

# **Aluminium silicate (Kaolin)**

## **DOCUMENT L-CA, Section 5**

### **TOXICOLOGICAL AND METABOLISM STUDIES ON THE ACTIVE SUBSTANCE**

**Sanco/12580/2012 – rev. 3.1**

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## Version history<sup>1</sup>

Date	Data points containing amendments or additions and brief description	Document identifier and version number
28/02/2018	Initial applicant's dossier	LCA-S5_2018-02-28

<sup>1</sup> It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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## CA 5 TOXICOLOGICAL AND METABOLISM STUDIES ON THE ACTIVE SUBSTANCE

All studies presented in grey have already been evaluated at EU level.

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 [REDACTED] Report number 4903 GLP Unpublished.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 GLP Unpublished	Y	N		Tessenderlo Group N.V.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 GLP Unpublished	Y	N		Tessenderlo Group N.V.

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 5.2.3/01	[REDACTED]	1997 a	M-97-009, Lot #09255 “Calcined Kaolin”- Acute Inhalation Toxicity Limit Test. [REDACTED] [REDACTED] Report number: 5405. GLP Unpublished	Y	N		Tessenderlo Group N.V.
KCA 5.2.3/02	[REDACTED]	1997 b	M-96-018 - Acute Inhalation Toxicity Limit Test. [REDACTED] [REDACTED] Report number 5424. GLP Unpublished	Y	N		Tessenderlo Group N.V.
KCA 5.2.4/01	[REDACTED]	1997	M-96-018, Lot #08145 - Primary Skin Irritation. [REDACTED] [REDACTED] Report number 4906. GLP Unpublished	Y	N		Tessenderlo Group N.V.
KCA 5.2.5/01	[REDACTED]	1997	M-96-018, Lot #08145 - Primary Eye Irritation. [REDACTED] [REDACTED] Report number 4905 GLP	Y	N		Tessenderlo Group N.V.

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
			Unpublished				
KCA 5.2.5/02		2000	Surround® WP Crop Protectant - Primary Eye Irritation Study in Rabbits. [REDACTED] Report number 9914 GLP Unpublished	Y	N		Tessenderlo Group N.V.
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.
KCA 5.5/01	Yanagisawa, R., et al	2007	Gene Expression Analysis of Murine Lungs Following Pulmonary Exposure to Asian Sand Dust Particles Exp Biol Med 232:1109–1118, 2007 No report number Not GLP Published	Y	N		Public
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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
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
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 Not GLP Published	N	N		Public
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
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		Tessenderlo Group N.V.
KCA 5.9.1/02	Ogle, CJ, Rundle, EM and Sugar ET	1989	China clay workers in the south west of England: analysis of chest radiograph readings, ventilatory capacity, and	N	N		Public



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