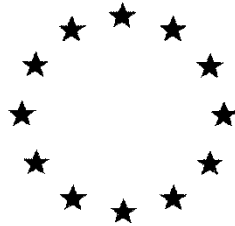


European Commission



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

Aluminium silicate Calcined (Kaolin Calcined)

Volume 3 – B.5 (AS)

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

MAY 2020

Version history

When	What
March 2008	Monograph, Aluminium Silicate, Vol 3 Annex B, Rapporteur Member State: Hungary
May 2011	Final addendum to the DAR, Monograph, Aluminium Silicate, Vol 3 Annex B, Rapporteur Member State: Hungary
May 2020	draft Renewal Assessment report (dRAR) – prepared by RMS EL in the context of the application for renewal of approval of the a.s. according to Reg (EU) No 1107/2009. New data/information submitted/reported for the purpose of renewal are in yellow shading.

Table of contents

B Summary of the data and information

B.5	Methods of analysis	4
B.5.1	Methods used for the generation of pre-approval data.....	4
B.5.1.1	Methods for the analysis of the active substance as manufactured.....	4
B.5.1.1.1	Determination of the pure active substance in the active substance as manufactured and specified in the dossier submitted in support of approval under Regulation (EC) No 1107/2009	4
B.5.1.1.2	Methods for the determination of relevant impurities and/or additives in the active substance as manufactured.....	4
B.5.1.2	Methods for risk assessment (CA 4.1.2)	4
B.5.1.2.1	Methods in soil, water, sediment, air and any additional matrices used in support of environmental fate studies (CA 4.1.2 (a)).....	4
B.5.1.2.2	Methods used in soil, water, sediment, air and any additional matrices used in support of efficacy studies (CA 4.1.2 (b))	4
B.5.1.2.3	Methods in feed, body fluids and tissues, air and any additional matrices used in support of toxicology studies (CA 4.1.2 (c))	5
B.5.1.2.4	Methods in body fluids, air and any additional matrices used in support of operator, worker, resident and bystander exposure studies B.5.1.1.1 (CA 4.1.2 (d)).....	5
B.5.1.2.5	Methods in or on plants, plant products, processed food commodities, food of plant and animal origin, feed and any additional matrices used in support of residues studies (CA 4.1.2 (e)).....	5
B.5.1.2.6	Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies (CA 4.1.2 (f))	5
B.5.1.2.7	Methods in water, buffer solutions, organic solvents and any additional matrices resulting from the physical and chemical properties tests. (CA 4.1.2 (g))	6
B.5.2	Methods for Post- Approval Control and Monitoring Purposes.....	6
B.5.2.1.	Methods for the determination of all components included in the monitoring residue definition as submitted in accordance with the provision of point 6.7.1 in order to enable Member States to determine compliance with established maximum residue levels (MRLs); they shall cover residues in or on food and feed of plant and animal origin (CA 4.2 (a))	6
B.5.2.2.	Methods for the determination of all components included for monitoring purposes in the residue definitions for soil and water as submitted in accordance with the provision of point 7.4.2. (CA 4.2 (b)).....	6
B.5.2.3.	Methods for the analysis in air of the active substance and relevant breakdown products formed during or after application, unless the applicant shows that exposure of operators, workers, residents or bystanders is negligible (CA 4.2 (c))	6
B.5.2.4	Methods for the analysis in body fluids and tissues for active substances and relevant metabolites (CA 4.2 (d))	6
B.5.3	References relied on	7

B.5 Methods of analysis

B.5.1 Methods used for the generation of pre-approval data

B.5.1.1 Methods for the analysis of the active substance as manufactured

B.5.1.1.1 Determination of the pure active substance in the active substance as manufactured and specified in the dossier submitted in support of approval under Regulation (EC) No 1107/2009

Tessenderlo: Please refer to Vol 4, Tessenderlo point 1.2.5.1

SOKA: Please refer to Vol 4, SOKA point 1.2.5.1

B.5.1.1.2 Methods for the determination of relevant impurities and/or additives in the active substance as manufactured

Tessenderlo: Please refer to Vol 4, Tessenderlo point 1.2.5.2

SOKA: Please refer to Vol 4, SOKA point 1.2.5.2

B.5.1.2 Methods for risk assessment (CA 4.1.2)

B.5.1.2.1 Methods in soil, water, sediment, air and any additional matrices used in support of environmental fate studies (CA 4.1.2 (a))

Tessenderlo declared the following: “No studies submitted. *Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases, except under very harsh conditions. Aluminium silicate has a similar chemical composition to common clay that is found in most soils and aquatic sediments the world over.*

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

SOKA declared the following: “*Not additional data/method provided. Not relevant.*”

B.5.1.2.2 Methods used in soil, water, sediment, air and any additional matrices used in support of efficacy studies (CA 4.1.2 (b))

Tessenderlo declared the following: “Not applicable. *Aluminium silicate (kaolin) is a type of clay, a natural substance present in soil, surface water, sediment and ground water. Aluminium silicate (kaolin) is the ultimate degradation product of silicate rocks and cannot be separated from naturally present aluminium silicate clays.*”

SOKA declared the following: “*Not additional data/method provided. Not relevant.*”

B.5.1.2.3 Methods in feed, body fluids and tissues, air and any additional matrices used in support of toxicology studies (CA 4.1.2 (c))

Tessenderlo declared the following: *“Not applicable. Aluminium silicate (kaolin) is not acutely toxic and holds no classification with regards to toxicity. Analytical methods in feed, body fluids and tissues or air are not required.”*

SOKA declared the following: *“Not additional data/method provided. Not relevant.”*

B.5.1.2.4 Methods in body fluids, air and any additional matrices used in support of operator, worker, resident and bystander exposure studies B.5.1.1.1 (CA 4.1.2 (d))

Tessenderlo declared the following: *“Not applicable. Aluminium silicate (kaolin) is not acutely toxic and holds no classification with regards to toxicity. Operator exposure studies are not required for aluminium silicate and therefore analytical methods in body fluids and tissues or air are not required.”*

SOKA declared the following: *“Not additional data/method provided. Not relevant.”*

B.5.1.2.5 Methods in or on plants, plant products, processed food commodities, food of plant and animal origin, feed and any additional matrices used in support of residues studies (CA 4.1.2 (e))

Tessenderlo declared the following: *“Not applicable. Aluminium silicate (kaolin) is exempt from Maximum Residue Limits and included in Annex IV of Regulation (EC) No 396/2005 through Regulation (EC) No 839/2008.”*

SOKA declared the following: *“Not additional data/method provided. Not relevant.”*

B.5.1.2.6. Methods in soil, water, sediment, feed and any additional matrices used in support of ecotoxicology studies (CA 4.1.2 (f))

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

SOKA declared the following: *“Not additional data/method provided. Not relevant.”*

B.5.1.2.7 Methods in water, buffer solutions, organic solvents and any additional matrices resulting from the physical and chemical properties tests. (CA 4.1.2 (g))

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

SOKA declared the following: *“Not additional data/method provided. Not relevant.”*

B.5.2 Methods for Post- Approval Control and Monitoring Purposes

B.5.2.1. Methods for the determination of all components included in the monitoring residue definition as submitted in accordance with the provision of point 6.7.1 in order to enable Member States to determine compliance with established maximum residue levels (MRLs); they shall cover residues in or on food and feed of plant and animal origin (CA 4.2 (a))

Not applicable. No residue definitions are set.

B.5.2.2. Methods for the determination of all components included for monitoring purposes in the residue definitions for soil and water as submitted in accordance with the provision of point 7.4.2. (CA 4.2 (b))

Not applicable. No residue definitions are set.

B.5.2.3. Methods for the analysis in air of the active substance and relevant breakdown products formed during or after application, unless the applicant shows that exposure of operators, workers, residents or bystanders is negligible (CA 4.2 (c))

Not applicable. No residue definitions are set.

5.2.2.4 Methods for the analysis in body fluids and tissues for active substances and relevant metabolites (CA 4.2 (d))

Not applicable. No residue definitions are set.

B.5.3 References relied on

Please refer to Vol 4