

Renewal Assessment Report

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Madex

Volume 3 – B.4 Further information

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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.4 Further information on the plant protection product

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

B.4.1.1 Packaging

Information already presented in the DAR for MADEX:

Reference:

Zingg, D. (2004), Spezifikation der Behälter zu MADEX und Capex - Specification of the containers for MADEX and CAPEX, (PHY2005-561)

MADEX is packaged in 5, 100 and 500 millilitre bottles fitted with a screw cap:

5 mL bottle

Bottle dimensions: 53.2 x 22.5 mm (height x diameter)

Diameter bottleneck: 27 mm

Materials: brown glass

Thread height: 13.7 mm

Thread diameter: 17.75 mm

100 mL bottle

Bottle dimensions: 94 x 48 mm (height x diameter)

Diameter bottleneck: 27 mm

Materials: polyethylene

Cap height: 24 mm

Cap diameter: 32 mm

500 mL bottle

Bottle dimensions: 148 x 82 mm (height x diameter)

Diameter bottleneck: 27 mm

Materials: polyethylene

Cap height: 24 mm

Cap diameter: 32 mm

B.4.1.2 Packaging suitability

Information already presented in the DAR for MADEX:

Reference:

Zingg, D. (2004), Spezifikation der Behälter zu MADEX und Capex - Specification of the containers for MADEX and CAPEX, (PHY2005-561)

Anonymous (2005), Chemical compatibility of PET, PKA, (PHY2006-422)

Taking into account the composition of the product and its physical and toxicological properties, MADEX is characterised as non-reactive and non-hazardous. Nevertheless, further investigations and tests were conducted. The packaging of the formulation MADEX is chemically resistant to a wide range of different chemicals which are more aggressive than MADEX.

B.4.1.3 Resistance of packaging to contents

Information about the packaging has been provided in the storage stability tests. No adverse effects were observed.

B.4.2 Procedures for cleaning application equipment

Information already presented in the DAR for MADEX:

Equipment cleaning procedure:	Rinse application equipment thoroughly with water and spray over already treated area.
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Protective clothing cleaning procedure:	Protective clothing shall be washed in the usual way.
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B.4.2.1 Effectiveness of the cleaning procedures

Information on the effectiveness of the cleaning procedure are missing.

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)
Pome fruit (apple, pear, quince, nashi) Stone fruit (peach, apricot) Walnut	SC 1×10^{13} GV/L		1×10^{13} GV/ha	0.1×10^{13} GV/hL	1
Pome fruit (apple, pear, quince, nashi, <i>Mespilus</i>) Walnut	SC 3×10^{13} GV/L		0.3×10^{13} GV/ha	$0.025 - 0.075 \times 10^{13}$ GV/hL	F
Stone fruit (apricot, peach, nectarine, almond, plum)	SC 3×10^{13} GV/L		0.3×10^{13} GV/ha	0.0375×10^{13} GV/hL	F
Pome fruit (apple, pear, quince, nashi) Walnut	SC 2×10^{13} GV/L		1.5×10^{13} GV/ha	$0.088 - 0.075 \times 10^{13}$ GV/hL	3

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:

Kessler (2016), Safety data sheet Madex, Andermatt Biocontrol (BVL no 3306567)

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 chemical-resistant gloves.
Eye protection:	No specific recommendations
Skin and body protection:	Use protective clothing, chemical-resistant gloves and boots.

B.4.5 Measures in the case of an accident

Reference:

Kessler (2016), Safety data sheet Madex, Andermatt Biocontrol (BVL no 3306568)

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.

	tion if there is difficulty in breathing. Seek medical advice after significant exposure. Symptomatic treatment is advised.
After ingestion:	No typical symptoms and affects known.
Most important symptoms and effects, both acute and delayed:	No typical symptoms and affects 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 protection claimed Y/N	Justification if data protection is claimed	Owner	Previously submitted Y/N* If Y => old data point
KMP 4.1	Zingg, D.	2004	SPECIFICATION OF THE CONTAINERS FOR MADEX AND CAPEX (GERMAN ORIGINAL) Andermatt Biocontrol GmbH / Probis GmbH, not applicable not applicable GLP/GEP: no Published: no PHY2005-561	no	yes	protected	PKA	Y KIIIM 4.1
KMP 4.1	Anonymous	2005a	CHEMICAL COMPATIBILITY OF PET Andermatt Biocontrol GmbH / Probis GmbH, not applicable Owens-Illinois GLP/GEP: no Published: no PHY2006-422	no	no	not protected	PKA	Y KIIIM 4.2
KMP 4.4/01	Kessler, P.	2016	SAFETY DATA SHEET MADEX Andermatt Biocontrol AG, CH, not stated Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no 3306567	no	no	not protected	ABA	N
KMP 4.5/01	Kessler, P.	2016	SAFETY DATA SHEET MADEX Andermatt Biocontrol AG, CH, not stated Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no 3306568	no	no	not protected	ABA	N