

Calcined Aluminium silicate (Calcined Kaolin)

DOCUMENT M-CA, Section 2

PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

Legislation
EU Regulation 1107/2009

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Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
February 2018		MCA-S2 Original version
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¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CA 2 PHYSICAL AND CHEMICAL PROPERTIES OF THE ACTIVE SUBSTANCE

All studies referenced in this section have already been evaluated at the EU level for the original inclusion of Aluminium silicate (kaolin) on the List of Approved Substances and were found acceptable. They fulfil also the information requirements as set in the Regulation (EU) 283/2013.

~~For ease of review, studies that have already been evaluated are shown in grey.~~

To comply with the RMS requirements, all new studies (not evaluated before) are highlighted in yellow.

To comply with RMS requirements, a new column providing the original dossier RMS comments has been added to this table.

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
CA 2.1 Melting point, boiling point	Not applicable	Not applicable	Aluminium silicate (kaolin) does not melt nor boil. Well known fact due to frequent use in pottery making and other industrial uses.	RMS HU 2008: no comments. EFSA Journal 2012;10(2):2517: out of determination range. Aluminium silicate does not sublime or decompose.	Not applicable	
	Not applicable	Not applicable	In pure form, the melting point of kaolinite is 2123 K.		Not applicable	Murray H.H. (2007) in Benazzouz et al, 2013
	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.					

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
CA 2.2 Vapour pressure, volatility	Not applicable		Not applicable: No vapour pressure. Aluminium silicate (kaolin) is a solid of infinite atomic structure. Aluminium silicate (kaolin) molecules do not exist.	RMS HU 2008: no comments. EFSA Journal 2012;10(2):2517: Aluminium silicate is involatile	Not applicable	Not applicable
	Not Applicable	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.		Not applicable	Not applicable
CA 2.3 Appearance (Physical state, colour)	Visual inspection	Calcined aluminium silicate	White powder, odourless	RMS HU 2008: no comments. EFSA Journal 2012;10(2):2517: no comments	N	International Programme on Chemical Safety
CA 2.4 Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity	Not applicable		<u>Molar extinction:</u> Not applicable. There are no UV/VIS spectra of kaolin and therefore no molar extinction. <u>Optical purity:</u> Not applicable. Kaolin is not optically active; there are no optical isomers of aluminium silicate.	EFSA Journal 2012;10(2):2517: <u>UV/VIS:</u> Not applicable. Due to insolubility and lack of volatility, UV/VIS spectra of kaolin are not feasible. <u>NMR:</u> Not applicable. Due to the presence of small amounts of paramagnetic	Not applicable	Not applicable

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
				<p>impurities, NMR spectra of kaolin are not feasible.</p> <p>IR: Broad bands for Si-O, Al-O and OH</p> <p>These bands are representative of all aluminium silicates and cannot be used to identify kaolin.</p> <p>MS: Not applicable.</p> <p>Due to insolubility and lack of volatility, MS spectra of kaolin are not feasible.</p>		
	Not applicable	Calcined aluminium silicate	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.		N	Castro L. 2019 No report number
CA 2.5 Solubility in water	Not applicable	Calcined aluminium silicate	Insoluble. Kaolin is insoluble because of its infinite two-dimensional structure and covalent bonding.	EFSA Journal 2012;10(2):2517: Aluminium silicate is insoluble in water.	N	International Programme on Chemical Safety

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
	<p>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.</p> <p>The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material.</p>					
CA 2.6 Solubility in organic solvents	Not applicable	Calcined aluminium silicate	<p>Insoluble.</p> <p>Kaolin will form stable slurries in organic solvents if its surfaces are sufficiently dried to remove the free moisture.</p>	EFSA Journal 2012;10(2):2517: Aluminium silicate is insoluble in organic solvents	Not applicable	Not applicable
	<p>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.</p> <p>The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material.</p>					
CA 2.7 Partition coefficient n-octanol/water	Not applicable		<p>Not applicable.</p> <p>Kaolin is insoluble in water and organic solvents.</p>	EFSA Journal 2012;10(2):2517: Aluminium silicate is insoluble in all organic liquids and water.	Not applicable	Not applicable
	<p>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.</p> <p>The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material.</p> <p>Therefore, kaolin cannot partition between octanol and water.</p>					

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
CA 2.8 Dissociation in water <ul style="list-style-type: none"> dissociation constant(s) (pKa values) identity of dissociated species dissociation constant(s) (pKa values) of the active principle 	Not applicable		<p>Kaolin is stable in water and will naturally become part of the sediment.</p> <p>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.</p>	<p>EFSA Journal 2012;10(2):2517: Aluminium silicate is stable in water and will naturally become part of the sediment.</p>	Not applicable	Not applicable
	<p>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.</p> <p>The general scientific consensus is that by nature, kaolin is a fully covalent stable, inert and insoluble material.</p> <p>As a fully covalently bonded substance, kaolin cannot dissolve nor ionize in solvents. There are no dissociation constants for kaolin.</p>					
CA 2.9 Flammability and self-	Not applicable	Calcined aluminium silicate	Kaolin is not flammable.	<p>EFSA Journal 2012;10(2):2517: Aluminium silicate is inert and therefore not flammable.</p>	N	International Programme on Chemical Safety

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
heating	Test N.1: test method for readily combustible solids (UN RTDG Manual of Tests and Criteria)	Calcined aluminium silicate	Kaolin is not flammable.	New statement following RMS request for further details	Y	Guillosson L, 2019, document number TKIKAO-2019-1
	Test N.4: test method for self-heating substances (UN RTDG Manual of Tests and Criteria)	Calcined aluminium silicate	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.	New statement following RMS request for further details	Y	Guillosson L, 2019, document number TKIKAO-2019-2
CA 2.10 Flash point	Not applicable		Not applicable: Kaolin is a solid at temperatures below 40°C.	RMS HU 2008: Not applicable. Kaolin is a solid at temperatures below 40°C, therefore no testing is required under this point. EFSA Journal 2012;10(2):2517: no comments.	Not applicable	Not applicable

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
CA 2.11 Explosive properties	EEC A14	Calcined aluminium silicate	Kaolin is not explosive.	EFSA Journal 2012;10(2):2517: Aluminium silicate not explosive.	N	Bosc-Guillosson L, 2004, Report n° SWP001
	UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/ Rev. 5 – Part I (Test series), section 11	Calcined aluminium silicate	Calcined aluminium silicate (kaolin) is a non-explosive compound. As such it will not represent a risk for explosion.	New statement following RMS request for further details	N	Guillosson L, 2019, document number TKIKAO-2019-3
CA 2.12 Surface tension	Not applicable		Not applicable: Kaolin does not have a surface tension	EFSA Journal 2012;10(2):2517: Aluminium silicate does not have a surface tension.		Not applicable
CA 2.13 Oxidising properties	EEC A17	Calcined aluminium silicate	Kaolin silicate is inert and therefore not oxidizing	EFSA Journal 2012;10(2):2517: Aluminium silicate is not oxidising.	N	Bosc-Guillosson L, 2004, Report n° SWP003

Test or Study & Data Point	Guideline and method	Test material purity and specification	Findings	DAR 2008 Conclusions (RMS HU)	GLP Y/N	Reference
	UN RTDG Manual of Tests and Criteria ST/SG/AC.10/11/ Rev. 5 – Part I (Test series), section 11	Calcined aluminium silicate	Calcined aluminium silicate (kaolin), is non-oxidising compound. As such it will not represent a risk for enhancing a fire propagation.	New statement following RMS request for further details	N	Guillosso L, 2019, document number TKIKAO-2019-4
CA 2.14 Other studies			None			

Summarising conclusions:

Aluminium silicate (kaolin) is a white, odourless powder that is insoluble in water and all organic solvents. Aluminium silicate (kaolin) has no dissociation constant and no partition coefficient. Aluminium silicate (kaolin) is non-explosive and non-oxidizing. Aluminium silicate (kaolin) is not flammable, does not melt and does not boil.

Aluminium silicate (kaolin) is inert and stable.