European Commission

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

Aluminium Silicate Calcinated

(Kaolin calcined)

SOKALCIARBO WP

SOKA

Volume 3 – B.8 (CP) Environmental fate and behaviour and environmental exposure assessment

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

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Version history

Date	Data points containing amendments or additions	Document identifier or version number
April 2019	Renewal Assessment Report (RAR)-prepared in the context of the application for renewal of approval of the a.s. according to Regulation (EC) No 1107/2009.	
February 2020	This version contains all the relevant comments made by the RMS.	
May 2020	Revised RAR prepared by RMS.	

Original DAR information are presented in gray shading

Additional information compared to the DAR are presented without any shading

RMS comments are presented below each study in a yellowish box

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CP 8 FATE AND BEHAVIOUR IN THE ENVIRONMENT

This document presents data and information on the environmental fate of SOKALCIARBO WP (active substance: Aluminium silicate) and is submitted in support of the renewal of approval for Aluminium silicate under Regulation (EC) 1107/2009. The applicant of SOKALCIARBO WP is Société Kaolinière Armoricain (SOKA).

Exposure assessment for the representative formulation (SOKALCIARBO WP) were conducted based on agricultural use pattern as summarized in the below table.

Table 8-1: Critical use pattern of the formulated product

Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications/minimum interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Crop growth stage (BBCH)	1st: BBCH 51-59 2nd-3th: BBCH 69-79 4th: post harvest	At the first capture of insect	1st generation: BBCH 01-59 2nd generation: BBCH 69-79	At beginning of fruit ripening and the first capture of insect	At the first capture of insect	At the first capture of insect (with olives on the trees)	BBCH 69-85
Application method	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray

CP 8.1 Fate and Behaviour in Soil

Study on degradation in soil with the representative formulation SOKALCIARBO WP was not performed, since it is possible to extrapolate from data obtained with the active substance.

Aluminium silicate is extremely stable and is a non-degradable natural component of the environment. Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases. Aluminium silicate has similar chemical composition to common clay that is found in most soils and aquatic sediments the world over. Aluminium silicate is essentially purified natural clay and is therefore not subject to adsorption on or desorption from soil particles. When applied to soil, the Aluminium silicate particles will readily mix with the other soil components. Some organic materials (for example fulvic acids) will adsorb onto the particle surfaces, similarly to the Aluminium silicate already existing in the soil. No increase in compaction, water penetration or aeration is anticipated since the existing clay

particles exist in a much larger particle size distribution (already agglomerated) than the narrow fraction that will be added.

CP 8.1.1 Rate of degradation in soil

CP 8.1.1.1 Laboratory studies

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.1.1.2 Field studies

CP 8.1.1.2.1 Soil dissipation studies

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.1.1.2.2 Soil accumulation studies

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.1.2 Mobility in soil

CP 8.1.2.1 Laboratory studies

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.1.2.2 Lysimeter studies

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.1.2.3 Field leaching studies

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.1.3 Estimation of concentrations in soil

Predicted environmental concentrations in soil (PEC_S)

The application of the representative formulation SOKALCIARBO WP is not expected to increase significantly the natural Aluminium silicate content of the soil.

However, as primary information, the initial amount of Aluminium silicate entering the soil from the use of SOKALCIARBO WP in agriculture was estimated using worse case calculation. Input parameters and worst case PECsoil calculations per concerned crop/use are presented in the table 8.1.3-1 and 8.1.3-2, respectively.

Table 8.1.3-1: Input parameters related to application for PECsoil calculations

Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications/minimum interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Crop interception (%)	60	50	50	80	20	70	60
Depth of soil	5	5	5	5	5	5	5

Table 8.1.3-2: Worst case PECsoil calculations for each concerned crop/use

Use No.	1, 2, 3, 4, ~~5,~~ 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Initial PEC_{soil} for single application (mg/kg)	26.67	40.00	20.00	13.33	16.00	20.00	10.67
Initial PEC_{soil} for multiple applications – cumulated applications (mg/kg)	74.67	140.00	**140.00**	53.33	67.20	80.00	42.67

Agricultural soils normally contain between 5 and 50 % clay. The calculated maximum PEC_{soil} Following the use of SOKALCIARBO WP is 140 mg/kg, which is equal to 0.014%. Therefore, the quantity of clay (Aluminium silicate) added through the use of SOKALCIARBO WP will not be significant to cause any measurable increase in the clay content of agricultural soils, even for use for decades.

RMS comments on PECsoil calculations:

Input parameters and application patterns are considered acceptable and in line with the proposed GAP. After the co-RMS proposal to include some information/statement regarding the potential impact of the additional aluminium added to soil from the use of aluminium silicate compared to the amounts that occur naturally in soils/surface water the following reply/explanation was given by SOKA:

"The calcined aluminium silicate is composed of aluminium oxide (Al_2O_3) and does not contains free aluminium (Al_3^+). Aluminium silicate is extremely stable and is a non-degradable natural component of the environment. Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases. Indeed, in order to obtain Al_3^+ from the calcined aluminium silicate, a very strong acid digestion is required.

As this strong acid digestion is not naturally expected in soils or water, the request to provide the potential impact of the additional aluminium added to soil from the use of aluminium silicate compared to the amounts that occur naturally in soils/surface water, is not relevant. Therefore, the application of SOKALCIARBO WP (calcined aluminium silicate) is not expected to increase the natural background concentration of aluminium in soils and surface water."

Finally, as per the proposal of coRMS the worst case PECsoil for Apples (7*30 kg, 0% crop interception) has been calculated and equals to 40 mg/kg for single application and 280 mg/kg for multiple application.

CP 8.2 Fate and Behaviour in Water and Sediment

Study on degradation in water/sediment systems with the representative formulation SOKALCIARBO WP was not performed, since it is possible to extrapolate from data obtained with the active substance.

Aluminium silicate is extremely stable and is a non-degradable natural component of the environment. Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases. Aluminium silicate has similar chemical composition to common clay that is found in most soils and aquatic sediments the world over. Aluminium silicate is essentially purified natural clay and is therefore not subject to adsorption on or desorption from soil particles. When applied to soil, the Aluminium silicate particles will readily mix with the other soil components. Some organic materials (for example fulvic acids) will adsorb onto the particle surfaces, similarly to the Aluminium silicate already existing in the soil. No increase in compaction, water penetration or aeration is anticipated since the existing clay particles exist in a much larger particle size distribution (already agglomerated) than the narrow fraction that will be added.

CP 8.2.1 Aerobic mineralisation in surface water

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.2.2 Water/sediment study

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.2.3 Irradiated water/sediment study

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.2.4 Estimation of concentrations in groundwater

CP 8.2.4.1 Calculation of concentrations in groundwater

Predicted environmental concentrations in groundwater (PEC_{GW})

The application of SOKALCIARBO WP is not expected to increase significantly the natural Aluminium silicate content of natural groundwater reservoirs. Based on the characteristics of Aluminium silicate using standard FOCUS calculations are impossible and meaningless. Aluminium silicate is not soluble in water, but forms suspended particles in water. Therefore, SOKALCIARBO WP can only reach groundwater via mechanical percolation through soil pores, and not through conventional dissolution in water and leaching through the soil column. Clay, including Aluminium silicate, is present in some natural groundwater reservoirs. Percolation through soil pores or the presence of clay seams allow naturally present clays to form suspensions in these water bodies. It is possible (but highly unlikely) that Aluminium silicate from SOKALCIARBO WP may percolate through soil and reach groundwater, where it will not be possible to be distinguished by analytical means from natural clays.

RMS comments on the PECgw calculations

No calculations are required.

CP 8.2.4.2 Additional field tests

No data are provided or required.

CP 8.2.5 Estimation of concentrations in surface water and sediment

Predicted environmental concentrations in surface water (PEC_{SW})

The application of SOKALCIARBO WP is not expected to increase significantly the natural Aluminium silicate content of natural water bodies. Based on the characteristics of Aluminium silicate using standard FOCUS calculations are impossible and meaningless. However the initial worst-case PEC_{sw} for Aluminium silicate following applications of SOKALCIARBO WP have been calculated taking into consideration a spray drift and a standard static water body of 30 cm depth, for one application and multiple applications. Input parameters and worst case PEC_{sw} calculations per concerned crop/use are presented in the table 9.2.5-1 and 9.2.5-2, respectively.

Table Σφάλμα! Χρησιμοποιήστε την καρτέλα "Κεντρική σελίδα", για να εφαρμόσετε το Titre 3 στο κείμενο που θέλετε να εμφανίζεται εδώ.**-1: Input parameters related to application for PEC_{SW} calculations**

Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications/minimum interval	4/7	6/10	7/7	6/7	5/7	6/10	4/7
Spray drift for single application*	15.73	15.73	29.20	15.73	2.77	15.73	8.02
Spray drift for multiple applications*	10.12	9.21	22.69	9.21	1.75	9.21	6.71

*Based on Rautmann drift values

Table Σφάλμα! Χρησιμοποιήστε την καρτέλα "Κεντρική σελίδα", για να εφαρμόσετε το Titre 3 στο κείμενο που θέλετε να εμφανίζεται εδώ.**-2: Worst case PEC_{SW} calculations for each concerned crop/use**

Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15

Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Initial PEC_{sw} for single application (mg/l)	2.62	3.14	2.92	2.62	0.14	2.62	0.53
Initial PEC_{sw} for multiple application (mg/l)	4.72	6.45	**15.88**	6.14	0.37	6.14	1.79

The maximum estimated PEC_{SW} of 15.88 mg Aluminium silicate per liter is expected after 7 applications of SOKALCIARBO WP on apple trees. As regards to risk assessment for aquatic organisms, this value cannot be compared to the natural Aluminium silicate content in natural water bodies. Indeed, Aluminium silicate is an integral part of the sediment and it occurs in suspended solids of natural water bodies. Its amount fluctuates due to different natural phenomena like storms, especially in shallow water, along the coast, where fish may spawn. The same variability applies to static water bodies although the Aluminium silicate content is expected to be higher in sediments due to its natural presence in most soils and aquatic sediments. Therefore, as regards to risk assessment, aquatic organisms are exposed to naturally occurring Aluminium silicate at levels higher than those released from the use of SOKALCIARBO WP.

Predicted environmental concentrations in sediment (PEC_{SED})

The application of SOKALCIARBO WP is not expected to increase significantly the natural Aluminium silicate content of natural water bodies. Based on the characteristics of Aluminium silicate using standard FOCUS calculations are impossible and meaningless. However the initial worst-case PEC_{SED} for Aluminium silicate following applications of SOKALCIARBO WP have been calculated taking into consideration a spray drift, a height of the sediment of 5 cm, a sediment density of 1.3 g/cm^3 and a standard static water body of 30 cm depth, for one application and multiple applications. Input parameters and worst case PEC_{SED} calculations per concerned crop/use are presented in the respective tables.

Table Σφάλμα! Χρησιμοποιήστε την καρτέλα "Κεντρική σελίδα", για να εφαρμόσετε το Titre 3 στο κείμενο που θέλετε να εμφανίζεται εδώ.**-3: Input parameters related to application for PEC_{SED} calculations**

Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Application rate (g as/ha)	50000 for 1st application 30000 for next applications	60000 for 1st application 30000 for next applications	30000	50000 for 1st application 30000 for next applications	15000 for 1st application 12000 for next applications	50000 for 1st application 30000 for next applications	20000
Number of applications	4	6/10	7	6	5	6	4
Spray drift for single application*	15.73	15.73	29.20	15.73	2.77	15.73	8.02

Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Spray drift for multiple applications*	10.12	9.21	22.69	9.21	1.75	9.21	6.71

*Based on Rautmann drift values

Table Σφάλμα! Χρησιμοποιήστε την καρτέλα "Κεντρική σελίδα", για να εφαρμόσετε το Titre 3 στο κείμενο που θέλετε να εμφανίζεται εδώ.**-4: Worst case PEC_{SED} calculations for each concerned crop/use**

Use No.	1, 2, 3, 4, 6, 7, 8, 9, 11, 16	5	10	12	13	14	15
Crop	Stone fruits, pome fruits, nuts fruits	Walnut tree	Apple tree	Citrus	Lavender	Olive tree	Grapevine
Initial PEC_{sed} for single application (mg/kg)	12.10	14.52	13.48	12.10	0.64	12.10	2.47
Initial PEC_{sed} for multiple application (mg/kg)	21.80	29.75	**73.31**	28.34	1.70	28.34	8.26

RMS comments on the PECsw/sed calculations

Input parameters and application patterns are considered acceptable and in line with the proposed GAP. Please refer to the maximum PECsw/sed values for further risk assessment.

Following the proposal of coRMS for the submission of FOCUS Step 1-2 calculations the Notifier SOKA responded:

"The applicant still maintain that the FOCUS STEP 1-2 tool is not adapted to the application of aluminium silicate. Indeed, aluminium silicate is a stable inorganic compound. It is insoluble and known to be inert to mineral acids and bases and not to be affected by photolytic processes under natural light. In this context, by using the FOCUS STEP 1-2 tool, default values must be used, because of the nature and characteristics of aluminium silicate, for: the water solubility, the DT50 in water, the DT50 in sediment, the DT50 in sediment/water, the DT50 in soil and the Koc. This means, all the required input parameters regarding the active substance! In this context, if FOCUS STEP 1-2 tool is used, the estimated PECsw will be a more than over estimated and will not represent what will be expected in surface water after a true application of SOKALCIARBO WP (aluminium silicate).

If FOCUS STEP 1-2 tool is used, the PECsw which will be determined may be very high (because of the use of default values) and therefore, a high mitigation measures may be required, which is aberrant for aluminium silicate, a natural inorganic substance classified as a low risk substance, as not classified and not harmful for humans and none target organisms.

Furthermore, in surface water aluminium silicate would be analytically undistinguished from natural suspended clay of the same size. As mentioned in the dossier aluminium silicate has similar chemical composition to common clay that is found in the environment. No increase in

compaction, water penetration or aeration is anticipated since the existing clay particles exist in a much larger particle size distribution (already agglomerated) than the narrow fraction that will be added. In addition, as regards to risk assessment for aquatic organisms, aluminium silicate is an integral part of the sediment and it occurs in suspended solids of natural water bodies. Its amount fluctuates due to different natural phenomena like storms, especially in shallow water, along the coast, where fish may spawn. The same variability applies to static water bodies although the aluminium silicate content is expected to be higher in sediments due to its natural presence in most soils and aquatic sediments. Therefore, as regards to risk assessment, aquatic organisms are exposed to naturally occurring aluminium silicate at levels higher than those released from the use of SOKALCIARBO WP."

In any case, RMS considers the current approach sufficient, due to the nature of the compound and the FOCUS model restrictions.

CP 8.3 Fate and Behaviour in Air

No data are provided or needed since the behaviour of the product can be predicted from that of the active substance.

CP 8.3.1 Route and rate of degradation in air and transport via air

Study on degradation in air with the representative formulation SOKALCIARBO WP was not performed, since it is possible to extrapolate from data obtained with the active substance.

CP 8.4 Estimation of Concentrations for Other Routes of Exposure

No other routes of exposure are considered to be relevant.

CP 8.5 References relied on

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