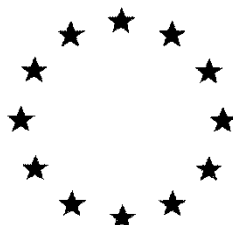


European Commission



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

Aluminium Silicate Calcined
(Kaolin calcined)
SOKALCIARBO WP
SOKA
Volume 3 (CP)-B2

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

May 2020

Version history

When	What
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.

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B.2 Physical and chemical properties

Physchem studies conducted with the plant protection product SOKALCIARBO WP have been submitted and presented for this renewal dossier.

A 2-year storage stability study at ambient temperature is on-going a final report will be provided as soon as available (expected in April 2018 for initial tests and in April 2020 for final tests), meantime, signed study plan is provided.

Minimum concentration declared: 2%

Maximum concentration declared: 10%.

According to GAP: 8 – 10 kg/100L

Recommendation is proposed: **The spray solution should be under continuous agitation**

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Conclusion/ Comment	GLP Y/N	Reference
CP 2.1 Appearance	-	-	Colour: White Physical state: Powder Odour: -	Acceptable	-	-

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Conclusion/ Comment	GLP Y/N	Reference
CP 2.2 Explosive and oxidising properties	Appendix 6 Section 3 of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourthe revised edition, 2003	Calcined Kaolin	Expert statement: Aluminium Silicate is not explosive.	Acceptable	N	S.S. Atwal and S.P. Tremain, 2011

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Conclusion/ Comment	GLP Y/N	Reference
	Appendix 6 Section 6 of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, Fourthe revised edition, 2003	Calcined Kaolin	Expert statement: Aluminium Silicate is not oxidising.	Acceptable	N	S.S. Atwal and S.P. Tremain, 2011

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Conclusion/ Comment	GLP Y/N	Reference
CP 2.3 Flammability and self-heating	Test N.4	Calcined Kaolin	Negative result using a 100 mm cube sample at 140°C. Furthermore, in line with the manufacturing process of the calcined aluminium silicate, the flammability and self-heating of the calcined aluminium silicate are > 1100°C.	Acceptable	Y	S.S. Atwal and S.P. Tremain, 2011
CP 2.4 Acidity/alkalinity and pH value	-	-	-	Data gap: A GLP study for the pH of 1% dilution of the plant protection product SOKALCIARBO WP is required to be submitted. Notifier responded that a test for the determination of the pH is going to be contracted with the laboratory “Defitraces/Anadiag”. The final report will	-	-

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Conclusion/ Comment	GLP Y/N	Reference
				be provided as soon as available.		
CP 2.5 Viscosity and surface tension	-	-	Not required for WP formulation.		-	-
CP 2.6 Relative density and bulk density	CIPAC MT 186	Sokalciarbo WP Batch No: 18022	Pour density: 0.435 g/mL Tap density: 0.544 g/mL	Acceptable	Y	Jean-Batiste C., 2019
CP 2.7 Storage Stability and shelf-life: effects of temperature on technical characteristics of the plant protection product	CropLife International Technical Monograph N°17	Sokalciarbo WP	Aluminium Silicate is extremely stable when heated. Therefore, accelerated storage stability study is not relevant, as well as 2-year storage stability study. However, the physical properties of the powder could change on storage. In this context, a 2-year storage stability study at ambient temperature is on-going on bulk density, wettability, suspensibility, wet sieve and particle size distribution.	2-year Shelf life: Study anticipated to be submitted in May 2020. The pH of 1% dilution of the plant protection product SOKALCIARBO WP is also required to be determined after storage. Accelerated storage stability test: Notifier declared that an accelerated storage stability test is going to be contracted with the laboratory “Defitraces/Anadiag”. The final report will be provided as soon as available. It is noted that the following physchem properties are required to be determined:	Y	Jean-Batiste C., 2018b (study plan)

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Conclusion/ Comment	GLP Y/N	Reference
				- pH - wet sieve test -suspensibility -wettability		
CP 2.8.1 Wettability	CIPAC MT 53.3	Sokalciarbo WP Batch No: 18022	Without swirling: 6 seconds With swirling: 10 seconds	Acceptable	Y	Jean-Batiste C., 2019
CP 2.8.2 Persistence of foaming	CIPAC MT 47.2	Sokalciarbo WP	0 mL after 10s, 1 min, 3 min and 12 min at 10.5% w/v at ambient temperature.	Acceptable The English translation is anticipated.	N	Marine Chapelle, 2013
CP 2.8.3 Suspensibility, spontaneity and dispersion stability	CIPAC MT 184 (gravimetric method)	Sokalciarbo WP Batch No: 18022	At a concentration of 2% w/v: 4.4% At a concentration of 10% w/v: 89.1%	Because of the low suspensibility at 2% w/v (< 60%) the following recommendation is proposed: The spray solution should be under continuous agitation	Y	Jean-Batiste C., 2019
CP 2.8.4 Degree of dissolution and dilution stability	-	-	Not required for WP formulation.		-	-
CP 2.8.5.1 Particle size distribution	CIPAC MT 187	Sokalciarbo WP Batch No: 18022	D _v (mean): 5.32 µm D _{sv} (mean): 1.62 µm D _v (10): 0.667 µm D _v (50): 3.18 µm	Acceptable	Y	Jean-Batiste C., 2019

Test or study & Data point	Guideline and method	Test material purity and specification	Findings	Conclusion/ Comment	GLP Y/N	Reference
			Dv (90): 12.3 µm			
CP 2.8.5.2 Dust content	-	-	Not required for WP formulation.		-	-
CP 2.8.5.3 Attrition	-	-	Not required for WP formulation.		-	-
CP 2.8.5.4 Hardness and integrity	-	-	Not required for WP formulation.		-	-
CP 2.8.6 Emulsifiability, re-emulsifiability, emulsion stability	-	-	Not required for WP formulation.		-	-
CP 2.8.7 Flowability, pourability and dustability	-	-	Not required for WP formulation.		-	-
CP 2.9 Physical and chemical compatibility with other products including other plant protection products with which its use is to be authorised	-	-	Not relevant. SOKALCIARBO is not intended to be used or mixed with other products.		-	-
CP 2.10 Adherence and distribution to seeds	-	-	Not relevant. SOKALCIARBO is not intended to be used for seed treatment.		-	-
CP 2.11 Other studies	-	-	-		-	-

B.2.1 References relied on**By Annex Point**

Annex Point / Reference Number	Author(s)	Year	Title Source Company Report Number GLP Published	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.	2018 b	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