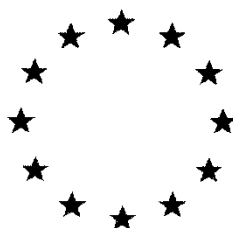


European Commission



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

Aluminium silicate Calcined
(Calcined Kaolin)

Volume 3 – B.7 (AS)

Rapporteur Member State: Greece
Co-Rapporteur Member State: France

May 2020

TABLE OF CONTENTS

B.7 RESIDUE DATA	4
B.7.1 Storage stability of residues	5
B.7.1.1 Matrices of plant origin.	5
B.7.1.2. Matrices of animal origin.	6
B.7.2 Metabolism, distribution and expression of residues.....	6
B.7.2.1 Metabolism, Distribution and Expression of Residues in Plants	6
B.7.2.3 Metabolism, distribution and expression of residues in livestock.....	6
B.7.2.3.1 Ruminants and poultry	6
B.7.2.3.2 FISH	6
B.7.3 Magnitude of residue trials in plants.....	6
B.7.4 Livestock feeding studies	8
B.7.5 Effects of industrial processing and/or household preparation	8
B.7.6 Residues in succeeding or rotational crops	8
B.7.7 Other studies	9
B.7.7.1 Effects in the residue level in pollen and bee products.....	9
B.7.8.1. Open literature review.....	9
B.7.9 Reference List, by Data Point	10

Volume 3- Annex B.7 (AS)

March 2008	Initial DAR Draft Assessment Report (DAR) – prepared in the context of the application for the first inclusion of the a.s. in Annex I to Council Directive 91/414/EEC.
February 2020	Renewal Assessment Report (RAR) prepared by RMS in the context of the application for renewal of approval of the a.s. according to Regulation (EC) No 1107/2009.

B.7 RESIDUE DATA

Metabolism and residue studies were not considered relevant for evaluation nor necessary for the first inclusion due to the nature and properties of the active substance, aluminium silicate (aka kaolin), and the situation is unchanged for the renewal of approval.

Aluminium silicate (kaolin) is a clay that is essentially kaolinite; a hydrated aluminium silicate. The substance is ubiquitous within the environment and is naturally occurring within soil. Aluminium silicate is widely used within industry, where it is incorporated into paper, paints, rubbers, plastics, medicines, building materials and ceramic pottery.

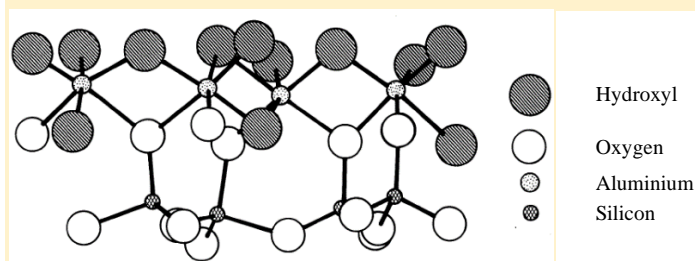
The intake of aluminium silicate through its use as a plant protection product will be negligible based on the intended application. No MRLs or residue definitions have been allocated for aluminium silicate (kaolin), based on its use as a plant protection product. Aluminium silicate is currently listed on Annex IV of Regulation 396/2005, in accordance with Reg 839/2008. No MRLs or residue definitions are proposed as part of the renewal.

Based on the DAR (2008) and the data submitted in the framework of the renewal, by the criteria below a waiver from the requirement of residue data and MRL is still suggested:

- Kaolin has no known mode of toxicity, is insoluble in water and does not become bioavailable when ingested.
- No Toxicological Reference Values (ADI and ARfD) have been defined for kaolin.
- When applied to crops it leaves a white deposit on the surface that is easily removed by gentle rubbing and washing. This would be a normal procedure before marketing and/or consuming any foodstuff treated with kaolin.
- Kaolin is naturally present in the environment and is likely to be frequently present on crops contaminated with soil or dust particles.
- Kaolin does not degrade under environmental conditions.
- Kaolin cannot be analysed by conventional spectroscopy techniques. Kaolin is a natural component of soil and therefore cannot be distinguished from existing clays, either in the soil or as an air born dust. It is impossible to differentiate between naturally present kaolin and kaolin from plant protection product.

For all the above reasons, the status of “active substance for which no MRLs are required” and the inclusion of aluminium silicate (kaolin) in the Annex IV of Regulation (EC) No 396/2005 as set in Reg. (EC) No 839/2008 is still supported.

The (repeating) structure of hydrous kaolin is summarised as follows:



Kaolin is a layered silicate mineral, with one tetrahedral sheet of silica (SiO_4) linked through oxygen atoms to one octahedral sheet of alumina (AlO_6) octahedra. The structure is covalently bonded. Individual

molecules of kaolin do not exist; it is a solid of infinite atomic structure and is consequently insoluble in water and all organic solvents.

Synonyms of aluminium silicate: aluminium silicate hydroxide, aluminium silicate hydroxide (kaolin), hydrated aluminium silicate, kaolin, kaolin (bound), oxo-oxoalumanyloxy-[oxo(oxoalumanyloxy)silyl]oxysilane; dihydrate.

It should be noted that while the active substance was ascribed the name ‘aluminium silicate’ during the original inclusion, the label is too broad to specify any one particular compound (it is analogous to naming ethanol as ‘alkyl alcohol’). The Notifier believes that kaolin is a better descriptor, as it distinguishes the active substance from other compounds which can be considered ‘aluminium silicates’. The bonding and structural properties of these other aluminium silicates can widely vary when compared to kaolin, which can lead to misunderstandings regarding the nature of the active substance compared to other compounds which are chemically classed as aluminium silicates.

The metabolism and residues data are not deemed to be necessary to support the renewal of aluminium silicate (kaolin).

As a general note, to address the potential for residues within treated products, food and feed for the first inclusion of aluminium silicate (kaolin) under Directive 91/414, many of the provided cases referred to aluminium silicate being a commonly used food additive within the EU. Through Regulation (EU) No. 380/2012 (enforced from 1st February 2014) amending Annex II to Regulation (EC) No. 1333/2008, the use of a number of aluminium-containing food additives was restricted. Among these were calcium aluminium silicate, bentonite and aluminium silicate (kaolin), which are no longer permitted to be used as food additives within the EU. This was due to exceedance of the Tolerable Weekly Intake for aluminium. A transitional period until 1st August 2014 was established by the regulation to allow manufacturers time to comply with the requirements, given the extensive use of aluminium compounds as coatings and colourants in existing produced food items.

As such, it is no longer considered appropriate to rely on such cases at renewal (which were based on kaolin being an approved food additive within the EU). It should however be noted that despite the food additive restriction, aluminium silicate (kaolin) is still considered to remain safe for the treatment of crops for human consumption based on the negligible exposure from the intended uses supported at renewal. Following the removal of aluminium silicate from the EU list of approved food additives, EFSA commented on the impact of the ruling on several aluminium-compound containing plant protection products (including aluminium silicate).

B.7.1 Storage stability of residues

B.7.1.1 Matrices of plant origin.

No data submitted, not required.

According to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no study or analysis is required regarding the storage stability of residues.

The conclusion of the initial DAR (2008) is still supported.

B.7.1.2. Matrices of animal origin.

No data required.

B.7.2 Metabolism, distribution and expression of residues**B.7.2.1 Metabolism, Distribution and Expression of Residues in Plants**

Aluminium silicate is insoluble in water and therefore not taken-up and translocated by plants. It is also chemically inert and is not metabolised into other compounds. Therefore, metabolism study is not required.

The conclusion of the initial DAR (2008) is still supported.

B.7.2.3 Metabolism, distribution and expression of residues in livestock

Kaolin is chemically inert, not bioavailable and not metabolised in mammals. Experience has shown that it is not absorbed through the gut wall. Any livestock metabolism study is therefore not required.

The conclusion of the initial DAR (2008) is still supported.

B.7.2.3.1 Ruminants and poultry

No data submitted, not required.

The conclusion of the initial DAR (2008) is still supported.

B.7.2.3.2 Fish

No data submitted, not required.

The conclusion of the initial DAR (2008) is still supported.

B.7.3 Magnitude of residue trials in plants

A summary of the critical GAPs for residues is presented in Table B.7.3-1.

Table B.7.3-1 Summary of the critical GAP

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (^e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (^f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha a) max per use b) max per season		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	--	Grapevine	F	<i>Frankliniella occidentalis</i>	Broadcast spraying of entire plant	BBCH 51 - 65	a) 1-4 b) 1-4	7	a) 30 kg/ha b) 120 kg/ha	a) 28.5 kg/ha b) 114 kg/ha	a) 500 – 1000 L/ha b) 2000 – 4000 L/ha	N/A	Apply from BBCH 51 at the beginning of the presence of <i>F. occidentalis</i> . Re-apply each 7-14 days depending on rainfall and crop development.

No data submitted, not required.

According to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no trial is required regarding the magnitude of residues in plants.

Therefore, the conduction of supervised residue trials is not relevant.

B.7.4 Livestock feeding studies

No data submitted, not required.

Aluminium silicate is chemically inert, not bioavailable, not metabolised in mammals and not absorbed through the gut wall. Furthermore, according to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. No maximum residue levels (MRLs) is required for Aluminium Silicate. Therefore, no feeding study in poultry is not required.

The conclusion of the initial DAR (2008) is still supported.

B.7.5 Effects of industrial processing and/or household preparation

Not applicable.

As a solid mineral, aluminium silicate (kaolin) is not readily degraded by typical household / industrial processes. It may only be structurally transformed by extreme temperatures / pressures (diagenesis or metamorphosis, which are two geological processes), or digested under harsh acidic conditions (concentrated nitric acid at reflux, for several hours). Consequently, kaolin will remain stable under the typical processing conditions described within OECD Guideline 507. A hydrolysis study is therefore not deemed to be necessary.

Aluminium silicate is insoluble in water and therefore not taken-up and translocated by plants. It is also chemically inert and is not metabolised into other compounds.

Furthermore, according to the Commission Regulation (EC) No 839/2008, Aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. Therefore, no data/information on processing study is required.

The conclusion of the initial DAR (2008) is still supported.

B.7.6 Residues in succeeding or rotational crops

Not applicable.

Aluminium silicate is insoluble in water and therefore not taken-up and translocated by plants. It is also chemically inert and is not metabolised into other compounds. Furthermore, Aluminium silicate is intended to be used on perennial crops only. According to the Commission Regulation (EC) No 839/2008, aluminium Silicate is included in Annex IV of the Regulation (EC) No 396/2005. Furthermore, Aluminium silicate is intended to be used on perennial crops only. Therefore, metabolism study in rotational crops nor trials regarding the magnitude of residues in rotational crops are not required.

The conclusion of the initial DAR (2008) is still supported.

B.7.7 Other studies

B.7.7.1 Effects in the residue level in pollen and bee products

Further studies are not deemed required.

B.7.8.1. Open literature review

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 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.

As far as Residues in or on treated products, food and feed are concerned, the criteria for relevance were:

- The application methods comply with Good Agriculture Practice (GAP).
- Appropriate in life/processing conditions are used and/or are well described.

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.7.8.1. Details of literature search for aluminium silicate and residues in or treated products, food and feed.

Details of literature search for aluminium silicate and residues in or treated products, food and feed		
Data requirements	Database	Database 1: Pubmed
Residues in/on treated products food and feed	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.
	Date of the search	January 15 th , 2018
	Date span of the search	2008-2018
	Search strategies used for this data requirement	18.1-3 and food ("aluminium silicates" [MeSH Terms] OR ("aluminium" [All Fields] AND "silicates" [All Fields]) OR "aluminium silicates" [All Fields] OR ("aluminium" [All Fields] AND "silicate" [All Fields] AND "1332-58-7" [All Fields] AND "food" [MeSH Terms] Or "food" [All Fields]) AND ("2008/01/19" [PDat]: "2018/01/15" [PDat])).
		Total numbers of records retrieved: 55 After removing duplicate: 48
		19.1-3 and food ("aluminium silicates" [MeSH Terms] OR ("aluminium" [All Fields] AND "silicates" [All Fields]) OR "aluminium silicates" [All Fields] OR ("aluminium" [All Fields] AND "silicate" [All Fields] AND "1332-58-7" [All Fields] AND "food" [MeSH Terms] Or "food" [All Fields]) AND ("2008/01/19" [PDat]: "2018/01/15" [PDat])).
		Total numbers of records retrieved: 9 After removing duplicate: 6
		20.1-3 and food ("aluminium silicates" [MeSH Terms] OR ("aluminium" [All Fields] AND "silicates" [All

		Fields]) OR "aluminium silicates"[All Fields] OR ("aluminium "[All Fields] AND "silicate "[All Fields]AND "1332-58-7" [All Fields] AND "food"[MeSH Terms] Or "food" [All Fields]) AND ("2008/01/19"[PDat]: "2008/01/19"[PDat])).
		Total numbers of records retrieved: 1 After removing duplicate: 1

B.7.9 Reference List, by Data Point

No study was submitted.