European Commission

Renewal Assessment Report
prepared according to Regulation (EC) N° 1107/2009

Aluminium silicate Calcined (Kaolin Calcined)

Volume 3 – B.2 (AS)

Rapporteur Member State: Greece
Co-Rapporteur Member State: France

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Version History

When	What
March 2008	Monograph, Aluminium Silicate, Vol 3 Annex B (B.1), Rapporteur Member State: Hungary
May 2011	Final addendum to the DAR, Monograph, Aluminium Silicate, Vol 3 Annex B (B.1), Rapporteur Member State: Hungary
May 2020	draft Renewal Assessment report (dRAR) – prepared by RMS EL in the context of the application for renewal of approval of the a.s. according to Reg (EU) No 1107/2009. New data/information submitted/reported for the purpose of renewal are in yellow shading.

Table of Contents

B.2 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
B.2.1 MELTING POINT AND BOILING POINT (CA 2.1)						
Melting Point	-	-	**Tessenderlo:** Aluminium silicate (kaolin) does not melt nor boil. Theoretically out of determination range	DAR: Well known fact due to frequent use in pottery making and other industrial uses.	-	In DAR 2008
	-	-	**Tessenderlo:** In pure form, the melting point of kaolinite is 2123 K. Calcined kaolin (calcined aluminium silicate) is a type of clay, a natural mineral that is inherently stable. Kaolin is the final degradation product of feldspar rocks.	RAR: Acceptable Measurements for boiling point shall be taken up to 360°C. Taking into consideration the manufacturing process and the cited reference no further data are required.	N	Murray H.H. (2007) in Benazzouz B. et al, 2013 Tessenderlo
	-	-	**Soka** These tests must be done at 360°C maximum. However, in line with the manufacturing process of the calcined aluminium silicate, the melting point of the calcined aluminium silicate is > 360°C.	RAR: Acceptable	-	Soka
Boiling Point	-	-	**Tessenderlo:** Aluminium silicate (kaolin) does not boil. Theoretically out of determination range Calcined kaolin (calcined aluminium silicate) is a type of clay, a natural mineral that is inherently stable. Kaolin is the final degradation product of feldspar rocks.	DAR: Well known fact due to frequent use in pottery making and other industrial uses RAR: Not required as melting point is above 360°C.	-	In DAR 2008

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
	-	-	**Soka** These tests must be done at 360°C maximum. However, in line with the manufacturing process of the calcined aluminium silicate (see document J), the boiling point of the calcined aluminium silicate is > 360°C.	RAR: Acceptable	-	Soka
B.2.2 VAPOUR PRESSURE, VOLATILITY (CA 2.2)						
Vapour pressure	-	-	**Tessenderlo:** Not applicable: No vapour pressure	DAR: Kaolin is a solid of infinite atomic structure. Kaolin molecules do not exist.	-	In DAR 2008
	-	-	**Tessenderlo:** Not applicable: As the melting point of kaolin is above 1800 K, and its boiling point is expected to be greater than 2000 K, a vapour pressure cannot be determined for kaolin.	RAR: Acceptable The active substance is involatile.	-	Tessenderlo
	-	-	**Soka** None of the recognized chemical institute/center/organization/agency (European Chemical Agency (ECHA), National Institutes of Health (NIH/PubChem-ToxNet); Centers for Disease Control and Prevenvention (CDC)/ National institute for Occupational Saftety and Health (NIOSH); International Labour Organization (ILO) World Health Oraganization (WHO); Occupational Safety and Health Administration (OSHA)) reports a volatility of Aluminium silicate because of its nature (inorganic component).	RAR: Acceptable The active substance is involatile.	-	Soka

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
Henry's law	-	-	**Tessenderlo** No Henry ‘s Law Constant.	Kaolin is insoluble solid in water with no vapour pressure.	-	-
B.2.3 APPEARANCE (PHYSICAL STATE, COLOUR) (CA 2.3)						
Physical state and colour of pure and technical active substance	Visual inspection	Calcined aluminium silicate	**Tessenderlo:** White powder, odourless	DAR: Acceptable RAR: Acceptable.	N	International Programme on Chemical Safety In DAR 2008
			Soka: Declaration: white powder, without odour.	RAR: Acceptable	-	-
B.2.4 SPECTRA (UV/VIS, IR, NMR, MS), MOLAR EXTINCTION AT RELEVANT WAVELENGTHS, OPTICAL PURITY (CA 2.4)						
Spectra of purified active substance	-	-	**Tessenderlo:** UV/VIS: Not applicable. Due to insolubility and lack of volatility, UV/VIS spectra of kaolin are not feasible. Molar extinction: Not applicable. There are no UV/VIS spectra of kaolin and therefore no molar extinction.	DAR: Acceptable RAR: Acceptable. Additional information for the IR spectrums is reported below.	-	In DAR 2008
			NMR: Not applicable. Due to the presence of small amounts of paramagnetic impurities, NMR spectra of kaolin are not feasible.			
			IR: Broad bands for Si-O, Al-O and OH These bands are representative of all aluminium silicates and cannot be used to identify kaolin.			

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
			MS: Not applicable. Due to insolubility and lack of volatility, MS spectra of kaolin are not feasible.			
	-	Calcined aluminium silicate	**Tessenderlo** Very broad and undefined peaks between 1500 cm^{-1} and 400 cm^{-1}. These peaks are representative of all aluminium silicates and cannot be used to identify kaolin.	RAR: Acceptable.	-	Castro L. 2019 Report No: N.A. Tessenderlo
	-	-	**Soka** -UV/VIS/MS not applicable/feasible due to insolubility and lack of volatility of the calcined aluminium silicate (DAR 2008) -NMR: not applicable/feasible due to the presence of small amounts of paramagnetic impurities (DAR 2008)	RAR: Acceptable for UV/VIS/MS/NMR. **Data gap: An IR study of the active substance by SOKA is required.**	-	-
Spectra for impurity compounds	-	-	Not available.	RAR: No new relevant organic impurity requiring identification in the active substance. Please refer to Vol. 4.	-	-
B.2.5 SOLUBILITY IN WATER (CA 2.5)						
Solubility of the purified active substance in water and effect of pH	-	-	**Tessenderlo** Insoluble.	DAR: Kaolin is insoluble because of its infinite two-dimensional structure and covalent bonding.	-	In DAR 2008
	-	-	**Tessenderlo** According to the PubChem database maintained as part of the US National Library of medicine (https://pubchem.ncbi.nlm.nih.gov/), kaolin is insoluble in water, ether, dilute acids and alkali hydroxides.	RAR: Acceptable. The active substance is insoluble in water.	-	Tessenderlo

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
			The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material.			
	-	-	**SOKA** None of the recognized chemical institute/center/organization/agency (European Chemical Agency (ECHA), National Institutes of Health (NIH/PubChem-ToxNet); Centers for Disease Control and Prevenvention (CDC)/National institute for Occupational Saftety and Health (NIOSH); International Labour Organization (ILO); World Health Oraganization (WHO); Occupational Safety and Health Administration (OSHA)) reports a solubility of Aluminium silicate because of its nature (inorganic component). For all of them, Aluminium silicate is insoluble in water.	RAR: Acceptable. The active substance is insoluble in water.	-	Soka
B.2.6 SOLUBILITY IN ORGANIC SOLVENTS (CA 2.6)						
Solubility in organic solvents	-	-	**Tessenderlo** Kaolin is insoluble in organic solvents.	DAR: Kaolin will form stable slurries in organic solvents if its surfaces are sufficiently dried to remove the free moisture.	-	In DAR 2008
	-	-	**Tessenderlo** According to the PubChem database maintained as part of the US National Library of medicine (https://pubchem.ncbi.nlm.nih.gov/), kaolin is insoluble in water, ether, dilute acids and alkali hydroxides. The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material.	RAR: Acceptable. The active substance is insoluble in organic solvents.	-	Tessenderlo
	-	-	**SOKA**	RAR: Acceptable.	-	Soka

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
			None of the recognized chemical institute/center/organization/agency (European Chemical Agency (ECHA), National Institutes of Health (NIH/PubChem-ToxNet); Centers for Disease Control and Prevenvention (CDC)/National institute for Occupational Saftety and Health (NIOSH); International Labour Organization (ILO); World Health Oraganization (WHO); Occupational Safety and Health Administration (OSHA)) reports a solubility of Aluminium silicate because of its nature (inorganic component). For all of them, Aluminium silicate is insoluble in organic solvents	The active substance is insoluble in organic solvents.		
B.2.7 PARTITION COEFFICIENT N-OCTANOL/WATER (CA 2.7)						
Partition Coefficient n-Octanol/water	-	-	**Tessenderlo** Not applicable.	DAR: Kaolin is insoluble in water and organic solvents.	-	In DAR 2008
	-	-	**Tessenderlo** According to the PubChem database maintained as part of the US National Library of medicine (https://pubchem.ncbi.nlm.nih.gov/), kaolin is insoluble in water, ether, dilute acids and alkali hydroxides. The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material. Therefore, kaolin cannot partition between octanol and water.	RAR: Acceptable	-	Tessenderlo
	-	-	**SOKA** None of the recognize chemical institute/center/organization/agency (European Chemical Agency (ECHA), National Institutes of Health (NIH/PubChem-ToxNet); Centers for Disease Control and Prevenvention	RAR: Acceptable		Soka

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
			(CDC)/National institute for Occupational Saftety and Health (NIOSH); International Labour Organization (ILO); World Health Oraganization (WHO); Occupational Safety and Health Administration (OSHA)) reports a partition co-efficient n-octanol/water of Aluminium silicate because of its nature (inorganic component) and its insolubility ion water.			
B.2.8 DISSOCIATION IN WATER (CA 2.8)						
Dissociation constant	-	-	**Tessenderlo** Kaolin is stable in water and will naturally become part of the sediment.	DAR: Kaolin is insoluble in water. A pKa value is dependent upon some limited solubility or disassociation of a molecule. Kaolin is insoluble because of its infinite two-dimensional structure and covalent bonding.	-	In DAR 2008
	-	-	**Tessenderlo** According to the PubChem database maintained as part of the US National Library of medicine (https://pubchem.ncbi.nlm.nih.gov/), kaolin is insoluble in water, ether, dilute acids and alkali hydroxides. The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material. As a fully covalently bonded substance, kaolin cannot dissolve nor ionize in solvents. There are no dissociation constants for kaolin.	RAR: Acceptable	-	Tessenderlo
	-	-	**SOKA** None of the recognize chemical institute/center/organization/agency (European	RAR: Acceptable	-	Soka

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
			Chemical Agency (ECHA), National Institutes of Health (NIH/PubChem-ToxNet); Centers for Disease Control and Prevenvention (CDC)/National institute for Occupational Saftety and Health (NIOSH); International Labour Organization (ILO); World Health Oraganization (WHO); Occupational Safety and Health Administration (OSHA)) reports a dissociation in water of Aluminium silicate because of its nature (inorganic component) and its insolubility ion water.			
B.2.9 FLAMMABILITY AND SELF-HEATING (CA 2.9)						
Flammability	-	-	**Tessenderlo** Kaolin is not flammable.	DAR: Kaolin is inert and therefore not flammable	N	International Programme on Chemical Safety In DAR 2008
	Expert Statement	-	**Tessenderlo** Calcined aluminium silicate is not a flammable solid. As such it will not represent a risk of ignition by brief contact with an ignition source. Testing according to the test method EEC A10 or UN N.1 is unnecessary and scientifically unjustified.	RAR: Acceptable	N	Guillosson L, 2019, Report No: TKIKAO-2019-1 Tessenderlo
	Statement	-	**SOKA** In line with the manufacturing process of the calcined aluminium silicate, the flammability and self-heating of the calcined aluminium silicate are > 1100°C.	RAR: Acceptable	Y	S.S. Atwal and S.P. Tremain, 2011, Report No: 41003110 Soka

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
Auto-Flammability	-	-	**Tessenderlo** Kaolin is not auto-flammable.	DAR: Kaolin is inert and therefore not auto-flammable	-	In DAR 2008
	Expert Statement	-	**Tessenderlo** Calcined aluminium silicate is not a self-heating substance. As such calcined aluminium silicate (kaolin) is not liable to self-heat by reaction with air, with or without energy supply. Testing according to the test methods EEC A.16 or UN N.4 are unnecessary and scientifically unjustified.	RAR: Acceptable	N	Guillosson L, 2019, Report No: TKIKAO-2019-2 Tessenderlo
	Test N.4 United Nations Recommendations on the Transport of Dangerous Goods, manual of Tests and Criteria, 4th revised edition, 2003	Calcined Kaolin, Batch: 87/1.4-01420090925	**SOKA** In line with the manufacturing process of the calcined aluminium silicate (see document J), the flammability and self-heating of the calcined aluminium silicate are > 1100°C. Negative result using a 100 mm cube sample at 140°C.	RAR: Acceptable	Y	S.S. Atwal and S.P. Tremain, 2011, Report No: 41003110 Soka
B.2.10 FLASH POINT (CA 2.10)						
Flash point	-	-	Not required since the substance is solid.	DAR: Not applicable. Kaolin is a solid at temperatures below 40ºC, therefore no testing is required under this point.	-	-
B.2.11 EXPLOSIVE PROPERTIES (CA 2.11)						
Explosive properties	Expert Statement	-	**Tessenderlo** Kaolin is not explosive.	DAR: Kaolin is inert and therefore not explosive	N	Bosc-Guillosson L, 2004, Report n° SWP001 In DAR 2008
	Expert Statement	-	**Tessenderlo**	RAR: Acceptable	N	Guillosson L, 2019, Report No: TKIKAO-2019-3

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
			Calcined aluminium silicate (calcined kaolin) is a non-explosive compound. As such it will not represent a risk for explosion. Testing according to the test method EEC A14 is unnecessary and scientifically unjustified.			Tessenderlo
	Expert Statement	-	**SOKA** Calcined Aluminium Silicate is not explosive. There are no chemical groups within the structure of the test item that would imply explosive properties	RAR: Acceptable	Y	S.S. Atwal and S.P. Tremain, 2011, Report No: 41003110 Soka
B.2.12 SURFACE TENSION (CA 2.12)						
Surface tension	-	-	**Tessenderlo** Not applicable: Kaolin does not have a surface tension	DAR: Not relevant. Surface energy measurements are very hard to do on powders. The usual contact measurements employed to measure solid surface energies or solid surface tension cannot be performed on powders.	-	-
			SOKA Not required for solid active substance.	RAR: Not applicable because of insolubility in water	-	-
B.2.13 OXIDISING PROPERTIES (CA 2.13)						
Oxidising properties	Expert Statement	-	**Tessenderlo** Kaolin is non oxidizing	DAR: Kaolin is inert and therefore not oxidizing	N	Bosc-Guillosson L, 2004, Report n° SWP003 In DAR 2008

Study	% purity	Method	Results	Comments/Conclusion	GLP	Reference (Author /year/ Report No)
	Expert Statement	-	**Tessenderlo** Calcined aluminium silicate (kaolin) is non-oxidising compound. As such it will not represent a risk for enhancing a fire propagation. Testing according to the test method EEC A17 is unnecessary and scientifically unjustified.	RAR: Acceptable	N	Guillosson L, 2019, Report No: TKIKAO-2019-4 Tessenderlo
	Expert Statement	-	**SOKA** Calcined Aluminium Silicate is not oxidising. There are no chemical groups within the structure of the test item that would imply oxidising properties	RAR: Acceptable	Y	S.S. Atwal and S.P. Tremain, 2011, Report No: 41003110 Soka
B.2.14 OTHER STUDIES (CA 2.14)						
Other studies			No other studies to be submitted.			

B.2.15 REFERENCES RELIED ON

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous submission/ evaluation
KCA 2.1	Murray H.H. (2007) in Benazzouz et al	2013	Determination of the melting temperature of kaolinite by means of the Z-method American Mineralogist, Volume 98, pages 1881–1885, 2013 Not GLP Published	N	N	N	Public	Submitted for the renewal of a.s.
KCA 2.3	Anonymous	1995	International Programme on Chemical Safety WHO Not GLP Published	N	N	N	Public	Included in DAR 2008
KCA 2.4 & MCP 5.1.1/02	Castro. L	2019	Additional information regarding Analytical methods used to characterize Calcined kaolin and SURROUND WP No report number Not GLP Unpublished	N	Y	New data provided.	Tessenderlo Kerley Inc.	Submitted for the renewal of a.s.
KCA 2.5	Anonymous		International Programme on Chemical Safety WHO Not GLP Published	N	N	N	Public	Included in DAR 2008
KCA 2.9/01	Guillosson L	2019a	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Flammability APC Report number TKIKAO-2019-1 Not GLP Unpublished-*+8 51	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous submission/ evaluation
KCA 2.9/01	Atwal S.S. & Tremain, S.P.	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the renewal of a.s.
KCA 2.9/02	Guillosson L	2019b	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Self-heating APC Report number TKIKAO-2019-2 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
KCA 2.11/01	Bosc-Guillosson L,	2004	Explosive Properties of Satintone® 5HB Swift Consulting Engelhard GmbH SWP001 Not GLP unpublished	N	N	N	Tessenderlo Group	Included in DAR 2008
KCA 2.11/02	Guillosson L	2019c	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Explosive properties APC Report number TKIKAO-2019-3 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
KCA 2.11/03	Atwal S.S. & Tremain, S.P.	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the renewal of a.s.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous submission/ evaluation
KCA 2.13/1	Bosc-Guillosson L,	2004	Oxidizing Properties of Satintone® 5HB Swift Consulting Engelhard GmbH SWP003 Not GLP unpublished	N	N	N	Tessenderlo Group	Included in DAR 2008
KCA 2.13/01	Guillosson L	2019c	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Oxidizing properties APC Report number TKIKAO-2019-4 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
KCA 2.13/02	Atwal S.S. & Tremain, S.P.	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the renewal of a.s.