

# **Renewal Assessment Report**

***Cydia pomonella* GV**

**Madex Twin**

**Volume 3 – B.4 Further information**

**Rev. 0 - 16 October 2020**

**Rapporteur Member State: Germany**

**Co-Rapporteur Member State: The Netherlands**

## Version history

When	What
16 October 2020	First version submitted to EFSA

*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.4 Further information on the plant protection product**

### **B.4.1 Packaging and compatibility of the preparation with proposed packaging materials**

MADEX TWIN contains the new CpGV isolate CpGV-V22 which, in contrast to the other CpGV isolates, also infects larvae of the oriental fruit moth, *Grapholita molesta*. CpGV-M and CpGV-V22 can only be distinguished by molecular genetic methods or by biotests with *G. molesta* larvae. The formulation of MADEX TWIN is identical to the formulation MADEX containing the isolate CpGV-M. MADEX and MADEX TWIN contain the same co-formulants in the same contents, but contain a different virus isolate.

The product MADEX was the representative formulation for the inclusion of *Cydia pomonella* Granulovirus in the list of approved substances of Regulation (EU) 1107/2009.

#### **B.4.1.1 Packaging**

See MADEX, B.4.1.1

#### **B.4.1.2 Packaging suitability**

See MADEX, B.4.1.2

#### **B.4.1.3 Resistance of packaging to contents**

See MADEX, B.4.1.3

### **B.4.2 Procedures for cleaning application equipment**

See MADEX, B.4.2

#### **B.4.2.1 Effectiveness of the cleaning procedures**

See MADEX, B.4.2.1

### **B.4.3 Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment**

#### **B.4.3.1 Pre-harvest intervals, re-entry or withholding periods to minimise residues in crops, plants, plant products, treated areas or spaces**

Pre-harvest interval (in days) for each relevant crop

Crop	Application				
	Formulation (type & content of a.s.)	No.	Rate kg a.s./ha	Spray conc. kg a.s./hl	Proposed pre-harvest interval (days)

Stone fruit (apricot, peach, nectarine, almond, plum)	MADEX TWIN SC-formulation $3 \times 10^{13}$ GV/	1	$0.3 \times 10^{13}$ GV/ha	$0.0375 \times 10^{13}$ /hL	Not authorised in DE
Stone fruit (apricot, peach, nectarine, almond, plum)	MADEX TWIN SC-formulation $3 \times 10^{13}$ GV/	2	$0.3 \times 10^{13}$ GV/ha	$0.0375 \times 10^{13}$ /hL	Not authorised in DE

#### B.4.3.2 Information on any specific agricultural, plant health or environmental conditions under which the preparation may or may not be used

There are no specific conditions under which the preparation may or may not be used.

#### B.4.4 Recommended methods and precautions concerning: handling, storage, transport or fire

##### Reference:

Anonymous (2016), Safety data sheet Madex Twin, Andermatt Biocontrol (BVL no 3306632)

##### B.4.4.1 Handling procedures for the storage

Precautions for safe handling:	The usual precautions for handling chemicals should be observed.
Conditions for safe storage, including any incompatibilities:	Store in original package only. Stored in the refrigerator (< 5°C) for two years. Stored at -18°C for years without any loss of activity.
Specific end use(s):	Biological insecticide

##### B.4.4.2 Transport

Not restricted.

##### B.4.4.3 Fire

Extinguishing media:	Suitable extinguishing media Water mist, alcohol resistant foam, carbon dioxide, dry powder Unsuitable extinguishing media: Water-jet, foam
Special hazards arising from the substance or mixture:	Vapours cause coughing At elevated temperatures (> 200°C), there is a risk of exothermic polymerization. At temperatures > 280°C, acrolein may be formed.
Advice for firefighters:	Avoid contact with oxidizing agents. Cool closed containers with water.

#### **B.4.4.4 Protective clothing and equipment**

General protective and hygienic measures:	The usual precautionary measures for handling chemicals should be observed
Respiratory protection:	No specific recommendations.
Hand protection:	Use protective clothing, chemical-resistant gloves and boots
Eye protection:	No specific recommendations.
Skin and body protection:	No specific recommendations.

#### **B.4.5 Measures in the case of an accident**

##### **Reference:**

Anonymous (2016), Safety data sheet Madex Twin, Andermatt Biocontrol (BVL no 3306633)

#### **B.4.5.1 Containment of spillages**

Person-related precaution measures:	Use protective clothing, chemical—resistant gloves and boots. Do not inhale.
Environment precautions:	Prevent entry into drains, waters, sewages etc. of the product; contact immediately the municipal technical management if the product enters such bodies.
Methods and material for containment and cleaning up:	Use adsorbent material to collect spillage (e.g. sawdust, peat, chemical binder). Place contaminated adsorbent in closable containers. Use a damp cloth to clean floors and other objects after removal of contaminated adsorbent. Also place used cleaning materials into closable receptacles.

#### **B.4.5.2 Decontamination of areas, vehicles and buildings**

See B.4.5.1

#### **B.4.5.3 Disposal of damaged packaging, absorbents and other materials**

Product/packaging disposal:	Use pressure rinsing devices or triple rinsing with water to reduce any product residues in the container to insignificant levels. Don't dispose product or containers on ponds, rivers or ditches. Don't re-use containers for other purposes. Waste disposal and recycling contractors will take cleaned containers. Waste resulting from the use of the product must be disposed on site or on an approved waste disposal facility. Empty the sprayer out in the field being treated by spraying out on to a relatively pest free part of the field left unsprayed or under-dosed for the crop.
Waste codes/waste designations according to LoW:	Not applicable
Waste treatment-relevant information:	None
Sewage disposal-relevant information:	Waste should not be disposed of by release to sewers.
Other disposal recommendations:	None.

#### **B.4.5.4 Protection of emergency worker and residents, including bystanders**

Use the recommended personal protective equipment.

#### **B.4.5.5 First aid measures**

General information:	Change any contaminated or wetted clothing at once. If poisoning occurs contact a doctor or Swiss Toxicology Centre.
After eye contact:	Rinse thoroughly with plenty of water. Eyelids should be held away from the eyeball to ensure thorough rinsing. Seek medical advice if irritation develops.
After skin contact:	Remove contaminated clothing. Seek medical advice if irritation develops. Launder clothes before reuse. After contact with skin, wash immediately with plenty of water.
After inhalation:	Only possible by exposure to HOT product. Move to fresh air, rest, half upright position, loosen clothing. Oxygen or artificial respiration if there is difficulty in breathing. Seek medical advice after significant exposure. Symptomatic treatment is advised.
After ingestion:	No typical symptoms and effects known.
Most important symptoms and effects, both acute and delayed:	No typical symptoms and effects known.
Indication of any immediate medical attention and special treatment needed:	None

#### **B.4.6 Procedures for destruction or decontamination of the plant protection product and its packaging**

##### **New SDS (Kessler, 2016)**

##### **Product/Packaging disposal:**

Use pressure rinsing devices or triple rinsing with water to reduce any product residues in the container to insignificant levels.

Don't dispose product or containers on ponds, rivers or ditches.

Don't re-use containers for other purposes.

Waste disposal and recycling contractors will take cleaned containers.

Waste resulting from the use of the product must be disposed on site or on an approved waste disposal facility. Empty the sprayer out in the field being treated by spraying out on to a relatively pest free part of the field left unsprayed or under-dosed for the crop. Waste should not be disposed of by release to sewers.

##### **B.4.6.1 Controlled incineration**

In accordance with local authority regulations, take to special waste incineration plant.

##### **B.4.6.2 Others**

Not applicable.

## B.4.7 References relied on

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not BVL registration number	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protection is claimed	Owner	Previously submit- ted Y/N*  If Y => old data point
KMP 4.4/01	Kessler, P.	2016	SAFETY DATA SHEET MADEX TWIN Andermatt Biocontrol AG, CH, not stated Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no 3306632	no	no	not protected	ABA	N
KMP 4.5/01	Kessler, P.	2016	SAFETY DATA SHEET MADEX TWIN Andermatt Biocontrol AG, CH, not stated Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no 3306633	no	no	New data for existing formu- lation, not pre- viously submit- ted nor evaluat- ed	ABA	N