, Walnut (F) | Foliar spray | Water dispersion | 0.3 x 10 ¹³ GV/ha (max. rate per appl.) 3 x 10 ¹³ GV/ha (max. rate per crop/season) |
| Pome fruit, Walnut (F) | Foliar spray | Water dispersion | 0.3 x 10 ¹³ GV/ha (max. rate per appl.) 3 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 |
|------------------------|-----------------------|------------------------|---|
| Pome fruit, Walnut (F) | Foliar spray | Tractor drawn | Suspension concentrate, 400 -1200 L/ha |
| Pome fruit, Walnut (F) | Foliar spray | Knapsack sprayer | Suspension concentrate, 400 -1200 L/ha |

B.3.7 Number and timing of applications

| Crop | Method of application | Maximum number of applications | Timing of application |
|------|-----------------------|--------------------------------|-----------------------|
|------|-----------------------|--------------------------------|-----------------------|

| | | | |
|---------------------------|--------------|----|--------|
| Pome fruit, Walnut (F) | Foliar spray | 10 | 6 days |
| Pome fruit, Walnut (F) | Foliar spray | 10 | 6 days |

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 |
|---------------------------|------------------------------|--|
| Pome fruit, Walnut (F) | Foliar spray | Before first larvae hatch from eggs |
| Pome fruit, Walnut (F) | Foliar spray | Before first larvae hatch from eggs |

B.3.8.1 Proposed instructions for use

Provided, see documents C.

B.3.9 Efficacy data / Effectiveness

MADEX is a biological insecticide formulated as a suspension concentrate (SC). It contains the active substance *Cydia pomonella* Granulovirus (CpGV). MADEX is to be applied at dose rates of 0.05 to 0.1 L/ha against the Codling moth (*Cydia pomonella* L.) in pome fruit 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 MMP 6, is not required for renewal of active substances. The product MADEX 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, 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 contains *Cydia pomonella* granulovirus isolate M (CpGV-M) belonging to genome type A.

For further details on resistance development, please refer to MMA part B 3.5. In the last years, several cases of reduced efficacy of CpGV-M formulations for the control of *Cydia pomonella* were reported and all over Europe 38 resistant populations of *C. pomonella* have been found. However, resistant populations are not abundant and occurred solely in orchards, where CpGV has been applied as the only plant protection product against *C. pomonella* for years. In laboratory experiments, LD₅₀-values differed by a factor of 1000 between resistant and susceptible laboratory and field strains. In the presence of the virus, resistance could be increased when compared to the initial orchard population. Therefore, further use of CpGV-M or even increased virus rates as a response of the farmer to reduced efficacy of the CpGV-M treatment are likely to lead to an enforcement of resistance in the *C. pomonella* population. The use of MADEX must be implemented in avoidance strategies against resistance development. To counteract the resistance, the use of various virus isolates is recommended. 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

No references relied on.