

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: MADEX DUO**

**Product name: MADEX DUO**

**Active Substance:**

***Cydia pomonella* Granulovirus isolate CpGV-V45  
(GV-0017)**

**Min. 3 x 10<sup>13</sup> OB/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(Marketing authorisation)**

**Applicant:**

**ANDERMATT BIOCONTROL SUISSE AG**

**Date: 22/08/2025**

# Table of Contents

<b>1</b>	<b>DETAILS OF THE APPLICATION.....</b>	<b>3</b>
1.1	APPLICATION BACKGROUND.....	3
1.2	ACTIVE SUBSTANCE APPROVAL.....	3
1.3	REGULATORY APPROACH.....	3
1.4	DATA PROTECTION CLAIMS.....	5
1.5	LETTER(S) OF ACCESS.....	5
<b>2</b>	<b>DETAILS OF THE AUTHORISATION.....</b>	<b>ERREUR ! SIGNET NON DEFINI.</b>
2.1	PRODUCT IDENTITY.....	5
2.2	CLASSIFICATION AND LABELLING.....	5
2.2.1	<i>Classification and labelling in accordance with Regulation (EC) No1272/2008.....</i>	<i>5</i>
2.2.2	<i>Other phrases in compliance with Regulation (EU) No 547/2011.....</i>	<i>6</i>
2.2.3	<i>Other phrases linked to the preparation.....</i>	<i>6</i>
2.3	PRODUCT USES.....	7
<b>3</b>	<b>RISK MANAGEMENT.....</b>	<b>10</b>
3.1	REASONED STATEMENT OF THE OVERALL CONCLUSIONS TAKEN IN ACCORDANCE WITH THE UNIFORM PRINCIPLES.....	10
3.1.1	<i>Physical and chemical properties.....</i>	<i>10</i>
3.1.2	<i>Methods of analysis.....</i>	<i>10</i>
3.1.3	<i>Mammalian Toxicology.....</i>	<i>11</i>
3.1.4	<i>Residues and Consumer Exposure.....</i>	<i>12</i>
3.1.5	<i>Environmental fate and behaviour.....</i>	<i>12</i>
3.1.6	<i>Ecotoxicology.....</i>	<i>12</i>
3.1.7	<i>Efficacy.....</i>	<i>12</i>
3.2	CONCLUSIONS ARISING FROM FRENCH ASSESSMENT.....	14
3.3	SUBSTANCES OF CONCERN FOR NATIONAL MONITORING.....	14
3.4	FURTHER INFORMATION TO PERMIT A DECISION TO BE MADE OR TO SUPPORT A REVIEW OF THE CONDITIONS AND RESTRICTIONS ASSOCIATED WITH THE AUTHORISATION.....	14
3.4.1	<i>Post-authorisation monitoring.....</i>	<i>14</i>
3.4.2	<i>Post-authorisation data requirements.....</i>	<i>14</i>
3.4.3	<i>Label amendments.....</i>	<i>14</i>
	<b>APPENDIX 1 – COPY OF THE FRENCH DECISION.....</b>	<b>15</b>
	<b>APPENDIX 2 – COPY OF THE DRAFT PRODUCT LABEL AS PROPOSED BY THE APPLICANT.....</b>	<b>16</b>
	<b>APPENDIX 3 – LETTER(S) OF ACCESS.....</b>	<b>ERREUR ! SIGNET NON DEFINI.</b>

## PART A – Risk Management

The company ANDERMATT BIOCONTROL SUISSE AG has requested marketing authorisation in France for the product MADEX DUO, containing minimum  $3 \times 10^{13}$  OB (occlusion bodies)/L *Cydia pomonella* granulovirus isolate CpGV-V45 (GV-0017) for use as an insecticide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to MADEX DUO where those data have not been considered in the EU peer review process. Otherwise, assessments for the safe use of MADEX DUO have been made using endpoints agreed in the EU peer review(s) of *Cydia pomonella* granulovirus.

This document describes the specific conditions of use and labelling required for France for the registration of MADEX DUO.

Appendix 1 of this document provides a copy of the French Decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

## 1 DETAILS OF THE APPLICATION

### 1.1 Application background

The present registration report concerns the evaluation of ANDERMATT BIOCONTROL SUISSE AG's application to market MADEX DUO in France as an insecticide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

### 1.2 Active substance approval

#### *Cydia pomonella*

Commission Implementing Regulation (EU) No 2023/1756 of 11 september 2023 renewing the approval of the low-risk active substance *Cydia pomonella* granulovirus (CpGV) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011

Specific provisions of Regulation 2023/1756 were as follows:

In this overall assessment Member States shall pay particular attention to:

— the strict maintenance of environmental conditions and quality control analysis during the manufacturing process to be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012,

—the protection of operators and workers, taking into account that microorganisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.

Conditions of use shall include risk mitigation measures, where appropriate.

An EFSA conclusion is available (EFSA Journal 2022;20(11):7630).

A Review Report is available (PLAN/2023/240 RR- Rev 2, 21 July 2023).

### 1.3 Regulatory approach

The present application (2023-2852) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern

zone, taking into account the worst-case uses (“risk envelope approach”)<sup>1</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017<sup>2</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>3</sup>, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>4</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Moreover, the French Order of 12 April 2021<sup>5</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>6</sup> is to supply “minor” crops with registered plant protection products.

Therefore, the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021<sup>7</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop<sup>8</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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<sup>1</sup> SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

<sup>2</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRGI632554A/jo/texte>

<sup>3</sup> REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

<sup>4</sup> COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

<sup>5</sup> SANCO document “guidance document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

<sup>6</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

<sup>7</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

<sup>8</sup> List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

#### 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of MADEX DUO, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

#### 1.5 Letter(s) of Access

Not necessary: the applicant is part of the task force for the renewal of the active substance and has provided letters of access for PPP data.

#### 1.6 Product identity

<b>Product name (code)</b>	MADEX DUO
<b>Authorisation number</b>	2250284
<b>Function</b>	insecticide
<b>Applicant</b>	ANDERMATT BIOCONTROL SUISSE AG
<b>Composition</b>	<i>Cydia pomonella</i> granulovirus isolate CpGV-V45 (GV-0017), 3 × 10 <sup>13</sup> OB/L
<b>Formulation type (code)</b>	Suspension concentrate [Code: SC]
<b>Packaging</b>	PET 50 mL, 100 mL, 200 mL, 500 mL and 1000 mL HDPE-PA 500 mL and 1000 mL - HDPE 5 L, 10 L and 20 L

#### 1.7 Classification and labelling

##### 1.7.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

<b>Physical hazards</b>	None
<b>Health hazards</b>	None
<b>Environmental hazards</b>	No environmental classification
<b>Hazard pictograms</b>	None
<b>Signal word</b>	None
<b>Hazard statements</b>	
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>

<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	Contains <i>Cydia pomonella</i> Granulovirus. Micro-organisms may have the potential to provoke sensitising reactions.
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See Part C for justifications of the classification and labelling proposals.

### 1.7.2 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres <sup>9</sup> to surface water bodies for the uses on pome fruit, stone fruit and walnut.

### 1.7.3 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>10</sup> : refer to the Decision in Appendix 1 for the details
Re-entry period <sup>11</sup> : 6 hours
Pre-harvest interval <sup>12</sup> : not necessary
Other mitigation measures: - product must be store at a temperature inferior at 5°C
The label may include the following recommendations:  <b>Agricultural recommendations:</b> In order to limit the risk of resistance, it would be recommended to avoid to treat 2 successive generations of the target with a product based on <i>Cydia pomonella</i> GranuloVirus and it would be recommended to alternate the type of isolate in the best possible way.  The label must reflect the conditions of authorisation.

<sup>9</sup> The legal basis for this is **Titre III Article 12** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

<sup>10</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

<sup>11</sup> The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

<sup>12</sup> According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

## 1.8 Product uses

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: **22/08/2025**

PPP (product name/code): **MADEX DUO**  
 Active substance 1: *Cydia pomonella granulovirus GV-0017*  
 Applicant: **ANDERMATT BIOCONTROL SUISSE AG**  
 Zone(s): southern <sup>(d)</sup>  
 Verified by MS: yes  
 Field of use: insecticide

Formulation type: **SC** <sup>(a, b)</sup>  
 Conc. of as 1: **3 x 10<sup>13</sup> OB/L** <sup>(c)</sup>  
 Professional use: ☒  
 Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha  RMS CONCLUSION <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Pome fruit crops (3PMFC)	F	<i>Cydia pomonella</i> (CARPPO), <i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a)15 b) 15	6	a) 3 × 10 <sup>12</sup> OB/ha b) 4.5 × 10 <sup>13</sup> OB/ha	400 / 1600	Not relevant	not necess ary	Acceptable
1	FR	Pome fruit crops (3PMFC)	F	<i>Cydia pomonella</i> (CARPPO), <i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 30 b) 30	6	a) 3 × 10 <sup>12</sup> OB/ha b) 9 × 10 <sup>13</sup> OB/ha	400 / 1600	Not relevant	not necess ary	Not acceptable (efficacy)
2	FR	Walnut (IUGRE)	F	<i>Cydia pomonella</i> (CARPPO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 15 ( b) 15 (	6	a) 3 × 10 <sup>12</sup> OB/ha b) 4.5 × 10 <sup>13</sup> OB/ha	400 / 1600	Not relevant	not necess ary	Acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha  RMS CONCLUSION <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
2	FR	Walnut (IUGRE)	F	<i>Cydia pomonella</i> (CARPPO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 30 b) 30	6	a) $3 \times 10^{12}$ OB/ha b) $9 \times 10^{13}$ OB/ha	400 / 1600	Not relevant	not necess ary	<b>Not acceptable</b> (efficacy)
3	FR	Almond crops (3ALMC): almond	F	<i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 15 b) 15	6	a) $3 \times 10^{12}$ OB/ha b) $4.5 \times 10^{13}$ OB/ha	400 / 1600	Not relevant	not necess ary	<b>Acceptable</b>
3	FR	Almond crops (3ALMC): almond	F	<i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 30 b) 30	6	a) $3 \times 10^{12}$ OB/ha b) $9 \times 10^{13}$ OB/ha	400 / 1600	Not relevant	not necess ary	<b>Not acceptable</b> (efficacy)
4	FR	Stone fruit crops (3STFC): Peach/apricot	F	<i>Cydia pomonella</i> (CARPPO), <i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 15 b) 15	6	a) $3 \times 10^{12}$ OB/ha b) $4.5 \times 10^{13}$ OB/ha	400 / 1600	Not relevant	not necess ary	<b>Acceptable</b>
4	FR	Stone fruit crops (3STFC): Peach/apricot	F	<i>Cydia pomonella</i> (CARPPO), <i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 30 b) 30	6	a) $3 \times 10^{12}$ OB/ha b) $9 \times 10^{13}$ OB/ha	400 / 1600	Not relevant	not necess ary	<b>Not acceptable</b> (efficacy)
5	FR	Stone fruit crops (3STFC): Plum	F	<i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 15 b) 15	6	a) $3 \times 10^{12}$ OB/ha b) $4.5 \times 10^{13}$ OB/ha	400 / 1600	Not relevant	not necess ary	<b>Acceptable</b>



1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha  RMS CONCLUSION <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha  a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
5	FR	Stone fruit crops (3STFC): Plum	F	<i>Grapholita molesta</i> (LASPMO)	Spraying (tractor drawn motor sprayer / knapsack sprayer)	Before first larvae hatch from eggs <sup>1)</sup>	a) 30 b) 30	6	a) $3 \times 10^{12}$ OB/ha b) $9 \times 10^{13}$ OB/ha	400 / 1600	Not relevant	not necess ary	<b>Not acceptable</b> (efficacy)

**Remarks  
table  
heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
 (b) Catalogue of pesticide formulation types and international coding system CropLife  
 International Technical Monograph n°2, 6th Edition Revised May 2008  
 (c) g/kg or g/L

- (d) Select relevant  
 (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be  
 given in column 1  
 (f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed  
 out when the notifier no longer supports this use.

**Remarks  
columns:**

- 1 Numeration necessary to allow references  
 2 Use official codes/nomenclatures of EU Member States  
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use  
 situation should be described (e.g. fumigation of a structure)  
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-  
 professional field use, G: professional greenhouse use, Gn: non-professional greenhouse  
 use, Gpn: professional and non-professional greenhouse use, I: indoor application  
 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the  
 common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar  
 fungi, weeds) and the developmental stages of the pests and pest groups at the moment of  
 application must be named.  
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants -  
 type of equipment used must be indicated.  
 7 Growth stage at first and 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  
 8 The maximum number of application possible under practical conditions of use must be provided.  
 9 Minimum interval (in days) between applications of the same product  
 10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty  
 rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g,  
 kg or L product / ha).  
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be  
 mentioned under "application: method/kind".  
 13 PHI - minimum pre-harvest interval  
 14 Remarks may include: Extent of use/economic importance/restrictions

## **2 RISK MANAGEMENT**

### **2.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles**

#### **2.1.1 Physical and chemical properties**

MADEX DUO is a grey-brown liquid with containing more than  $3 \times 10^{13}$  OB/L of CpGV-GV-0017 (SC). The preparation is not considered to have oxidising and explosive properties. MADEX DUO is neither highly flammable, nor auto-flammable. The pH value of a 1 % aqueous dilution of the preparation is 6.46.

Storage at 0 °C during 7 days has no effect on the stability of the preparation. Study on shelf-life following storage at 5°C during 12 months in commercial packaging was provided and considered as acceptable. As the product MADEX TWIN is produced with the same co-formulants, with the same manufacturing process and at the same plant location, we can consider that the results who will obtained for the product MADEX TWIN would be extrapolated to MADEX DUO. Study on shelf life of MADEX TWIN following storage at 5°C during 24 months in commercial packaging was provided and considered as acceptable.

The MADEX DUO product must be store at a temperature inferior at 5°C (indicated on label).

The formulation is classified as a surface active. After dilution, the preparation forms foam in acceptable limit. Suspensibility and pourability of the preparation are in acceptable limit. At wet sieve test study, 1.1% residues were retained on a 75 µm sieve (acceptable limit).

Its technical characteristics are acceptable for a *capsule suspension* formulation.

The formulation contains <10 % hydrocarbons.

The formulation does not contain co-formulates classified H304 cat.1 >10 %

MADEX DUO is used at the concentration of 0.003125 to 0.025 % v/v

#### **2.1.2 Methods of analysis**

##### **3.1.2.1 Analytical method for the formulation**

MADEX TWIN was one of the representative formulations in the EU review of CpGV. Analytical methods for determination of CpGV and impurities in MADEX TWIN were evaluated as part of the EU review of CpGV. The methods are considered adequate. These methods are applicable for MADEX DUO because MADEX TWIN contains the same components as MADEX DUO, with the only exception that another CpGV isolate is used.

##### **3.1.2.2 Analytical methods for residues**

The nature of the product and its active substance are not adequately described and assessed by applying the term 'residue', or by quantifying 'residues', since this definition commonly implies a toxicological concern of the residual deposit of a plant protection product, which is not attributable to CpGV, for the following reasons:

- CpGV is of natural origin and not genetically modified. It belongs to the family of Baculoviridae, which are naturally present in our environment. Therefore, their application in pest control means only a fluctuation of the virus titre in the biotope of the pest insect.
- Baculoviruses are highly arthropod-specific viruses, which are not harmful to non-arthropods, including domestic animals and humans.
- The experience that contact of baculoviruses with humans or animals does not involve any risk for their health has been confirmed by numerous acute and subacute toxicity studies. In addition, tests with mammalian cell cultures as well as studies on mutagenicity, teratogenicity and carcinogenicity all gave negative results.
- Baculoviruses do not produce toxins or secondary metabolites of toxicological concern.
- Baculoviruses are unable to enter plant tissues and to infest them. They are also unable to multiply on plant surfaces.
- Baculoviruses and especially CpGV are rapidly inactivated by the UV-portion in sunlight. Stable virus deposits, therefore, are not assumed.

- In general, the period between MADEX DUO application and harvest is several weeks and certainly enough for avoiding relevant residues on the harvested fruits.

*Cydia pomonella granulovirus* (CpGV) is not pathogenic to humans and is not expected to produce toxins that are relevant for human health. In view of those conclusions, the Commission considers that the inclusion of such substance in Annex IV to Regulation (EC) No 396/2005 is appropriate (please refer to 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)). In consequence no MRL are required in crops, in foodstuffs and feeding stuffs, in animal and human body tissues and fluids. Additionally, no residue definition is proposed for environmental matrices (soil, water and air). Therefore, methods for the determination and quantification of residues are currently not required.

### **2.1.3 Mammalian Toxicology**

The derivation of reference values was not necessary based on the absence of toxicity, infectivity and pathogenicity indications of the micro-organism.

#### **2.1.3.1 Acute Toxicity**

MADEX DUO has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the skin or eye and is not a skin sensitiser.

#### **3.1.3.2 Operator Exposure**

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not necessary (EFSA Journal 2022;20(11):7630). Therefore, no unacceptable risk for operators is expected following the claimed uses.

Taking into account that microorganisms are per se considered as potential sensitisers, adequate personal protective equipment is necessary as a condition of use.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

#### **3.1.3.3 Bystander Exposure**

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not necessary (EFSA Journal 2022;20(11):7630). Therefore, no unacceptable risk for bystanders is expected following the claimed uses.

#### **3.1.3.4 Worker Exposure**

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not necessary (EFSA Journal 2022;20(11):7630). Therefore, no unacceptable risk for workers is expected following the claimed uses.

Taking into account that microorganisms are per se considered as potential sensitisers, adequate personal protective equipment is necessary as a condition of use.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

#### **3.1.3.5 Resident Exposure**

Based on the lack of significant toxicity, infectivity and pathogenicity potential in the available studies, the setting of reference values is not necessary (EFSA Journal 2022;20(11):7630). Therefore, no unacceptable risk for residents is expected following the claimed uses.

#### 2.1.4 Residues and Consumer Exposure

In the framework of EU evaluations on Baculovirus (Review report 'PLAN/2023/240 RR – Rev. 2) and EFSA conclusions (EFSA Journal 2022;20(11):7630), it was concluded that:

- CpGV are not pathogenic to humans or mammals.
- *Cydia pomonella* GV (CpGV) are not able to produce antimicrobial substances, toxins or secondary metabolites,
- Baculoviruses are not infective for mammals, replication does not occur in mammalian cells, and they do not produce any metabolites and toxins.
- No pathogenic, genotoxic, mutagenic, or carcinogenic effects of baculoviruses were ever observed in mammals,
- Based on the lack of significant toxicity, infectivity or pathogenicity in the available toxicological studies the setting of dietary toxicological values was not relevant.

Consequently, *Cydia pomonella* granulovirus was included in Annex IV of Regulation (EC) No 396/2005. Therefore, it is considered that the risk of residue on pome fruits, walnuts and stone fruits can be considered as negligible and that no further information is considered necessary.

In the preparation MADEX DUO, contamination with *Bacillus cereus* is within the acceptable limits established for the manufacturing plant protection product. ( $<10^7$  CFU/g).

Consequently, it can be concluded that the intended uses of MADEX DUO do not represent a risk for the consumer.

#### 2.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

*C. pomonella* granulovirus is naturally present in the environment. According to the available information in the literature, *C. pomonella* granulovirus does not produce metabolites of concern.

PECsoil and PECsw derived for the active substance are used for the eco-toxicological risk assessment. No unacceptable risk of groundwater contamination for microorganism is expected for the intended uses.

#### 2.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and their metabolite were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.2.2.

#### 2.1.7 Efficacy

##### Considering the data submitted:

The effectiveness level of MADEX DUO at 0.1 L/ha with a maximum of 15 applications against *Cydia pomonella* on pome fruits and walnuts is considered acceptable for this type of product based on microorganisms.

The effectiveness level of MADEX DUO at 0.1 L/ha with a maximum of 15 applications against *Grapholita molesta* is considered acceptable for this type of product based on microorganisms.

**However, as the interest of the 30 applications claimed at 0.05 L/ha has not been demonstrated for these same uses in the current resistance context, the assessment cannot be finalized for the 30 applications at the specific dose of 0.05 L/ha.**

The phytotoxicity level of MADEX DUO is considered negligible for all the requested uses.

The risks of negative impact on yield, quality, transformation processes (cider-making) and propagation are considered negligible.

The risk of negative impact on adjacent crops is considered negligible.

There is a risk of resistance to CpGV GV-0017 for *Cydia pomonella* requiring a monitoring.

In the current context of resistance, the level of effectiveness of the product on based on *Cydia pomonella* GranuloVirus could be affected locally. **Consequently, it would be recommended to avoid to treat 2 successive generations of the target with a product based on *Cydia pomonella* GranuloVirus, and to alternate the type of isolate in the best possible way.**

In order to limit the resistance risk, agricultural recommendations are proposed.

### **Resistance monitoring data**

A monitoring of resistance to CpGV GV-0017 for *Cydia pomonella* should be put in place.

A report on the results of the survey put in place for all products based on this substance should be provided at the time of the demand of renewal for the product.

### **Agricultural recommendations**

**It would be recommended to avoid to treat 2 successive generations of the target with a product based on *Cydia pomonella* GranuloVirus, and to alternate the type of isolate in the best possible way.**

## **2.2 Conclusions arising from French assessment**

Taking into account the above assessment, an **authorisation can be granted** as proposed in Appendix 1 – Copy of the product Decision.

## **2.3 Substances of concern for national monitoring**

No information stated.

## **2.4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation**

### **2.4.1 Post-authorisation monitoring**

A monitoring of resistance to CpGV GV-0017 for *Cydia pomonella* should be put in place.

A report on the results of the survey put in place for all products based on this substance should be provided at the time of the demand of renewal for the product.

### **2.4.2 Post-authorisation data requirements**

The French Decision requests the submission of post-authorisation confirmatory pieces of information:

- none

### **2.4.3 Label amendments**

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

## **Appendix 1 – Copy of the French Decision**



MADEXDUO\_PAMM\_  
2023-2852\_D.pdf

## Appendix 2 – Copy of the draft product label as proposed by the applicant



# Madex® Duo

## Insecticide de biocontrôle

Virus de la granulosose de *Cydia pomonella*, isolat GV-0017 : 3 x 10<sup>13</sup> corps viraux/L.

Traitement des parties aériennes fruits à noyau, à pépins, et à coque contre les chenilles foreuses des fruits : *Cydia pomonella* et *Grapholita molesta* : **0,1 L/ha**. Formulation : suspension concentrée (SC).

AMM N°XXXXXX par Andermatt Biocontrol Suisse AG, Stahlermatten 6, 6146 Grossdietwil, Suisse.

Produit utilisable en Agriculture Biologique selon la réglementation en vigueur.

# 1L

**Dose d'emploi :** La dose maximale à appliquer est de 0,1 L / ha.

**Recommandations d'emploi :** Madex® Duo est efficace sur les jeunes larves du **carpeographe et tordeuse orientale du pichet**. Madex® Duo peut être appliqué 15 fois par an contre carpeographe des pommes et des poires et 15 fois par an contre tordeuse orientale du pichet. **Délai avant récolte :** aucun / **Délai de Réentré :** aucun / **Zone Non traitée :** 5 mètres / **Peut être dangereux pour les abeilles.** **Application possible durant la floraison et sur les zones de butinage dans les 2 heures qui précèdent le coucher du soleil ou les 3 heures suivant le coucher du soleil.**

**Préparation de la bouillie :** Respecter les conseils de prudence. Remplir la cuve à moitié d'eau, verser directement Madex® Duo puis, compléter le volume de bouillie. Maintenir une agitation efficace pendant la préparation. Après l'utilisation, rincer et nettoyer les appareils soigneusement avec de l'eau conformément à la réglementation en vigueur. Effectuer une pulvérisation homogène avec un volume de bouillie suffisant pour mouiller les feuilles, rameaux et fruits.

**Volume de bouillie appliqué :** Il est essentiel d'effectuer une pulvérisation homogène avec un volume de bouillie suffisant sans provoquer la formation de grosses gouttelettes ou le ruissellement.

**Mode d'action :** Madex® Duo est un baculovirus qui agit par ingestion. Arrivés dans l'intestin des larves, les corps viraux libèrent des virus qui se multiplient et attaquent d'autres tissus du ravageur. Les larves cessent de s'alimenter et meurent en se liquéfiant.

**Compatibilité :** Respecter la législation en vigueur. Ne pas mélanger Madex® Duo avec tout produit pouvant conduire à un pH dans la cuve inférieur à 5 ou supérieur à 8,5 ; Mélange avec

les cuivres : nous consulter.

**Stockage :** Ce produit, d'origine naturelle, est sensible aux conditions de stockage. Stocké dans son emballage d'origine fermé, au froid (réfrigérateur ou chambre froide spécifiques) à 5 °C ou congelé à -18°C, cette préparation se conserve pendant 2 ans. Madex® Duo reste liquide quelle que soit la température et peut être utilisé dès la sortie du congélateur.

**IMPORTANT :** Conduisez sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tout facteur particulier concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces. Le fabricant garantit la qualité des produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise en marché du Ministère chargé de l'Agriculture.

**Précautions d'emploi**

**Premiers soins :** En cas d'inhalation (ceci n'est possible que par exposition à un produit chaud), passer à l'air frais, se reposer, en position à demi-verticale, desserrer les vêtements. Oxygène ou respiration artificielle en cas de difficulté de respiration. Consulter un médecin après une exposition importante. Le traitement symptomatique est conseillé.

**En cas de contact avec la peau :** Retirer les vêtements contaminés. Consulter un médecin en cas d'irritation. Mettre les vêtements à la blanchisserie avant réutilisation. Après un contact avec la peau, lever immédiatement et abondamment à l'eau.

**En cas de contact avec les yeux :** Rincer abondamment à l'eau. Soulever les paupières du globe oculaire pour assurer le rinçage en profondeur. Consulter un médecin en cas d'irritation.

**En cas d'ingestion :** Pas de symptômes ni d'effets typiques connus. Consulter un médecin.

**MADEX® Duo - SANS CLASSEMENT**

Contient *Cydia pomonella* granulovirus. Peut entraîner une réaction de sensibilisation.

- P101 : En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette.

- P102 : Tenir hors de portée des enfants.

- P270 : Ne pas manger, boire ou fumer en manipulant le produit.

- EUH401 : Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

- SP1 : Ne pas polluer l'eau avec le produit ou son emballage. (Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes).

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau.

Pour protéger l'opérateur, porter :

**Pendant le mélange/chargement :**

Gants en nitrile certifiés EN374-3 ; combinaison de travail en polyester 65 %/coton 35% avec un grammage de 230g/m2 ou plus avec traitement déperlant ; EPI partiel (blouse) de catégorie III et de type PB 3 à porter par-dessus la combinaison précitée ; lunettes de sécurité conformes à la réglementation et selon la norme EN166 ; bottes de protection conformes à la réglementation et selon la norme EN13832-3 ; demi-masque filtrant anti-aérosols (EN149) de classe FFP3 ou demi-masque (EN140) connecté à un filtre anti-aérosols (EN143) de classe P3.

**Pendant l'application :**

Combinaison de travail en polyester 65%/coton 35% avec un grammage de 230g/m2 ou plus avec traitement déperlant ; bottes de protection conformes à la réglementation et selon la norme EN13832-3.

**Si application avec tracteur sans cabine :**

Gants en nitrile certifiés EN374-2 à usage unique ; demi-masque filtrant anti-aérosols (EN149) de classe FFP3 ou demi-masque (EN140) connecté à un filtre anti-aérosols (EN143) de classe P3 ; lunettes de sécurité conformes à la réglementation et selon la norme EN166.

**Si application avec tracteur avec cabine :**

Gants en nitrile certifiés EN374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et stockés après utilisation à l'extérieur de la cabine.

**Si application avec une lance ou un pulvérisateur à dos :** Gants en nitrile certifiés EN374-3 réutilisables ; demi-masque filtrant anti-aérosols (EN149) de classe FFP3 ou demi-masque (EN140) connecté à un filtre anti-aérosols (EN143) de classe P3.

**Pendant le nettoyage du matériel de pulvérisation :** Gants en nitrile certifiés EN374-3 ; combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230g/m2 ou plus avec traitement déperlant ; EPI partiel (blouse) de catégorie III et de type PB 3 à porter par-dessus la combinaison précitée ; bottes de protection conformes à la réglementation et selon la norme EN13832-3 ; lunettes de sécurité conformes à la réglementation et selon la norme EN166 ; demi-masque filtrant anti-aérosols (EN149) de classe FFP3 ou demi-masque (EN140) connecté à un filtre anti-aérosols (EN143) de classe P3.

Pour protéger le travailleur, porter une combinaison de travail tissée en polyester 65%/coton 35% avec un grammage de 230g/m2 ou plus avec traitement déperlant.

Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage

dans la cuve du pulvérisateur. Éliminer les emballages vides via un système de collecte spécifique. RÉEMPLOI DE L'EMBALLAGE INTERDIT. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

En cas d'urgence, appeler le 15 ou le centre anti-poison, puis signaler vos symptômes ou réseau Phyt' attitude : N° Vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fiche de données de sécurité disponible via Quick-FDS ou sur demande.

**RESERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL :** Utilisez les produits phytosanitaires avec précaution. Avant toute utilisation, lisez l'étiquette et les informations concernant le produit.

**ANDERMATT FRANCE**

150 chemin de l'Aviation - Domaine du Makila - Bât A - 64200 Bassussarry - Tél. : 05 64 11 51 04 - [contact@andermarkt.fr](mailto:contact@andermarkt.fr) - [www.andermarkt.fr](http://www.andermarkt.fr)

Préparation fabriquée et emballée par Andermatt Biocontrol Suisse AG (Grossdietwil, Suisse), marque déposée ® par Andermatt Group AG.

**Numéro de lot et date de fabrication : voir indications sur le bouchon.**