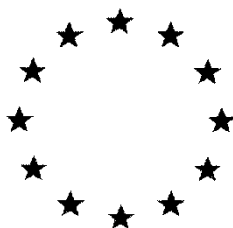


European Commission



Renewal Assessment Report
prepared according to the Commission Regulation (EU) N° 1107/2009

Aluminium silicate Calcined (Kaolin Calcined)

Volume 2

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

May 2020

Version History

When	What
May 2020	Renewal Assessment Report (RAR) – 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. <i>NOTE: The RAR is a stand-alone document containing the evaluations already displayed in the initial DAR, as well as the new assessments.</i>

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A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED

A.1. IDENTITY

A.1.1. Active substance

Confidential data. Please refer to Vol 4 – Tessenderlo & Vol 4 SOKA

A.1.2. Preparation

Confidential data. Please refer to Vol 4 – Tessenderlo & Vol 4 SOKA

A.2. PHYSICAL AND CHEMICAL PROPERTIES**A.2.1. Active substance****By annex 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	Previous submission/ evaluation
KCA 2.1	Murray H.H. (2007) in Benazzouz et al	2013	Determination of the melting temperature of kaolinite by means of the Z-method American Mineralogist, Volume 98, pages 1881–1885, 2013 Not GLP Published	N	N	N	Public	Submitted for the renewal of a.s.
KCA 2.3	Anonymous	1995	International Programme on Chemical Safety WHO Not GLP Published	N	N	N	Public	Included in DAR 2008
KCA 2.4 & MCP 5.1.1/02	Castro. L	2019	Additional information regarding Analytical methods used to characterize Calcined kaolin and SURROUND WP No report number Not GLP Unpublished	N	Y	New data provided.	Tessenderlo Kerley Inc.	Submitted for the renewal of a.s.
KCA 2.5	Anonymous		International Programme on Chemical Safety WHO Not GLP Published	N	N	N	Public	Included in DAR 2008
KCA 2.9/01	Guillosson L	2019a	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Flammability APC Report number TKIKAO-2019-1 Not GLP Unpublished-+8 51	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.

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	Previous submission/ evaluation
KCA 2.9/01	Atwal S.S. & Tremain, S.P.	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the renewal of a.s.
KCA 2.9/02	Guillosso L	2019b	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Self-heating APC Report number TKIKAO-2019-2 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
KCA 2.11/01	Bosc-Guillosso L,	2004	Explosive Properties of Satintone® 5HB Swift Consulting Engelhard GmbH SWP001 Not GLP unpublished	N	N	N	Tessenderlo Group	Included in DAR 2008
KCA 2.11/02	Guillosso L	2019c	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Explosive properties APC Report number TKIKAO-2019-3 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
KCA 2.11/03	Atwal S.S. & Tremain, S.P.	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the renewal of a.s.

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	Previous submission/ evaluation
KCA 2.13/1	Bosc-Guillosson L,	2004	Oxidizing Properties of Satintone® 5HB Swift Consulting Engelhard GmbH SWP003 Not GLP unpublished	N	N	N	Tessenderlo Group	Included in DAR 2008
KCA 2.13/01	Guillosson L	2019c	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Oxidizing properties APC Report number TKIKAO-2019-4 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
KCA 2.13/02	Atwal S.S. & Tremain, S.P.	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the renewal of a.s.

By author

Author(s)	Data point	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*	Previous submission/evaluation
Anonymous	KCA 2.3	1995	International Programme on Chemical Safety WHO Not GLP PUBLISHED	N	N	N	Public	Included in DAR 2008
Anonymous	KCA 2.5		International Programme on Chemical Safety WHO Not GLP Published	N	N	N	Public	Included in DAR 2008
Atwal S.S. & Tremain, S.P.	KCA 2.9/01 <i>Submitted also in KCA 2.11/03 KCA 2.13/02</i>	2011	CALCINED KAOLIN: DETERMINATION OF HAZARDOUS PHYSICO-CHEMICAL PROPERTIES HARLAN, REPORT NO. 41003110 GLP: YES PUBLISHED: NO	N	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the renewal of a.s.
Bosc-Guillosson L,	KCA 2.11/01	2004	Explosive Properties of Satintone® 5HB Swift Consulting Engelhard GmbH SWP001 Not GLP unpublished	N	N	N	Tessenderlo Group	Included in DAR 2008
Bosc-Guillosson L,	KCA 2.13/1	2004	Oxidizing Properties of Satintone® 5HB Swift Consulting Engelhard GmbH SWP003 Not GLP unpublished	N	N	N	Tessenderlo Group	Included in DAR 2008

Author(s)	Data point	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*	Previous submission/evaluation
Castro. L	KCA 2.4 & MCP 5.1.1/02	2019	Additional information regarding Analytical methods used to characterize Calcined kaolin and SURROUND WP No report number Not GLP UNPUBLISHED	N	Y	New data provided.	Tessenderlo Kerley Inc.	Submitted for the renewal of a.s.
Guillosso L	KCA 2.9/01	2019a	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Flammability APC Report number TKIKAO-2019-1 Not GLP Unpublished-*+851	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
Guillosso L	KCA 2.9/02	2019b	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Self-heating APC Report number TKIKAO-2019-2 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
Guillosso L	KCA 2.11/02	2019c	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Explosive properties APC Report number TKIKAO-2019-3 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.

Author(s)	Data point	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*	Previous submission/ evaluation
Guillosso L	KCA 2.13/01	2019c	Calcined Aluminium silicate (Calcined Kaolin) Theoretical assessment of Oxidizing properties APC Report number TKIKAO-2019-4 Not GLP Unpublished	N	Y	New statement	Tessenderlo Group	Submitted for the renewal of a.s.
Murray H.H. (2007) in Benazzouz et al	KCA 2.1	2013	Determination of the melting temperature of kaolinite by means of the Z-method American Mineralogist, Volume 98, pages 1881–1885, 2013 Not GLP Published	N	N	N	Public	Submitted for the renewal of a.s.

A.2.2. Preparation**A.2.2.1. SURROUND® WP CROP PROTECTANT - Tessenderlo Group N.V.**

Notifier has already been asked to complete column “Justification if data protection is claimed” appropriately.

By Annex Point

Annex Point / Reference Number	Author(s)	Year	Title Source Company Report GLP Published Number	Vertebrate study Y/N	Data Protection Claimed	Justificati on if data protection is claimed	Owner	Previously submitted Y/N
CP 2.1/01 CP 2.7/01 CP 2.8.1/01 CP 2.8.2/01 CP 2.8.3/01	Norris D.	2006	Determination of Storage Stability and Shelf Life Specification Data for Surround, a Kaolin Formulation Stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. David Norris Analytical Laboratories Ltd., UK Report number DNA0080 GLP Unpublished	N	Y		Tessenderlo Group N.V.	N
CP 2.1/02 CP 2.4/01 CP 2.6/01 CP 2.7/03 CP 2.8.1/02 CP 2.8.3/02 CP 2.8.5.1/01	Miller R	2012	Final Report for “Storage Stability and Corrosion Characteristics of Surround WP” ARC Inc., USA Report number ARC-EX-848-012-P-1 GLP Unpublished	N	Y		Tessenderlo Group N.V.	N

Annex Point / Reference Number	Author(s)	Year	Title Source Company Report GLP Published Number	Vertebrate study Y/N	Data Protection Claimed	Justificati on if data protection is claimed	Owner	Previously submitted Y/N
CP 2.2/01	Bosc- Guillosso L	2004	Explosive Properties of Surround®WP Crop Protectant Swift Consulting, Pech Luna, France. Report number SWP002 Not GLP Unpublished.	N	N		Tessenderlo Group N.V.	Y DAR Vol 3, 2011
CP 2.2/02	Bosc- Guillosso L	2004	Oxidizing Properties of Surround®WP Crop Protectant Swift Consulting, Pech Luna, France. Report number SWP004 Not GLP Unpublished.	N	N		Tessenderlo Group N.V.	Y DAR Vol 3, 2011
CP 2.2/03	Guillosso L	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Explosive Properties APC Report number TKIKAO-2019-7 Not GLP Unpublished.	N	Y		Tessenderlo Group N.V.	N
CP 2.2/04	Guillosso L	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Oxidising Properties APC Report number TKIKAO-2019-8 Not GLP Unpublished.	N	Y		Tessenderlo Group N.V.	N

Annex Point / Reference Number	Author(s)	Year	Title Source Company Report GLP Published Number	Vertebrate study Y/N	Data Protection Claimed	Justificati on if data protection is claimed	Owner	Previously submitted Y/N
CP 2.3/01 CP 2.3/02	Anonymou s	2015	SURROUND WP CROP PROTECTANT EPA Safety Data Sheet Tessenderlo Kerley No report number Not GLP Published	N	N		Public	N
CP 2.3/03	Guillosso n L	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Flammability APC Report number TKIKAO-2019-5 Not GLP Unpublished	N	Y		Tessenderlo Group N.V.	N
CP 2.3/04	Guillosso n L	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Self-heating APC Report number TKIKAO-2019-6 Not GLP Unpublished	N	Y		Tessenderlo Group N.V.	N
CP 2.7/02 CP 2.8.3/03	Norris D	2017	Determination of Storage Stability and Shelf Life Specification Data for a Formulation containing Kaolin Clay stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. Report number DNA3876 GLP Unpublished	N	Y		Tessenderlo Group N.V.	N

Annex Point / Reference Number	Author(s)	Year	Title Source Company Report GLP Published Number	Vertebrate study Y/N	Data Protection Claimed	Justificati on if data protection is claimed	Owner	Previously submitted Y/N
CP 2.7/03	Norris D	2019	Determination of Storage Stability and Shelf Life Specification Data for a Formulation containing Kaolin Clay stored at ambient temperature for 2 years, in Compliance with Good Laboratory Practice Report number DNA3877 GLP Unpublished	N	Y	Data never previously submitted at EU level. Ongoing study – study plan provided	Tessenderlo Group N.V.	N

By Author

Author(s)	Annex Point / Reference Number	Year	Title Source Company Report GLP Published	Number	Vertebrate study Y/N	Data Protection Claimed	Justification if data protection is claimed	Owner
Anonymous	CP 2.3/01 CP 2.3/02	2015	SURROUND WP CROP PROTECTANT EPA Safety Data Sheet Tessenderlo Kerley No report number Not GLP Published		N	N		Public
Bosc- Guillosso L	CP 2.2/01	2004	Explosive Properties of Surround®WP Crop Protectant Swift Consulting, Pech Luna, France. Report number SWP002 Not GLP Unpublished.		N	N		Tessenderlo Group N.V.
Bosc- Guillosso L	CP 2.2/02	2004	Oxidizing Properties of Surround®WP Crop Protectant Swift Consulting, Pech Luna, France. Report number SWP004 Not GLP Unpublished.		N	N		Tessenderlo Group N.V.
Guillosso L	CP 2.2/03	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Explosive Properties APC Report number TKIKAO-2019-7 Not GLP Unpublished.		N	Y	Data never previously submitted at EU level.	Tessenderlo Group N.V.

Author(s)	Annex Point / Reference Number	Year	Title Source Company Report GLP Published Number	Vertebrate study Y/N	Data Protection Claimed	Justification if data protection is claimed	Owner
Guillosso L	CP 2.2/04	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Oxidising Properties APC Report number TKIKAO-2019-8 Not GLP Unpublished.	N	Y	Data never previously submitted at EU level.	Tessenderlo Group N.V.
Guillosso L	CP 2.3/03	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Flammability APC Report number TKIKAO-2019-5 Not GLP Unpublished	N	Y	Data never previously submitted at EU level.	Tessenderlo Group N.V.
Guillosso L	CP 2.3/04	2019	SURROUND® WP CROP PROTECTANT (950 g calcined aluminium silicate/kg) Theoretical assessment of Self-heating APC Report number TKIKAO-2019-6 Not GLP Unpublished	N	Y	Data never previously submitted at EU level.	Tessenderlo Group N.V.
Miller R	CP 2.1/02 CP 2.4/01 CP 2.6/01 CP 2.7/03 CP 2.8.1/02 CP 2.8.3/02 CP 2.8.5.1/01	2012	Final Report for “Storage Stability and Corrosion Characteristics of Surround WP” ARC Inc., USA Report number ARC-EX-848-012-P-1 GLP Unpublished	N	Y	Data never previously submitted at EU level.	Tessenderlo Group N.V.

Author(s)	Annex Point / Reference Number	Year	Title Source Company Report GLP Published Number	Vertebrate study Y/N	Data Protection Claimed	Justification if data protection is claimed	Owner
Norris D.	CP 2.1/01 CP 2.7/01 CP 2.8.1/01 CP 2.8.2/01 CP 2.8.3/01	2006	Determination of Storage Stability and Shelf Life Specification Data for Surround, a Kaolin Formulation Stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. David Norris Analytical Laboratories Ltd., UK Report number DNA0080 GLP Unpublished	N	Y	Data never previously submitted at EU level.	Tessenderlo Group N.V.
Norris D	CP 2.7/02 CP 2.8.3/03	2017	Determination of Storage Stability and Shelf Life Specification Data for a Formulation containing Kaolin Clay stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice. Report number DNA3876 GLP Unpublished	N	Y	Data never previously submitted at EU level.	Tessenderlo Group N.V.
Norris D	CP 2.7/03	2017	Determination of Storage Stability and Shelf Life Specification Data for a Formulation containing Kaolin Clay stored at ambient temperature for 2 years, in Compliance with Good Laboratory Practice Report number DNA3877 GLP Unpublished	N	Y	Data never previously submitted at EU level. Ongoing study – study plan provided	Tessenderlo Group N.V.

A.2.2.2. SOKALCIARBO WP - SOKA**By Annex Point**

Annex Point / Reference Number	Author(s)	Year	Title Source Company Report GLP Published Number	Vertebrate study Y/N	Data Protection Claimed	Justification if data protection is claimed	Owner	Previously submitted Y/N
K-CP 2.2/01 (CP 2.2, CP 2.3)	Atwal S.S. & Tremain, S.P.	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	KPC-Europe aisbl	N
K-CP 2.6/01 (CP 2.6, CP 2.8.1, CP 2.8.3, CP 2.8.5.1)	Jean-Batiste C.	2019	Physical and chemical properties of one batch of SOKALCIARBO WP ANADIAG, Report No. B8032 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA	N
K-CP 2.7/01	Jean-Batiste C.	2018b	Study plan: Determination of physical and chemical properties one batch of SOKALCIARBO WP – storage stability after 2 years of storage at ambient temperature ANADIAG, Report No. B8033 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA	N
K-CP 2.8.2/01	Chapelle M.	2013	TEST REPORT (in French) SGS, Report No. RN13-01579.004 GLP: No Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA	N

By Author

Author(s)	Annex Point / Reference Number	Year	Title Source Company Report GLP Published	Vertebrate study Y/N	Data Protection Claimed	Justification if data protection is claimed	Owner	Previously submitted Y/N
Atwal S.S. & Tremain, S.P.	K-CP 2.2/01 (CP 2.2, CP 2.3)	2011	Calcined kaolin: determination of hazardous physico-chemical properties Harlan, Report No. 41003110 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	KPC-Europe aisbl	N
Chapelle M.	K-CP 2.8.2/01	2013	TEST REPORT (in French) SGS, Report No. RN13-01579.004 GLP: No Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA	N
Jean-Batiste C.	K-CP 2.6/01 (CP 2.6, CP 2.8.1, CP 2.8.3, CP 2.8.5.1)	2019	Physical and chemical properties of one batch of SOKALCIARBO WP ANADIAG, Report No. B8032 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA	N
Jean-Batiste C.	K-CP 2.7/01	2018b	Study plan: Determination of physical and chemical properties one batch of SOKALCIARBO WP – storage stability after 2 years of storage at ambient temperature ANADIAG, Report No. B8033 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA	N

A.3. DATA ON APPLICATION AND EFFICACY

A.3.1. Active substance

A.3.2. Preparation

A.4. FURTHER INFORMATION

A.4.1. Active substance

A.4.1.1. Task Force

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner*

A.4.1.2. Task Force

Data point	Author(s)	Year	Title Owner, Report No. Source (where different from owner) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner*

A.4.2. Preparation

1107/2009 Data point	Author(s)	Year	Title Source (where different from company) Company Report No. Report date (YYYY-MM-DD) GLP or GEP status (where relevant), Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation

A.5. METHODS OF ANALYSIS

A.5.1. Active substance

Confidential data. Please refer to Vol 4 – Tessenderlo & Vol 4 SOKA

A.5.2. Preparation

Confidential data. Please refer to Vol 4 – Tessenderlo & Vol 4 SOKA

A.6. TOXICOLOGY AND METABOLISM DATA**A.6.1. Active substance -SOKA**

Data point	Author(s)	Year	Title Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner	Previous submission/ evaluation
K-CA 5.2.1/01	██████████	2016a	Kaolin: acute oral toxicity in the rat – fixed dose method ████████████████████ GLP: Yes Published: No	Y	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the purpose of the a.s. renewal
K-CA 5.2.2/01	██████████	2016b	Kaolin: acute dermal toxicity (limit test) in the rat ████████████████████ GLP: Yes Published: No	Y	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the purpose of the a.s. renewal
K-CA 5.2.3/01	██████████	2016	Kaolin: acute inhalation toxicity (nose only) study in the rat ████████████████████ GLP: Yes Published: No	Y	Y	New study for renewal dossier - confirmatory data	KPC-Europe aisbl	Submitted for the purpose of the a.s. renewal

Data point	Author(s)	Year	Title Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner	Previous submission/ evaluation
K-CA 5.2.6/01	██████████	2016c	Kaolin: local lymph node assay in the mouse – pooled method ████████████████████ GLP: Yes Published: No	Y	Y	Study required according to Regulation (EU) no. 283/2013	KPC- Europe aisbl	Submitted for the purpose of the a.s. renewal
K-CA 5.3.3/01	██████████	2019	Study Plan: Kaolin and Kaolinitic Clay: Toxicity Study by Inhalation administration to Han Wistar Rats for 2 Weeks ████████████████████ GLP: Yes Published: No	Y	Y	Study required according to Regulation (EU) no. 283/2013	KPC- Europe aisbl	Submitted for the purpose of the a.s. renewal
K-CA 5.4.1/01	Wisher, M.	2017	Kaolin: Reverse Mutation Assay 'Ames Test' using <i>Salmonella</i> <i>typhimurium</i> and <i>Escherichia coli</i> ENVIGO, Report No. LF13TQ GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 283/2013	KPC- Europe aisbl	Submitted for the purpose of the a.s. renewal

Data point	Author(s)	Year	Title Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner	Previous submission/ evaluation
K-CA 5.8.2/01	Yanagisawa R., Takano H., Ichinose T., Mizushima K., Nishikawa M., Mori I., Inoue K., Sadakane K. and Yoshikawa T.	2007	Gene expression analysis of murine lungs following pulmonary exposure to Asian sand dust particles Exp Biol Med (Maywood) 2007 Sep;232(8):1109-18 GLP: No Published: Yes	N	N	-	Public literature	

In addition, reference was made to data already evaluated at EU Peer Review of Aluminium Silicate:

- Hungary, 2008. Draft Assessment Report on the active substance Aluminium silicate prepared by the rapporteur Member State Hungary in the framework of Council Directive 91/414/EEC, August 2008
- Hungary, 2011: Final addendum to the Draft Assessment Report on the active substance Aluminium silicate prepared by the rapporteur Member State Hungary in the framework of Council Directive 91/414/EEC, May 2011
- EFSA, 2012: Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium silicate, EFSA Journal 2012;10(2):2517

Author(s)	Data point	Year	Title Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner	Previous submission/ evaluation
████████	K-CA 5.2.1/01	2016a	Kaolin: acute oral toxicity in the rat – fixed dose method ██████████ GLP: Yes Published: No	Y	Y	New study for renewal dossier - confirmatory data	KPC- Europe aisbl	Submitted for the purpose of the a.s. renewal
████████	K-CA 5.2.2/01	2016b	Kaolin: acute dermal toxicity (limit test) in the rat ██████████ GLP: Yes Published: No	Y	Y	New study for renewal dossier - confirmatory data	KPC- Europe aisbl	Submitted for the purpose of the a.s. renewal
████████	K-CA 5.2.6/01	2016c	Kaolin: local lymph node assay in the mouse – pooled method ██████████ GLP: Yes Published: No	Y	Y	Study required according to Regulation (EU) no. 283/2013	KPC- Europe aisbl	Submitted for the purpose of the a.s. renewal
████████	K-CA 5.2.3/01	2016	Kaolin: acute inhalation toxicity (nose only) study in the rat ██████████ GLP: Yes Published: No	Y	Y	New study for renewal dossier - confirmatory data	KPC- Europe aisbl	Submitted for the purpose of the a.s. renewal

Author(s)	Data point	Year	Title Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner	Previous submission/ evaluation
██████████	K-CA 5.3.3/01	2019	Study Plan: Kaolin and Kaolinitic Clay: Toxicity Study by Inhalation administration to Han Wistar Rats for 2 Weeks ██████████ GLP: Yes Published: No	Y	Y	Study required according to Regulation (EU) no. 283/2013	KPC-Europe aisbl	Submitted for the purpose of the a.s. renewal
Wisher, M.	K-CA 5.4.1/01	2017	Kaolin: Reverse Mutation Assay 'Ames Test' using <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> ENVIGO, Report No. LF13TQ GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 283/2013	KPC-Europe aisbl	Submitted for the purpose of the a.s. renewal
Yanagisawa R., Takano H., Ichinose T., Mizushima K., Nishikawa M., Mori I., Inoue K., Sadakane K. and Yoshikawa T.	K-CA 5.8.2/01	2007	Gene expression analysis of murine lungs following pulmonary exposure to Asian sand dust particles Exp Biol Med (Maywood) 2007 Sep;232(8):1109-18 GLP: No Published: Yes	N	N	-	Public literature	

In addition, reference was made to data already evaluated at EU Peer Review of Aluminium Silicate:

- Hungary, 2008. Draft Assessment Report on the active substance Aluminium silicate prepared by the rapporteur Member State Hungary in the framework of Council Directive 91/414/EEC, August 2008
- Hungary, 2011: Final addendum to the Draft Assessment Report on the active substance Aluminium silicate prepared by the rapporteur Member State Hungary in the framework of Council Directive 91/414/EEC, May 2011
- EFSA, 2012: Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium silicate, EFSA Journal 2012;10(2):2517



A.6.2. Active substance - TESSENDERLO

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	Previous submission/evaluation
KCA 5.2.1/01		1997a	Satintone® 5HB, Lot #10146 “Calcined Kaolin” - Acute Oral Toxicity Limit Test. [REDACTED] Report number 4903 GLP Unpublished.	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCA 5.2.1/02		1997b	M-96-018, Lot #08145 - Acute Oral Toxicity Limit Test. [REDACTED] Report number 5003. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCA 5.2.2/01		1997c	Satintone® 5HB, Lot #10146 - Acute Dermal Toxicity Limit Test. [REDACTED] Report number 4904.	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

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	Previous submission/ evaluation
			GLP Unpublished					
KCA 5.2.3/01		1997d	M-97-009, Lot #09255 “Calcined Kaolin”- Acute Inhalation Toxicity Limit Test. Report number: 5405. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCA 5.2.3/02		1997e	M-96-018 - Acute Inhalation Toxicity Limit Test. Report number 5424. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCA 5.2.4/01		1997f	M-96-018, Lot #08145 - Primary Skin Irritation. Report number 4906. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCA 5.2.5/01		1997g	M-96-018, Lot #08145 - Primary Eye Irritation. Report number 4905 GLP	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

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	Previous submission/ evaluation
			Unpublished					
KCA 5.2.5/02		2000	Surround® WP Crop Protectant - Primary Eye Irritation Study in Rabbits. Report number 9914 GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCA 5.2.6/01		2017	Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Kligman. Report number SMK-PH-17/0024 R1 GLP Unpublished	Y	Y	New data not previously submitted	Tessenderlo Kerley Inc.	Submitted for the purpose of the a.s. renewal
KCA 5.5/01	Schepers, G.W.H.	1971	Lung tumors of primates and rodents Industrial Medicine, Vol. 40 (1), pp32-37. No report number Not GLP Published	N	N	-	Public	In DAR (2008)
KCA 5.5/02	Wagner, J.C., Griffiths, D.M., Munday, D.E.	1987	Experimental studies with palygorskite dusts. Br. J. Ind. Med. 44:749-763 No report number Not GLP Published	N	N	-	Public	In DAR (2008)
KCA 5.6/01	Patterson, E.C., Staszak, D.J.	1977	Effects of geophagia (kaolin ingestion) on the maternal blood and embryonic development in the pregnant rat. J. Nut. 107:2020-2025 No report number	N	N	-	Public	In DAR (2008)

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	Previous submission/ evaluation
			Not GLP Published					
KCA 5.7	Committee on Food Chemicals Codex	1996	Food Chemicals Codex – Fourth Edition 208/FCC IV/Monograph Specifications No report number Not GLP Published	N	N	-	Public	In DAR (2008)
KCA 5.9.1/01	Rawlings, W. Jr.	1997	Letter to J L Etheridge Washington County Internal Medicine P.C. No report number Not GLP Unpublished	N	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCA 5.9.1/02	Ogle, C.J., Rundle, E.M. and Sugar, E.T.	1989	China clay workers in the south west of England: analysis of chest radiograph readings, ventilatory capacity, and respiratory symptoms in relation to type and duration of occupation. British Journal of Industrial Medicine 1989; 46:261-270 No report number Not GLP Published	N	N	-	Public	Submitted for the purpose of the a.s. renewal

Author(s)	Data point	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	Previous submission/ evaluation
Committee on Food Chemicals Codex	KCA 5.7	1996	Food Chemicals Codex – Fourth Edition 208/FCC IV/Monograph Specifications No report number Not GLP Published	N	N	-	Public	In DAR (2008)
	KCA 5.2.5/02	2000	Surround® WP Crop Protectant - Primary Eye Irritation Study in Rabbits.  Report number 9914 GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
Ogle, C.J., Rundle, E.M. and Sugar, E.T.	KCA 5.9.1/02	1989	China clay workers in the south west of England: analysis of chest radiograph readings, ventilatory capacity, and respiratory symptoms in relation to type and duration of occupation. British Journal of Industrial Medicine 1989; 46:261-270 No report number Not GLP Published	N	N	-	Public	Submitted for the purpose of the a.s. renewal
Patterson, E.C., Staszak, D.J.	KCA 5.6/01	1977	Effects of geophagia (kaolin ingestion) on the maternal blood and embryonic development in the pregnant rat. J. Nut. 107:2020-2025 No report number Not GLP Published	N	N	-	Public	In DAR (2008)

Author(s)	Data point	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	Previous submission/ evaluation
Rawlings, W. Jr.	KCA 5.9.1/01	1997	Letter to J L Etheridge Washington County Internal Medicine P.C. No report number Not GLP Unpublished	N	N	N	Tessenderlo Group N.V.	In DAR (2008)
██████████	KCA 5.2.6/01	2017	Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Kligman. Report number SMK-PH-17/0024 R1 GLP Unpublished	Y	Y	New data not previously submitted	Tessenderlo Kerley Inc.	Submitted for the purpose of the a.s. renewal
Schepers, G.W.H.	KCA 5.5/01	1971	Lung tumors of primates and rodents Industrial Medicine, Vol. 40 (1), pp32-37. No report number Not GLP Published	N	N	-	Public	In DAR (2008)
Wagner, J.C., Griffiths, D.M., Munday, D.E.	KCA 5.5/02	1987	Experimental studies with palygorskite dusts. Br. J. Ind. Med. 44:749-763 No report number Not GLP Published	N	N	-	Public	In DAR (2008)
██████████	KCA 5.2.1/01	1997a	Satintone® 5HB, Lot #10146 "Calcined Kaolin" - Acute Oral Toxicity Limit Test. ██ Report number 4903 GLP Unpublished.	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

Author(s)	Data point	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	Previous submission/ evaluation
	KCA 5.2.1/02	1997b	M-96-018, Lot #08145 - Acute Oral Toxicity Limit Test. [REDACTED] Report number 5003. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
	KCA 5.2.2/01	1997c	Satintone® 5HB, Lot #10146 - Acute Dermal Toxicity Limit Test. [REDACTED] Report number 4904. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
	KCA 5.2.3/01	1997d	M-97-009, Lot #09255 "Calcined Kaolin"- Acute Inhalation Toxicity Limit Test. [REDACTED] Report number: 5405. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
	KCA 5.2.3/02	1997e	M-96-018 - Acute Inhalation Toxicity Limit Test. [REDACTED] Report number 5424. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
	KCA 5.2.4/01	1997f	M-96-018, Lot #08145 - Primary Skin Irritation.	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

Author(s)	Data point	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	Previous submission/ evaluation
			[REDACTED] [REDACTED] number 4906. GLP Unpublished					
[REDACTED]	KCA 5.2.5/01	1997g	M-96-018, Lot #08145 - Primary Eye Irritation. [REDACTED] Report number 4905 GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

A.6.3. Preparation SURROUND® WP

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	Previous submission/ evaluation
KCP 7.1.1/01	[REDACTED]	1997 a	Satintone® 5HB, Lot #10146 “Calcined Kaolin” - Acute Oral Toxicity Limit Test. [REDACTED] [REDACTED] Report number 4903 GLP Unpublished.	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCP 7.1.1/02	[REDACTED]	1997 b	M-96-018, Lot #08145 - Acute Oral Toxicity Limit Test. [REDACTED] [REDACTED] Report number 5003. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCP 7.1.2/01	[REDACTED]	1997	Satintone® 5HB, Lot #10146 - Acute Dermal Toxicity Limit Test. [REDACTED] [REDACTED] [REDACTED] Report number 4904. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

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	Previous submission/ evaluation
KCP 7.1.3/01	[REDACTED]	1997 a	M-97-009, Lot #09255 “Calcined Kaolin”- Acute Inhalation Toxicity Limit Test. [REDACTED] [REDACTED] Report number: 5405. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCP 7.1.3/02	[REDACTED]	1997 b	M-96-018 - Acute Inhalation Toxicity Limit Test. [REDACTED] [REDACTED] [REDACTED] Report number 5424. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCP 7.1.4/01	[REDACTED]	1997	M-96-018, Lot #08145 - Primary Skin Irritation. [REDACTED] [REDACTED] [REDACTED] Report number 4906. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

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	Previous submission/ evaluation
KCP 7.1.5/01	[REDACTED]	2000	Surround® WP Crop Protectant - Primary Eye Irritation Study in Rabbits. [REDACTED] [REDACTED] Report number 9914 GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCP 7.1.5/02	[REDACTED]	1997	M-96-018, Lot #08145 - Primary Eye Irritation. [REDACTED] [REDACTED] Report number 4905 GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
KCP 7.1.6/01	[REDACTED]	2017	Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Kligman. Report number SMK-PH-17/0024 R1 GLP Unpublished	Y	Y	New data not previously submitted	Tessenderlo Kerley Inc.	Submitted for the purpose of the a.s. renewal

Author(s)	Data point	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	Previous submission/ evaluation
[REDACTED]	KCP 7.1.5/01	2000	Surround® WP Crop Protectant - Primary Eye Irritation Study in Rabbits. [REDACTED] Report number 9914 GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
[REDACTED]	KCP 7.1.6/01	2017	Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Kligman. Report number SMK-PH-17/0024 R1 GLP Unpublished	Y	Y	New data not previously submitted	Tessenderlo Kerley Inc.	Submitted for the purpose of the a.s. renewal
[REDACTED]	KCP 7.1.1/01	1997 a	Satintone® 5HB, Lot #10146 “Calcined Kaolin” - Acute Oral Toxicity Limit Test. [REDACTED] Report number 4903 GLP Unpublished.	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

Author(s)	Data point	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	Previous submission/ evaluation
██████████	KCP 7.1.1/02	1997 b	M-96-018, Lot #08145 - Acute Oral Toxicity Limit Test. ██████████ ██████████ Report number 5003. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
██████████	KCP 7.1.2/01	1997	Satintone® 5HB, Lot #10146 - Acute Dermal Toxicity Limit Test. ██████████ Report number 4904. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
██████████	KCP 7.1.3/01	1997 a	M-97-009, Lot #09255 "Calcined Kaolin"- Acute Inhalation Toxicity Limit Test. ██████████ Report number: 5405. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

Author(s)	Data point	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	Previous submission/ evaluation
[REDACTED]	KCP 7.1.3/02	1997 b	M-96-018 - Acute Inhalation Toxicity Limit Test. [REDACTED] [REDACTED] [REDACTED] Report number 5424. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
[REDACTED]	KCP 7.1.4/01	1997	M-96-018, Lot #08145 - Primary Skin Irritation. [REDACTED] [REDACTED] Report number 4906. GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)
[REDACTED]	KCP 7.1.5/02	1997	M-96-018, Lot #08145 - Primary Eye Irritation. [REDACTED] [REDACTED] Report number 4905 GLP Unpublished	Y	N	N	Tessenderlo Group N.V.	In DAR (2008)

A.7. RESIDUE DATA

A.7.1. Active substance

Author(s)	Data point	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

A.7.2. Preparation

A.8. ENVIRONMENTAL FATE AND BEHAVIOUR**A.8.1. Active substance**

Author(s)	Data point	Year	Title Company Report Source (where different from company) GLP or GEP status Published or not	No.	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Veatch O. , McCallie S.W.	8.1.1	1909	Geological survey of Georgia, Bulletin n°18, Second report on the clay deposits of Georgia		N	N	-	-
Sutherland B.R. et al.	8.2	2014	Clay settling in fresh and salt water, Environ Fluid Mech, volume 15, Issue 1, pp 147–160		N	N	-	-

A.8.2. Preparation

Author(s)	Data point	Year	Title Company Report Source (where different from company) GLP or GEP status Published or not	No.	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
	-							

A.9. ECOTOXICOLOGY DATA**A.9.1. Active substance**

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
KCA 8.1.1.3/01	Owen, O.J., Nodu, M.B., Dike, U.A., Ideozu, H.M.	2012	The effects of dietary kaolin (clay) as feed additive on the growth performance of broiler chickens GLP not reported Published; Greener Journal of Agricultural Sciences Vol. 2(6): 233-236	Y	N	Not relevant	Public literature
K-CA 8.1/01	N.J. Dominy, E. Davoust and M. Minekus	2004	Adaptive function of soil consumption: an in vitro study modeling the human stomach and small intestine. The Journal of Experimental Biology 207, 319-324 GLP: No	N	N	-	Public literature
K-CA 8.1/02	Paula A. Pebsworth, Gretchen L. Seim, Michael A. Huffman, Raymond P. Glahn, Elad Tako & Sera L. Young	2013	Soil Consumed by Chacma Baboons is Low in Bioavailable Iron and High in Clay. J Chem Ecol. 2013 Mar;39(3):447-9 GLP: No	N	N	-	Public literature
K-CA 8.1/03	Chieu Anh Kim Ta, Paula A. Pebsworth, Rui Liu, Stephen Hillier, Nia Gray, John T. Arnason & Sera L. Young	2017	Soil eaten by chacma baboons adsorbs polar plant secondary metabolites representative of those found in their diet. Environ Geochem Health. 2018 Apr;40(2):803-813 GLP: No	N	N	-	Public literature

K-CA 8.1/04	M. Safaeikatoouli, F. Boldaji, B. Dastar & S. Hassani	2012	The Effect of Dietary Silicate Minerals Supplementation on Apparent Ileal Digestibility of Energy and Protein in Broiler Chickens. Int. J. Agric. Biol., Vol. 14, No. 2, 2012 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.1/06	B. A. Mullens, D. Soto, C. D. Martin, B. L. Callahan, and A. C. Gerry	2012	Northern fowl mite (<i>Ornithonyssus sylviarum</i>) control evaluations using liquid formulations of diatomaceous earth, kaolin, sulfur, azadirachtin, and <i>Beauveria bassiana</i> on caged laying hens. The Journal of Applied Poultry Research 21(1):111-116, March 2012	N	N	-	Public literature
K-CA 8.1/07	C.D. Martin and B.A. Mullens	2012	Housing and dustbathing effects on northern fowl mites (<i>Ornithonyssus sylvarum</i>) and chicken body lice (<i>Menacanthus stramineus</i>) on hens. Medical and Veterinary Entomology (2012) 26,323-333	N	N	-	Public literature
K-CA 8.1/08	Mumpton F.A.	1999	La Roca magica: Uses of natural zeolites in agriculture and industry Proceedings of the National Academy of Sciences of the United States of America Vol 96, pp 3463-3470, March 1999	N	N	-	Public literature
K-CA 8.1/09	Brightsmith et al.	2010	Nutritional Content of the diets of free living Scarlet Macaw Chicks in Southeastern Peru Journal of Avian Medicine and Surgery 24(1): 9-23, 2010	N	N	-	Public literature
KCA 8.2.1/02	McFarland, V.A., and Peddicord, R.K.	1980	Lethality of a suspended clay to a diverse selection of marine and estuarine macrofauna GLP not reported Published; Archives of Environmental Contamination and Toxicology (1980), volume 9, pages 733-741	Y	N	Not relevant	Public literature

KCA 8.2.1/03	Isono, R.S., Kita, J., and Setoguma, T.	1998	Acute effects of kaolinite suspension on eggs and larvae of some marine teleosts GLP not reported Published; Comparative Biochemistry and Physiology Part C (1998) volume 120, pages 449-455	Y	N	Not relevant	Public literature
KCA 8.2.1/04	Sherk J.A. Jr., O'Connor J.M., Neumann D.A., Prince R.D., and Wood K.V.,	1973	Effects of Suspended and Deposited Sediments on Estuarine Organisms, PHASE II GLP not reported Published; U.S. Department of Commerce, National Technical Information Service	Y	N	Not relevant	Public literature
KCA 8.2.2/01	Goldes, S.A., Ferguson, H.W., Moccia, R.D. and Daoust, P.Y.	1988	Histological effects of the inert suspended clay kaolin on the gills of juvenile rainbow trout, <i>Salmo gairdneri</i> GLP not reported Published; Journal of Fish Diseases (1988), volume 11 pages 23-33	Y	N	Not relevant	Public literature
KCA 8.2.2/02	Redding, J.M., Schreck, C.B., and Everest, F.	1987	Physiological Effects on Coho Salmon and Steelhead of Exposure to Suspended Solids GLP not reported Published; Transactions of the American Fisheries Society (1987), volume 116, pages: 737- 744	Y	N	Not relevant	Public literature
KCA 8.2.2.1/01	Hashimoto, Y., Yamaguchi, M., Itō, T., and Tōi, J.	1986	Effects of Kaolin on Hatching, Growth and Feeding Behaviour of Rainbow Trout, <i>Salmo gairdneri</i> GLP not reported Published; Bull. Tokai Reg. Fish. Res. Lab., (1986), volume 120 pages: 39 - 42	Y	N	Not relevant	Public literature

KCA 8.2.4.1/01	Robinson, S.E., Capper, N.A., and Klaine, S.J.	2009	The effects of continuous and pulsed exposures of suspended clay on the survival, growth and reproduction of <i>Daphnia magna</i> GLP not reported Published; Environmental Toxicology and Chemistry Vol 29 (1): 168-175	N	N	Not relevant	Public literature
KCA 8.3.1.1.1/01	Hoxter, K.A., Palmer, S.J., and Krueger, H.O.	1997	M-96-018 Kaolin: An Acute Dietary Toxicity Study with the Honey Bee Report no.: 469-102 GLP: Yes Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.
KCA 8.3.1.1.2/01	Hoxter, K.A., Palmer, S.J., and Krueger, H.O.	1997	M-96-018 Kaolin: An Acute Contact Toxicity Study with the Honey Bee Report no.: 469-101 GLP: Yes Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.
KCA 8.3.2/01	Puterka, G.J.	1997	Report on the Effect of M-96-018 Kaolin on Insect Predators Report no.: - GEP: No Unpublished	N	N	Data out of 10 year protection	Tessenderlo Group N.V.
KCA 8.3.2/02	Gharbi, N., and Abdallah, S.B.	2016	Laboratory evaluation of side-effects of kaolin on two predator species found on olive groves GLP not reported Published; Tunisian Journal of Plant Protection vol 11, no. 1: 83-90	N	N	Not relevant	Public literature

KCA 8.3.2/03	Bestete, L.R., Torres J.B., Pereira, F.F.	2018	Harmonious interaction of kaolin and two insect predator species in plant protection GLP not reported Published; International Journal of Pest Management, 64 (2): 166-172	N	N	Not relevant	Public literature
K-CA 8.3.2/01	Porcel, M., Cotes B and Campos M	2011	Biological and behavioural effects of kaolin particle film on larvae and adults <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae). Biological Control 59:98-105 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/02	Bengochea P.R., Saelicesa, F. Amora, Á. Adána, F. Budiaa, P. del Estala, E. Viñuelaa & P. Medinaa	2014	Non-target effects of kaolin and copper applied on olive trees for the predatory lacewing <i>Chrysoperla carnea</i> . Biocontrol Science and Technology, vol 24, no 6:625-640 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/03	Bengochea P., F. Amor, R. Saelices, S. Hernando, F. Budia, A. Adán, P. Medina	2013	Kaolin and copper bases products applications. Ecotoxicology on four natural enemies. Chemosphere 91: 1189-1195 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/04	Pascual S, Cobos G., Serris E. and Gonzalez-Numez M.	2010	Effect of processed kaolin on pests and non-target arthropods in a Spanish olive grove. Journal of Pest Science 83:121-133 GLP: No Published: Yes	N	N	-	Public literature

K-CA 8.3.2/05	Marko V., Bogya S., Kondorosy E. and Blommers, L.H.M.	2009	Side effects of kaolin particle films on apple orchard bug, beetle and spider communities. International Journal of Pest Management vol 56: 189-199 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/06	Bengochea, Hernando, Saelices, Adan, Budia, Gonzalez Nunez, Vinuela, Medina	2010	Side effects of kaolin on natural enemies found on olive crops. Pesticides and Beneficial Organisms vol 55: 61-67 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/07	T. E. Sackett, C. M. Buddle and C. Vincent	2007	Effects of kaolin on the composition of generalist predator assemblages and parasitism of <i>Choristoneura rosaceana</i> (Lep., Tortricidae) in apple orchards. J. Appl. Entomol. 131(7), 478–485 (2007) GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/08	Bengochea, Budia, Vinuela, Medina	2013	Are kaolin and copper treatments safe to the olive fruit fly parasitoid <i>Psytalia concolor</i> ? Journal of Pest Science GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/09	Ismael Sánchez-Ramos, Aránzazu Marcotegui, Susana Pascual, Cristina E. Fernández, Guillermo Cobos, and Manuel González- Núñez	2017	Compatibility of organic farming treatments against <i>Monosteira unicostata</i> with non-target arthropod fauna of almond trees canopy. Spanish Journal of Agricultural research 15(2), e1004, 10 pages (2017) GLP: No Published: Yes	N	N	-	Public literature

K-CA 8.3.2/10	Christina E. Pease, Jesus F. Lopez-Olguin, Ignacio Perez-Moreno, and Vicente Marco-Mancebon	2016	Effects of Kaolin on <i>Lobesia botrana</i> (Lepidoptera: Tortricidae) and Its Compatibility With the Natural Enemy, <i>Trichogramma cacoeciae</i> (Hymenoptera: Trichogrammatidae). Journal of Economic Entomology GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/11	Susana Pascual, Guillermo Cobos, Pilar Medina, Flor Budia, Elisa Viñuela, Manuel González-Núñez	2010	Field assessment of effects of control strategies against the olive fruit fly (<i>Bactrocera oleae</i> (Rossi)) on predatory arthropods: comparison of different methods of data analysis. Pesticides and Beneficial Organisms IOBC/wprs Bulletin Vol. 55, 2010 pp. 11-18 GLP: No	N	N	-	Public literature
K-CA 8.3.2/12	Luziani Rezende Bestete, Jorge Braz Torres and Fabricio Fagundes Pereira	2017	Harmonious interaction of kaolin and two insect predator species in plant protection. International Journal of pest management GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/13	AL Knight, BA Christianson, TR Unruh	2001	Impacts of seasonal kaolin particle films on apple pest management. The Canadian Entomologist 133: 413-428 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/14	Christina E. Pease, Jesus F. Lopez-Olguin, Ignacio Perez-Moreno, and Vicente Marco-Mancebon	2016	Effects of Kaolin on <i>Lobesia botrana</i> (Lepidoptera: Tortricidae) and Its Compatibility With the Natural Enemy, <i>Trichogramma cacoeciae</i> (Hymenoptera: Trichogrammatidae). Journal of Economic Entomology GLP: No Published: Yes	N	N	-	Public literature

K-CA 8.3.2/15	Susana Pascual, 2010 Guillermo Cobos, Pilar Medina, Flor Budia, Elisa Viñuela, Manuel González-Núñez	Field assessment of effects of control strategies against the olive fruit fly (<i>Bactrocera oleae</i> (Rossi)) on predatory arthropods: comparison of different methods of data analysis. Pesticides and Beneficial Organisms IOBC/wprs Bulletin Vol. 55, 2010 pp. 11-18 GLP: No	N	N	-	Public literature
K-CA 8.3.2/16	Nino Iannotta, Tiziana Belfiore, Marie Elena Noce, Stefano Scalercio, Veronica Vizzarri	The impact of some compounds utilized in organic olive groves on the non-target arthropod fauna: canopy and soil levels. Pesticides and Beneficial Organisms C-Ecological Aspects GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/17	Iannotta, N, Belfiore, T, 2010 Noce, M. E, Scalercio, S, & Vizzarri, V	Impact of kaolin and <i>Beauveria bassiana</i> treatments against olive fly on the non-target arthropods of the olive ecosystem. Acta horticulture. September 2010 GLP: No Published: Yes	N	N	-	Public literature
K-CA 8.3.2/18	Viktor Marko, Leo H.M. 2006 Blommers, Sandor Bogya and Herman Helsen	The effects of kaolin treatments on phytopagous and predatory arthropods in the canopies of apple trees. Journal of fruit and Ornamental Plant Research Vol 14 (Suppl 3), 2006 GLP: No Published: Yes	N	N	-	Public literature
KCA 8.8/01	Cary, G.A., McMahon, 1987 J.A., and Kuc W. J.	The effect of suspended solids and naturally occurring dissolved organics in reducing the acute toxicities of cationic polyelectrolytes to aquatic organisms GLP not reported Published; Environmental Toxicology and Chemistry (1987), volume 6, pages 469-474	N	N	Not relevant	Public literature

KCA 8.8/02	Maki, W., and Bishop, W.E.	1979	Acute Toxicity Studies of Surfactants to <i>Daphnia magna</i> and <i>Daphnia pulex</i> GLP not reported Published; Archives of Environmental Contamination and Toxicology (1979), volume 8, pages 599-612	N	N	Not relevant	Public literature
KCA 8.8/03	Valenta, S., and Svobodova, Z.	1980	An Ichthyotoxicological Evaluation of Electrically Conductive Resins and Coating Mixtures used in the Paper Industry GLP not reported Published; Buletin VÚRH Vodňany (1980), volume 2	N	N	Not relevant	Public literature

A.9.2. Preparation Surround WP

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
KCP 10.2.1/01	Goodband, T.J.	2006	Surround WP crop protectant: Acute toxicity to <i>Daphnia magna</i> Report number: 2120/0004 SafePharm Laboratories GLP Unpublished	N	Y	Data never submitted at EU level	Tessenderlo Group N.V.

KCP 10.2.1/02	Vryenhoef, H.	2006	Surround WP crop protectant: Algal inhibition test Report number: 2120/0003 SafePharm Laboratories GLP Unpublished	N	Y	Data never submitted at EU level	Tessenderlo Group N.V.
KCP 10.3.1.1.1/01	Goodband, T.J.	2006	Surround WP crop protectant: Acute toxicity to honeybees (<i>Apis mellifera</i>) Report number: 2120/0005 SafePharm Laboratories GLP Unpublished	N	Y	Data never submitted at EU level	Tessenderlo Group N.V.
KCP 10.3.1.2/01	Ansaloni, T.	2018 9	Effects of Surround WP – Chronic oral toxicity to adult worker honey bees, <i>Apis mellifera</i> L. under laboratory conditions Report number: TRC17-208BA TrailCamp GLP Unpublished	N	Y	New data in support of submission	Tessenderlo Group N.V.
KCP 10.3.1.3/01	Ansaloni, T.	2017 9	Effects of Surround WP on honeybee larvae (<i>Apis mellifera</i> L.) after a repeated exposure under laboratory conditions: non-GLP Range Finding Test Report number: TRC17-184BA Range Finder TrailCamp Non-GLP Unpublished	N	Y	New data in support of submission	Tessenderlo Group N.V.
KCP 10.3.1.6/01	Mayer, D.F.	1999a	Honey bee foraging in pear orchards treated with kaolin particle film Report number: - Non-GLP Unpublished	N	N	Data out of protection,	Tessenderlo Group N.V.

KCP 10.3.1.6/02	Mayer, D.F.	1999b	Honey bee foraging in apple orchards treated with kaolin particle film Report number: - Non-GLP Unpublished	N		Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.2/01	Porcel, M., Cotes, B., and Campos, M.	2011	Biological and behavioural effects of kaolin particle film on larvae and adults of <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae) Report number: - GLP: unknown Published in: Biological Control 59: 98-105	N	N	Not relevant	Public literature
KCP 10.3.2.2/02	Bengochea P., <i>et al.</i>	2010	Side effects of kaolin on natural enemies found on olive crops Report number: - GLP: unknown Published in: Pesticides and Beneficial Organisms vol 55: 61-67	N	N	Not relevant	Public literature
KCP 10.3.2.2/03	Bengochea P., <i>et al.</i>	2014	Non-target effects of kaolin and copper applied on olive trees for the predatory lacewing <i>Chrysoperla carnea</i> Report number: - GLP: unknown Published in: Biocontrol Science and Technology, vol 24, no 6: 625-640	N	N	Not relevant	Public literature
KCP 10.3.2.2/04	Bengochea P., <i>et al.</i>	2013	Kaolin and copper-based products applications: Ecotoxicology on four natural enemies Report number: - GLP: unknown Published in: Chemosphere 91: 1189-1195	N	N	Not relevant	Public literature

KCP 10.3.2.2/05	Bengochea, P., Budia, F., Viñuela, E., and Medina, P.	2014	Are kaolin and copper treatments safe to the olive fruit fly parasitoid <i>Psytalia concolor</i> ? Report number: - GLP: unknown Published in: J Pest Sci 87: 351-359	N	N	Not relevant	
KCP 10.3.2.2/06	Pease, C.E., López-Olguín, J. F., Pérez-Moreno, I., Marco-Mancebón, V.	2016	Effects of kaolin on <i>Lobesia botrana</i> (Lepidoptera: Tortricidae) and its compatibility with the natural enemy, <i>Trichogramma cacoeciae</i> (Hymenoptera: Trichogrammatidae) Report number: - GLP: unknown Published in: Journal of Economic Entomology, 109(2): 740-745	N	N	Not relevant	
KCP 10.3.2.4/01	Lepin, J.	2004	Evaluate the efficacy of Surround against <i>Cacopsylla pyri</i> , applied just after the end of the winter period Report number: FENG045059 SOLEVI GEP: yes Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/02	Fraser, H.	2002a	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-1 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.

KCP 10.3.2.4/03	Fraser, H.	2002b	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-2 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/04	Fraser, H.	2002c	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-5 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/05	Fraser, H.	2002d	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-6 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/06	Fraser, H.	2002e	Evaluation of a season long insect pest control programme with Surround WP in an Ontario apple orchard Report number: 2002-7 Engelhard GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.

KCP 10.3.2.4/07	Peusens, G., and Creemers, O.	2004a	Biological efficacy evaluation of Surround WP against the pear sucker, <i>Cacopsylla pyri</i> L., on pear Report number: 20040617 412 BE 388 GEP RSF GEP: yes Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/08	Peusens, G., and Creemers, O.	2004b	Biological efficacy evaluation of Surround WP against the pear sucker, <i>Cacopsylla pyri</i> L., on pear Report number: 20040617 460 BE 421 GEP RSF GEP: yes Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/09	Puterka, G.J.	2001	Impact of Surround® WP Particle Film on Arthropod Predators in Tree Fruits Report number: - USDA GEP: no Unpublished	N	N	Data out of protection	Tessenderlo Group N.V.
KCP 10.3.2.4/10	Pascual, S., Cobos, G., Seris, E., and Gonzalez- Nunez, M.	2010	Effects of processed kaolin on pests and non-target arthropods in a Spanish olive grove Report number: - GEP: - Published in: J Pest Sci 83:121-133	N	N	Not relevant	Public literature
KCP 10.3.2.4/11	Marko, V., Bogya, S., Kondorosy, E., and Blommers, L.H.M	2009	Side effects of kaolin particle films on apple orchard bug, beetle and spider communities Report number: - GEP: - Published in: International Journal of Pest Management vol 56: 189-199	N	N	Not relevant	Public literature

KCP 10.3.2.4/12	Markó, V., Blommers, L.H.M., Bogya, S., Helsen, H.	2006	The effect of kaolin treatments on phytophagous and predatory arthropods in the canopies of apple trees Report number: - GEP: - Published in: J Fruit Ornam Plant Res, 14 (suppl 3): 79-87	N	N	Not relevant	
KCP 10.3.2.4/13	Iannotta, N., Belifiore, T., Noce, M.E., Scalerico, S., Vizzarri, V.	2007	The impact of some compounds utilized in organic olive groves on the non-target arthropod fauna: canopy and soil levels Report number: - GEP: - Published in: Ecoliva 2007, VI Jornadas Internacionales de Olivar Ecologico, Puente de Génave (Jaén), España, 22-25 marzo 2007	N	N	Not relevant	
KCP 10.3.2.4/14	Knight, A.L., Christian- son, B.A., Unruh, T.A.	2001	Impacts of seasonal kaolin particle films on apple pest management Report number: - GEP: - Published in: The Canadian Entomologist 133: 413-428	N	N	Not relevant	
KCP 10.3.2.4/15	Pascual, S., Cobos, G., Medina, P., Budía, F., Viñuela, E., González- Núñez, M.	2010	Field assessment of effects of control strategies against the olive fruit fly (<i>Bactrocera oleae</i> (Rossi)) on predatory arthropods: comparison of different methods of data analysis Report number: - GEP: - Published in: Pesticides and Beneficial Organisms IOBC/wprs Bulletin vol 55: 11-18	N	N	Not relevant	

KCP 10.3.2.4/16	Sánchez- Ramos, I., Marcotegui, A., Pascual, S., Fernández, C.E., Cobos, G, González- Núñez, M.	2017	Compatibility of organic farming treatments against <i>Monosteira unicastata</i> with non-target arthropod fauna of almond trees Report number: - GEP: - Published in: Spanish Journal of Agricultural Research 15(2), e1004	N	N	Not relevant	
KCP 10.3.2.4/17	Sackett, T.E., Buddle, C.M., Vincent, C.	2007	Effects of kaolin on the composition of generalist predator assemblages and parasitism of <i>Choristoneura rosaceana</i> (Lep., Tortridae) in apple orchards Report number: - GEP: - Published in: J. Appl. Entomol. 131(7): 478-485	N	N	Not relevant	
KCP 10.3.2.4/18	Showler, A.T, and Sétamou, M.	2004	Effects of kaolin particle film on selected arthropod populations in cotton in the lower Rio Grande Valley of Texas Report number: - GEP: - Published in: Southwestern Entomologist, 29(2): 137-146	N	N	Not relevant	
KCP 10.3.2.4/19	Scalerio, S., Belfiore, T., Noce, M.E., Vizzarri, V., Iannotta, N.	2010	Impact of kaolin and <i>Beauveria bassiana</i> treatments against olive fly on the non-target arthropods of the olive ecosystem Report number: - GEP: - Published in: Acta Horticulturae, 873: 329-336	N	N	Not relevant	

A.9.3. Preparation SOKALCIARBO WP

Data point	Author(s)	Year	Title Source (where different from company) Compagny, Report No GLP or GEP (where relevant), Published	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection	Owner
K-CP 10.2.1/01	Vryenhoef H.	2018	SOKALCIARBO WP: Algal Growth Inhibition test ENVIGO, Report No. HM69VD GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA
K-CP 10.3.1.1.2 /1	Mamet O.	2008	« Détermination de la DL ₅₀ de contact sur abeille domestique (<i>Apis mellifera</i>) par différentes applications de SOKALCIARBO WP » Testapi, Report N°139-2008 GLP: Yes Published: No	N	Y	Required according to Reg. (EU) no. 284/2013.	SOKA
CP 10.3.1.2	Mamet O.	2019	Evaluation of the chronic oral toxicity of Sokalciarbo WP on honey bees (<i>Apis mellifera</i> L.). Calculation of Lethal Concentration (LC ₅₀) and Lethal Dietary Dose (LDD ₅₀). Laboratory conditions. TESTAPI, Report No. 371-2018 GLP: Yes Published: No	N	Y	Study required according to Regulation (EU) no. 284/2013	SOKA