Calcined Aluminium silicate (Calcined Kaolin)

DOCUMENT M-CA, Section 1

IDENTITY OF THE ACTIVE SUBSTANCE

Legislation
EU Regulation 1107/2009

OWNERSHIP STATEMENT

This document, the data contained in it and copyright therein are owned by Tessenderlo Group N.V.. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Tessenderlo Group N.V..

The summaries and evaluations contained in this document are based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either:

- **From Tessenderlo Group N.V.; or**
- **From other applicants once the period of data protection has expired.**

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
February 2018	CA 1.2: removal of one of the mining sites and change of responsible person.	MCA-S1
September 2019	Updates following RMS comments	MCA-S1-V2

[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

Table of Contents

CA 1 IDENTITY OF THE ACTIVE SUBSTANCE 5
CA 1.1 Applicant 5
CA 1.2 Producer 5
CA 1.3 Common Name Proposed or ISO-accepted and synonyms 5
CA 1.4 Chemical Name (IUPAC and CA nomenclature) 5
CA 1.5 Producer's Development Code Numbers 5
CA 1.6 CAS, EC and CIPAC Numbers 6
CA 1.7 Molecular and Structural Formula, Molar Mass 6
CA 1.8 Method of Manufacture (synthesis pathway) of the active substance 7
CA 1.9 Specification of Purity of the Active Substance in g/kg 7
CA 1.10 Identity and Content of Additives (such as Stabilisers) and impurities 7
CA 1.10.1 Additives 7
CA 1.10.2 Significant impurities 7
CA 1.10.3 Relevant impurities 8
CA 1.11 Analytical Profile of Batches 8

CA 1 IDENTITY OF THE ACTIVE SUBSTANCE

CA 1.1 Applicant

Name:	Tessenderlo Chemie
Address:	Rue du Trône 130 B-1050 Bruxelles Belgique
Contact :	[redacted]
Telephone number:	[redacted]
Fax:	[redacted]
E-mail:	[redacted]

CA 1.2 Producer

Company:	BASF Corporation
Address:	100 Park Avenue Florham Park, NJ 07932 USA
Manufacturing site:	[redacted]
Contact person:	[redacted]
Telephone number:	[redacted]
Mobile:	
E-mail:	[redacted]

CA 1.3 Common Name Proposed or ISO-accepted and synonyms

Calcined kaolin (Calcined aluminium silicate)

CA 1.4 Chemical Name (IUPAC and CA nomenclature)

IUPAC: Not available

CAS: Kaolin

CA 1.5 Producer's Development Code Numbers

The active substance used in the manufacturing of Surround® WP Crop Protectant is M99SP1, (100% kaolin).

Some tests were carried out with other potential active substances:

- M-96-018, 98.8% kaolin
- M-97-009, 100% kaolin

CA 1.6 CAS, EC and CIPAC Numbers

CAS Nº: ~~1332-58-7~~ 92704-41-1

CIPAC Nº: 841

EEC Nº: ~~310-127-6 (E559)~~ 296-473-8

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), a co-formulant used in the manufacture of the representative product (SURROUND® WP CROP PROTECTANT).

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[1] 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).

Calcined kaolin is not approved as a food additive.

Hydrous kaolin was approved as a food additive (E559) until 31 January 2014.

CA 1.7 Molecular and Structural Formula, Molar Mass

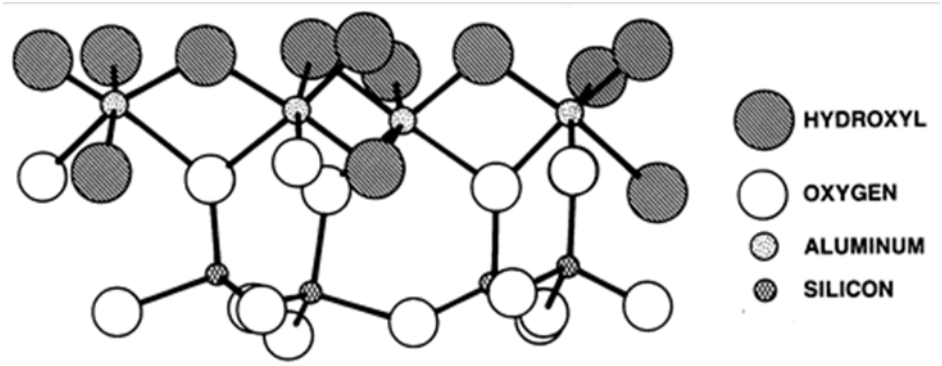
Empirical formula:

~~Hydrous aluminium silicate: $Al_4Si_4O_{10}(OH)_8$~~ (Not relevant to the active substance described herewith.)

Calcined aluminium silicate: $Al_4Si_4O_{14}$

Structural formula for hydrous kaolin:

[1] https://echa.europa.eu/substance-information/-/substanceinfo/100.087.663



This structural formula is not strictly applicable to the active substance discussed here, which is calcined kaolin. The calcination process of kaolin, as described under point CA 1.8 below, consists in heating the purified and pulverised hydrous kaolin to 1100°C. This process results in two physical effects:

- Evolution of water and loss of approximately 14% in weight through the loss of hydroxyl moieties.
- Disorganisation of the crystalline structure and loss of the characteristic X-ray diffraction pattern of hydrous kaolin.

CA 1.8 Method of Manufacture (synthesis pathway) of the active substance

CONFIDENTIAL information - data provided separately (Document J).

CA 1.9 Specification of Purity of the Active Substance in g/kg

Minimum purity:

Calcined aluminium silicate (Kaolin): 999.0 g/kg minimum

The reduced minimum purity is an artefact of the quantification limit of the technique used to quantify crystalline silica: the limit of detection of the X-Ray Diffraction technique is 0.1% or 1 g/kg.

CA 1.10 Identity and Content of Additives (such as Stabilisers) and impurities

CA 1.10.1 Additives

CONFIDENTIAL information - data provided separately (Document J).

CA 1.10.2 Significant impurities

All significant impurities in calcined kaolin are relevant. Please see Point CA 1.10.3 bellow.

CA 1.10.3 Relevant impurities

Compound	Content
Arsenic:	< 1.0 mg/kg
Lead:	< 5.0 mg/kg.
Cadmium	< 0.20 mg/kg*
Mercury	< 0.02 mg/kg*
TEQ-WHO PCDD/F *	< 0.20 ng/kg*
TEQ-WHO dl-PCB *	< 0.15 ng/kg
TEQ-WHO ndl-PCB *	< 5.0 µg/kg*
Respirable crystalline silica (< 50 µm)	< 1 g/kg***
TOTAL	**< 1.0 g/kg**

* Set at the Limit of Quantification of the method
**: based on Toxic Equivalency Factors (TEFs) (WHO 2005)
***: Set at the Limit of Detection of the method. No tridymite or cristobalite detected

CA 1.11 Analytical Profile of Batches

CONFIDENTIAL information - data provided separately (Document J).