

Renewal Assessment Report

***Cydia pomonella* GV**

Madex

Volume 3 – B.2 Physical and chemical properties

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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.2 Physical and chemical properties of the plant protection product MADEX

Formulation: Suspensions concentrate (SC)

For the physical and chemical properties tests the following batches were used:

Batch number: 240 MADEX
Batch number: 331 MADEX
Batch number: 256 MADEX
Batch number: 249 MADEX
Batch number: 271 MADEX
Batch number: 64 CAPEX

The formulation is the same as was evaluated during the first EU-peer review. The studies evaluated in the DAR were reevaluated for renewal and are still considered acceptable by RMS if not stated otherwise.

Data gaps

- Storage stability tests regarding physical and chemical properties and the growth of contaminating micro-organism are missing.
- For the determination of viscosity it has to be either demonstrated that the composition of CAPEX is identical to MADEX or a new study for viscosity is required.

Study	Guideline and method	Test material	Results	Conclusion/ Comment	GLP	Reference
B.2.1 Appearance (MP 2.1)						
Appearance	Visual assessment	MADEX Batchnumber missing	Colour: grey-brown Odour: odourless Physical state: liquid	DAR acceptable	N	Andermatt (2000) PHY2006-382

B.2.2 Storage stability and shelf life (MP 2.2)																											
Storage stability and Shelf life	GIFAP Monograph 17	Batch: 240	<p>Results after storage at 5 °C for 42 months:</p> <p>The product was stored in originally closed Pharma bottles (100 mL Pharma bottle Amber, Owens-Illinois International BV, The Netherlands: article: 02901001A) as they are used for product packaging.</p> <p>Stability of the original test item container (visual):The test item was given in Pharma bottles. No damage of the test item containers was observed</p> <p>Weight change of the test item container: No significant loss in weight was found after storage.</p> <p>Activity of active ingredient: LD₅₀ of the test item was not significantly lower than that of the reference item.</p> <p>Before and after storage the LD₅₀ of the test item is not significantly lower than that of the reference item. Therefore, the test item is considered to be stable when stored for 42 months at 5 °C.</p> <p>.</p> <p>Storage of MADEX at 5 °C - Determination of biological activity by bioassay</p> <table><tr><th>Time [month]</th><th>LD₅₀ of test item MADEX [µL]</th><th>Relative potency of test item to reference item</th></tr><tr><td>0</td><td>73</td><td>1.7</td></tr><tr><td>6</td><td>17</td><td>2.8</td></tr><tr><td>12</td><td>49</td><td>2.8</td></tr><tr><td>18</td><td>42</td><td>1.8</td></tr><tr><td>24</td><td>48</td><td>2.8</td></tr><tr><td>42</td><td>51</td><td>1.7</td></tr></table> <p>Applied method: see B.5 Madex</p>	Time [month]	LD ₅₀ of test item MADEX [µL]	Relative potency of test item to reference item	0	73	1.7	6	17	2.8	12	49	2.8	18	42	1.8	24	48	2.8	42	51	1.7	<p>New study</p> <p>Acceptable only for biological stability. Physical properties determined before and after storage are missing. Contaminating micro-organism determined before and after storage are missing.</p>	Y	Walter (2008) BVL no 3335626
Time [month]	LD ₅₀ of test item MADEX [µL]	Relative potency of test item to reference item																									
0	73	1.7																									
6	17	2.8																									
12	49	2.8																									
18	42	1.8																									
24	48	2.8																									
42	51	1.7																									
Effect of low temperatures on stability	CIPAC MT 39.3	Batch: 331	<p>7 days at 0 °C</p> <p>The formulation does not show any significant changes in the</p>	<p>DAR</p> <p>acceptable</p>	N	Fanger (2007) BVL no 1692517																					

			measured parameters (appearance, colour, odour, suspensibility, wet sieving and packaging stability) during storage of seven days at 0 °C.				
			RMS Renewal: Additional information from the study				
			Before storage	After storage			
	Appearance		Grey brown liquid	Grey brown liquid			
	Suspensibility CIPAC MT 161		105 %	106 %			
	Wet sieve CIPAC MT 59.3		0.8 %	0.9 %			
B.2.3 Explosivity and oxidizing properties (MP 2.3)							
Explosive properties	Statement	-	The formulation is water based and does not have explosive properties.	DAR acceptable	N	Document M III, Section 1, Point 2	
Oxidising properties	Statement	-	The formulation is water based and does not have oxidising properties. The formulants used are without oxidative properties as well.	DAR acceptable	N	Document M III, Section 1, Point 2	
B.2.4 Flash point and other indications of flammability or spontaneous ignition (MP 2.4)							
Flash point	Statement	-	The formulation is water based and is not flammable at all.	DAR acceptable	N	Document M III, Section 1, Point 2	
Flammability			Not relevant as the preparation is a liquid formulation.				
Self-heating	Statement	-	The formulation is water based and is not flammable at all.	DAR acceptable	N	Document M III, Section 1, Point 2	
B.2.5 Acidity, alkalinity and if necessary pH value (MP 2.5)							
Acidity or alkalinity and			Not applicable				

pH						
pH of a 1 % aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Batch: 240	pH of a 1 % dispersion: 6.4 (20.1 °C)	DAR acceptable	Y	Walter (2004) PHY2005-553
B.2.6 Viscosity and surface tension (MP 2.6)						
Viscosity	OECD 114 (capillary viscosimeter)	CAPEX Batch: 64	Instead of MADEX a similar product CAPEX was used. The results are 39 mm ² /s, 25 mm ² /s and 17.1 mm ² /s at 20 °C, 30 °C and 40 °C, respectively.	DAR Acceptable New evaluation Not acceptable Either it has to be demonstrated that the contents of co-formulants in CAPEX is identical to MADEX or a new study for viscosity is required.	Y	Franke (2005) BVL no 1692520
	-	MADEX Batch number missing	1200 mPa s	DAR Not acceptable, since only the value is given.	N	Andermatt (2000) PHY2006-382
Surface tension	EC A.5	Batch: 240	39.9 mN/m at 20 °C (0.1 % aqueous solution)	DAR acceptable	Y	Walter (2004) PHY2005-554
B.2.7 Technical characteristics of the plant protection product (MP 2.7)						
B.2.7.1 Wettability						
Wettability			Not relevant as the preparation is a suspension concentrate (SC).			

B.2.7.2 Persistence foaming						
Persistence of foaming	CIPAC MT 47.2	Batch: 256	50 µL MADEX in 200 mL water: after 10 sec 0 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL	DAR acceptable	N	Fanger (2005) PHY2006-392
B.2.7.3 Suspensibility and suspension stability						
Suspensibility	CIPAC MT 161	Batch: 249	Suspensibility after 30 min of standing (0.25 mL/L): 89.4 %	DAR acceptable	N	Fanger (2005) PHY2005-556
Spontaneity of dispersion	CIPAC MT 160	Batch: 249	Spontaneity of dispersion after 5 min. of standing : 96.7 %	DAR acceptable	Y	Fanger (2005) PHY2005-560
B.2.7.4 Dry sieve test and wet sieve test						
Dry sieve test			Not relevant as the preparation is a suspension concentrate (SC).			
Wet sieve test	CIPAC MT 59.3	Batch: 271	Wet sieve test: 75 µm: 2.5 % residues 100 µm: 1.6 % residues 125 µm: 1.2 % residues 140 µm: 1.1 % residues	DAR acceptable	N	Fanger (2005) PHY2005-557
B.2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)						
Particle size distribution			Not applicable			
Dust content			Not relevant as the preparation is a suspension concentrate (SC).			
Attrition and friability			Not relevant as the preparation is a suspension concentrate (SC).			

B.2.7.6 Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation			Not relevant as the preparation is a suspension concentrate (SC).			
Stability of dilute emulsions and of preparations which are emulsions			Not relevant as the preparation is a suspension concentrate (SC).			
B.2.7.7 Flowability, pourability (rinsability) and dustability						
Flowability			Not relevant as the preparation is a suspension concentrate (SC).			
Pourability	CIPAC MT 148	Batch: 249	Residue: 1.05 % Rinsed residue: 0.16 %	DAR acceptable	N	Fanger (2005) PHY2006-397
Dustability			Not relevant as the preparation is a suspension concentrate (SC).			
B.2.8 Physical, chemical and biological compatibility with other products including plant protection products with which its use is to be authorized (MP 2.8)						
Physical and biological compatibility of tank mixtures			Not applicable (tank mixtures with other pesticides are not recommended)			
B.2.9 Adherence and distribution to seeds (MP 2.9)						
Distribution (seed treatment)			No seed dressing formulation.			
Adherence (seed treatment)			No seed dressing formulation.			

B.2.10 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 2.1	Andermatt, M.	2000	MADEX:FILE OF THE FORMULATED PRODUCT (PHYSICAL AND CHEMICAL PROPERTIES) Andermatt Biocontrol GmbH / Probis GmbH, not ap- plicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no PHY2006-382	no	no	not protected	PKA	Y KIIIM 2.1
KMP 2.2	Fanger, U.	2007	7 DAY STORAGE STABILITY OF MADEX AT 0 °C Andermatt Biocontrol AG, CH, not applicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no 1692517	no	no	not protected	ABA	Y KIIIM 2.2
KMP 2.2	Walter, D.	2008	Final report: Madex - 3.5 year storage stability at 5°C Andermatt Biocontrol AG, CH, 20041161/01-PCTY eurofins-GAB GmbH, Niefern-Öschelbronn, Germany GLP: yes Published: no 3335626	no	yes	New data for existing formu- lation, not pre- viously submit- ted nor evaluat- ed	ABA	N

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 2.5	Walter, D.	2004	PH OF THE FORMULATION MADEX Andermatt Biocontrol GmbH / Probis GmbH, 20041161/01-PCPH GAB Biotechn. GmbH & GAB Analytik GmbH, Niefern-Öschelbronn GLP: yes Published: no PHY2005-553	no	no	not protected	PKA	Y KIIIM 2.3.3
KMP 2.6	Walter, D.	2004	SURFACE TENSION OF THE FORMULATION MADEX Andermatt Biocontrol GmbH / Probis GmbH, 20041161/01-PCST GAB Biotechn. GmbH & GAB Analytik GmbH, Niefern-Öschelbronn GLP: yes Published: no PHY2005-554	no	no	not protected	PKA	Y KIIIM 2.3.4
KMP 2.7.2	Fanger, U.	2005	PERSISTENT FOAM (CIPAC MT47.1) FOAMING OF SUSPENSION CONCENTRATES (CIPAC MT47.2) OF MADEX CAPEX CRYPTEX Andermatt Biocontrol GmbH / Probis GmbH, CIPAC MT 47 Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no PHY2006-392	no	no	not protected	PKA	Y KIIIM 2.4.2
KMP 2.7.3	Fanger, U.	2005	SUSPENSIBILITY (CIPAC MT 161) OF MADEX Andermatt Biocontrol GmbH / Probis GmbH, not applicable Andermatt Biocontrol GmbH, Germany GLP/GEP: no Published: no PHY2005-556	no	no	not protected	PKA	Y KIIIM 2.4.3

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 2.7.3	Fanger, U.	2005c	SPONTANEITY OF DISPERSION (CIPAC MT 160) OF MADEX Andermatt Biocontrol AG, CH, not applicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no PHY2005-560	no	no	not protected	ABA	Y KIIIM 2.4.3
KMP 2.7.4	Fanger, U.	2005d	SIEVE ANALYSIS (CIPAC MT59) OF MADEX CAPEX CRYPTEX Andermatt Biocontrol GmbH / Probis GmbH, not applicable Andermatt Biocontrol AG, Grossdietwil, Switzerland GLP/GEP: no Published: no PHY2005-557	no	no	not protected	PKA	Y KIIIM 2.4.4
KMP 2.7.7	Fanger, U.	2005e	POURABILITY (CIPAC MT 148) OF MADEX CAPEX CRYPTEX Andermatt Biocontrol GmbH / Probis GmbH, not applicable Andermatt Biocontrol GmbH, Germany GLP/GEP: no Published: no PHY2006-397	no	no	not protected	PKA	Y KIIIM 2.4.7