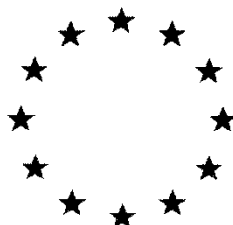


# ***European Commission***



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

**Aluminium Silicate Calcined**  
**(Kaolin Calcined)**

**Volume 3 – B.1 (CA)**

Rapporteur Member State: GREECE  
Co-Rapporteur Member State: FRANCE

**MAY 2020**

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**Version History**

<b>When</b>	<b>What</b>
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>B.1. IDENTITY</b>	4
<b>B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE</b>	4
B.1.1.1. Common name proposed or ISO-accepted and synonyms	4
B.1.1.2. Chemical name (IUPAC and CA nomenclature)	4
B.1.1.3. Producer's development code number	4
B.1.1.4. CAS, EC and CIPAC numbers	4
B.1.1.5. Molecular and structural formula, molecular mass	4
B.1.1.6. Method of manufacture (synthesis pathway) of the active substance	5
B.1.1.7. Specification of purity of the active substance in g/kg	5
B.1.1.8. Identity and content of additives (such as stabilisers) and impurities	5
B.1.1.9. Analytical profile of batches	5
<b>B.1.2. REFERENCES RELIED ON</b>	5

**B.1 IDENTITY****B.1.1 IDENTITY OF THE ACTIVE SUBSTANCE**

<b>B.1.1.1. Common name proposed or ISO-accepted and synonyms</b>	Kaolin calcined (aluminium silicate calcined)
<b>B.1.1.2. Chemical name (IUPAC and CA nomenclature)</b>	
IUPAC	Not available
CA	Kaolin
<b>B.1.1.3. Producer's development code number</b>	<b>TESSENDERLO:</b> M99SP1, M-96-018, M-97-009, <b>SOKA:</b> SOKALCIARBO WP, SOKALCIARBO, BAIKAL WP
<b>B.1.1.4. CAS, EC and CIPAC numbers</b>	
CAS	92704-41-1
EC	296-473-8
CIPAC	841
<b>B.1.1.5. Molecular and structural formula, molecular mass</b>	
Molecular formula	Al <sub>4</sub> Si <sub>4</sub> O <sub>14</sub> Note: A single molecule cannot exist
Structural formula	Not available
Molecular mass	Not applicable

<b>B.1.1.6. Method of manufacture (synthesis pathway) of the active substance</b>	Confidential information. Please refer to Vol. 4		
<b>B.1.1.7. Specification of purity of the active substance in g/kg</b>	Tessenderlo: 999.0 g/kg minimum SOKA: Open		
<b>B.1.1.8. Identity and content of additives (such as stabilisers) and impurities</b>			
<i>B.1.1.8.1. Additives</i>	Confidential information. Please refer to Vol. 4		
<i>B.1.1.8.2. Significant impurities</i>	Confidential information. Please refer to Vol. 4		
<i>B.1.1.8.3. Relevant impurities</i>			
		Tessenderlo	SOKA
	Arsenic:	< 1.0 mg/kg	12 mg/kg
	Lead:	< 5.0 mg/kg	15 mg/kg
	Cadmium	< 0.20 mg/kg	< 2 mg/kg
	Mercury	< 0.02 mg/kg	< 0.1 mg/kg
	TEQ-WHO PCDD/F (sum of congeners)	< 0.20 ng/kg	< 0.5 ng/kg
	TEQ-WHO dl-PCB (sum of congeners)	< 0.15 ng/kg	< 0.5 ng/kg
	TEQ-WHO PCDD/F/dl-PCB (sum of congeners)	< 0.35 ng/kg	< 0.5 ng/kg
	Sum of ndl-PCB:	< 5.0 µg/kg	< 0.5 µg/kg
	Respirable crystalline silica (< 10 µm)	< 1.0 g/kg	(open)
<b>B.1.1.9. Analytical profile of batches</b>	Confidential information. Please refer to Vol. 4		

#### Discussion on CAS and EINECS Numbers by Tessenderlo :

At the request of the RMS (EL), the CAS and EEC numbers of the active substance are being modified to avoid confusion with kaolin (hydrous).

However, the Notifier wishes to indicate that the requested CAS number (92704-41-1, EEC number 296-473-8) does not correctly describe the active substance presented herewith. Moreover, the substance description presented in the ECHA Infocard for CAS number 92704-41-1 is incorrect and misleading as it presents a non-covalent substance susceptible to ionization, which is not the case for calcined kaolin, a covalently bound two-layered phyllosilicate that is insoluble in any solvents and stable over geological timescales (i.e. millions of years).

RMS, EL taking into consideration that the active substance already approved with the name “Aluminium Silicate”, and now under consideration for renewal, concerns the calcined aluminium silicate (anhydrous/amorphous aluminium silicate) as declared by both Notifiers (Tessenderlo and SOKA), is of the opinion that the CAS No (1332-58-7) and EC No (310-194-1) used in DAR (2008 & 2011, HU) which refer to the hydrous aluminium silicate should not be maintained in the framework of the renewal.

RMS, EL also agrees that the substance description presented in the ECHA Infocard for CAS number 92704-41-1 and name “Kaolin, calcined” could be misleading as it presents a substance with ionic species. However, based on all the available information on the identity of the active substance for the renewal EL considers that the most proper CAS No is 92704-41-1 and EC No 296-473-8.

Please refer to Vol 4, C.1.3.2. for further information

**Molecular formula**

It is noted that the molecular formula presented in dRAR for aluminium silicate is  $\text{Al}_4\text{Si}_4\text{O}_{14}$  with the note that “A single molecule cannot exist” as it was in DAR as well. In the ECHA Infocard for CAS number 92704-41-1 the molecular formula is  $\text{Al}_2\text{O}_7\text{Si}_2$  which uses the half numbers of the individual atoms comparing to the molecular formula used in dRAR. EL considers that the molecular formula is indicative of the kinds of the atoms that constitute the active substance in a specific ratio which is the same in both cases.

**B.1.2. REFERENCES RELIED ON**

Please refer to Reference list of Vol 4.