European Commission

Renewal Assessment Report

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

Aluminium silicate Calcined (Calcined Kaolin)

Volume 3 – B.8 (AS)

Rapporteur Member State : Greece

Co-Rapporteur Member State : France

May 2020

Version history[1]

Date	**Data points containing amendments or additions and brief description**	**Document identifier and version number**
February 2020	Renewal Assessment Report (RAR)-prepared in the context of the application for renewal of approval of the a.s. according to Regulation (EC) No 1107/2009.	
May 2020	Revised RAR prepared by RMS. It is pointed out that since the CA and CP RAR contains only data from open scientific literature and general statements and no protected laboratory studies the RMS decided to add all the references together in a way that better supports the renewal of the a.s. and fulfills the format criteria. The only studies provided by the applicants were the literature reviews; where each "owner" was indicated.	

[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

Original DAR information are presented in gray shading Additional information compared to the DAR are presented without any shading RMS comments are presented below each study in a yellowish box

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B.8 FATE AND BEHAVIOUR IN THE ENVIRONMENT

This document has been prepared to evaluate the application of Aluminium Silicate submitted by Société Kaolinière Armoricain (SOKA) and Tessenderlo Group N.V., for EU renewal of the Annex I inclusion. The document supplements and updates the corresponding Annex B section of the Draft Assessment Report produced during the first review of Aluminium Silicate, completed in 2009. In this report new data for the renewal of the approval of Aluminium Silicate has been evaluated. In addition the conclusions of the studies reported in the DAR are presented and have been re-assessed for validity. Each old study (where available) was amended, where critical information was missing.

This dossier refers to calcined kaolin, registered in 2008 under the term "Aluminium silicate". The regulatory term used throughout this dossier is therefore aluminium silicate, although in geological and mineralogical terms, the substance described therein is known as calcined kaolin.

Aluminium silicate is extremely stable and is a non-degradable natural component of the environment. 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. Aluminium silicate is essentially purified natural clay and is therefore not subject to adsorption on or desorption from soil particles. When applied to soil, the Aluminium silicate particles will readily mix with the other soil components. Some organic materials (for example fulvic acids) will adsorb onto the particle surfaces, similarly to the Aluminium silicate already existing in the soil. No increase in compaction, water penetration or aeration is anticipated since the existing clay particles exist in a much larger particle size distribution (already agglomerated) than the narrow fraction that will be added.

Since Aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies.

Representative formulation for SOKA is SOKALCIARBO WP and contains 1000 g/kg anhydrous Aluminium Silicate (Kaolin), formulated as WP (Wettable Powder). Representative formulation for Tessenderlo is SURROUND WP CROP PROTECTANT and contains 950 g/kg calcined aluminium silicate also known as kaolin, formulated as WP (Wettable Powder). Aluminium Silicate is an insect repellent and the representative product (SOKALCIARBO WP) is intended to be used on pome/stone fruits, nuts/walnut trees, citrus, lavender, olive trees and grapevines with the maximum proposed application amount to be 210 kg a.s./ha (60 kg a.s./ha for first application and 30 kg a.s./ha for the next 5 applications; 6 applications in total). Tessenderlo's representative product (SURROUND WP CROP PROTECTANT) is intended to be used on vines with the maximum proposed application amount to be 120 kg a.s./ha (30 kg a.s./ha for four applications in total). Aluminium silicate was included in Annex I to Directive 91/414/EEC on 1 September 2009 pursuant to Article 24b of the Regulation (EC) No 2229/2004 (hereinafter referred to as „the Regulation‟), and has subsequently been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. This active substance is an approved active substance under Regulation (EC) 1107/2009.

Table B.8-1: Critical use pattern of Aluminium Silicate for for SOKA - SOKALCIARBO WP

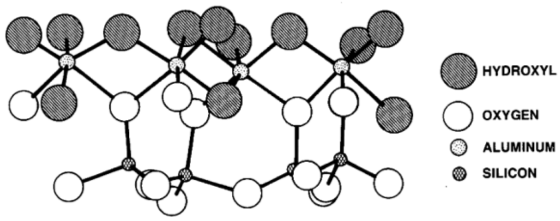
Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st	60000 for 1st	30000	50000 for 1st	15000 for 1st	50000 for 1st	20000

	application 30000 for next applications	application 30000 for next applications		application 30000 for next applications	application 12000 for next applications	application 30000 for next applications	
Number of applications/minium interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Crop growth stage (BBCH)	1st: BBCH 51-59 2nd-3th: BBCH 69-79 4th: post harvest	At the first capture of insect	1st generation: BBCH 01-59 2nd generation: BBCH 69-79	At beginning of fruit ripening and the first capture of insect	At the first capture of insect	At the first capture of insect (with olives on the trees)	BBCH 69-85
Application method	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray

Table B.8-2: Critical use pattern of Aluminium Silicate for for Tessenderlo - SURROUND

Crop	Application rate	Max number of Applications	Min Interval	Application period
Vine	30 kg/ha	4	7 days	Up to BBCH 65

Table B.8-3: Aluminium Silicate and metabolites considered in the assessment

Compound	**Denomination (IUPAC)**	**Structure**	**Compartment**
Aluminium silicate	-		Soil Surface water

B.8.1 Fate and Behaviour in Soil

B.8.1.1 Route and rate of degradation in soil

Aluminium silicate is ubiquitous in soil and agricultural soils. Aluminium silicate has similar chemical composition to common clay that is found in most soils over the world. Aluminium silicate is extremely stable, insoluble, photolytically stable and inert even to mineral acids and bases. When applied to soil, the Aluminium silicate particles will readily mix with the other soil components. Very old Aluminium silicate's quarries are found all around the word because Aluminium silicate does not degrade in soil, therefore, it is not appropriated or suitable to perform studies to show the route and rate of degradation in soil of Aluminum silicate as it is not possible.

Reference:	KCA 7/01, Veatch O. , McCallie S.W., 1909
Title:	Geological survey of Georgia, Bulletin n°18, Second report on the clay deposits of Georgia
Report No.:	Not applicable
Guideline(s):	Not applicable
Deviation(s):	Not applicable
GLP:	No

Origin and age of Kaolin deposits in Georgia, USA:

Chapter 1, pp. 17-18:

"All clays are of secondary origin and have been derived directly or indirectly from the decay and breaking down of the original igneous rocks or the earth's crust. This decay has taken place mainly through the atmospheric agencies, rain, frost, changes in temperature, wind, and through atmospheric gases and organic agencies, plants and animals, all of which may be included under the term weathering. The minerals of igneous rocks, which have been the chief source of kaolinite, or the clay base or clay substance of clays, are the feldspars. Other aluminous minerals, however, have doubtless been a source of the kaolinite of clays, and the following list of minerals has been noted by Prof. C. R. Van Hise as having produced kaolinite through chemical alteration: Andalusite, anorthoclase, biotite, cyanite, epidote, leucite, microcline, nephelite, orthoclase, plagioclase, scapolite, sillimanite, sodalite, topaz and zoisite."

Aluminium silicate (kaolin), like other clays, is therefore a by-product of natural erosion of rocks.

Chapter 4, p. 65:

"The clays of Georgia of commercial value have a wide geological distribution, ranging from the pre-Cambrian igneous and metamorphic rocks to the alluvial deposits of the Pleistocene."

Therefore, aluminium silicate deposits mined today range from > 600 million years-old (pre-Cambrian) to > 1 million years old (Pleistocene).

Therefore, assessing the route and rate of degradation of aluminium silicate under the required framework would not contribute to the regulatory database, nor be practical, as the presence of aluminium silicate (kaolin) is measured in millions of years. Aluminium silicate (kaolin) does not degrade at human timescales.

RMS comments on B.8.1.1

Aluminium silicate has similar chemical composition to common clay that is found in most soils over the world. Aluminium silicate is extremely stable, insoluble, photolytically stable and inert even to mineral acids and bases. Therefore, a waiver to perform environmental studies was requested and accepted by the RMS.

B.8.1.1.1 Aerobic degradation

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies. Please refer to point 7.1.1.

RMS comments on B.8.1.1.1

No further comments.

B.8.1.1.2 Anaerobic degradation

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies. Please refer to point 7.1.1.

RMS comments on B.8.1.1.2

No further comments.

B.8.1.1.3 Soil photolysis

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies. Please refer to point 7.1.1.

RMS comments on B.8.1.1.3

No further comments.

B.8.1.1.4 Field studies

No studies have been submitted or required.

RMS comments on B.8.1.1.4

No further comments.

B.8.1.2 Adsorption and desorption in soil

B.8.1.2.1 Adsorption and desorption of the active substance

A waiver is requested for adsorption and desorption data on aluminium silicate (kaolin).

Aluminium silicate (kaolin) is essentially purified natural clay and is therefore not subject to adsorption on or desorption from soil particles, as it is a component of said soil particles. Aluminium silicate (kaolin) particles will readily mix with the other soil components. Some organic materials (for example fulvic acids) will adsorb onto the particle surfaces, similarly to the aluminium silicate (kaolin) already existing in the soil. Adsorption and desorption of aluminium silicate (kaolin) to soil contaminants is therefore well described in regulatory evaluation dossiers as all adsorption/desorption studies involving standard soils will involve aluminium silicate as a soil component.

This is exemplified in OECD Guidance n°106, Adsorption - Desorption Using a Batch Equilibrium Method.

In this guidance, paragraph 7 states: "The soil parameters that are believed most important for adsorption are: organic carbon content [references]; clay content and soil texture [references]; and pH for ionisable compounds [references]."

Paragraph 18 of OECD Guidance n°106 also states: "The soils should be characterised by three parameters considered to be largely responsible for the adsorptive capacity: organic carbon, clay content and soil texture, and pH. As already mentioned in paragraph 7, other physico-chemical properties of the soil may have an impact on the adsorption/desorption of a particular substance and should be considered in such cases."

OECD Guidance n°106 also provides guidance for the selection of soils based on pH range, organic carbon, clay content and soil texture:

Table 1: Guidance for selection of soil samples for adsorption-desorption

Soil type	pH range (in 0.01 M $CaCl_2$)	Organic carbon content (%)	Clay content (%)	Soil texture*
1	4.5-5.5	1.0-2.0	65-80	clay
2	> 7.5	3.5-5.0	20-40	clay loam
3	5.5-7.0	1.5-3.0	15-25	silt loam
4	4.0-5.5	3.0-4.0	15-30	loam
5	< 4.0-6.0§	< 0.5-1.5§ ‡	< 10-15§	loamy sand
6	> 7.0	< 0.5-1.0§ ‡	40-65	clay loam/clay
7	< 4.5	> 10	< 10	sand/loamy sand

* According to FAO and the US system (85).
§ The respective variables should preferably show values within the range given. If, however, difficulties in finding appropriate soil material occur, values below the indicated minimum are accepted.
‡ Soils with less than 0.3% organic carbon may disturb correlation between organic content and adsorption. Thus, it is recommended the use of soils with a minimum organic carbon content of 0.3%.

The generic term "clay" is not defined in the guidance; a definition of "clay" is provided in Bergaya et al. (Ed), Handbook of Clay Science, 1st Edition, Development in Clay Science 1, Elsevier Ed. 2006.

Chapter 1, pp. 3-5 states: "There is, as yet, no uniform nomenclature for clay and clay material. Nonetheless, we do not seek a consensus about the meaning of the terms ‘clay’, ‘clays’, and ‘clay minerals’ […]. Georgius Agricola (1494–1555), the founder of geology, was apparently the first to have formalized a definition of clay (Guggenheim and Martin, 1995). The latest effort in this direction was made nearly five centuries later by the joint nomenclature committees (JNCs) of the Association Internationale pour l’Etude des Argiles (AIPEA) and the Clay Minerals Society (CMS). The JNCs have defined ‘clay’ as "…a naturally occurring material composed primarily of fine-grained minerals, which is generally plastic at appropriate water contents and will harden with (sic) dried or fired" (Guggenheim and Martin, 1995). […]Although particle size is a key parameter in all definitions of clay, there is no generally accepted upper limit. Some disciplines and professions, however, have conventionally set a maximum size of clay particles. In pedology, for example, the ‘clay fraction’ refers to a class of materials whose particles are smaller than 2 µm in equivalent spherical diameter (e.s.d.). In geology, sedimentology, and geoengineering the size limit is commonly set at 0.4 µm e.s.d. (Moore and Reynolds, 1997), while in colloid science the value of 0.1 µm is generally accepted. Indeed, Weaver (1989) has suggested that the term ‘clay’ should only be used in the textural sense to indicate material that is finer than 4 µm."

Under these criteria the active substance Aluminium silicate (kaolin), which presents a particle size within the range of 0.7 to 11 µm (CP 2.8.5.1, particle size distribution, in Miller 2012 , report number ARC-EX-848-012-P-1) is clearly a clay.

Under those circumstances, adsorption and desorption testing with aluminium silicate (kaolin) is meaningless as the test would involve adding clay to soil, rather than adding an organic substance capable of interacting with the test medium.

Expectations are that by using kaolin instead of another pesticide having toxic residues, the soil biodiversity will improve under aluminium silicate treated fields, since none of the present organisms would be exposed to additional potential toxins.

RMS comments on B.8.1.2.1

Since aluminium silicate is a naturally occurring material (clay) composed primarily of fine grained minerals. As such a test according to OECD 106 cannot be conducted and therefore RMS accepts the applicants’ waiver.

B.8.1.2.2 Adsorption and desorption of metabolites, breakdown and reaction products

No data submitted, nor required. Aluminium silicate does not have any metabolites.

RMS comments on B.8.1.2.2

No metabolites will occur from aluminium silicate as it does not degrade. No further comments.

B.8.1.3 Mobility in soil

Not applicable. Aluminium silicate is not mobile. When applied to soil, aluminium silicate particles will readily mix with other soil components and remain in the topsoil unless physically mixed with the subsoil layer. Therefore, a waiver for mobility studies is requested.

The mobility of clay particles in soil has not been investigated because because clays such as aluminium silicate (kaolin) are known to be insoluble in water, as demonstrated in the presence of an impermeable clay layer in most ponds, lakes or reservoirs. Therefore, aluminium silicate (kaolin) cannot be transported as solute through the soil layer.

Numerous literature sources refer to the clay content expected in soils in general and agricultural soils in particular, such as Newman A.C.D, The significance of clays in agriculture and soils, Phil. Trans. R. Soc. Land. A 311, 375-389 (1984) states (pp. 155-156):

"A soil usually contains at least some clay, and its clay content strongly influences its management and productivity (Davies et al. 1972). Soils with very little clay can be just as difficult to manage, for different reasons, as soils that contain large amounts, and in broad terms loam soils containing 15- 25% clay with particle sizes of under 2 µm and a larger proportion of silt particles sized 2-60 µm are the most productive. Such soils seem to contain enough clay to provide an adequate surface for interaction with water and nutrients, and to have a friable structure beneficial for tillage and root growth. Soils with more than 30-35 % by mass weight of clay tend to take on the properties of the clay itself, with the implications that they waterlog more easily during periods of excess rainfall, stay wet longer, require greater draft in cultivation and form large aggregates (clods) that must be broken down to form a favourable seed bed. In short, they pose more management problems than loamy soils.

Despite these apparently unfavourable properties conferred on soils by an excess of clay, clay makes a vital contribution to soil fertility. In combination with organic matter and sesquioxides, clay contributes coherence and structural stability which enables the soil to resist the mechanically destructive effects of rain and wind. Because clays have a large specific surface that is predominantly negatively charged, they retain cationic nutrients like K^+ and NH_4^+, and also absorb toxic substances. Layer silicate clays may also have plant nutrients present in their structure, and K^+ and Mg^{2+} can be released to soil solution under appropriate conditions."

RMS comments on the B.8.1.3

No further comments. Aluminium silicate is a clay for which no mobility is expected to occur as it would be for an organic compound, hence, waiver is accepted.

B.8.1.3.1 Column leaching studies

B.8.1.3.1.1 Column leaching of the active substance

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.1.3.1.2 Column leaching of metabolites, breakdown and reaction products

No data submitted, nor required.
Aluminium silicate does not have any metabolite.

B.8.1.3.2 Lysimeter studies

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.1.3.3 Field leaching studies

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2 Fate and Behaviour in Water and Sediment

Aluminium silicate is extremely stable. 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. Since aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies. The following reference discusses settling behaviour of clays when water with natural clay from estuaries and deltas enters marine water. Although the experiments described herein focus on saltwater sedimentation, insight on the behaviour of clay particles in fresh water is also provided.

Reference:	KCA 7.2/01, Sutherland B.R. et al, 2014
Title:	Clay settling in fresh and salt water, Environ Fluid Mech, volume 15, Issue 1, pp 147–160
Report No.:	Not applicable
Guideline(s):	Not applicable
Deviation(s):	Not applicable
GLP:	No

Materials and methods

A specified mass of clay is suspended in a fixed volume of water and settling of the particles is observed over time by means of a photographic camera.

Test material: K-WHITE 5000, calcined aluminium silicate powder [45 (±2) % Al_2O_3 and 52 (±2) % SiO_2] from American Elements. Referred to hereafter as "KW5000 clay", 90 % of the powder consisted of particles with size near 2 μm with <0.005 % of the particles having size above ∼45 μm.

Test material concentration: between 15 and 40 ppt by weight (15 to 40 μg/kg).
The KW5000 clay powder was added to the water in the tank and the water was stirred vigorously with a mixer until the mixture was uniform. The stirrer was then extracted and this was taken to be the start time (t = 0) of experiments. To examine the effect of particle consolidation and possible de-gassing of the particles, in some experiments the clay was allowed to settle overnight and then the mixture was re-stirred.

Results and discussion:

Figure 2 shows snapshots and vertical time series constructed from four experiments with KW5000 clay settling in fresh and salt water. In Fig. 2a, clay added to fresh water remained well suspended even after 25 min. This is apparent because the intensity of light passing through the tank changed little over time from top to bottom. Experiments of this type which were conducted for long periods showed that it took over 10 h before all the clay had settled to the bottom 1 cm of the tank. This is consistent with the settling time predicted for individual spherical particles of radius r_p = 1 μm and density ρ_p = 2 g/cm3 to fall H = 10 cm at the Stokes settling velocity,

$$w_s=\frac{2}{9}\frac{g' r_p^2}{\nu} \quad (1)$$

in which $g' = g(\rho_p - \rho_w)/\rho_w$ is the reduced gravity, and ρ_w = 0.9982 g/cm3 and ν = 0.01 cm2/s are respectively the density and kinematic viscosity of fresh water at room temperature. Explicitly, we estimate $w_s \approx 2 \times 10^{-4}$ cm/s, which gives a setting time of $H/w_s = 5 \times 10^4$ s ≈ 13 h.

Figure 2c shows the results of an experiment in which KW5000 clay was allowed to settle overnight in fresh water before being remixed. Here a fraction of the particles are observed to settle out in the first 10 min of the experiment.

Presumably, these were particles that formed flocs while consolidating at the bottom of the tank. However, a substantial fraction of the clay particles remained in suspension even after 25 min, as evidenced by the relatively low intensity of light passing through the tank even near the surface.

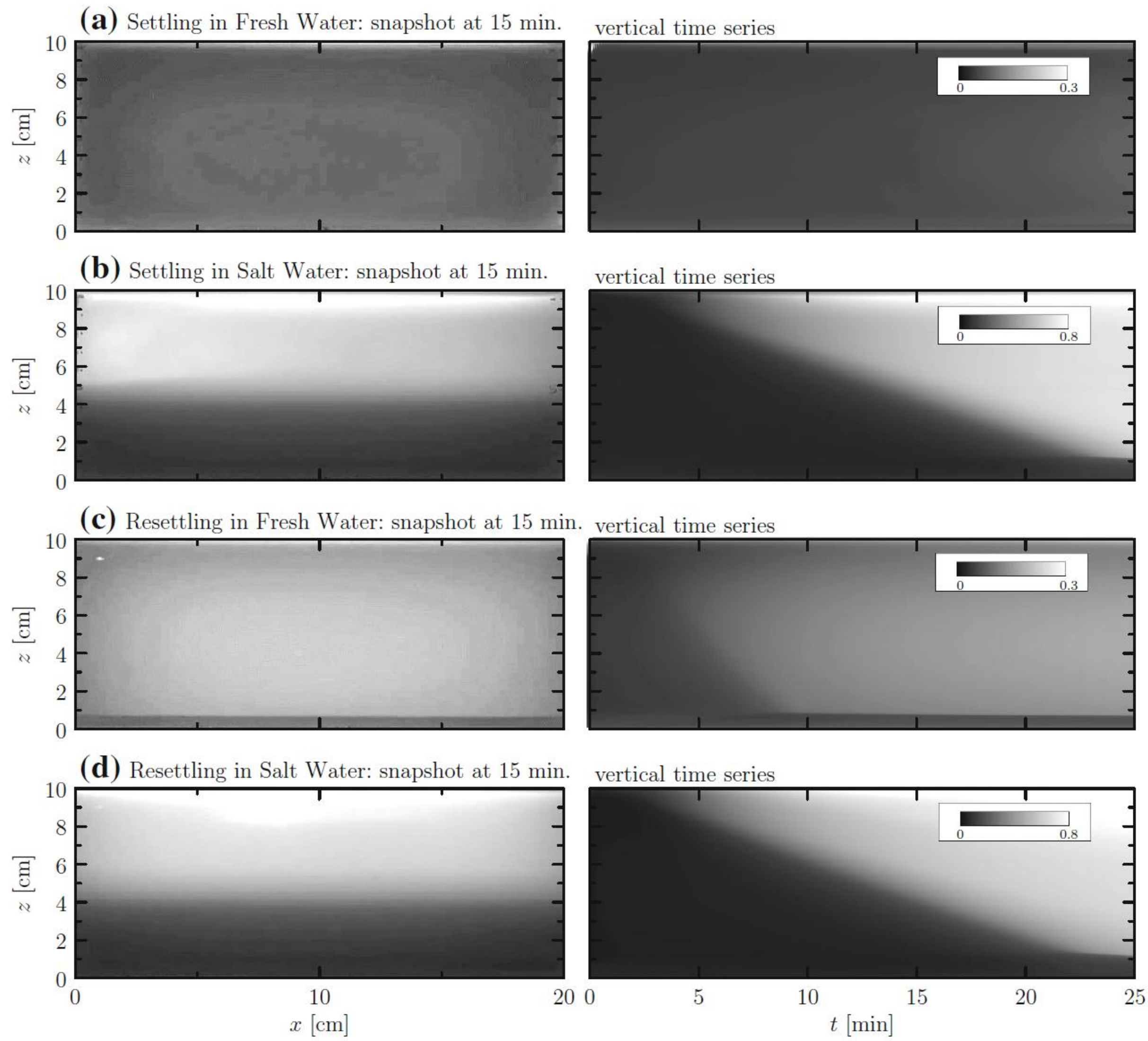


Fig. 2 Snapshots after 15 min (*left column*) and vertical time series of along-tank-averaged light intensity (*right column*) taken from experiments with 14.7 ppt KW5000 clay settling in fresh and salt water: **a** dry clay mixed with fresh water, **b** dry clay mixed with 5 psu saline water (11.0g NaCl added to tank), **c** clay in fresh water settles 20 h and is then remixed before start of experiment, **d** after this experiment, 11.0g NaCl added to tank and the 5 psu saline water is mixed with resuspended clay before start of experiment. The *gray scale* for intensity in each snapshot and corresponding time series is indicated in the *top-right* of each time series plot. Note the intensity of light passing through the tank is significantly brighter near the surface in the salt-water experiments (time-lapse movies of these experiments can be viewed as supplemental material)

Conclusion:

Clay may settle quickly in fresh water if it has already undergone processes that permit the formation of large flocs.

Discussion on the applicability of this article with regards to the fate and behaviour of aluminium silicate (kaolin) in water and sediment

The test material used in this article is similar to the active ingredient aluminium silicate (kaolin) in terms of quality (kaolin clay, calcined aluminium silicate powder) and particle size (90% around 2 µm when the representative product contains 90% of particles around 6 to 7 µm).
The principal elements one can infer from this article from an environmental fate perspective are:

- Aluminium silicate (kaolin) does not dissolve nor degrade in fresh or salt water, therefore no further testing is necessary;
- Aluminium silicate (kaolin) is naturally present in riverine sediment;
- Aluminium silicate (kaolin) will settle more readily when particles have already agglomerated in water and are re-suspended,

The calcined kaolin particles that compose 95-100% of the representative product will be subjected to agglomeration when suspended in the spray prior to application to the crop. Therefore, settling of the particles will be comparatively more rapid than that reported for the test material in the reported article.

RMS comments on the B.8.2

Aluminium silicate is ubiquitous in soil and aquatic sediments. Aluminium silicate has similar chemical composition to common clay that is found in most soils the world over. Aluminium silicate is extremely stable, insoluble, photolytically stable and inert even to mineral acids and bases. Aluminium silicate does not degrade in water. Therefore, it is not appropriated or suitable to perform studies to show the route and rate of degradation in water of Aluminum silicate as it is not possible. Therefore, a waiver to perform environmental studies was requested, and is accepted by the RMS.

B.8.2.1 Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

B.8.2.1.1 Hydrolytic degradation

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2.1.2 Direct photochemical degradation

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2.1.3 Indirect photochemical degradation

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2.2 Route and rate of biological degradation in aquatic systems

Aluminium silicate is extremely stable and a non-degradable natural component of the environment. Aluminium silicate is ubiquitous in soil and aquatic sediments. Aluminium silicate has similar chemical composition to common clay that is found in most soils the world over. Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases.

Therefore, it is not appropriated or suitable to perform studies to show the route and rate of degradation in aquatic system of Aluminum silicate as it is not possible.

B.8.2.2.1 "Ready biodegradability"

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2.2.2 Aerobic mineralisation in surface water

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2.2.3 Water/sediment studies

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2.2.4 Irradiated water/sediment study

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.2.3 Degradation in the Saturated Zone

No data submitted, nor required.
Aluminium silicate is ubiquitous in soil and aquatic sediments. Aluminium silicate has similar chemical composition to common clay that is found in most soils the world over. Aluminium silicate is extremely stable, insoluble, photolytically stable and inert even to mineral acids and bases.

RMS general comments on the B.8.2

Waiving of the studies was requested by the applicants due to nature of aluminium silicate. The RMS accepts the waiver. No further comments.

B.8.3 Fate and Behaviour in Air

Aluminium silicate is not vaporized, extremely stable, insoluble, photolytically stable and inert even to mineral acids and bases. Therefore it is assumed it does not degrade in air. It is not appropriated or suitable to perform studies to show the fate and behaviour of Aluminum silicate in air as it is not possible. Therefore, the applicant asks for a waiver to perform environmental studies.

B.8.3.1 Route and rate of degradation in air

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.3.2 Transport via air

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

B.8.3.3 Local and global effects

No data submitted, nor required. The applicant asks for a waiver to perform environmental studies.

RMS general comments on the B.8.3

Waiving of the studies was requested by the applicants due to nature of aluminium silicate. The RMS accepts the waiver. No further comments.

B.8.4 Definition of the Residue

B.8.4.1 Definition of the residue for risk assessment

Aluminium silicate is ubiquitous in soil (including agricultural soils) and aquatic sediments, and applied Aluminium silicate will be indistinguishable from naturally present clay. Therefore, the concept of residue in the environment does not apply to Aluminium silicate.

B.8.4.2 Definition of the residue for monitoring

No data submitted, nor required.

B.8.5 Monitoring Data

Aluminium silicate is ubiquitous in soil (including agricultural soils) and aquatic sediments, and applied Aluminium silicate will be indistinguishable from naturally present clay. Therefore, the concept of environmental monitoring does not apply to Aluminium silicate.

B.8.6 Review of scientific open literature

An open literature search was carried out by both Notifiers. Relevance and reliability of articles found in the search process were appraised in adherence with EFSA guidelines (EFSA Journal 2011;9(2):2092 and EFSA supporting publication 2013:EN-511). A summary of the results of the search are presented below.

Applicant SOKA

Introduction

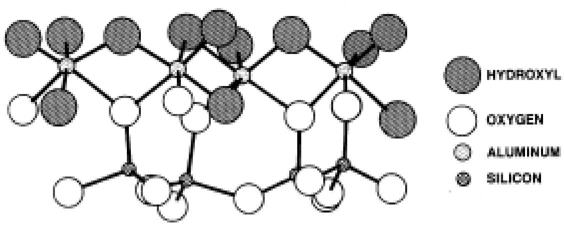
ISO-common name: Kaolin
Synonym: Aluminium Silicate

Chemical name (IUPAC): Not available
Chemical name (CAS): Kaolin

CAS No: 1332-58-7
CIMAP No: 841
EC No: 310-194-1 (E559)

Empirical formula: Hydrous aluminium silicate: $Al_4Si_4O_{10} (OH)_8$
Calcined aluminium silicate: $Al_4Si_4O_{14}$

Structural formula:



Article 8(5) of Regulation (EC) No 1107/2009 requires applicants submitting dossiers for approval and renewal of active substances to provide relevant scientific peer reviewed open literature. This summary of scientific peer reviewed open literature conforms to EFSA guidance "Submission of scientific peer-reviewed open literature under Regulation (EC) No 1107/2009, EFSA Journal 2011; 9(2):2092".

Peer reviewed open literature containing data and analysis dealing with the side effects on health, the environment, and non-target species for common name. The data published within the last ten years before the date of the submission of Aluminium Silicate renewal dossier were reviewed for this document. The document contains the search criteria and results of those searches of "scientific peer-reviewed open literature" performed under Regulation (EC) No 1107/2009 for Aluminium Silicate.

Relevance criteria

Peer reviewed open literature relevant to the dossier may satisfy or partially satisfy data requirements as set out in Regulation (EC) No 1107/2009. The relevance criteria chosen for the selection of peer reviewed scientific open literature is consistent with the OECD guidance and does not restrict the selection of literature (Table B.8.6-1). The relevance criteria guide the selection of literature dealing with the side effects on health, environment and non-target species for Aluminium Silicate. Non-Good Laboratory Practice studies in open literature may be considered relevant if the design and execution of the study is consistent with generally accepted scientific practice and guidelines. Clearly non-relevant studies are excluded.

Table B.8.6-1: Criteria for relevance

Data requirement(s) Indicated by the correspondent data point number(s) as identified in Commission Regulation (EU) No 283/2013	**Criteria for relevance**
All data points	1. The test system, target crop, or species are prescribed by regulation (EC) No 1107/2009 or the relevance is explained if not standard.
	2. Well identified test material, including its purity and impurity profile is described
	3. Study design and/or execution are consistent with relevant study guidelines
	4. The endpoint is relevant to an EU data point as prescribed by Commission Regulation (EU) No 283/2013 and No 284/2013
Toxicological and metabolism studies (CA 5)	5. Description of the observations, examinations, analysis performed, or necropsy are well described.
	6. The conditions of exposure should be from legally registered use of the product
Residues in or on treated products, food and feed (CA 6)	7. The application methods complies with Good Agriculture Practice (GAP)
	8. Appropriate in life/processing conditions are used and/or are well described
Fate and behaviour in the environment (CA 7)	9. The model is appropriate for European regulatory requirements
	10. The input parameters selection is appropriate based on European regulatory requirements
	11. The pedoclimatic conditions are appropriate
Ecotoxicological studies (CA 8)	12. A relevant route of exposure is presented

Search criteria

Reasonable effort was taken to locate all sources of relevant peer reviewed open literature concentrated on comprehensive databases containing worldwide coverage of biology, chemistry, biomedical, agricultural and environmental fields. The search ranged up to 10 years and within 6 months of the submission date of the renewal dossier for Aluminium silicate. The initial search is a single concept search capturing all data points using search terms and synonyms for the active substance. If a large number of search results are returned from the single concept search making assessment for relevance impractical, a separate, focused search is conducted for grouped data points.

Table B.8.6-2: Details of literature search for Aluminium Silicate and Fate and behaviour in the environment (CA 7)

Details of the searches: Fate and behaviour in the environment (CA 7)				
Data requirement(s)	Database	Database 1: PubMed	Database 2: PubAg	Database 3: NAL catalog (Agricola) and Article citation database
Fate and behaviour in the environment (CA 7)	Justification for choosing the source	PubMed is a free search engine accessing primarily the MEDLINE database of references and abstracts on life sciences and biomedical topics.	A bibliographic database containing selective worldwide coverage of agriculture and related fields. (4.2+ million records)	
	Date of the search	January 15th, 2018	January 15th, 2018	January 15th, 2018
	Date span of the search	2008-2018	2008-2018	2008-2018
	Search strategies used for this data requirement	**23. 1-3 and soil** ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND ("soil"[MeSH Terms] OR "soil"[All Fields]) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])	**23. 1-2 and soil**	**23. 1-2 and soil**
		Total number of records retrieved: 129 After removing duplicate: 109	Total number of records retrieved: 3	Total number of records retrieved: 7
		24. 1-3 and behavior and soil ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("behaviour"[All Fields] OR "behavior"[MeSH Terms] OR "behavior"[All Fields]) AND ("soil"[MeSH Terms] OR "soil"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])	**24. 1-2 and behavior and soil**	**24. 1-2 and behavior and soil**
		Total number of records retrieved: 17	Total number of records	Total number of records

		After removing duplicate: 0	retrieved: 3 After removing duplicate: 0	retrieved: 0

Details of the searches: Fate and behaviour in the environment (CA 7) (continued)				
Data requirement(s)	Database	Database 1: PubMed	Database 2: PubAg	Database 3: NAL catalog /Article citation
Fate and behaviour in the environment (CA 7)	Search strategies used for this data requirement	**25. 1-3 and soil and accumulation** ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("soil"[MeSH Terms] OR "soil"[All Fields]) AND accumulation[All Fields]) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])	**25. 1-2 and soil and accumulation**	**25. 1-2 and soil and accumulation**
		Total number of records retrieved: 5 After removing duplicate: 0	Total number of records retrieved: 3 After removing duplicate: 0	Total number of records retrieved: 1 After removing duplicate: 0
		26. 1-3 and soil and dissipation ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (("soil"[MeSH Terms] OR "soil"[All Fields]) AND dissipation[All Fields]) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])	**26. 1-2 and soil and dissipation**	**26. 1-2 and soil and dissipation**
		Total number of records retrieved: 0	Total number of records retrieved: 0	Total number of records retrieved: 0
		27. 1-3 and residues and water ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND	**27. 1-2 and residues and water**	**27. 1-2 and residues and water**

		"silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (, residues[All Fields] AND ("water"[MeSH Terms] OR "water"[All Fields] OR "drinking water"[MeSH Terms] OR ("drinking"[All Fields] AND "water"[All Fields]) OR "drinking water"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])		
		Total number of records retrieved: 2 After removing duplicate: 0	Total number of records retrieved: 1 /After removing duplicate: 0	Total number of records retrieved: 0

Details of the searches: Fate and behaviour in the environment (CA 7) (continued)				
Data requirement(s)	Database	Database 1: PubMed	Database 2: PubAg	Database 3: NAL catalog (Agricola) and Article citation database
Fate and behaviour in the environment (CA 7)	Search strategies used for this data requirement	**28. 1-3 and residues and air** ("aluminum silicates"[MeSH Terms] OR ("aluminum"[All Fields] AND "silicates"[All Fields]) OR "aluminum silicates"[All Fields] OR ("aluminium"[All Fields] AND "silicate"[All Fields]) OR "aluminium silicate"[All Fields]) AND "1332-58-7"[All Fields] AND (, residues[All Fields] AND ("air"[MeSH Terms] OR "air"[All Fields])) AND ("2008/01/19"[PDat] : "2018/01/15"[PDat])	**28. 1-2 and residues and air**	**28. 1-2 and residues and air**
		Total number of records retrieved: 0	Total number of records retrieved: 1 After removing duplicate: 0	Total number of records retrieved: 0
		Total number of summary records retrieved after removing duplicates: 109	**Total number of summary records retrieved after removing duplicates: 3**	**Total number of summary records retrieved after removing duplicates: 7**
		Total number of summary records retrieved after removing duplicates: 119		

Relevant study selection -results of the selection process

Obviously non-relevant studies in open literature search were excluded by applying the relevance criteria previously defined in Table B.8.6-1 of this document. A total of 119 summary records were reviewed, all of which were not relevant.

Table B.8.6-3: Results of the selection process for Fate and behaviour in the environment (CA 7)

Data requirement(s) captured in the search	Number
Total number of summary records retrieved after all searches of peer-reviewed literature (excluding duplicates)	119
Number of records excluded from the search results after rapid assessment for relevance	119
Total number of full text documents assessed in detail	0
Number of studies excluded from the dossier after detailed assessment for relevance	0
Number of studies not present in the basic search	0
Number of studies included in the dossier	0

Literature included in the dossier after detailed assessment

Table B.8.6-4: Report of all relevant studies included after detailed assessment of full text documents (ordered by author) section CA.7

None of the article obtained were relevant to environmental fate with regards to degradation, dissipation, absorption/desorption, leaching, water/sediment contamination or air contamination.

Literature excluded after detailed assessment

Obviously non-relevant studies found in the open literature search were excluded by applying the relevance criteria previously defined in this document.

Table B.8.6-5: Report of all non-relevant studies excluded after detailed assessment of full text documents (ordered by author) section CA.7

All articles/studies were excluded rejected from the first step

Literature excluded from the first selection stage

Table B.8.6-6: Report of all non- relevant studies excluded (ordered by author) section E-Fate

Authors	Year	Title	Source (journal, volume, pages)	Comment
Alcántara T, Pazos M, Cameselle C, Sanromán MA	2008	Electrochemical remediation of phenanthrene from contaminated kaolinite	Environ Geochem Health. 2008 Apr;30(2):89-94.	Not relevant
Alcantara T, Pazos M, Gouveia S, Cameselle C, Sanroman MA	2008	Remediation of phenanthrene from contaminated kaolinite by electroremediation-Fenton technology.	J Environ Sci Health A Tox Hazard Subst Environ Eng. 2008 Jul 1;43(8):901-6.	Not relevant
Aljuboori AH, Idris A, Al-joubory HH, Uemura Y, Ibn Abubakar BS	2015	Flocculation behavior and mechanism of bioflocculant produced by Aspergillus flavus	J Environ Manage. 2015 Mar 1;150:466-71	Not relevant
Badea SL, Lundstedt S, Liljelind P, Tysklind M	2013	The influence of soil composition on the leachability of selected hydrophobic organic compounds (HOCs) from soils using a batch leaching test	J Hazard Mater. 2013 Jun 15;254-255:26-35.	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Behera SK, Oh SY, Park HS	2010	Sorption of triclosan onto activated carbon, kaolinite and montmorillonite: effects of pH, ionic strength, and humic acid	J.Hazard Mater. 2010 Jul 15;179(1-3):684-91	Not relevant
Bo X, Gao B, Peng N, Wang Y, Yue Q, Zhao Y	2012	Effect of dosing sequence and solution pH on floc properties of the compound bioflocculant-aluminum sulfate dual-coagulant in kaolin-humic acid solution treatment	Bioresour Technol. 2012 Jun;113:89-96	Not relevant
Bothe, Hermann	2015	The lime -silicate question	Soil Biology and Biochemistry Volume 89, october 2015, page 172-183	Not relevant
Brosky RT, Pamukcu S	2013	Role of DDL processes during electrolytic reduction of Cu(II) in a low oxygen environment	J Hazard Mater. 2013 Nov 15;262:878-82	Not relevant
Cai P, Zhu J, Huang Q, Fang L, Liang W, Chen W.	2009	Role of bacteria in the adsorption and binding of DNA on soil colloids and minerals	Colloids Surf B Biointerfaces. 2009 Feb 15;69(1):26-30	Not relevant
Carmeis Filho AC, Crusciol CA, Guimarães TM, Calonego JC, Mooney S	2016	Impact of Amendments on the Physical Properties of Soil under Tropical Long-Term No Till Conditions	PLoS One. 2016 Dec 13;11(12):e0167564	Not relevant
Chandrajith R, Kudavidanage E, Tobschall HJ, Dissanayake CB.	2009	Geochemical and mineralogical characteristics of elephant geophagic soils in Udawalawe National Park, Sri Lanka.	Environ Geochem Health. 2009 Jun;31(3):391-400.	
Chen H, Gao B, Yang LY, Ma LQ	2015	Montmorillonite enhanced ciprofloxacin transport in saturated porous media with sorbed ciprofloxacin showing antibiotic activity.	J Contam Hydrol. 2015 Feb;173:1-7	Not relevant
Chen W, Zheng H, Teng H, Wang Y, Zhang Y, Zhao C, Liao Y.	2015	Coagulation-Flocculation Performance of Iron-Based Coagulants: Effects of PO4(3-) and SiO3(2-) Modifiers.	PLoS One. 2015 Sep 4;10(9):e0137116.	Not relevant
Chipeng ZhangPan WuChangyuan TangEmail authorXiuzhen TaoZhiwei HanJing SunHong Liu	2013	The study of soil acidification of paddy field influenced by acid mine drainage	Environmental Earth Sciences, december 2013, Volume 70, Issue 7, page 2931-2940	Not relevant
Choi YJ, Lee LS	2017	Partitioning Behavior of Bisphenol Alternatives BPS and BPAF Compared to BPA	Environ Sci Technol. 2017 Apr 4;51(7):3725-3732	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Chu YB, Zhou XZ, Wang Y, Wang Q	2010	[Effect of composite flocculants made of polyaluminium chloride and polydimethyldially ammonium chloride on ultra-filtration membrane characteristics]	Huan Jing Ke Xue. 2010 May;31(5):1206-10	Not relevant
David A.C. Manning	2010	Mineral sources of potassium for plant nutrition. A review	Agron.Sustain.Dev. 30(2010) 281-294	Not relevant
Dong W, Wan J	2014	Additive surface complexation modeling of uranium (VI) adsorption onto quartz-sand dominated sediments	Environ Sci Technol. 2014 Jun 17;48(12):6569-77	Not relevant
dos Santos EV, Sáez C, Martínez-Huitle CA, Cañizares P, Rodrigo MA.	2015	Combined soil washing and CDEO for the removal of atrazine from soils	J Hazard Mater. 2015 Dec 30;300:129-34	Not relevant
Droge ST, Goss KU	2013	Sorption of organic cations to phyllosilicate clay minerals: CEC-normalization, salt dependency, and the role of electrostatic and hydrophobic effects	Environ Sci Technol. 2013 Dec 17;47(24):14224-32	Not relevant
Du YJ, Wei ML, Reddy KR, Liu ZP, Jin F	2014	Effect of acid rain pH on leaching behavior of cement stabilized lead-contaminated soil	J Hazard Mater. 2014 Apr 30;271:131-40.	Not relevant
F. S. Kot A B , R. Farran A , M. Kochva A and A. Shaviv A	2011	Boron in humus and inorganic components of Hamra and Grumosol soils irrigated with reclaimed wastewater	Soil Research 50(1) 30-43	Not relevant
Fang D, Shi C	2016	Characterization and flocculability of a novel proteoglycanproduced by Talaromyces trachyspermus OU5	J Biosci Bioeng. 2016 Jan;121(1):52-56	Not relevant
Gao Q, Zhu XH, Mu J, Zhang Y, Dong XW.	2009	Using Ruditapes philippinarum conglutination mud to produce bioflocculant and its applications in wastewater treatment	Bioresour Technol. 2009 Nov;100(21):4996-500	Not relevant
Gardner CM, Gunsch CK	2017	Adsorption capacity of multiple DNA sources to clay minerals and environmental soil matrices less than previously estimated.	Chemosphere. 2017 May;175:45-51	Not relevant
Garoma T, Skidmore L.	2011	Modeling the influence of ethanol on the adsorption and desorption of selected BTEX compounds on bentonite and kaolin	J Environ Sci (China). 2011;23(11):1865-72	Not relevant
Ghorbanzadeh N, Lakzian A, Halajnia A, Kabra AN, Kurade MB, Lee DS, Jeon BH.	2015	Influence of clay minerals on sorption and bioreduction of arsenic under anoxic conditions	Environ Geochem Health. 2015 Dec;37(6):997-1005	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Gianotti V, Benzi M, Croce G, Frascarolo P, Gosetti F, Mazzucco E, Bottaro M, Gennaro MC.	2008	The use of clays to sequestrate organic pollutants. Leaching experiments	Chemosphere. 2008 Dec;73(11):1731-6	Not relevant
Gomes HI, Dias-Ferreira C, Ribeiro AB	2012	Electrokinetic remediation of organochlorines in soil: enhancement techniques and integration with other remediation technologies	Chemosphere. 2012 Jun;87(10):1077-90	Not relevant
Gómez J, Alcántara MT, Pazos M, Sanromán MA	2009	A two-stage process using electrokinetic remediation and electrochemical degradation for treating benzo[a]pyrene spiked kaolin	Chemosphere. 2009 Mar;74(11):1516-21	Not relevant
Guinoiseau D, Gélabert A, Moureau J, Louvat P, Benedetti MF	2016	Zn Isotope Fractionation during Sorption onto Kaolinite	Environ Sci Technol. 2016 Feb 16;50(4):1844-52	Not relevant
Han CW, Qiao XL, Chen JW, Cai XY	2009	[Enhanced sorption of OTC on clays via complexation with Zn2+	Huan Jing Ke Xue. 2009 Aug 15;30(8):2408-1	Not relevant
Han Z, Zhang F, Lin D, Xing B.	2008	Clay minerals affect the stability of surfactant-facilitated carbon nanotube suspensions	Environ Sci Technol. 2008 Sep 15;42(18):6869-75	Not relevant
Harendra S, Vipulanandan C	2013	Sorption and transport studies of cetyl trimethylammonium bromide (CTAB) and Triton X-100 in clayey soil.	J Environ Sci (China). 2013 Mar 1;25(3):576-84	Not relevant
He Y, Zeng F, Lian Z, Xu J, Brookes PC	2015	Natural soil mineral nanoparticles are novel sorbents for pentachlorophenol and phenanthrene removal	Environ Pollut. 2015 Oct;205:43-51	Not relevant
Horii Y, Ohtsuka N, Minomo K, Nojiri K, Kannan K, Lam PK, Yamashita N	2011	Distribution, characteristics, and worldwide inventory of dioxins in kaolin ball clays	Environ Sci Technol. 2011 Sep 1;45(17):7517-24	Not relevant
Huang G, Guo H, Zhao J, Liu Y, Xing B	2016	Effect of co-existing kaolinite and goethite on the aggregation of graphene oxide in the aquatic environment	Water Res. 2016 Oct 1;102:313-320.	Not relevant
Huang Q, Zhu J, Qiao X, Cai P, Rong X, Liang W, Chen W	2009	Conformation, activity and proteolytic stability of acid phosphatase on clay minerals and soil colloids from an Alfisol	Colloids Surf B Biointerfaces. 2009 Nov 1;74(1):279-83.	Not relevant
Ivory SJ, McGlue MM, Ellis GS, Lézine AM, Cohen AS, Vincens A	2014	Vegetation controls on weathering intensity during the last deglacial transition in southeast Africa	PLoS One. 2014 Nov 18;9(11)	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Jacques, D.; Simunek, J.; Mallants, D.; van Genuchten, M.T.	2008	Modeling Coupled Hydrologic and Chemical Processes: Long-Term Uranium Transport following Phosphorus Fertilization	Vadose zone journal 2008 v.7 no.2 pp. 698-711	Not relevant
Jermann D, Pronk W, Boller M	2008	Mutual influences between natural organic matter and inorganic particles and their combined effect on ultrafiltration membrane fouling	Environ Sci Technol. 2008 Dec 15;42(24):9129-36	Not relevant
Jiao R, Xu H, Xu W, Yang X, Wang D	2015	Influence of coagulation mechanisms on the residual aluminum--the roles of coagulant species and MW of organic matter	J. Hazard Mater. 2015 Jun 15;290:16-25	Not relevant
Jordão CP, Fernandes RB, de Lima Ribeiro K, de Souza Nascimento B, de Barros PM	2009	Zn (II) adsorption from synthetic solution and kaolin wastewater onto vermicompost	J Hazard Mater. 2009 Mar 15;162(2-3):804-11	Not relevant
Kang S, Jeong HY	2015	Sorption of a nonionic surfactant Tween 80 by minerals and soils	J Hazard Mater. 2015 Mar 2;284:143-50	Not relevant
Kaniu MI, Angeyo KH, Mwala AK, Mwangi FK	2012	Energy dispersive X-ray fluorescence and scattering assessment of soil quality via partial least squares and artificial neural networks analytical modeling approaches.	Talanta. 2012 Aug 30;98:236-40	Not relevant
Kautenburger R, Beck HP	2010	Influence of geochemical parameters on the sorption and desorption behaviour of europium and gadolinium onto kaolinite	J Environ Monit. 2010 Jun;12(6):1295-301	Not relevant
Kavurmaci SS, Bekbolet M	2014	Non-selective oxidation of humic acid in heterogeneous aqueous systems: a comparative investigation on the effect of clay minerals	Environ Technol. 2014 Sep-Oct;35(17-20):2389-400	Not relevant
Kim J, Kim M, Hyun S, Kim JG, Ok YS	2012	Sorption of acidic organic solute onto kaolinitic soils from methanol-water mixtures	J Environ Sci Health B 2012;47(1):22-9	Not relevant
Kumar J, Nisar K, Shakil NA, Walia S, Parsad R	2010	Controlled release formulations of metribuzin: release kinetics in water and soil.	J Environ Sci Health B. 2010 May;45(4):330-5	Not relevant
L. Barão W. Clymans F. Vandevenne P. Meire D. J. Conley E. Struyf	2015	Pedogenic and biogenic alkaline-extracted silicon distributions along a temperate land-use gradient	European Journal of Soil Science volume 65, issue 5 september 2015 page 693-705	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Li D, Xiong Z, Nie Y, Niu YY, Wang L, Liu YY	2012	Near-anode focusing phenomenon caused by the high anolyte concentration in the electrokinetic remediation of chromium (VI)-contaminated soil	J Hazard Mater. 2012 Aug 30;229-230:282-91	Not relevant
Li R, Gao B, Huang X, Dong H, Li X, Yue Q, Wang Y, Li Q	2014	Compound bioflocculant and polyaluminum chloride in kaolin-humic acid coagulation: factors	Bioresour Technol. 2014 Nov;172:8-15	Not relevant
Li Z, Hong H, Liao L, Ackley CJ, Schulz LA, MacDonald RA, Mihelich AL, Emard SM	2011	A mechanistic study of ciprofloxacin removal by kaolinite. Colloids Surf B	Biointerfaces. 2011 Nov 1;88(1):339-44.	Not relevant
Lin D, Ma W, Jin Z, Wang Y, Huang Q, Cai P	2016	Interactions of EPS with soil minerals: A combination study by ITC and CLSM	Colloids Surf B Biointerfaces.2016 Feb 1;138:10-6	Not relevant
Liu JJ, Liang DL, Wu XL, Qu GZ, Qian X	2014	[Effect of Cr (VI) anions on the Cu (II) adsorption behavior of two kinds of clay minerals in single and binary solution]	Huan Jing Ke Xue. 2014 Jan;35(1):254-62	Not relevant
Liu X, Li J, Wu X, Zeng Z, Wang X, Hayat T, Zhang X.	2017	Adsorption of carbon dots onto Al(2)O(3) in aqueous: Experimental and theoretical studies	Environ Pollut. 2017 Aug;227:31-38.	Not relevant
Liu Z, Guo H, He H, Sun C	2012	Sorption and cosorption of the nonionic herbicide mefenacet and heavy metals on soil and its components	J Environ Sci (China) 2012;24(3):427-34	Not relevant
Liu Z, Liu S, Cai Y, Fang W	2015	Electrical resistivity characteristics of diesel oil-contaminated kaolin clay and a resistivity-based detection method	Environ Sci Pollut Res Int. 2015 Jun;22(11):8216-23	Not relevant
López-Vizcaíno R, Sáez C, Mena E, Villaseñor J, Cañizares P, Rodrigo MA.	2011	Electro-osmotic fluxes in multi-well electro-remediation processes	J Environ Sci Health A Tox Hazard Subst Environ Eng. 2011;46(13):1549-57.	Not relevant
Luo X, Yu L, Wang C, Yin X, Mosa A, Lv J, Sun H	2017	Sorption of vanadium (V) onto natural soil colloids under various solution pH and ionic strength conditions.	Chemosphere. 2017 Feb;169:609-617.	Not relevant
Lv G, Stockwell C, Niles J, Minegar S, Li Z, Jiang WT	2013	Uptake and retention of amitriptyline by kaolinite	J Colloid Interface Sci. 2013 Dec 1;411:198-203.	Not relevant
M.B.OgundiranaH.W.NugterenaG.J.Witkampb	2013	Immobilisation of lead smelting slag within spent aluminate—fly ash based geopolymers	Journal of hazardous Materials, Volume 248-249, 15 March 2013, page 29-36	Not relevant
Mackay AA, Seremet DE	2008	Probe compounds to quantify cation exchange and complexation interactions of ciprofloxacin with soils	Environ Sci Technol. 2008 Nov 15;42(22):8270-6	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Markiewicz M, Mrozik W, Rezwan K, Thöming J, Hupka J, Jungnickel C.	2013	Changes in zeta potential of imidazolium ionic liquids modified minerals--Implications for determining mechanism of adsorption	Chemosphere. 2013 Jan;90(2):706-12	Not relevant
Martin DF, Nabar N	2014	Studies on the removal of Lissamine Green B from clays and soil in comparison with contemporary approaches	J Environ Sci Health A Tox Hazard Subst Environ Eng. 2012;47(2):260-6	Not relevant
Matzke M, Thiele K, Müller A, Filser J	2009	Sorption and desorption of imidazolium based ionic liquids in different soil types	Chemosphere. 2009 Jan;74(4):568-74	Not relevant
Mittal H, Jindal R, Kaith BS, Maity A, Ray SS	2015	Flocculation and adsorption properties of biodegradable gum-ghatti-grafted poly (acrylamide-co-methacrylic acid) hydrogels	Carbohydr Polym. 2015 Jan 22;115:617-28	Not relevant
Moussas PA, Zouboulis AI	2009	A new inorganic-organic composite coagulant, consisting of polyferric sulphate (PFS) and polyacrylamide (PAA	Water Res. 2009 Aug;43(14):3511-24	Not relevant
Moyo F, Tandlich R, Wilhelmi BS, Balaz S	2014	Sorption of hydrophobic organic compounds on natural sorbents and organoclays from aqueous and non-aqueous solutions: a mini-review	Int J Environ Res Public Health. 2014 May 9;11(5):5020-48	Not relevant
Naseem S, Rafique T, Bashir E, Bhanger MI, Laghari A, Usmani TH	2010	Lithological influences on occurrence of high-fluoride groundwater in Nagar Parkar area, Thar Desert, Pakistan	Chemosphere. 2010 Mar;78(11):1313-21	Not relevant
Ng CW, Chen ZK, Coo JL, Chen R, Zhou C	2015	Gas breakthrough and emission through unsaturated compacted clay in landfill final cover	Waste Manag. 2015 Oct;44:155-63	Not relevant
nil C.DubeyR.BhavaniBirendraSingh	2009	Development of Pusa 5SD for seed dressing and Pusa Biopellet 10G for soil application formulations of Trichoderma harzianum and their evaluation for integrated management of dry root rot of mungbean (Vigna radiata)	Biological control, volume 5, issue 3, september 2009, pages 231-242	Not relevant
Nisar K, Kumar J, Shakil NA, Walia S, Parmar BS	2009	Controlled release formulations of acephate: water and soil release kinetics	J Environ Sci Health B. 2009 Aug;44(6):533-7	Not relevant
Oonnittan A, Shrestha RA, Sillanpää M.	2009	Removal of hexachlorobenzene from soil by electrokinetically enhanced chemical oxidation	J Hazard Mater. 2009 Mar 15 ;162(2-3) :989-93	Not relevant
Ouhadi VR, Yong RN, Shariatmadari N,	2010	M. Impact of carbonate on the efficiency of heavy metal	J Hazard Mater. 2010 Jan 15 ;173(1-3)	Not

Authors	Year	Title	Source (journal, volume, pages)	Comment
Saeidijam S, Goodarzi AR, Safari-Zanjani		removal from kaolinite soil by the electrokinetic soil remediation method	:87-94	relevant
Parikh, Sanjai J.; Goyne, Keith W.; Margenot, Andrew J.; Mukome, Fungai N. D.; Calderón, Francisco J.	2014	Soil chemical insights provided through vibrational spectroscopy	Advances in agronomy 2014 v.126 pp. 1-112	Not relevant
Pazos M, Gouveia S, Sanroman MA, Cameselle C.	2008	Electromigration of Mn, Fe, Cu and Zn with citric acid in contaminated clay.	J Environ Sci Health A Tox Hazard Subst Environ Eng. 2008 Jul 1 ;43(8) :823-31	Not relevant
Qinyan Y, Ying L, Baoyu G.	2009	Impact factors and thermodynamic characteristics of aquatic humic acid loaded onto kaolin	Colloids Surf B Biointerfaces. 2009 Sep 1;72(2):241-7	Not relevant
Ranger, Christopher M.; Singh, Ajay P.; Frantz, Jonathan M.; Cañas, Luis; Locke, James C.; Reding, Michael E.; Vorsa, Nicholi	2009	Influence of Silicon on Resistance of Zinnia elegans to Myzus persicae (Hemiptera: Aphididae)	Environmental entomology 2009 v.38 no.1 pp. 129-136	Not relevant
Roach N, Reddy KR, Al-Hamdan AZ	2009	Particle morphology and mineral structure of heavy metal-contaminated kaolin soil before and after electrokinetic remediation	J Hazard Mater. 2009 Jun 15 ;165(1-3):548-57	Not relevant
Rong X, Huang Q, He X, Chen H, Cai P, Liang W.	2008	Interaction of Pseudomonasputida with kaolinite and montmorillonite: a combination study by equilibrium adsorption, ITC, SEM and FTIR	Colloids Surf B Biointerfaces. 2008 Jun 15;64(1):49-55	Not relevant
Sachs S, Bernhard G.	2008	Sorption of U(VI) onto an artificial humic substance-kaolinite-associate	Chemosphere. 2008 Aug;72(10):1441-7	Not relevant
Sarkar B, Naidu R, Krishnamurti GS, Megharaj M	2013	Manganese (II)-catalyzed and clay-minerals-mediated reduction of chromium (VI) by citrate	Environ Sci Technol. 2013;47(23):13629-36	Not relevant
Shrestha RA, Pham TD, Sillanpää M	2009	Effect of ultrasound on removal of persistent organic pollutants (POPs) from different types of soils	J Hazard Mater. 2009 Oct 30;170(2-3):871-5	Not relevant
Sun C, Qiu J, Zhang Z, Marhaba TF, Zhang Y.	2016	Coagulation behavior and floc characteristics of a novel composite poly-ferric aluminum chloride-polydimethyl diallylammonium chloride coagulant with different OH/(Fe(3+) + Al(3+)) molar ratios	Water Sci Technol. 2016 Oct;74(7):1636-1643	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Sun PF, Lin H, Wang G, Lu LL, Zhao YH	2015	Preparation of a new-style composite containing a key bioflocculant produced by Pseudomonas aeruginosa ZJU1 and its flocculating effect on harmful algal blooms	J Hazard Mater. 2015 Mar 2;284:215-21	Not relevant
Suzuki T, Kawai K, Moribe M, Niinae M.	2014	Recovery of Cr as Cr(III) from Cr(VI)-contaminated kaolinite clay by electrokinetics coupled with a permeable reactive barrier	J Hazard Mater. 2014 Aug 15;278:297-303	Not relevant
Teixeira SC, Oliveira A, Duarte P, Vieira Ferreira LF, Moreira JC, Peréz DV, Marques MR	2013	Pyrene photochemical species in commercial clays	Chemosphere. 2013 Jan;90(2):657-64.	Not relevant
Turhan S.	2009	Radiological impacts of the usability of clay and kaolin as raw material in manufacturing of structural building materials in Turkey	J Radiol Prot. 2009 Mar;29(1):75-83	Not relevant
Ueno S, Fujita T, Kuchar D, Kubota M, Matsuda H.	2009	Ultrasound assisted extraction and decomposition of Cl-containing herbicide involved in model soil.	Ultrason Sonochem. 2009 Jan;16(1):169-75	Not relevant
Walshe GE, Pang L, Flury M, Close ME, Flintoft M	2010	Effects of pH, ionic strength, dissolved organic matter, and flow rate on the co-transport of MS2 bacteriophages with kaolinite in gravel aquifer media	Water Res. 2010 Feb;44(4):1255-69	Not relevant
Wan J, Wang L, Lu X, Lin Y, Zhang S	2011	Partitioning of hexachlorobenzene in a kaolin/humic acid/surfactant/water system: combined effect of surfactant and soil organic matter	J Hazard Mater. 2011 Nov 30;196:79-85	Not relevant
Wang H, Dong YN, Zhu M, Li X, Keller AA, Wang T, Li F	2015	Heteroaggregation of engineered nanoparticles and kaolin clays in aqueous environments	Water Res.2015 Sep 1;80:130-8.	Not relevant
Wang H, Hwang J, Huang J, Xu Y, Yu G, Li W, Zhang K, Liu K, Cao Z, Ma X, Wei Z, Wang Q	2017	Mechanochemical remediation of PCB contaminated soil.	Chemosphere.2017 Feb;168:333-340	Not relevant
Wang L, Sun H, Wu Y, Xin Y	2009	Effect of sorbed nonylphenol on sorption of phenanthrene onto mineral surface	J Hazard Mater. 2009 Jan 30;161(2-3):1461-5.	Not relevant
Wang TH, Li MH, Teng SP.	2008	Cs diffusion in local Taiwan laterite with different solution concentration, pH and packing density	Appl Radiat Isot. 2008 , Sep;66(9):1183-9.	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Wasserman MA, Bartoly F, Viana AG, Silva MM, Rochedo ER, Perez DV, Conti CC	2008	Soil to plant transfer of 137Cs and 60Co in Ferralsol, Nitisol and Acrisol	J. Environ Radioact. 2008 Mar;99(3):546-53	Not relevant
Wu L, Zhong D, Du Y, Lu S, Fu D, Li Z, Li X, Chi Y, Luo Y, Yan J	2013	Emission and control characteristics for incineration of Sedum plumbizincicola biomass in a laboratory-scale entrained flow tube furnace	Int J Phytoremediation. 2013;15(3):219-31.	Not relevant
Wu Q, Li Z, Hong H, Li R, Jiang WT	2013	Desorption of ciprofloxacin from clay mineral surfaces	Water Res. 2013 Jan 1;47(1):259-68	Not relevant
Wu Y, Si Y, Zhou D, Gao J	2015	Adsorption of diethyl phthalate ester to clay minerals	Chemosphere. 2015 Jan;119:690-6	Not relevant
Xie J, Lin J, Zhou X, Li M, Zhou G	2014	Plutonium partitioning in three-phase systems with water, granite grains, and different colloids	Environ Sci Pollut Res Int. 2014;21(11):7219-26	Not relevant
Yang F, Zhao L, Gao B, Xu X, Cao X	2016	The Interfacial Behavior between Biochar and Soil Minerals and Its Effect on Biochar Stability	Environ Sci Technol. 2016	Not relevant
Yang M, Annable MD, Jawitz JW	2015	Back diffusion from thin low permeability zones	Environ Sci Technol. 2015 Jan 6;49(1):415-22	Not relevant
Yang M, Annable MD, Jawitz JW	2014	Light reflection visualization to determine solute diffusion into clays	J Contam Hydrol. 2014 Jun;161:1-9	Not relevant
Yang Z, Ren K, Guibal E, Jia S, Shen J, Zhang X, Yang W.	2016	Removal of trace nonylphenol from water in the coexistence of suspended inorganic particles and NOMs by using a cellulose-based flocculant	Chemosphere. 2016 Oct;161:482-490.	Not relevant
Yang ZL, Gao BY, Yue QY, Jiang YS	2010	[Relationship among coagulation effect of Al-based coagulant, content and speciation of residual aluminum]	Huan Jing Ke Xue. 2010 Jun;31(6):1542-7	Not relevant
Yang ZL, Gao BY, Yue QY, Wang Y	2010	Effect of pH on the coagulation performance of Al-based coagulants and residual aluminum speciation during the treatment of humic acid-kaolin synthetic water	J Hazard Mater. 2010 Jun 15;178(1-3):596-603.	Not relevant
Ye P, Kong L, Lemley AT.	2009	Kinetics of carbaryl degradation by anodic Fenton treatment in a humic-acid-amended artificial soil slurry	Water Environ Res. 2009 Jan;81(1):29-39	Not relevant
Yu C, Bi E	2015	Roles of functional groups of naproxen in its sorption to kaolinite	Chemosphere. 2015 Nov;138:335-9	Not relevant

Authors	Year	Title	Source (journal, volume, pages)	Comment
Zhang K, Huang J, Wang H, Liu K, Yu G, Deng S, Wang B	2014	Mechanochemical degradation of hexabromocyclododecane and approaches for the remediation of its contaminated soil	Chemosphere. 2014 Dec;116:40-5	Not relevant
Zhao J, Liu F, Wang Z, Cao X, Xing B	2015	Heteroaggregation of graphene oxide with minerals in aqueous phase	Environ Sci Technol. 2015 Mar 3;49(5):2849-57	Not relevant
Zhao Y, Gu X, Li S, Han R, Wang G	2015	Insights into tetracycline adsorption onto kaolinite and montmorillonite: experiments and modeling	Environ Sci Pollut Res Int. 2015 Nov;22(21):17031-40	Not relevant
Zhong R, Zhang X, Xiao F, Li X	2011	Effects of humic acid on recoverability and fractal structure of alum-kaolin flocs	J Environ Sci (China). 2011;23(5):731-7	Not relevant
Zhong R, Zhang X, Xiao F, Li X, Cai Z.	2011	Effects of humic acid on physical and hydrodynamic properties of kaolin flocs by particle image velocimetry.	Water Res. 2011 Jul;45(13):3981-90	Not relevant
Zhong RS, Zhang XH, Xiao F, Li XY	2009	Effects of fractal structure on settling velocities of flocs	Huan Jing Ke Xue. 2009 Aug 15;30(8):2353-7	Not relevant
Zhu D, Zhong H	2015	Potential bioavailability of mercury in humus-coated clay minerals	J Environ Sci (China). 2015 Oct 1;36:48-55	Not relevant
Zhu X, He J, Su S, Zhang X, Wang F	2016	Concept model of the formation process of humic acid-kaolin complexes deduced by trichloroethylene sorption experiments and various characterizations	Chemosphere. 2016 May;151:116-23	Not relevant
Zhu XJ, He JT, Su SH	2015	Forming mechanism of humic acid-kaolin complexes and the adsorption of trichloroethylene	Huan Jing Ke Xue. 2015 Jan;36(1):227-36	Not relevant
Zhu Y, Ma LQ, Gao B, Bonzongo JC, Harris W, Gu B	2012	Transport and interactions of kaolinite and mercury in saturated sand media.	J Hazard Mater. 2012 Apr 30;213-214:93-9	Not relevant

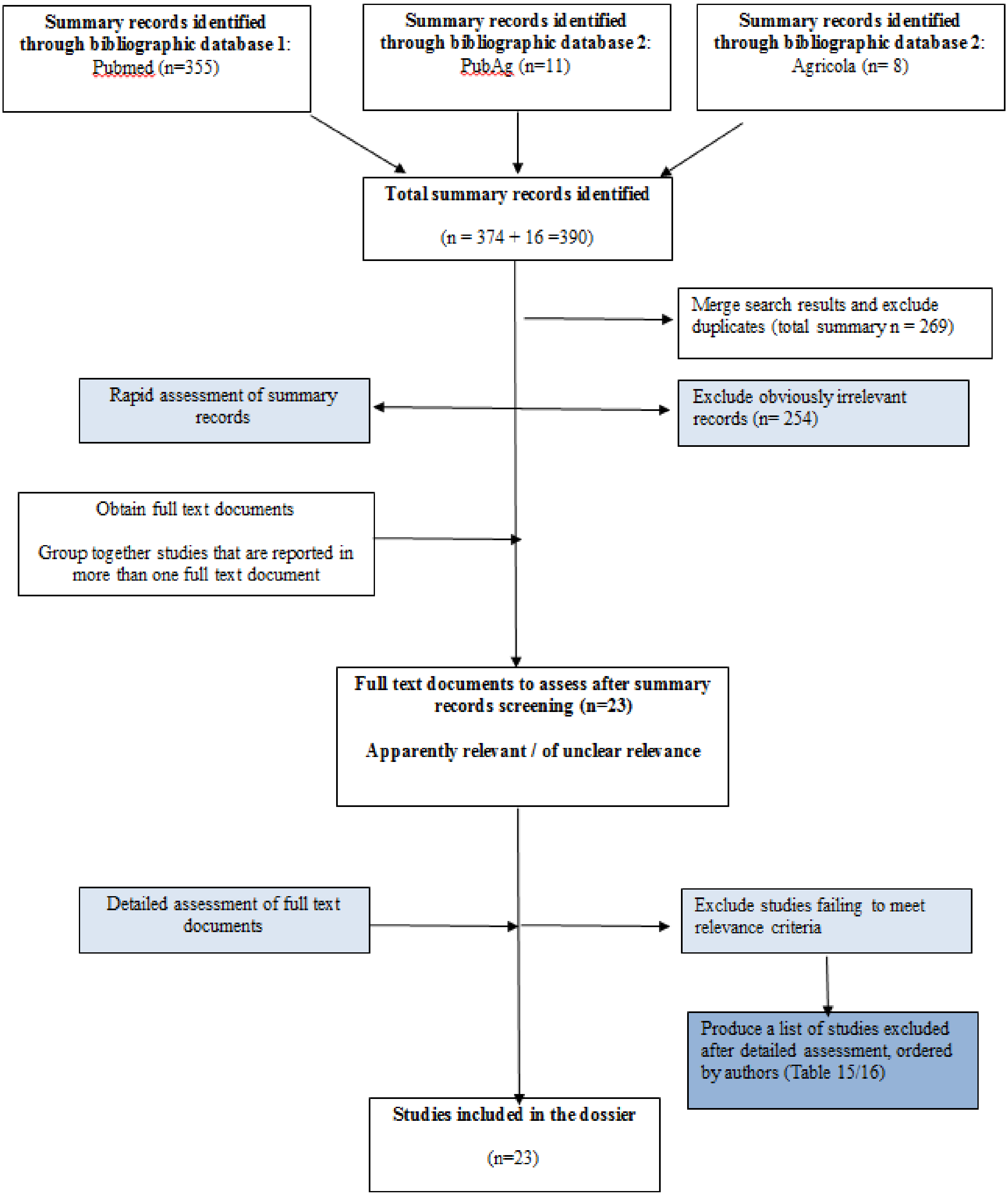


Figure B.8.6-1: Process for selecting studies to be included in the dossier.

RMS comment on literature search performed by SOKA:

Open literature data search have been conducted following EFSA guidance document (EFSA Journal 2011;9(2):2092). No further comments.

Applicant Tessenderlo

Introduction

Under Article 8(5) of Regulation 1107/2009, a literature review must be submitted as part of the renewal dossier for plant protection products:

"*Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last ten years before the date of dossier submission shall be added by the applicant to the dossier*".

In compliance with Article 8.5 of Regulation (EC) No 1107/2009 and Part A of Commission Regulation (EU) No 283/2013, a search of the scientific peer reviewed open literature relative to aluminium silicate (kaolin) was performed and included in the dossier.

The literature search was performed between 1 November 2017 and 15 November 2017.

The search was organised in two parts, with an initial search focusing on identifying literature relative to aluminium silicate, kaolin and derivatives, including trade names, and a final part focusing on identifying literature relevant to each compartment of the dossier. Details of the search term, data mining strategies and results are presented herewith.

Literature search timing

Literature search span: the search was limited to the period spanning from 1 January 2005 (year of submission of the original Aluminium silicate (kaolin) inclusion dossier) until 8 November 2017. The search therefore covered eleven years and ten months of peer-reviewed publications and was performed less than six months before renewal dossier submission deadline (28 February 2018).

Methodology

Search environment

The literature search was performed on the following databases: CAB, PubMed, Toxnet and Science Direct. In addition, relevant documents from Google, Google Scholar, ECHA, ResearchGate and the United States Environmental Protection agency database were downloaded and processed separately.

Identification of peer-reviewed literature pertaining to the Chemical Active aluminium silicate (kaolin)

The reference collections were queried by name, with a typical query string presented below.

Typical name query	Kaolin OR "china clay" OR kaolinite OR "calcined kaolin" OR "hydrous kaolin" OR "Aluminium silicate" OR "Aluminum silicate" OR Aluminosilicate OR "Satintone 5HB" OR "Surround WP" OR "Sokalciarbo WP" OR "Argical Pro" OR "Agri Jardin".

Underlined text refers to trade names of aluminium silicate-containing products.

In addition, the following CAS numbers were included in the search:

Identification number (List)	Identity
1318-74-7 (CAS)	Kaolinite

Identification number (List)	**Identity**
1332-58-7 (CAS)	Kaolin
296-473-8 (EC)	Kaolin, calcined
310-194-1 (EC)	Kaolin
92704-41-1 (CAS)	Kaolin, calcined

The topics of interest, such as human toxicity, fate, residues, etc., were not included as a key element of the search strategy. Often an event or outcome is not explicitly described by the subject at the title or abstract level and it would be difficult to adequately describe the individual toxic effects one can envisage using key words and/or subject headings in a complex search query. Therefore, a sequential approach was preferred, and once a pool of documents referencing the chemical active had been identified and duplicates removed, a different approach was used to identify relevant literature.

This granular information was captured during the text processing phase using customised gazetteer lists such as the extract given in the table below for toxTestSystem and toxStudyType. In total the gazetteer list of terms describing tox Test Systems contained 81 entries and the tox study type gazetteer contained 97 entries.

Extract from "ToxTestSystem" and "ToxStudyType"

ToxTestSystem list	ToxStudyType list
CHO	Absorbtion
Chromosome aberration test	Acute toxicity
Comet assay	Adverse event
Corrositex®	Endocrine disruption
Corrositex	Endocrine disruptor
Dog	Inhibition
Dogs	Neurotoxicity
Dog	Reproductive toxicity
E. coli WP2 uvrA	Sensitisation
Epidermis	Sublethal
Erythrocyte	Toxicity

Identification of relevant literature in the selected peer-reviewed literature

The search strategy highlighted 14,796 documents of potential interest to this literature review upon execution, including 676 from non-peer-reviewed literature. These were dismissed. The remaining 14120 documents contained a number of duplicates as a result of searching the reference collections separately.

To identify which of these 14,120 records mentioned the aspects of interest to this particular project, a pipeline of processing resources (PR) was applied to each document in turn and only those which specifically mentioned toxic effects, environmental fate and behaviour, etc., of kaolin or its common variants, were identified as a positive result. This granular information was captured during the text processing phase using customised gazetteer lists.

Each PR focused on a specific compartment and performs a different function and in general terms the approach taken was to Tokenise (identify individual words and features) and Sentence-split the documents; use the Gazetteer lists to identify any important key words and phrases such as dietary exposure; identify the Title and Abstract part of the document; look within the Title and Abstract for patterns matching the natural language expressions describing to the toxic effects of each active substance on humans, for example; and index the results. The rules used to identify these passages of text also make a simple allowance for co-referencing where we try to associate a word or phrase (the anaphor) with a previously mentioned entity (the antecedent). This technique was used to assist with the questions on Residue and Human Toxicity at the Sentence level only.

The results of the search were loaded into Microsoft Excel and duplicate records removed using several algorithms.

The entire collection of records was clustered to help with the identification of common themes and the output (network visualisation and density heat map) is provided in Figures 1 and 2

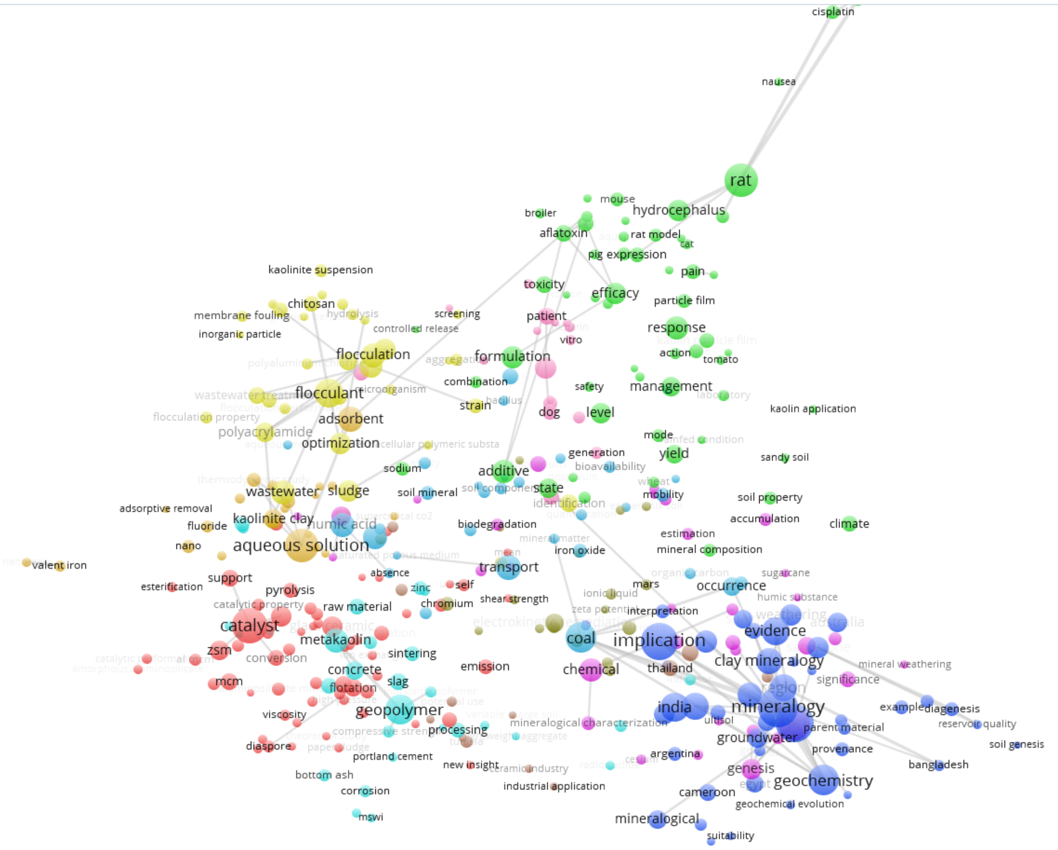


Table B.8.6-8: Kaolin network visualisation

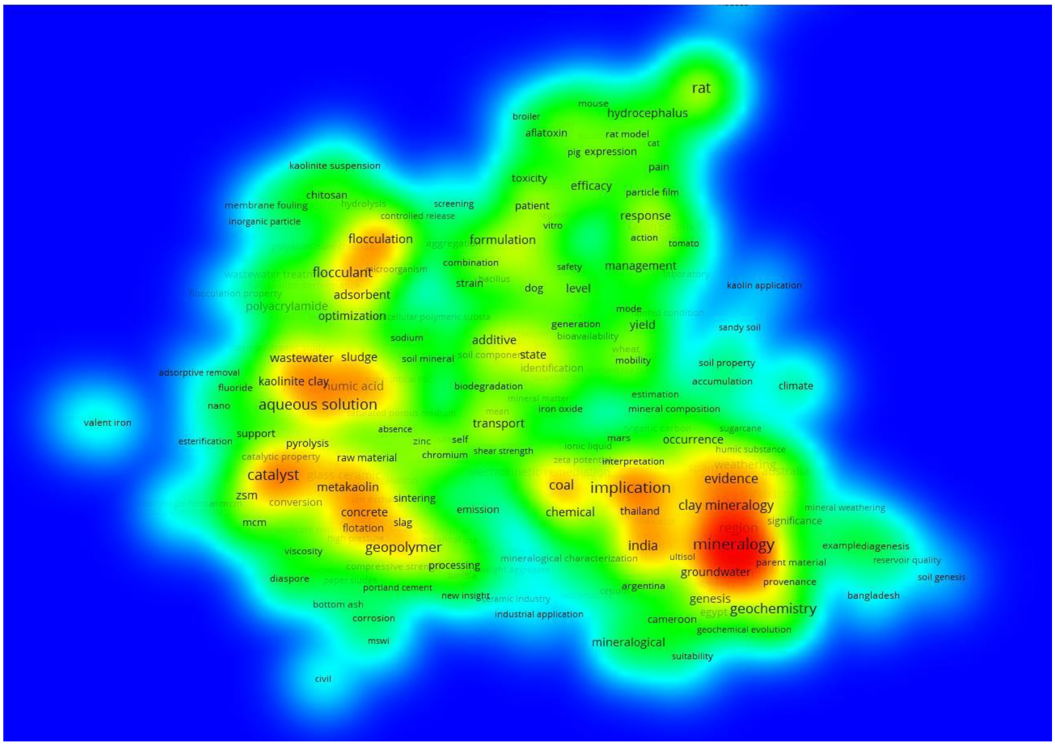


Table B.8.6-9: Kaolin density heat map

Results

As a result of applying the text mining pipeline to the document corpus, a number of documents were identified as being of potential relevance to the four questions fundamental to the project, toxicity, ecotoxicology, fate & behaviour, and residues. No potentially relevant documents were identified for the Occupational health and safety category.

The following tables summarise the total number of documents retrieved from each reference collection noting that the total count in Table B.8.6-11 will include duplicate records found in two or more reference collections. The results presented in Table B.8.6-12 refer to unique records and show the number of documents identified by text mining as potentially relevant.

Table B.8.6-10: Number of documents retrieved from each reference location*

Reference Collection	**Total Document Retrieved**
CAB	4,396
PubMed	2,873
ScienceDirect	6,807
Toxnet	44
Total	14,120

*: includes duplicate documents

Table B.8.6-11: Number of documents identified as potentially relevant by text mining

Compartment	**Unique Documents Identified**
Toxicity	301
Residues	52

Environmental Fate	248
Ecotoxicity	241

For each compartment described in Table B.8.6-11, an excel spreadsheet was provided. Each potentially relevant entry consisted of one line, split into several columns: Database source and record number, date of publication, title, journal reference and author, URL and abstract.
The lists were screened for potential relevance, i.e. references that did not appear to be relevant based on title or abstract only were dismissed. The remaining references were obtained and screened for relevance again.

Lists of relevant and non-relevant articles by dossier sections

Environmental fate evaluation table (relevant articles)

None of the articles obtained were relevant to environmental fate with regards to degradation, dissipation, adsorption/desorption, leaching, water/sediment contamination or air contamination:

- Degradation of kaolin takes place through geological processes that happen at geological timescales. For all intent and purposes, kaolin is stable at human timescales.

- When dissipation takes place, kaolin from the use of the plant protection product and natural kaolin cannot be distinguished and undergo the same fate.

- As a component of artificial soils used as adsorption/desorption substrate, kaolin cannot be tested for adsorption/desorption. In that respect, one can state that kaolin is very strongly bound to soil and may have variable adsorptive capacity towards exogenous molecules.

- As an insoluble substance, kaolin cannot undergo leaching, which is the transport of solute through soil pores. Kaolin can reach groundwater through mechanical percolation through soil pores; however, any kaolin from the use of the plant protection product will be indistinguishable from natural kaolin.

- Kaolin is generally present in still or slow-moving water bodies (slow rivers, ponds, lakes, seas or oceans) as part of the sediment. Any addition from the use of the plant protection product will be marginal, as evidenced in PECsw calculations. In fast-moving water bodies (streams for example), kaolin particles will be washed off until they can deposit in the sediment and be indistinguishable from naturally-present kaolin.

- Kaolin is non-volatile. As such, it cannot be volatilized and deposited. However, kaolin particles can be suspended in air and re-deposited as fine solids. Extreme storms occurring over non-vegetated areas (arid landscapes) may lift significant concentrations of particles that are later redeposited via rain. However, with an application rate of 30 kg/ha, equivalent to 3 g/m^2, kaolin particles from the use of the plant protection product will be marginal in concentration compared to that of natural soil or sand particles.

Environmental fate evaluation table (non-relevant articles)

Authors	Year	Title	Reference	Fulfills data require ments	Comments	Discussion on relevance
Ahn MY, Filley TR, Jafvert CT, Nies L, Hua I, Bezares-Cruz J.	2006	Photodegradation of Decabromodiphenyl Ether Adsorbed onto Clay Minerals, Metal Oxides, and Sediment	Environ. Sci. Technol. Vol 40, p.215-220	No	This article refers to the degradation of organic contaminant on clay-type particles.	Not relevant. Degradation of contaminants bound to clay particles does not affect the substrate.
Beini Gong, Pingxiao Wu, Zhujian Huang, Yuewu Li, Zhi Dang, Bo Ruan, Chunxi Kang, Nengwu Zhu	2016	Enhanced degradation of phenol by Sphingomonas sp. GY2B with resistance towards suboptimal environment through adsorption on kaolinite	Chemosphere, 148 p.388-394	No	Kaolin is effective at enhancing bacterial degradation of phenols by *Sphingomonas* sp.GY2B.	Not relevant to environmental fate or the agricultural use of the active substance.
Chizallet C, Raybaud P.	2009	Pseudo-bridging silanols as versatile Bronsted acid sites of amorphous aluminosilicate surfaces.	Angewandte Chemie International 48 (16), p2891-3	No	This article refers to the preparation of pseudo-bridging silanols on amorphous silica-alumina (SAS) surfaces. The material used (alumina, Al_2O_3) is not representative of kaolin and the article refers to the grafting of silanol ($Si(OR)_4$) groups on alumina to form SAS. None of the information presented has any relevance to the environmental fate of kaolin.	Not relevant to environmental fate.
Comber S. D. W., Gardner M. J., Churchley J.	2005	Aluminium speciation: implications of wastewater effluent dosing on river water quality.	Chemical Speciation and Bioavailability 17, 117-128	No	Refers to aluminium ions dosage in waste water treatment plants. The objective of the experiment was to determine whether quantification of total aluminium (i.e. including undissolved inert particles of aluminosilicates) could allow for extrapolation of reactive (i.e. toxic) aluminium species. Results showed total aluminium is not a suitable surrogate for reactive aluminium	Not relevant. Analysis of total aluminium does not allow for quantification of reactive aluminium
Congrong Yu, Bin Gao, Rafael Muñoz-Carpena, Yuan Tian, Lei Wu, Oscar Perez-Ovilla	2011	A laboratory study of colloid and solute transport in surface runoff on saturated soils.	Journal of Hydrology 402 (159-164)	No	When subsurface flow or drainage is limited, colloid surface transport is equivalent to solute transport when colloid particles are 0.4 µm in size or smaller. Particle size analysis or kaolin particles in SURROUND WP CROP PROTECTANT shows that 10% of particles are 0.786 µm in size or smaller. Therefore, it can be assumed that colloid transport of SURROND WP CROP PROTECTANT concerns less than 10% of the product.	Not relevant for risk assessment.
Hongfei Cheng, Qinfu Liu,	2010	Thermogravimetric analysis	Thermochimica Acta,	No	This article refers to analysis of specific coal-bearing kaolinite	Not relevant to the active substance.

Jing Yang, Ray L.Frost		of selected coal-bearing strata kaolinite	Vol 507-508, p. 84-90		seams from China and is not relevant to the specific kaolin ores mined un Georgia (USA) and used in the preparation of aluminium silicate used in SURROUND WP CROP PROTECTANT.	
Hongfei Cheng, Jing Yang, Qinfu Liu, Junkai He, Ray L.Frost	2010	Thermochimica Acta, Vol 507-508, p. 106-114	Thermochimica Acta, Vol 507-508, p. 106-114	No	This article refers to analysis of specific coal-bearing kaolinite seams from China and is not relevant to the specific kaolin ores mined in Georgia (USA) and used in the preparation of aluminium silicate used in SURROUND WP CROP PROTECTANT.	Not relevant to the active substance.
Jolin WC, Sullivan J, Vasudevan D, MacKay AA.	2016	Column Chromatography To Obtain Organic Cation Sorption Isotherms	Environmental science & technology 50 (15) p.8196-8204	No	This article refers to establishing a simpler method for the determination of soil sorption isotherms. However, none of the substrates involved in the experiments was kaolin.	Not relevant. Adsorption/desorption testing considers kaolin as substrate for adsorption, not as adsorbed substance.
Lecomte K. L., Pasquini A. I., Depetris P. J.	2005	Mineral weathering in a semiarid mountain river: its assessment through PHREEQC inverse modeling.	Aquatic Geochemistry 11:173–194	No	This article documents the reverse modelling process investigated to elucidate mountain weathering processes via analysis of minerals dissolved in overlying river water. However, this article confirms that erosion of granite rocks will lead to kaolinite, while erosion of gneiss will give rise to illite.	Not relevant. Erosion modelling of river basins
Lesturgez G., Poss R., Noble A., Grünberger O., Chintachao W., Tessier D.	2006	Soil acidification without pH drop under intensive cropping systems in Northeast Thailand.	Agriculture ecosystems and environment 114, 239-248	No	Refers to kaolin as a soil component in field trials.	Not relevant as the target substance is not applied as test material
MacCarthy Jennifer, Nosrati Ataollah, Skinner William, Addai-Mensah Jonas	2015	Effect of mineralogy and temperature on atmospheric acid leaching and rheological behaviour of model oxide and clay mineral dispersions	Powder Technology, 286 p.420-430	No	The article refers to rheology and composition of mining slurries and pulps for the mining industry.	Not relevant to environmental fate and agricultural applications.
Santos B. M., Salame-Donoso T. P., Whidden A. J.	2012	Reducing sprinkler irrigation volumes for strawberry transplant establishment in Florida.	HortTechnology 22, 224-227	No	Although the use of Kaolin spray is effective at reducing water needs for strawberry transplants, this article presents no data on the environmental fate of kaolin	Not relevant to environmental fate
Steenari B.-M., Karlfeldt Fedje K.	2010	Addition of kaolin as potassium sorbent in the combustion of wood fuel - Effects on fly ash properties	Fuel 89, p.2026-2032	No	The addition of kaolin to forest residue during combustion reduces ash settling time and improves ash structure.	Not relevant to agricultural uses of the active substance.
Ta CAK, Pebsworth PA, Liu R, Hillier S, Gray N, Arnason JT, Young SL.	2017	Soil eaten by chacma baboons adsorbs polar plant secondary metabolites representative of those found in their diet.	Environ Geochem Health	No	This article refers to investigating whether Baboons will preferentially choose the most efficacious type of clay for adsorbing plant secondary metabolites. No dosages or histology performed	Not relevant to environmental fate.
Táborosi A, Szilágyi RK.	2016	Behaviour of the surface hydroxide groups of exfoliated kaolinite in the gas	Dalton Transactions, vol 45 (6), p. 2523-2535	No	Computerised model of the behavior of exfoliated kaolin sheets, investigating the reactivity of disorganised surface hydroxyl groups. Theoretical research.	Not relevant to environmental fate

		phase and during water adsorption				
Tokarčíková Michaela, Tokarský Jonáš, Čabanová Kristina, Matějka Vlastimil, Mamulová Kutláková Kateřina, Seidlerová Jana	2014	The stability of photoactive kaolinite/TiO_2 composite	Composites Part B, 67 p.262-269	No	When kaolin and calcined kaolin are leached with deionized water, leaching of aluminium is marginal (0.62 and 0.16 mg/L for kaolin and calcined kaolin respectively). Leaching in pH2 buffer (H_2SO_4) or pH12 (NaOH) released higher quantities of aluminium, however, these pH values are not representative of soil water or surface water natural pH ranges in agricultural areas	Not relevant to environmental fate. Leaching conditions not representative of soil water or surface water natural pH ranges in agricultural areas
Tokarčíková Michaela; Mamulová Kutláková Kateřina, Seidlerová Jana	2016	Leaching test for calcined kaolinite and kaolinite/TiO_2 photoactive composite	Chemical Papers, Volume 70, Issue 9, pp 1253–1261	No	Calcination of kaolinite has no impact on elemental leaching in deionized water and in H_2SO_4/HNO_3 mix at pH 3.95	Not relevant to environmental fate and agricultural applications.
Tokarčíková Michaela, Tokarský Jonáš, Mamulová Kutláková Kateřina, Seidlerová Jana	2017	Testing the stability of magnetic iron oxides/kaolinite nanocomposite under various pH conditions	Journal of Solid State Chemistry 253 329–335	No	Kaolin and nanocomposite kaolin bound with magnetite (Fe_xO_y) subject to extraction in pH 2, 4, 6.7, 9 and 11 do not release significant amounts of aluminium.	Not relevant to the active substance, which is a calcined form of kaolin.
Werner JJ, McNeill K, Arnold WA.	2009	Photolysis of Chlortetracycline on a Clay Surface	J. Agric. Food. Chem., Vol 57, p. 6932-6937	No	As with most adsorption/desorption work, this article refers to the behavior of an organic contaminant when adsorbed on kaolin clay. Kaolin clay is part of standard soil composition and as such cannot be tested for adsorption/desorption properties on itself.	Not relevant. Adsorption/desorption testing considers kaolin as substrate for adsorption, not as adsorbed substance.
World Health Organisation	2005	Bentonite, kaolin and selected clays	Environmental health criteria, 231	No	This publication is more concerned about human and animal health than environmental fate. The report states in its conclusions to the environmental effects of kaolin and bentonite: "*There is no reason to believe that the mining or processing of bentonite, kaolin, and other clays poses significant toxicological dangers to the environment. However, physical disturbance to the land, excessive stream sedimentation, and similar destructive processes resulting from the large-scale mining and processing of clays, like any large-scale mining operation, have a potential for significant environmental damage*."	Not relevant to environmental fate.
Zhou Yong, Yao Jun, He Minyan, Choi Martin M.F., Feng Liang, Chen Huilun, Wang Fei, Chen Ke, Zhuang Rensheng, Maskow Thomas, Wang Gejiao, Zaray Gyula.	2010	Reduction in toxicity of arsenic(III) to *Halobacillus* sp. Y35 by kaolin and their related adsorption studies	Journal of Hazardous Materials 176 487–494	No	The combination of kaolin and *Halobacillus* sp. Y35 shows more binding affinity to arsenic(III) than either kaolin or *Halobacillus* sp. Y35 alone	Not relevant to agricultural uses of the active substance.

RMS comment on literature search performed by Tessenderlo:

Open literature data search have been conducted following EFSA guidance document (EFSA Journal 2011;9(2):2092). No further comments.

B.8.7 Reference List, by Data point

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
8.1.1	Veatch O. , McCallie S.W.	1909	Geological survey of Georgia, Bulletin n°18, Second report on the clay deposits of Georgia	N	N	-	-
8.2	Sutherland B.R. et al.	2014	Clay settling in fresh and salt water, Environ Fluid Mech, volume 15, Issue 1, pp 147–160	N	N	-	-