

# **Renewal Assessment Report**

***Cydia pomonella* GV**

**Carpovirusine**

**Volume 3 – B.2 Physical and chemical properties**

**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.2 Physical and chemical properties of the plant protection product CARPOVIRUSINE

Formulation: Suspensions concentrate (SC)

New data is included for CARPOVIRUSINE under each point below. The formulation of CARPOVIRUSINE has changed since first evaluation of CpGV as active substance. Please refer to Doc J (ARY) for details on both compositions. The old formulation of CARPOVIRUSINE has the following code I1136ab / ARY-0453a-03 and was the representative formulation during first evaluation for Arysta LifeScience S.A.S. The new formulation of CARPOVIRUSINE, which is the representative formulation of Arysta LifeScience S.A.S in the dossier for renewal of CpGV as active substance is coded I1136aa / ARY-0453a-04.

Sample of 'ARY-0453a-04' Carpovirusine new formulation:

- Batch number: 2094/Cfr
- Batch number: 2247/Cfr
- Batch number: 2308/Cfr
- Batch number: 2516/Cfr
- Batch number: 2520/Cfr
- Batch number: 2697/Cfr

Open Point:

- Two storage stability tests are currently ongoing and should be provided when finalised.
- For storage studies on biological stability information on packing material is missing.

Study	Guideline and method	Test material	Results	Conclusion/ Comment	GLP	Reference
<b>B.2.1 Appearance (MP 2.1)</b>						
Appearance	Visual assessment	Batch: 2520/Cfr	The sample consisted of a free flowing homogenous liquid with bright red colour (Munsell book of colour reference 5R5/14). No signs of separation or sedimentation were observed. There were some suspended solids observed.	acceptable	Y	Cheng (2013) BVL no 3306327

Study	Guideline and method	Test material	Results	Conclusion/Comment	GLP	Reference																								
B.2.2 Storage stability and shelf life (MP 2.2)																														
Storage stability and shelf life	Internal method	Batch: 2094/Cfr	<p>Biological activity, 24 months at -18 °C. Information on packing material is missing.</p> <p>Statistical comparison of the quotient of the LD<sub>50</sub> values of reference item and test item proved that there was no significant difference between the values obtained for time 0 to 24 months at -18 °C.</p> <p>Therefore, it can be concluded that the activity of CARPOVIRUSINE remained stable when stored at -18 °C over the testing period from beginning of the experiment until 24 months.</p> <p>Content of CpGV in Carpovirusine : 1.2 x 10<sup>13</sup> granules/L</p> <p>Storage of Carpovirusine at -18 °C - Determination of biological activity by bioassay</p> <table><thead><tr><th>Time [month]</th><th>LD<sub>50</sub> Dilution factor of Carpovirusine</th><th>Relative LD<sub>50</sub> of reference CpGV to Carpovirusine</th></tr></thead><tbody><tr><td>0</td><td>4.8 x 10<sup>-8</sup></td><td>0.13</td></tr><tr><td>1</td><td>5.6 x 10<sup>-8</sup></td><td>0.11</td></tr><tr><td>3</td><td>5.6 x 10<sup>-8</sup></td><td>0.10</td></tr><tr><td>6</td><td>8.7 x 10<sup>-8</sup></td><td>0.09</td></tr><tr><td>12</td><td>3.2 x 10<sup>-8</sup></td><td>0.35</td></tr><tr><td>18</td><td>2.9 x 10<sup>-8</sup></td><td>0.77</td></tr><tr><td>24</td><td>3.2 x 10<sup>-8</sup></td><td>0.23</td></tr></tbody></table> <p>All 95% fiducial limits after storage did overlap with those at month 0.</p> <p>Applied method: See B.5 Carpovirusine</p>	Time [month]	LD <sub>50</sub> Dilution factor of Carpovirusine	Relative LD <sub>50</sub> of reference CpGV to Carpovirusine	0	4.8 x 10 <sup>-8</sup>	0.13	1	5.6 x 10 <sup>-8</sup>	0.11	3	5.6 x 10 <sup>-8</sup>	0.10	6	8.7 x 10 <sup>-8</sup>	0.09	12	3.2 x 10 <sup>-8</sup>	0.35	18	2.9 x 10 <sup>-8</sup>	0.77	24	3.2 x 10 <sup>-8</sup>	0.23	Acceptable CpGV is biologically stable during storage of Carpovirusine at – 18 °C. Information on packing material is missing.	Y	Wahl-Ermel/Jehle/ Eberle (2011) BVL no 3306328
	Time [month]	LD <sub>50</sub> Dilution factor of Carpovirusine	Relative LD <sub>50</sub> of reference CpGV to Carpovirusine																											
0	4.8 x 10 <sup>-8</sup>	0.13																												
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18	2.9 x 10 <sup>-8</sup>	0.77																												
24	3.2 x 10 <sup>-8</sup>	0.23																												
	Internal method	Batch:	Biological activity, 12 months at 4°C, Information on packing	Acceptable	Y	Wahl-Ermel/Jehle																								

Study	Guideline and method	Test material	Results	Conclusion/ Comment	GLP	Reference																							
		2308/Cfr	<p>material is missing.</p> <p>Statistical comparison of the quotient of the LD<sub>50</sub> values of Reference Item CpGV-M (Neustadt) and Test Item (CARPOVIRUSINE) proved that there was no significant difference between the values obtained for time 0 to 12 months at 4°C.</p> <p>Therefore, it can be concluded that the activity of CARPOVIRUSINE remained stable when stored at 4°C ± 4°C over the testing period from beginning of the experiment until 12 months.</p> <p>Content of CPGV in Carpovirusine : 1 x 10<sup>13</sup> granules/L</p> <p>Storage of Carpovirusine at 4 °C - Determination of biological activity by bioassay</p> <table><tr><th rowspan="2">Time [month]</th><th colspan="2"></th></tr><tr><th>LD<sub>50</sub> Dilution factor of Carpovirusine</th><th>Relative LD<sub>50</sub> of reference CpGV to Carpovirusine</th></tr><tr><td>0</td><td>4.2 x 10<sup>-7</sup></td><td>0.10</td></tr><tr><td>2</td><td>5.1 x 10<sup>-8</sup></td><td>0.09</td></tr><tr><td>4</td><td>5.5 x 10<sup>-8</sup></td><td>0.08</td></tr><tr><td>6</td><td>2.7 x 10<sup>-8</sup></td><td>0.11</td></tr><tr><td>8</td><td>5.5 x 10<sup>-8</sup></td><td>0.10</td></tr><tr><td>12</td><td>4.8 x 10<sup>-8</sup></td><td>0.07</td></tr></table> <p>All 95% fiducial limits from month 1 to month 12 did overlap. The LD<sub>50</sub> dilution factor for month 1 to month 12 are in the same magnitude of order as was found in the study at -18 °C (see above). The higher LD<sub>50</sub> dilution factor at month 0 was attributed in the study to a dilution error which was also observed for the reference item of CpGV.</p> <p>Applied method: See B.5 Carpovirusine</p>	Time [month]			LD <sub>50</sub> Dilution factor of Carpovirusine	Relative LD <sub>50</sub> of reference CpGV to Carpovirusine	0	4.2 x 10 <sup>-7</sup>	0.10	2	5.1 x 10 <sup>-8</sup>	0.09	4	5.5 x 10 <sup>-8</sup>	0.08	6	2.7 x 10 <sup>-8</sup>	0.11	8	5.5 x 10 <sup>-8</sup>	0.10	12	4.8 x 10 <sup>-8</sup>	0.07	CpGV is biologically stable during storage of Carpovirusine at 4 °C. Information on packing material is missing.		(2012) BVL no 3306329
Time [month]																													
	LD <sub>50</sub> Dilution factor of Carpovirusine	Relative LD <sub>50</sub> of reference CpGV to Carpovirusine																											
0	4.2 x 10 <sup>-7</sup>	0.10																											
2	5.1 x 10 <sup>-8</sup>	0.09																											
4	5.5 x 10 <sup>-8</sup>	0.08																											
6	2.7 x 10 <sup>-8</sup>	0.11																											
8	5.5 x 10 <sup>-8</sup>	0.10																											
12	4.8 x 10 <sup>-8</sup>	0.07																											

Study	Guideline and method	Test material	Results	Conclusion/ Comment	GLP	Reference																																																												
	Internal method	Batch: 2516/Cfr	<p>12 months at -18 °C, 8 month at 4 °C or 1 month at 25 °C. (Packaging material: HDPE 1 L bottle) The concentration in aerobic mesophilic flora is stable throughout the storage duration. Concentration of aerobic mesophilic flora in Carpovirusine 2516/Cfr after storage at -18°C, 4°C and 25°C (method: AFNOR XP V 08-034)</p> <table><tr><th>Time [month]</th><th>- 18 °C</th><th>4 °C</th><th>25 °C</th></tr><tr><td>0</td><td>4.8 x 10<sup>5</sup></td><td>4.8 x 10<sup>5</sup></td><td>4.8 x 10<sup>5</sup></td></tr><tr><td>1</td><td>2.4 x 10<sup>5</sup></td><td>1.9 x 10<sup>5</sup></td><td>4.8 x 10<sup>5</sup></td></tr><tr><td>3</td><td>3.0 x 10<sup>5</sup></td><td>2.1 x 10<sup>5</sup></td><td>-</td></tr><tr><td>6</td><td>3.2 x 10<sup>5</sup></td><td>3.0 x 10<sup>5</sup></td><td>-</td></tr><tr><td>8</td><td>2.6 x 10<sup>5</sup></td><td>7.9 x 10<sup>5</sup></td><td>-</td></tr><tr><td>12</td><td>3.7 x 10<sup>5</sup></td><td>-</td><td>-</td></tr></table> <p>Concentration of <i>Bacillus cereus</i> in Carpovirusine 2516/Cfr after storage at -18°C, 4°C and 25°C (method: NF EN ISO 7932)</p> <table><tr><th>Time [month]</th><th>- 18 °C</th><th>4 °C</th><th>25 °C</th></tr><tr><td></td><td colspan="3">[CFU/g]</td></tr><tr><td>0</td><td>2.2 x 10<sup>5</sup></td><td>2.2 x 10<sup>5</sup></td><td>2.2 x 10<sup>5</sup></td></tr><tr><td>1</td><td>0.5 x 10<sup>5</sup></td><td>2.7 x 10<sup>5</sup></td><td>0.4 x 10<sup>5</sup></td></tr><tr><td>3</td><td>1.4 x 10<sup>5</sup></td><td>1.3 x 10<sup>5</sup></td><td>-</td></tr><tr><td>6</td><td>3.2 x 10<sup>5</sup></td><td>2.7 x 10<sup>5</sup></td><td>-</td></tr><tr><td>8</td><td>0.2 x 10<sup>5</sup></td><td>0.14 x 10<sup>5</sup></td><td>-</td></tr><tr><td>12</td><td>0.4 x 10<sup>5</sup></td><td>-</td><td>-</td></tr></table>	Time [month]	- 18 °C	4 °C	25 °C	0	4.8 x 10 <sup>5</sup>	4.8 x 10 <sup>5</sup>	4.8 x 10 <sup>5</sup>	1	2.4 x 10 <sup>5</sup>	1.9 x 10 <sup>5</sup>	4.8 x 10 <sup>5</sup>	3	3.0 x 10 <sup>5</sup>	2.1 x 10 <sup>5</sup>	-	6	3.2 x 10 <sup>5</sup>	3.0 x 10 <sup>5</sup>	-	8	2.6 x 10 <sup>5</sup>	7.9 x 10 <sup>5</sup>	-	12	3.7 x 10 <sup>5</sup>	-	-	Time [month]	- 18 °C	4 °C	25 °C		[CFU/g]			0	2.2 x 10 <sup>5</sup>	2.2 x 10 <sup>5</sup>	2.2 x 10 <sup>5</sup>	1	0.5 x 10 <sup>5</sup>	2.7 x 10 <sup>5</sup>	0.4 x 10 <sup>5</sup>	3	1.4 x 10 <sup>5</sup>	1.3 x 10 <sup>5</sup>	-	6	3.2 x 10 <sup>5</sup>	2.7 x 10 <sup>5</sup>	-	8	0.2 x 10 <sup>5</sup>	0.14 x 10 <sup>5</sup>	-	12	0.4 x 10 <sup>5</sup>	-	-	acceptable for mesophilic flora and <i>Bacillus cereus</i> at the respective temperatures and times of storage	N	Besse (2014) BVL no 3306330
Time [month]	- 18 °C	4 °C	25 °C																																																															
0	4.8 x 10 <sup>5</sup>	4.8 x 10 <sup>5</sup>	4.8 x 10 <sup>5</sup>																																																															
1	2.4 x 10 <sup>5</sup>	1.9 x 10 <sup>5</sup>	4.8 x 10 <sup>5</sup>																																																															
3	3.0 x 10 <sup>5</sup>	2.1 x 10 <sup>5</sup>	-																																																															
6	3.2 x 10 <sup>5</sup>	3.0 x 10 <sup>5</sup>	-																																																															
8	2.6 x 10 <sup>5</sup>	7.9 x 10 <sup>5</sup>	-																																																															
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Time [month]	- 18 °C	4 °C	25 °C																																																															
	[CFU/g]																																																																	
0	2.2 x 10 <sup>5</sup>	2.2 x 10 <sup>5</sup>	2.2 x 10 <sup>5</sup>																																																															
1	0.5 x 10 <sup>5</sup>	2.7 x 10 <sup>5</sup>	0.4 x 10 <sup>5</sup>																																																															
3	1.4 x 10 <sup>5</sup>	1.3 x 10 <sup>5</sup>	-																																																															
6	3.2 x 10 <sup>5</sup>	2.7 x 10 <sup>5</sup>	-																																																															
8	0.2 x 10 <sup>5</sup>	0.14 x 10 <sup>5</sup>	-																																																															
12	0.4 x 10 <sup>5</sup>	-	-																																																															
Storage stability for 24 months at -18 °C	Guidelines of CropLife International	Batch: 2094/Cfr	<p>24 months at -18 °C to -25 °C Stable for two years at -18 °C to -25 °C in the original packaging (PE containers with screw cap). Additional intermediate results after 12 months and 18 months are included in the report but do not differ significantly from the results presented.</p>	acceptable	Y	Paulus (2011) BVL no 3306331																																																												

Study	Guideline and method	Test material	Results	Conclusion/Comment	GLP	Reference
			No significant changes in the properties of CARPOVIRUSINE were observed over the complete storage period of 24 months at -18 °C to -25 °C. No packaging abnormality and no incompatibility product/packaging was detected.			
			Before storage:			
	Visual assessment		Strawberry red, viscous liquid			
	CIPAC MT 191 (Acidity)		0.89 % H <sub>2</sub> SO <sub>4</sub>			
	CIPAC MT 75.3 (pH)		5.01 (1 % w/v at 25 °C)			
	CIPAC MT 184 (Suspensibility)		100 % (0.1 % w/v in CIPAC water C)			
	CIPAC MT 160 (Spontaneity of dispersion)		109 % (5 % w/v in CIPAC water C)			
	CIPAC MT 185 (Wet sieve)		0 % residue with a 75 µm sieve			
	CIPAC MT 148 (Pourability)		Residue: 0.8 % Rinsing residue: 0.2 %			
		Batch: 2697/Cfr	Study plan Physical-chemical properties of I1136aa product during two years of shelf life at -18 °C (BT289/16) The study is on-going.	Study should be provided as soon as finalised. Contaminating micro-organisms will be determined within this study	Y	Buccella (2016) BVL no 3306337



Study	Guideline and method	Test material	Results	Conclusion/Comment	GLP	Reference
Storage stability for 12 months at 4 °C		Batch: 2308/Cfr	12 months at 4 °C Stable for 12 months at 4 °C in the original packaging (HDPE) Generally, the physical and chemical properties of Carpovirusine as determined in this study have not changed adversely after 12 months storage at 4 °C. The supernatant separation seen after storage is easily re-homogenised. No significant change in the pack appearance and integrity after completion of the storage test and no obvious incompatibility between the product and the packaging.	acceptable	Y	Morgan (2012) BVL no 3306332
			Before storage:			
	Visual assessment		Red, free flowing liquid			
			After storage:			
			Red, free flowing liquid with ~ 50 % reddish supernatant but with no sediment. The supernatant was homogenised in 3 x 360° inversions.			
	CIPAC MT 75.3 (pH)		5.2 (1 % in deionised water)			
	CIPAC MT 184 (Suspensibility)		5.3 (1 % in deionised water)			
	CIPAC MT 160 (Spontaneity of dispersion)		92 % (0.1 % w/v in CIPAC water D)			
	CIPAC MT 185 (Wet sieve)		91 % (5 % w/v in CIPAC water D)			
	CIPAC MT 148 (Pourability)		1.44 % residue with a 75 µm sieve	0.89 % residue with a 75 µm sieve		
			Residue: 0.51 % Rinsing residue: 0.10 %	Residue: 0.57 % Rinsing residue: 0.11 %		
		Batch: 2697/Cfr	Study plan Physical - Chemical properties of I1136AA product before and after 12 months of shelf life at 4°C. The study is on-going.	Study should be provided as soon as finalised Contaminating	Y	Bucella (2016) BVL no 3306336

Study	Guideline and method	Test material	Results		Conclusion/Comment	GLP	Reference
					micro-organisms will be determined within this study		
Storage stability for 7 days at 0 °C	CIPAC MT 39.3	Batch: 2697/Cfr	Stable for 7 days at 0 °C		acceptable	Y	Bucella (2017) BVL no 3306736
			Before storage:	After storage:			
	POS BT228		Aerobic plate count: 1.14 x 10 <sup>6</sup> CFU/mL	Aerobic plate count: 1.16 x 10 <sup>6</sup> CFU/mL			
	POS BT228		<i>Bacillus cereus</i> : 6.77 x 10 <sup>5</sup> CFU/mL	<i>Bacillus cereus</i> : 6.59 x 10 <sup>5</sup> CFU/mL			
	POS BT 235		<i>Escherichia coli</i> : Absent in 1 mL of test item	<i>Escherichia coli</i> : Absent in 1 mL of test item			
	POS BT 235		<i>Salmonella spp.</i> : Absent in 25 mL of test item	<i>Salmonella spp.</i> : Absent in 25 mL of test item			
	POS BT 235		<i>Staphylococcus aureus</i> : Absent in 1 mL of test item	<i>Staphylococcus aureus</i> : Absent in 1 mL of test item			
	POS BT228		Viable yeast and moulds: < 1 CFU/mL	Viable yeast and moulds: < 1 CFU/mL			
	CIPAC MT 184 (Suspensibility)		106.54 % (0.1 % v/v in CIPAC water D)	106.95 % (0.1 % v/v in CIPAC water D)			
	CIPAC MT 160 (Spontaneity of dispersion)		109.76 % (0.1 % v/v in CIPAC water C)	109.88 % (0.1 % v/v in CIPAC water C)			
	CIPAC MT 185 (Wet sieve)		0.59 % residue (75 µm sieve)	0.60 % residue (75 µm sieve)			
Stability after 5 freeze-thaw cycles at -18°C		Batch: 2247/Cfr	Stability after 5 freeze-thaw cycles at -18°C The stability of the formulated product was assessed initially and after 5 freeze-thaw cycles where one cycle consists of a		Additional information (freeze-thaw-	Y	Morgan (2010) BVL no 3306333

Study	Guideline and method	Test material	Results	Conclusion/ Comment	GLP	Reference
			minimum of 24 hours at approx. -18 °C followed by a minimum of 24 hours at +20 °C. Generally, the physical properties of CARPOVIRUSINE have not changed adversely after 5 freeze/thaw cycles. There were no significant change in the pack appearance and integrity after completion of the storage test and not obvious incompatibility between the product and the pack. (1L HDPE bottle with screw cap)	cycles are not a data requirement) acceptable		
			Before storage:			
	Visual assessment		Red, free flowing liquid			
	CIPAC MT 75.3 (pH)		5.1 (1 % in deionised water)			
	CIPAC MT 184 (Suspensibility)		106 % (0.1 % w/v in CIPAC water D at 30 °C)			
	CIPAC MT 160 (Spontaneity of dispersion)		98 % (5 % w/v in CIPAC water D at 30 °C)			
	CIPAC MT 185 (Wet sieve)		0.80 % residue (75 µm sieve)			
	CIPAC MT 148 (Pourability)		Residue: 0.67 % Rinsing residue: 0.23 %			
		Batch: 2697/Cfr	5 freeze-thaw cycles at -18°C (1L HDPE bottle) The stability of the formulated product was assessed initially and after 5 freeze-thaw cycles where one cycle consists of a minimum of 24 hours at approx. -18 °C followed by a minimum of 24 hours at +20 °C.	Additional information (freeze-thaw-cycles are not a data requirement) acceptable	Y	Bucella (2017) BVL no 3306737
			Before storage:			
	POS BT228		Aerobic plate count:			

Study	Guideline and method	Test material	Results		Conclusion/Comment	GLP	Reference
			1.14 x 10 <sup>6</sup> CFU/mL	1.35 x 10 <sup>6</sup> CFU/mL			
	POS BT228		<i>Bacillus cereus</i> : 6.77 x 10 <sup>5</sup> CFU/mL	<i>Bacillus cereus</i> : 6.86 x 10 <sup>5</sup> CFU/mL			
	POS BT 235		<i>Escherichia coli</i> : Absent in 1 mL of test item	<i>Escherichia coli</i> : Absent in 1 mL of test item			
	POS BT 235		<i>Salmonella spp.</i> : Absent in 25 mL of test item	<i>Salmonella spp.</i> : Absent in 25 mL of test item			
	POS BT 235		<i>Staphylococcus aureus</i> : Absent in 1 mL of test item	<i>Staphylococcus aureus</i> : Absent in 1 mL of test item			
	POS BT228		Viable yeast and moulds: < 1 CFU/mL	Viable yeast and moulds: < 1 CFU/mL			
	Container		Plastic bottle (HDPE) of 1 L with screw cap	Plastic bottle (HDPE) of 1 L with screw cap			
	Weight loss		-	0.0035 %			
	Visual assessment		Strawberry red, homogeneous liquid	Strawberry red, homogeneous liquid			
	CIPAC MT 75.3 (pH)		5.75 (1 % v/v)	5.78 (1 % v/v)			
<b>B.2.3 Explosivity and oxidizing properties (MP 2.3)</b>							
Explosive properties	Expert statement	-	Explosive properties of the test item are not expected and therefore the test item should be classified as not explosive.		acceptable	N	Paulus (2010) BVL no 3306340
Oxidising properties	Expert statement	-	Oxidizing properties of the test item are not expected and therefore the test item should be classified as not oxidizing.		acceptable	N	Paulus (2010) BVL no 3306341
<b>B.2.4 Flash point and other indications of flammability or spontaneous ignition (MP 2.4)</b>							
Flash point	EC A.9	Batch:	No flash point could be determined. Boiling and decomposition		acceptable	Y	Paulus (2010)

Study	Guideline and method	Test material	Results	Conclusion/Comment	GLP	Reference
		2094/Cfr	of the test item was observed at > 100 °C.			BVL no 3306342
Flammability			Not relevant as the preparation is a liquid formulation.			
Self-heating	EC A.15	Batch: 2094/Cfr	Auto ignition temperature: 460 °C	acceptable	Y	Paulus (2010) BVL no 3306343
<b>B.2.5 Acidity, alkalinity and if necessary pH value (MP 2.5)</b>						
Acidity or alkalinity and pH			Acidity/alkalinity not required as the preparation is neither strongly acidic (pH < 4) nor strongly alkaline (pH > 10).			
pH of a 1 % aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Batch: 2520/Cfr	6.03 (undiluted at 20 °C) 6.15 (1 % sample dilution in distilled water at 20 °C)	acceptable	Y	Cheng (2013) BVL no 3306344
	CIPAC MT 75.3	Batch: 2094/Cfr	5.01 (1 % w/v at 25 °C)	acceptable	Y	Paulus (2011) BVL no 3306345
	CIPAC MT 75.3	Batch: 2308/Cfr	5.2 (1 % in deionised water)	acceptable	Y	Morgan (2012) BVL no 3306346
	CIPAC MT 75.3	Batch: 2247/Cfr	5.1 (1 % in deionised water)	acceptable	Y	Morgan (2010) BVL no 3306347
<b>B.2.6 Viscosity and surface tension (MP 2.6)</b>						
Viscosity	CIPAC MT 192 (OECD 114)	Batch: 2247/Cfr	43 mPa/s at 100 s <sup>-1</sup> at 20 °C 152 mPa/s at 10 s <sup>-1</sup> at 20 °C	acceptable	Y	Morgan (2010) BVL no 3306348
Surface tension	EC A.5	Batch: 2094/Cfr	44.71 mN/m at 20 °C As the measured mean value lies below 60 mN/m CARPOVIRUSINE is classified as surface active.	acceptable	Y	Paulus (2010) BVL no 3306349

Study	Guideline and method	Test material	Results	Conclusion/Comment	GLP	Reference
<b>B.2.7 Technical characteristics of the plant protection product (MP 2.7)</b>						
<b>B.2.7.1 Wettability</b>						
Wettability			Not relevant as the preparation is a suspension concentrate (SC).			
<b>B.2.7.2 Persistence foaming</b>						
Persistence of foaming	CIPAC MT 47.2	Batch: 2094/Cfr	0.1 % v/v in CIPAC water C: after 10 sec 26 mL after 1 min 18 mL after 3 min 12 mL after 12 min 8 mL	acceptable	Y	Paulus (2010) BVL no 3306350
<b>B.2.7.3 Suspensibility and suspension stability</b>						
Suspensibility	CIPAC MT 184	Batch: 2094/Cfr	100 % (0.1 % w/v in CIPAC water D at 30 °C)	acceptable	Y	Paulus (2011) BVL no 3306351
	CIPAC MT 184	Batch: 2308/Cfr	92 % (0.1 % w/v in CIPAC water D at 30 °C)	acceptable	Y	Morgan (2012) BVL no 3306352
	CIPAC MT 184	Batch: 2247/Cfr	106 % (0.1 % w/v in CIPAC water D at 30 °C)	acceptable	Y	Morgan (2010) BVL no 3306353
Spontaneity of dispersion	CIPAC MT 160	Batch: 2094/Cfr	109 % (5 % w/v in CIPAC water D at 30 °C)	acceptable	Y	Paulus (2011) BVL no 3306351
	CIPAC MT 160	Batch: 2308/Cfr	91 % (5 % w/v in CIPAC water D at 30 °C)	acceptable	Y	Morgan (2012) BVL no 3306352
	CIPAC MT 160	Batch: 2247/Cfr	98 % (5 % w/v in CIPAC water D at 30 °C)	acceptable	Y	Morgan (2010) BVL no 3306353

Study	Guideline and method	Test material	Results	Conclusion/Comment	GLP	Reference
<b>B.2.7.4 Dry sieve test and wet sieve test</b>						
Dry sieve test			Not relevant as the preparation is a suspension concentrate (SC).			
Wet sieve test	CIPAC MT 185	Batch: 2094/Cfr	0 % residue with a 75 µm sieve	acceptable	Y	Paulus (2011) BVL no 3306354
	CIPAC MT 185	Batch: 2308/Cfr	1.44 % residue with a 75 µm sieve	acceptable	Y	Morgan (2012) BVL no 3306355
	CIPAC MT 185	Batch: 2247/Cfr	0.80 % residue with a 75 µm sieve	acceptable	Y	Morgan (2010) BVL no 3306356
<b>B.2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)</b>						
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>B.2.7.6 Emulsifiability, re-emulsifiability, emulsion stability</b>						
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).			

Study	Guideline and method	Test material	Results	Conclusion/Comment	GLP	Reference
<b>B.2.7.7 Flowability, pourability (rinsability) and dustability</b>						
Flowability			Not relevant as the preparation is a suspension concentrate (SC).			
Pourability	CIPAC MT 148	Batch: 2094/Cfr	Residue: 0.8 % Rinsing residue: 0.2 %	acceptable	Y	Paulus (2011) BVL no 3306357
	CIPAC MT 148	Batch: 2308/Cfr	Residue: 0.51 % Rinsing residue: 0.10 %	acceptable	Y	Morgan (2012) BVL no 3306358
	CIPAC MT 148	Batch: 2247/Cfr	Residue: 0.67 % Rinsing residue: 0.23 %	acceptable	Y	Morgan (2010) BVL no 3306359
Dustability			Not relevant as the preparation is a suspension concentrate (SC).			
<b>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)</b>						
Physical and biological compatibility of tank mixtures			Not applicable (tank mixtures with other pesticides are not recommended)			
<b>B.2.9 Adherence and distribution to seeds (MP 2.9)</b>						
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	Cheng, K.M.	2013	"ARY-0453A-042" - DETERMINATION OF THE APPEARANCE AND PH VALUE OF A SAMPLE OF CARPOVIRUSINE FORMULATION Arysta LifeScience S.A.S., OA02383 Oxford Analytical Ltd., Bicester, Oxon GLP: yes Published: no 3306327	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	N
KMP 2.2.1	Wahl-Ermel, B., Jehle, J., Eberle, K.	2011	STORAGE STABILITY OF CARPOVIRUSINE Arysta LifeScience S.A.S., ARY06 Dienstleistungszentrum Ländlicher Raum, Neustadt an der Weinstraße GLP: yes Published: no 3306328	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	N
KMP 2.2.1	Wahl-Ermel, B., Jehle, J.	2012	STORAGE STABILITY OF CARPOVIRUSINE Arysta LifeScience S.A.S., ARY07 Dienstleistungszentrum Ländlicher Raum, Neustadt an der Weinstraße GLP: yes Published: no 3306329	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	N
KMP 2.2.1	Besse, S.	2014	STORAGE MICROBIOLOGICAL STABILITY OF TWO BATCHES OF CARPOVIRUSINE AT 25°C DURING 1 MONTH, AT 4°C DURING 8 MONTHS AND AT -18°C DURING 12 MONTHS Arysta LifeScience S.A.S., 14/03 Natural Plant Protection, Pau GLP/GEP: no Published: no 3306330	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	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 2.2.1	Paulus, J.	2011	DETERMINATION OF THE SHELF LIFE OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO THE GUIDELINES OF CROPLIFE INTERNATIONAL Arysta LifeScience S.A.S., 09072401G001 Laus GmbH, Germany GLP: yes Published: no 3306331	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.2.1	Morgan, L.	2012	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER 12 MONTHS AT 4°C Arysta LifeScience S.A.S., TM/10/006/2 Battelle UK LTD. GLP: yes Published: no 3306332	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.2.1	Buccella, M.	2016	Study Plan: Physical - Chemical properties of I1136AA product before and after 12 months of shelf life at 4°C Natural Plant Protection, BT287/16 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no 3306336	no	yes	New data for new formulation, not previously submitted nor evaluated	NPP	N
KMP 2.2.1	Buccella, M.	2016	Study plan: Physical-Chemical properties of I1136AA product during two years of shelf life at -18°C Natural Plant Protection, BT289/16 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no 3306337	no	yes	New data for new formulation, not previously submitted nor evaluated	NPP	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 2.2.1	Buccella, M.	2017	Final report: Cold storage stability of I1136AA product Natural Plant Protection, BT290/16 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no 3306736	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	NPP	N
KMP 2.3	Paulus, J.	2010	Statement concerning Explosive Properties 09072401G  GLP: N/GEP: N Published: N 3306340	N	Y		ALS	
KMP 2.3	Paulus, J.	2010	Statement concerning Oxidising Properties 09072401G  GLP: N/GEP: N Published: N 3306341	N	Y		ALS	
KMP 2.4	Paulus, J.	2010b	DETERMINATION OF THE FLASH POINT OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO EU A.9 Arysta LifeScience S.A.S., 09072401G964 Laus GmbH, Germany GLP: yes Published: no 3306342	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	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 2.4	Paulus, J.	2010c	DETERMINATION OF THE AUTO IGNITION TEMPERATURE OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO EU A.15 Arysta LifeScience S.A.S., 09072401G962 Laus GmbH, Germany GLP: yes Published: no 3306343	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	N
KMP 2.5	Cheng, K.M.	2013	"ARY-0453A-042" - DETERMINATION OF THE APPEARANCE AND PH VALUE OF A SAMPLE OF CARPOVIRUSINE FORMULATION Arysta LifeScience S.A.S., OA02383 Oxford Analytical Ltd., Bicester, Oxon GLP: yes Published: no 3306344	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	N
KMP 2.5	Paulus, J.	2011	DETERMINATION OF THE SHELF LIFE OF CAR- POVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO THE GUIDELINES OF CROPLIFE INTERNA- TIONAL Arysta LifeScience S.A.S., 09072401G001 Laus GmbH, Germany GLP: yes Published: no 3306345	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	N
KMP 2.5	Morgan, L.	2012	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER 12 MONTHS AT 4°C Arysta LifeScience S.A.S., TM/10/006/2 Battelle UK LTD. GLP: yes Published: no 3306346	no	yes	New data for new formula- tion, not previ- ously submitted nor evaluated	ALS	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	Morgan, L.	2010a	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER FREEZE-THAW CYCLING Arysta LifeScience S.A.S., TM/10/005/1 Battelle UK LTD. GLP: yes Published: no 3306347	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.6	Morgan, L.	2010b	VISCOSITY OF CARPOVIRUSINE Arysta LifeScience S.A.S., TM/10/004/1 Battelle UK LTD. GLP: yes Published: no 3306348	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.6	Paulus, J.	2010d	DETERMINATION OF THE SURFACE TENSION OF AN AQUEOUS SOLUTION OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO OECD 115 RESP. EU A.5 Arysta LifeScience S.A.S., 09072401G960 Laus GmbH, Germany GLP: yes Published: no 3306349	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.7.2	Paulus, J.	2010e	DETERMINATION OF THE PERSISTENT FOAMING OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO CIPAC, MT 47.2 Arysta LifeScience S.A.S., 09072401G968 Laus GmbH, Germany GLP: yes Published: no 3306350	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	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 2.7.3	Paulus, J.	2011	DETERMINATION OF THE SHELF LIFE OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO THE GUIDELINES OF CROPLIFE INTERNATIONAL Arysta LifeScience S.A.S., 09072401G001 Laus GmbH, Germany GLP: yes Published: no 3306351	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.7.3	Morgan, L.	2012	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER 12 MONTHS AT 4°C Arysta LifeScience S.A.S., TM/10/006/2 Battelle UK LTD. GLP: yes Published: no 3306352	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.7.3	Morgan, L.	2010a	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER FREEZE-THAW CYCLING Arysta LifeScience S.A.S., TM/10/005/1 Battelle UK LTD. GLP: yes Published: no 3306353	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	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 2.7.4	Paulus, J.	2011	DETERMINATION OF THE SHELF LIFE OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO THE GUIDELINES OF CROPLIFE INTERNATIONAL Arysta LifeScience S.A.S., 09072401G001 Laus GmbH, Germany GLP: yes Published: no 3306354	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.7.4	Morgan, L.	2012	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER 12 MONTHS AT 4°C Arysta LifeScience S.A.S., TM/10/006/2 Battelle UK LTD. GLP: yes Published: no 3306355	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.7.4	Morgan, L.	2010a	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER FREEZE-THAW CYCLING Arysta LifeScience S.A.S., TM/10/005/1 Battelle UK LTD. GLP: yes Published: no 3306356	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	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 2.7.7	Paulus, J.	2011	DETERMINATION OF THE SHELF LIFE OF CARPOVIRUSINE (1X10 <sup>13</sup> GV/L, SC) ACCORDING TO THE GUIDELINES OF CROPLIFE INTERNATIONAL Arysta LifeScience S.A.S., 09072401G001 Laus GmbH, Germany GLP: yes Published: no 3306357	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.7.7	Morgan, L.	2012	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER 12 MONTHS AT 4°C Arysta LifeScience S.A.S., TM/10/006/2 Battelle UK LTD. GLP: yes Published: no 3306358	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N
KMP 2.7.7	Morgan, L.	2010a	PHYSICAL AND CHEMICAL PROPERTIES OF CARPOVIRUSINE: STORAGE STABILITY AFTER FREEZE-THAW CYCLING Arysta LifeScience S.A.S., TM/10/005/1 Battelle UK LTD. GLP: yes Published: no 3306359	no	yes	New data for new formulation, not previously submitted nor evaluated	ALS	N