

Renewal Assessment Report

***Bacillus thuringiensis*
subsp. *aizawai* strain GC-
91**

- Agree 50 WG -

Volume 3 – B.2 Physical and chemical properties

July 2018

Rapporteur Member State: The Netherlands

Co-Rapporteur Member State: Germany

Version history

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B.2 Physical and chemical properties of the plant protection product Agree 50 WG

Agree 50 WG was not the representative formulation for original approval of Bta strain GC-91. Hence, no data have been submitted or evaluated for this formulation before.

The in-use concentrations for the product are 0.133 – 0.4%. Physical, chemical and technical properties as well as storage stability were determined for the plant protection product Agree 50 WG.

Persistent foaming and suspensibility has not been determined at appropriate concentrations to cover the in-use concentration range. All other studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a pale brown, water dispersible granules-based formulation with a fish meal odour. It is not explosive nor flammable, and it has no oxidising properties. In aqueous solution, it has a pH value around 6.40. The data indicate that Agree 50 WG is stable when stored at 30°C for 18 weeks and 2 years at 20°C in polyester. The technical properties are acceptable according to the FAO guidelines and acceptable for an WGG-formulation.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1 Appearance						
Physical state and colour B.2.1/01	Visual and smelling FAO, PSD and Pesticide Chemistry Branch Specification of PPP	Agree WG, batch n°: 4093650 Purity: not stated	Small pale granules with a fishmeal odour. Colour specification: RAL 8025	Acceptable	Y	Aversa, 2013 Report n°: BT067/11 (KMP 2.1/01)
B.2.2 Explosive and oxidising properties						
Explosive properties B.2.2/01	92/96/EEC Method A.14	Agree WG, batch n°: 4093650	The formulation has no explosive properties according to European Commission Regulation (EC) No 440/2008.	Acceptable	Y	Ahrens, 2011a Report n°: 20110112.02

		Purity: 3.8% of a.i.				(KMP 2.3/01)
Oxidising properties B.2.2/02	92/96/EEC Method A.17	Agree WG, batch n°: 4093650 purity: 3.8% of a. i.	The formulation has no oxidising properties according to European Commission Regulation (EC) No 440/2008.	Acceptable	Y	Ahrens, 2011b Report n°: 20110112.04 (KMP 2.3/02)
B.2.3 Flammability and auto-flammability						
Flash point of the liquids formulations B.2.3/01						
Flammability of solid formulations B.2.3/02	92/69/EEC Method A.10	Agree WG, batch n°: 4093650 purity: 3.8% a. i.	The formulation is neither a highly flammable according to European Commission Regulation (EC) No 440/2008, nor a flammable solid according to the classification criteria as laid down in Regulation (EC) No 1272/2008.	Acceptable	Y	Ahrens, 2011c Report n°: 20110112.01 (KMP 2.4/01)
Self-heating of formulations B.2.3/03	92/69/EEC Method A.16	Agree WG, batch n°: 4093650 purity: 3.8% a. i.	The relative self-ignition temperature is 392°C at atmospheric pressure.	Acceptable	Y	Ahrens, 2011d Report n°: 20110112.03 (KMP 2.4/02)
B.2.4 Acidity/alkalinity and pH value						
pH of the neat aqueous formulation B.2.4/01			Not applicable			
pH of a 1 % dilution of the solid or non aqueous	CIPAC MT	Agree WG,	pH of a 1% dispersion: 6.40 (25°C)	Acceptable	Y	Aversa, 2013

formulation B.2.4/02	75.3	batch n°: 4093650 Purity: not stated				(MP 2.5/01) (Submitted in KMP 2.1/01)
Acidity / Alkalinity B.2.4/03			Because the pH was < 10 and > 4, the acidity/alkalinity test was not performed.	Acceptable		
B.2.5 Viscosity and surface tension						
Viscosity of the liquid formulation B.2.5/01			Not applicable			
Surface tension of the formulation B.2.5/02			Not applicable			
B.2.6 Relative density and bulk density						
Relative density of the liquid formulation B.2.6/01			Not applicable			
Bulk density (pour and tap) of powder or granules B.2.6/02	CIPAC MT 186	Agree WG, batch n°: 4093650	The pour density is 0.477 g/mL. The tap density is 0.536 g/mL.	Acceptable	Y	Aversa, 2011b Report n°: BT065/11 (KMP 2.7.2/01)
B.2.7 Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product						
Stability after accelerated storage (54°C during 14	Visual control of the	Agree WG, batch n°:	Results after accelerated storage (18 weeks at 30 ± 2°C).	Acceptable	Y	Aversa, 2011a

days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) B.2.7/01	test item container. Weight change of the test item container. Control of activity by bioassay.	4093650 Purity: not stated Agree WG Lot 99-98	No damage of the test item containers was observed. No loss in weight was found after storage. The activity of the test item was not significantly changed after the storage. The test item is stable after 18 weeks at $30 \pm 2^\circ\text{C}$. The study was carried out polyester containers.			Report n°: BT066/11 (KMP 2.2/02) Chen, 2012 (KMP 2.2/03)
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	Content of active ingredient (viable spores), validated method BT 064/11		Before storage: 2.80×10^{10} CFU/g After storage: 2.38×10^{10} CFU/g			
	CIPAC MT 75.3		<u>pH of the diluted items (1% w/v in water)</u> Before storage: 6.40 After storage: 6.28			
	CIPAC MT 53.3.1-53.3.2		<u>Static wettability</u> Before storage: 2 s After storage: 2 s <u>Dynamic wettability</u> Before storage: 1 s After storage: 1 s			
	CIPAC MT 184		<u>Suspensibility of the diluted item at 0.07% (w/v in water D)</u> Before storage: 82% After storage: 84% <u>Suspensibility of the diluted item at 0.4% (w/v in water D)</u> Before storage: 75% After storage: 68%			
	CIPAC MT 174		<u>Dispersibility of the diluted item at 1% (w/v in water D)</u> Before storage: 93% After storage: 101%			

	CIPAC MT 185		<u>Wet Sieve Test (residue at 200 mesh – 75 µm ASTM)</u> Before storage: 1.97% After storage: 1.95%			
	CIPAC MT 178.2		<u>Friability and attrition resistance</u> Before storage: 99.96% After storage: 99.92%			
	CIPAC MT 170		<u>Dry sieve analysis (particle size distribution)</u> Before storage: 0.125 – 0.5 mm After storage: 0.125 – 0.5 mm			
	CIPAC MT 171		<u>Dust content</u> Before storage: Nearly dust-free (2.99 mg) After storage: Nearly dust-free (3.71 mg)			
	Bioassay with <i>Trichoplusia ni</i> for determination of the biopotency of the end-use product		<p>The biopotency given in International Units (IU/mg) is considered the main specification (and activity giving) parameter for Bt products. The data given below refer to Billion IU/LB and can be converted to IU/mg assuming 1 LB = 453592.37 mg.</p> <p>The data demonstrate that during storage of Agree WG at 20°C for 24 months, the biopotency of the product is maintained at a level meeting the specification of the product (25000 IU/mg or 11.2 BIU/LB). The</p>			

			slightly lower number of IU for the time point 24 months is a result of the conversion factor from LB to mg. (Chen, 2012)																					
			<table><tr><td>Months</td><td>Biopotency [BIU/LB]</td><td>Biopotency [IU/mg]</td></tr><tr><td>0</td><td>15.0</td><td>33069</td></tr><tr><td>3</td><td>16.1</td><td>35494</td></tr><tr><td>6</td><td>12.6</td><td>27778</td></tr><tr><td>12</td><td>14.7</td><td>32408</td></tr><tr><td>24</td><td>11.2</td><td>24692</td></tr></table>	Months	Biopotency [BIU/LB]	Biopotency [IU/mg]	0	15.0	33069	3	16.1	35494	6	12.6	27778	12	14.7	32408	24	11.2	24692			
Months	Biopotency [BIU/LB]	Biopotency [IU/mg]																						
0	15.0	33069																						
3	16.1	35494																						
6	12.6	27778																						
12	14.7	32408																						
24	11.2	24692																						
Effect of low temperature on stability of liquid formulation B.2.7/02			Not applicable																					
Shelf life following storage at ambient temperature B.2.7/03	Visual control of the test item container. Weight change of the test item container. Control of activity by bioassay.	Agree WG, batch n°: 4093650 Purity: not stated	Results after shelf life storage (2 years at 20 ± 2°C). Neither damage nor loss in weight of the test item containers (aluminium bag) was observed. The activity of the test item was not significantly changed after the storage. The test item is stable after 2 years at 20 ± 2°C. The study was carried out polyster containers.	Acceptable	Y	Aversa, 2013 (KMP 2.2/01) (Submitted in KMP 2.1/01) Gallager, 2013 (Submitted in KMP 2.2/04)																		
	Content of active ingredient (viable spores)		Before storage: 2.80 × 10 ¹⁰ CFU/g After storage: 1.16 × 10 ⁹ CFU/g The decrease in CFU counts is likely																					

			due to a loss in culturability and is not expected to have any negative influence on the efficacy of the product as the insecticidal activity is not necessarily correlated to the CFU counts. An internal storage stability study based on determination of the biopotency confirms this assumption. Please refer to Chen (2012) presented above (B.2.7/01).			
	CIPAC MT 75.3		<u>pH of the diluted items (1% w/v in water)</u> Before storage: 6.40 After storage: 6.33			
	CIPAC MT 53.3.1-53.3.2		<u>Static wettability</u> Before storage: 2 s After storage: 2.5 s <u>Dynamic wettability</u> Before storage: 1 s After storage: 1 s			
	CIPAC MT 184		<u>Suspensibility of the diluted item at 0.07% (w/v in water D)</u> Before storage: 82% After storage: 78.5% <u>Suspensibility of the diluted item at 0.4% (w/v in water D)</u> Before storage: 75% After storage: 93%			
	CIPAC MT 174		<u>Dispersibility of the diluted item at 1% (w/v in water D)</u>			

			Before storage: 93% After storage: 94%			
	CIPAC MT 185		<u>Wet Sieve Test (residue at 200 mesh – 75 µm ASTM)</u> Before storage: 1.97% After storage: 1.35%			
	CIPAC MT 178.2		<u>Friability and attrition resistance</u> Before storage: 99.96% After storage: 99.84%			
	CIPAC MT 170		<u>Dry sieve analysis (particle size distribution)</u> Before storage: 0.125 – 0.5 mm After storage: 0.125 – 0.5 mm			
	CIPAC MT 171		<u>Dust content:</u> Before storage: Nearly dust-free (2.99 mg) After storage: Nearly dust-free (3.60 mg)			
	Microbial contaminants Methods: MFLP-44 April 1998 NF EN ISO 4832:2006 NF EN ISO 6888-3:2003 NF EN ISO 21567:2005		No data were obtained before storage. After storage: Anaerobic spore formers: < 10 ⁵ CFU/g or mL Coliforms: < 10 CFU/g or mL <i>Staphylococcus aureus</i> : absent in 1 g or 1 mL <i>Shigella</i> sp.: absent in 25 g or 25 mL <i>Salmonella</i> sp.: absent in 25 g or 25 mL			

	NF EN ISO 6579:2002 NF EN ISO 11290-1/A1:2005		<i>Listeria monocytogenes</i> : absent in 25 g or 25 mL The amount of material tested for the presence of <i>Listeria monocytogenes</i> is lower than indicated in SAN-CO/12116/2012. However, as all other indicators for hygienic or environmental contamination are in the acceptable limits the data set is considered sufficient.			
B.2.8 Technical characteristics of the plant protection product						
B.2.8.1 Wettability						
Wettability of solid formulation B.2.8.1/01	CIPAC MT 53.3.1 CIPAC MT 53.3.2	Agree WG, batch n°: 4093650 Purity: not stated	2 s (static) 1 s (dynamic)	Acceptable	Y	Aversa, 2013 (MP 2.7.1/01) (Submitted in KMP 2.1/01)
B.2.8.2 Persistence foaming						
Persistence of foaming of the diluted formulation B.2.8.2/01	CIPAC MT 47.2	Agree WG, batch n°: 4093650 Purity: not stated	The persistent foaming of diluted suspensions (at 0.5% w/v standard water D) was found to be: 49 mL after 10 s, 11 mL after 1 min, 5 mL after 3 min, 2 mL after 12 min.	Acceptable Persistent foaming is tested at 0.5%, which represents the highest in-use concentration of 0.4%. The foam after 1 min. does not exceed the maximum criterion of 60 mL.	Y	Aversa, 2011b Report n°: BT065/11 (KMP 2.7.2/01)

B.2.8.3 Suspensibility						
Suspensibility of water dispersible formulation B.2.8.3/01	CIPAC MT 184	Agree WG, batch n°: 4093650 Purity: not stated	Suspensibility of the diluted item at 0.07% water D: 82% Suspensibility of the diluted item at 0.4% (w/v in water D): 75%	Acceptable Suspensibility is tested at 0.07% and 0.5%, which represents the lowest in-use concentration and highest in-use concentration of 0.133% and 0.4% respectively. The suspensibility is higher than the criterion of 60%.		Aversa, 2013 (KMP 2.7.3/01) (Submitted in KMP 2.1/01)
Spontaneity of dispersion of water dispersible formulation B.2.8.3/02	CIPAC MT 174	Agree WG, batch n°: 4093650 Purity: not stated	<u>Dispersibility of the diluted item at 1% (w/v in water D): 93%</u>	Acceptable		Aversa, 2013 (KMP 2.7.3/01) (Submitted in KMP 2.1/01)
Dispersion stability of SE, OD or EG formulation B.2.8.3/03			Not applicable			
B.2.8.4 Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation B.2.8.4/01			Not applicable			
Dilution stability of water soluble formulation B.2.8.4/02			Not applicable			
B.2.8.5 Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1 Particle size distribution						
Wet sieve test of water dispersible formulation B.2.8.5.1/01	CIPAC MT 185	Agree WG, batch n°: 4093650	Wet Sieve Test (residue at 200 mesh – 75 µm ASTM): 1.97%	Acceptable	Y	Aversa, 2013 (KMP 2.7.4/01)

		Purity: not stated				(Submitted in KMP 2.1/01)
Size distribution of particles of powder or suspension concentrate formulation B.2.8.5.1/02	CIPAC MT 170	Agree WG, batch n°: 4093650 Purity: not stated	<u>Dry sieve analysis (particle size distribution)</u> Before storage: 0.125 – 0.5 mm	Acceptable	Y	Aversa, 2013 (KMP 2.7.5/01) (Submitted in KMP 2.1/01)
Nominal size range of granule B.2.8.5.1/03			Not applicable			
B.2.8.5.2 Dust content						
Dust content of granular formulation B.2.8.5.2/01	CIPAC MT 171	Agree WG, batch n°: 4093650 Purity: not stated	<u>Dust content</u> Before storage: Nearly dust-free (2.99 mg)	Acceptable	Y	Aversa, 2013 (KMP 2.7.5/01) (Submitted in KMP 2.1/01)
B.2.8.5.3 Attrition						
Attrition characteristics of granules and tablets B.2.8.5.3/01	CIPAC MT 178.2	Agree WG, batch n°: 4093650 Purity: not stated	<u>Friability and attrition resistance</u> Before storage: 99.96%	Acceptable	Y	Aversa, 2013 (KMP 2.7.5/01) (Submitted in KMP 2.1/01)
B.2.8.5.4 Hardness and integrity						
Hardness of tablets B.2.8.5.4/01			Not applicable			
Integrity of tablets B.2.8.5.4/02			Not applicable			

B.2.8.6 Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation B.2.8.6/01			Not applicable			
B.2.8.7 Flowability, pourability and dustability						
Flowability of granular formulation B.2.8.7/01	CIPAC MT172	Agree WG, batch n°: 4093650 Purity: not stated	The product Agree WG flows naturally through the sieve (5 mm mesh size) and no residue remains on the sieve.	Acceptable	Y	Aversa, 2011b (KMP 2.7.7/01) (Submitted in KMP 2.7.2/01)
Pourability of suspensions B.2.8.7/02			Not applicable			
Dustability of dustable powders after accelerated storage B.2.8.7/03			Not applicable			
B.2.9 Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised						
Physical and biological compatibility of tank mixtures B.2.9/01			Product dispensability in water does not negatively affect the possibility of preparing tank mixes with other plant protection products in solid or liquid form, given that they are equally soluble/dispersible.	As no data have been provided, the compatibility of tank mixtures is not demonstrated. Therefore no tankmixtures can be proposed on the product label. If tank mixtures with other plant protection products are to be proposed on the product label, information on the physical and		

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Chemical compatibility of tank mixtures B.2.9/02			The nature of the active ingredient and the co-formulants contained in Agree 50 WG and the recommended distribution in aqueous dispersions, exclude the possibility of chemical reactions with other plant protection products commonly used in agriculture.	chemical (and biological) compatibility should be provided during the zonal application.		
			The form of the active ingredient Bta strain GC-91 in Agree 50 WG is the dormant spore and crystal protein inclusions therein. Germination and growth of the bacterium is not required for insecticidal activity that relies on the ingestion of the spores by the target pests. Due to the nature of the spore coat, spores are generally considered to be highly resistant against treatments to which vegetative cells exhibit sensitivity such as exposure to organic solvents, heat treatment, enzymatic attack or desiccation. It can be therefore concluded, that the probability that insecticidal properties of Agree 50 WG are adversely affected by the presence of other pesticides in tank mixes appears to be rather low			
B.2.10 Adherence and distribution to seeds						
Distribution and adhesion to seeds B.2.9.10/01			The product is not intended for seed treatment.			

B.2.11 Other studies						
			Not applicable			

B.2.12 References relied on

Data point CAD-DY (ongoing numbering)	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	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 2.1/01 (KMP 2.1/02)	Aversa, S.	2013	PHYSICO-CHEMICAL PROPERTIES OF PRODUCT AGREE WG AFTER 2 YEARS SHELF LIFE Certis Europe B.V., NL, BT067/11 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.2/01 (KMP 2.2./03)	Aversa, S.	2013	PHYSICO-CHEMICAL PROPERTIES OF PRODUCT AGREE WG AFTER 2 YEARS SHELF LIFE Certis Europe B.V., NL, BT067/11 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.2/02 (KMP 2.2/04)	Aversa, S.	2011a	PHYSICAL-CHEMICAL PROPERTIES OF PRODUCT AGREE WG BEFORE AND AFTER ACCELERATED STORAGE AT 30 ± 2°C FOR 18 WEEKS Certis Europe B.V., NL, BT066/11 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.2/03 (KMP 2.2/05)	Chen, C.-Y.	2012	STORAGE STABILITY OF AGREE WG Certis USA LLC, not available ██ GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CEU	N

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Data point CAD-DY (ongoing numbering)	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	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 2.2/04 (KMP 2.2/06) 1. additional submission	Gallager, S.	2013	STATEMENT ON PACKAGING AGREE 50 WG Certis USA LLC, not applicable not available GLP/GEP: no Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CEU	N
KMP 2.3/01 (KMP 2.3/02)	Ahrens, A.	2011a	AGREE WG BATCH NO.: 4093650 EXPLOSIVE PROPERTIES A.14 (OPPTS 830.6316) Certis Europe B.V., NL, 20110112.02 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.3/02 (KMP 2.3/03)	Ahrens, A.	2011b	AGREE WG BATCH NO.: 4093650 OXIDIZING PROPERTIES A.17 Certis Europe B.V., NL, 20110112.04 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.4/01 (KMP 2.4/03)	Ahrens, A.	2011c	AGREE WG BATCH NO.: 4093650 FLAMMABILITY(SOLIDS) A.10 Certis Europe B.V., NL, 20110112.01 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N

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Data point CAD-DY (ongoing numbering)	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	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 2.4/02 (KMP 2.4/04)	Ahrens, A.	2011d	AGREE WG BATCH NO.: 4093650 AUTO-FLAMMABILITY (SOLIDS-DETERMINATION OF RELATIVE SELF-IGNITION TEMPERATURE) A.16 Certis Europe B.V., NL, 20110112.03 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany GLP: yes Published: no	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.5/01 (KMP 2.5/02)	Aversa, S.	2013	PHYSICO-CHEMICAL PROPERTIES OF PRODUCT AGREE WG AFTER 2 YEARS SHELF LIFE Certis Europe B.V., NL, BT067/11 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.7.1/01 (KMP 2.7.1/02)	Aversa, S.	2013	PHYSICO-CHEMICAL PROPERTIES OF PRODUCT AGREE WG AFTER 2 YEARS SHELF LIFE Certis Europe B.V., NL, BT067/11 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N
KMP 2.7.5/01 (KMP 2.7.5/02)	Aversa, S.	2013	PHYSICO-CHEMICAL PROPERTIES OF PRODUCT AGREE WG AFTER 2 YEARS SHELF LIFE Certis Europe B.V., NL, BT067/11 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.1/01	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N

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Data point CAD-DY (ongoing numbering)	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	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 2.7.7/01	Aversa, S.	2011b	PHYSICAL-CHEMICAL PROPERTIES: FLOWABILITY, BULK DENSITY AND PERSISTENT FOAMING OF PRODUCT AGREE WG Certis Europe B.V., NL, BT065/11 Biotechnologie BT Srl, Fraz. Pantalla, Italy GLP: yes Published: no Submitted in: KMP 2.7.2/01	no	yes	New data for existing formulation, not previously submitted nor evaluated	CER	N