

Aluminium silicate (Kaolin)

DOCUMENT M-CA, Section 4

ANALYTICAL METHODS

Annex to EU Regulation 283/2013 & 284/2013

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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 4 ANALYTICAL METHODS

Introduction

Aluminium silicate (kaolin) is a type of clay mineral, a natural substance present in soil, surface water, sediment and ground water.

Clay minerals, including kaolin, are alteration or weathering products of silicate rocks such as basalt and granite, and are referred to as sediment. In geology, the term "sediment" refers to "mineral or organic matter deposited by water, air or ice".

This sediment can, in turn, undergo diagenesis to form sedimentary rock. The most common sedimentary rocks formed during kaolin diagenesis are tonsteins, sandstones and conglomerates. These rocks can then be eroded back to clay minerals, including kaolin, or migrate into the crust to be metamorphosed.

Aluminium silicate (kaolin) is extremely stable. The ores that are being mined today were formed over 25 million years ago. Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases. Aluminium silicate has similar chemical composition to common clay that is found in most soils and aquatic sediments the world over.

CA 4.1 Methods used for the Generation of Pre-Approval Data

All methods used to determine the pure active substance in the active substance as manufactured are confidential and described in Document J. Please refer to Document J for further details.

CA 4.1.1 Methods for the analysis of the active substance as manufactured

(a) Determination of the pure active substance in the active substance as manufactured and specified in the dossier submitted in support of approval under Regulation (EC) No 1107/2009

All methods used to determine the pure active substance in the active substance as manufactured are confidential and described in Document J. Please refer to Document J for further details.

Furthermore, please note that the methods have also been provided in support of the Technical Specifications Dossier submitted on 12 June 2013 to the European Commission, the original RMS (Hungary), as well as Belgium, France, Greece and Spain, where the product SURROUND® WP CROP PROTECTANT, containing aluminium silicate (Kaolin) as active substance was registered at the time.

EFSA's conclusions on the Technical Specifications Dossier have been published in 2014¹.

¹ EFSA (European Food Safety Authority), 2014; Outcome of the consultation with Member States, applicant and EFSA on the pesticide risk assessment of confirmatory data submitted for the active substance aluminium silicate. EFSA supporting publication 2014:EN-625. 10 pp.

(b) Determination of significant and relevant impurities and additives (such as stabilisers) in the active substance as manufactured

Not applicable.

~~There are no significant or relevant impurities in aluminium silicate (kaolin) as manufactured. Aluminium silicate (kaolin) as manufactured does not contain any additives.~~

All methods used to determine relevant impurities in the pure active substance in the active substance as manufactured are confidential and described in Document J. Please refer to Document J for further details.

CA 4.1.2 Methods for risk assessment**(a) Methods In soil, water, sediment, air and any additional matrices used in support of environmental fate studies**

Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases, except under very harsh conditions. Aluminium silicate has a similar chemical composition to common clay that is found in most soils and aquatic sediments the world over.

Since aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies and therefore no analytical methods for quantification in soil, water, sediment, air or any additional matrices is presented.

(b) Methods in soil, water and any additional matrices used in support of efficacy studies

Not applicable.

Aluminium silicate (kaolin) is a type of clay, a natural substance present in soil, surface water, sediment and ground water. Aluminium silicate (kaolin) is the ultimate degradation product of silicate rocks and cannot be separated from naturally present aluminium silicate clays.

(c) Methods in feed, body fluids and tissues, air and any additional matrices used in support of toxicological studies

Not applicable.

Aluminium silicate (kaolin) is not acutely toxic and holds no classification with regards to toxicity. Analytical methods in feed, body fluids and tissues or air are not required.

(d) Methods in body fluids, air and any additional matrices used in support of operator, worker, resident and bystander exposure studies

Not applicable.

Aluminium silicate (kaolin) is not acutely toxic and holds no classification with regards to toxicity. Operator exposure studies are not required for aluminium silicate and therefore analytical methods in body fluids and tissues or air are not required.

(e) Methods in or on plants, plant products, processed food commodities, food of plant and animal origin, feed and any additional matrices used in support of residues studies

Not applicable.

Aluminium silicate (kaolin) is exempt from Maximum Residue Limits and included in Annex IV of Regulation (EC) No 396/2005 through Regulation (EC) No 839/2008.

(f) Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies

Not applicable.

Aluminium silicate (kaolin) is a type of clay, a natural substance present in soil, surface water, sediment and ground water. Aluminium silicate (kaolin) is the ultimate degradation product of silicate rocks and as such is infinitely stable. Ecotoxicology studies performed using aluminium silicate (kaolin) assume that under atmospheric conditions of pressure and temperature, and in the absence of very strong acids and bases, aluminium silicate (kaolin) cannot be decomposed into its elemental components and therefore quantitative analysis is not required.

(g) Methods in water, buffer solutions, organic solvents and any additional matrices resulting from the physical and chemical properties tests

Not applicable.

Aluminium silicate (kaolin) is a type of clay, a natural substance present in soil, surface water, sediment and ground water. Aluminium silicate (kaolin) is the ultimate degradation product of silicate rocks and as such is infinitely stable. Quantification of aluminium silicate in the physical and chemical properties tests is not required and therefore analytical methods are not available.

CA 4.2 Methods for Post-Approval Control and Monitoring Purposes**(a) Methods for the determination of all components included in the monitoring residue definition as submitted in accordance with the provision of point 6.7.1 in order to enable Member States to determine compliance with established maximum residue levels (MRLs); they shall cover residues in or on food and feed of plant and animal origin**

Not applicable.

Aluminium silicate (kaolin) is exempt from Maximum Residue Limits and included in Annex IV of Regulation (EC) No 396/2005 through Regulation (EC) No 839/2008.

(b) Methods for the determination of all components included for monitoring purposes in the residue definitions for soil and water as submitted in accordance with the provisions of point 7.4.2

Not applicable.

Aluminium silicate (kaolin) is a type of clay, a natural substance present in soil, surface water, sediment and ground water. Aluminium silicate (kaolin) is the ultimate degradation product of silicate rocks and cannot be separated from naturally present aluminium silicate clays. There is no residue definition for soil and water for aluminium silicate (kaolin).

(c) Methods for the analysis in air of the active substance and relevant breakdown products formed during or after application, unless the applicant shows that exposure of operators, workers, residents or bystanders is negligible

Not applicable.

Operator, worker, bystander and resident exposure risk assessment presented in this application indicate exposure is negligible for these groups. Analytical methods for the quantification of aluminium silicate (kaolin) in air are not required.

(d) Methods for the analysis in body fluids and tissues for active substances and relevant metabolites

Not applicable.

Aluminium silicate (kaolin) is not acutely toxic and holds no classification with regards to toxicity. Aluminium silicate (kaolin) is not absorbed nor metabolised by mammals. Analytical methods for the analysis of aluminium silicate (kaolin) are not required.