European Commission

Renewal Assessment Report

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

Aluminium Silicate Calcined

(Kaolin calcined)

SURROUND® WP CROP PROTECTANT

Tessenderlo

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
May 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	Supplementary info added by the Notifier following request from the RMS. 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 SURROUND® WP CROP PROTECTANT (active substance: Aluminium silicate), containing calcined kaolin which was registered in 2008 under the term "Aluminium silicate". The applicant of SURROUND® WP is TESSENDERLO Group N.V.. It is submitted in support of the renewal of approval for Aluminium silicate under Regulation (EC) 1107/2009.

Aluminium silicate is extremely stable. The kaolin ores that are being mined today to produce aluminium silicate used in the product SURROUND® WP CROP PROTECTANT were formed 50 to 85 million years ago in what is now the state of Georgia, United States of America.

Aluminium silicate is insoluble, photolytically stable and inert even to mineral acids and bases, except under very harsh conditions. Aluminium silicate has a similar chemical composition to common clay that is found in most soils and aquatic sediments the world over. 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. Expectations are that by using kaolin instead of another pesticide having toxic residues, the soil biodiversity will improve under Surround treated fields, since none of the present organisms would be exposed to additional potential toxins.

Since aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies.

CP 8.1 Fate and Behaviour in Soil

Not applicable, aluminium silicate does not degrade in soil.

CP 8.1.1 Rate of degradation in soil

CP 8.1.1.1 Laboratory studies

Not applicable, aluminium silicate does not degrade in soil.

CP 8.1.1.2 Field studies

CP 8.1.1.2.1 Soil dissipation studies

Not applicable, aluminium silicate does not degrade in soil.

CP 8.1.1.2.2 Soil accumulation studies

Not applicable, aluminium silicate does not degrade in soil.

CP 8.1.2 Mobility in soil

Not applicable.

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.

Expectations are that by using kaolin instead of another pesticide having toxic residues, the soil biodiversity will improve under aluminium silicate treated fields, since none of the present organisms would be exposed to additional potential toxins.

CP 8.1.2.1 Laboratory studies

Not applicable.

CP 8.1.2.2 Lysimeter studies

Not applicable.

CP 8.1.2.3 Field leaching studies

Not applicable.

CP 8.1.3 Estimation of concentrations in soil

Predicted environmental concentrations in soil (PEC_S)

The representative GAP considered for the renewal application is shown in Table 8.1.3-1.

Table 8.1.3-1: Application pattern

Crop	Application rate	Max number of Applications	Min Interval	Application period
Vine	30 kg/ha	4	7 days	Up to BBCH 65

The application of aluminium silicate is not expected to increase significantly the natural aluminium silicate content of the soil. However, the amount of aluminium silicate entering the soil from the use of Surround® WP Crop Protectant in agriculture was estimated using the following worst case calculation (Surround® WP Crop Protectant contains 95% calcined aluminium silicate, however an aluminium silicate content of 100% is taken for the calculations).

Aluminium silicate does not degrade in soil, therefore calculations are presented both for a single application and for a cumulative application without degradation.

$$PEC_{SOIL}\ (mg/kg) = \frac{\text{Application rate (g/ha) x [1-crop interception (decimal)]}}{\text{(Soil volume (cm}^3\text{) x soil density (g/cm}^3\text{)) x 10 (conversion factor)}}$$

Table 8.1.3-2: Worst case PECs for aluminium silicate in soil – use in vines – late treatment

	Max single spray	**Total season**
Application rate (vines)	30 000 g/ha	120 000 g/ha*
Interception (vines, without leaves)	0.4	0.4
Spray deposit (g/m^2)	1.8	7.2
Soil weight (1 m^2 x 5 cm depth x 1.5 g/cm^3)	75 kg	75 kg
PEC_{SOIL} (mg/kg)	**24.0**	**96.0**

* based on a maximum application rate of 4 x 30 kg/ha

Agricultural soils normally contain between 5 and 50 % clay; therefore the quantity of kaolin added through the use of Surround® WP Crop Protectant will not be sufficient to cause any measurable increase in the clay (aluminium silicate) content of agricultural soils, even after decades of use.

There are no metabolites of aluminium silicate in soil. Please refer to Point CP 9 above and Document M-CA Section 7, Point CA 7 for further details.

RMS comments on PECsoil calculations:

Input parameters and application patterns are considered acceptable and in line with the proposed GAP. The respective worst case considering 0% crop interception has been calculated by the RMS after coRMS proposal and equals to 40 mg/kg for single and 120 mg/kg for multiple application as proposed in the GAP.

Following a request from the coRMS (France), the Notifier was requested to justify the potential impact of the additional aluminium added to soil from the use of calcined aluminium silicate compared to the amounts that occur naturally in soils/surface water.

Calcined aluminium silicate is also known as calcined kaolin or calcined kaolin clay and belongs to the phyllosilicate class of aluminosilicate minerals. Calcined aluminium silicate is thus a calcined clay. Calcined aluminium silicate has the theoretical molecular formula $Al_4Si_4O_{14}$, and a theoretical molecular weight of 444.28 g/mol, of which aluminium represents 24.29%. Therefore, for each gram of **calcined aluminium silicate** applied to soil, we will consider 24.29% of the mass applied is aluminium.

Clay in its natural state is hydrous and therefore we will consider soil clay as the natural hydrous form of aluminium silicate. Hydrous aluminium silicate has the theoretical molecular formula $Al_4Si_4O_{10}(OH)_8$ and a theoretical molecular weight of 516.28 g/mol, of which aluminium represents 21.28%. Therefore, each gram of clay in the soil can be considered to have an aluminium content of 21.28%.

According to the European Soil Data Centre (ESDAC[1]), clay is one of the major components of soil and a Europe-wide map of clay distribution in soil was produced and is presented in Figure 1 below.

[1] European Soil Data Centre (ESDAC), European Commission Joint Research Centre, European Soil Database & Soil Properties, Topsoil physical properties for Europe (based on LUCAS topsoil data), available to download at: https://esdac.jrc.ec.europa.eu/content/topsoil-physical-properties-europe-based-lucas-topsoil-data

As indicated in ESDAC databases, clay content in soil is variable and can represent as little as 6% of the topsoil to over 95% of the topsoil. As a worst-case (most conservative assumption), the aluminium added through agricultural applications of kaolin will be calculated based on a 6% clay content, or 60 g clay per kg soil background concentration. On this basis, for a kg of top soil containing 60 g of clay, the estimated aluminium content is [60 * 21.28 / 100] = 12.8 g/kg (12800 mg/kg soil).

The PEC_{soil} for calcined aluminium silicate following the agricultural use of Surround at the maximum application rate is 96 mg/kg soil for four cumulative applications.

When we consider that 24.29% of calcined aluminium silicate is aluminium, we obtain an extra aluminium load of 23.3 mg/kg soil [96 * 0.2429], or 0.182% of the lowest estimated average aluminium content in soil.

Estimated aluminium content in soil based on ESDAC (lowest estimated concentration)	Estimated addition of aluminium from SURROUND (cumulative application)	% Added aluminium
12800 mg/kg soil	96 * 24.29 / 100 = 23.3 mg/kg soil	23.3/12800 * 100 = 0.182%

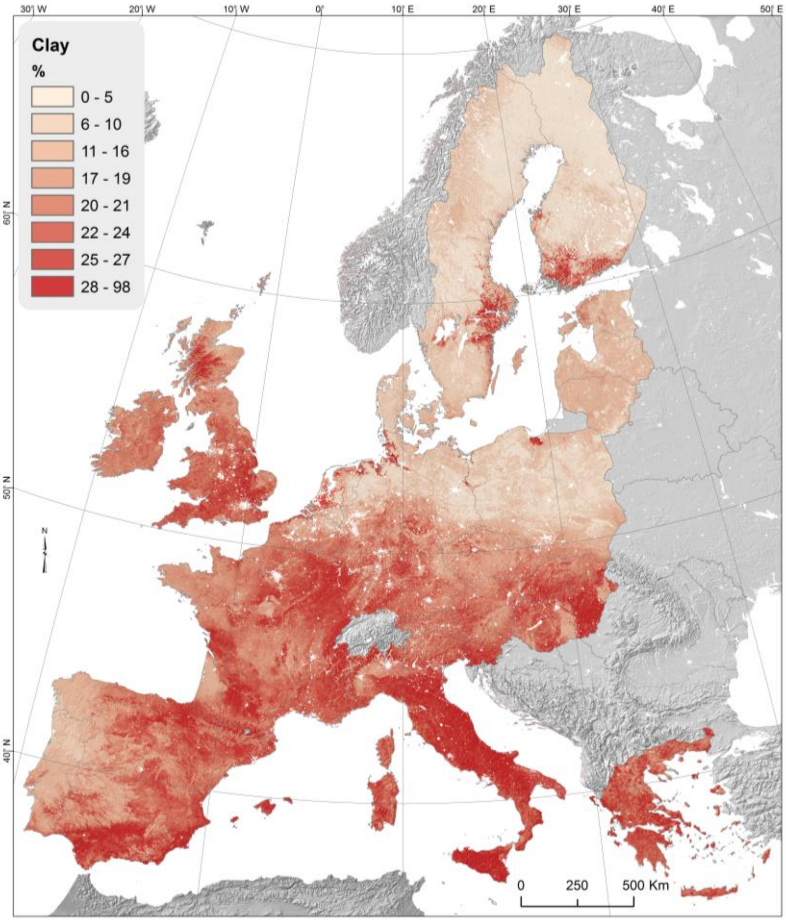

Figure 1: LUCAS topsoil data – Clay (%) https://esdac.jrc.ec.europa.eu/public_path/clay.png

Aluminium is not a heavy metal and although European soil aluminium concentrations are not monitored by ESDAC, interest has been expressed in evaluating the potential toxicity of and exposure to the **ionic form of aluminium**. The French initiative GisSol[2] did report a map of topsoil aluminium levels across mainland France, and the islands of Guadeloupe and Martinique. Aluminium levels in French soils are presented in Figure 2. The lowest quantified level of aluminium reported in French soil is 2 g/100 g or 20 g/kg, which is of a similar order of magnitude as the concentration described in the LUCAS Topsoil database.

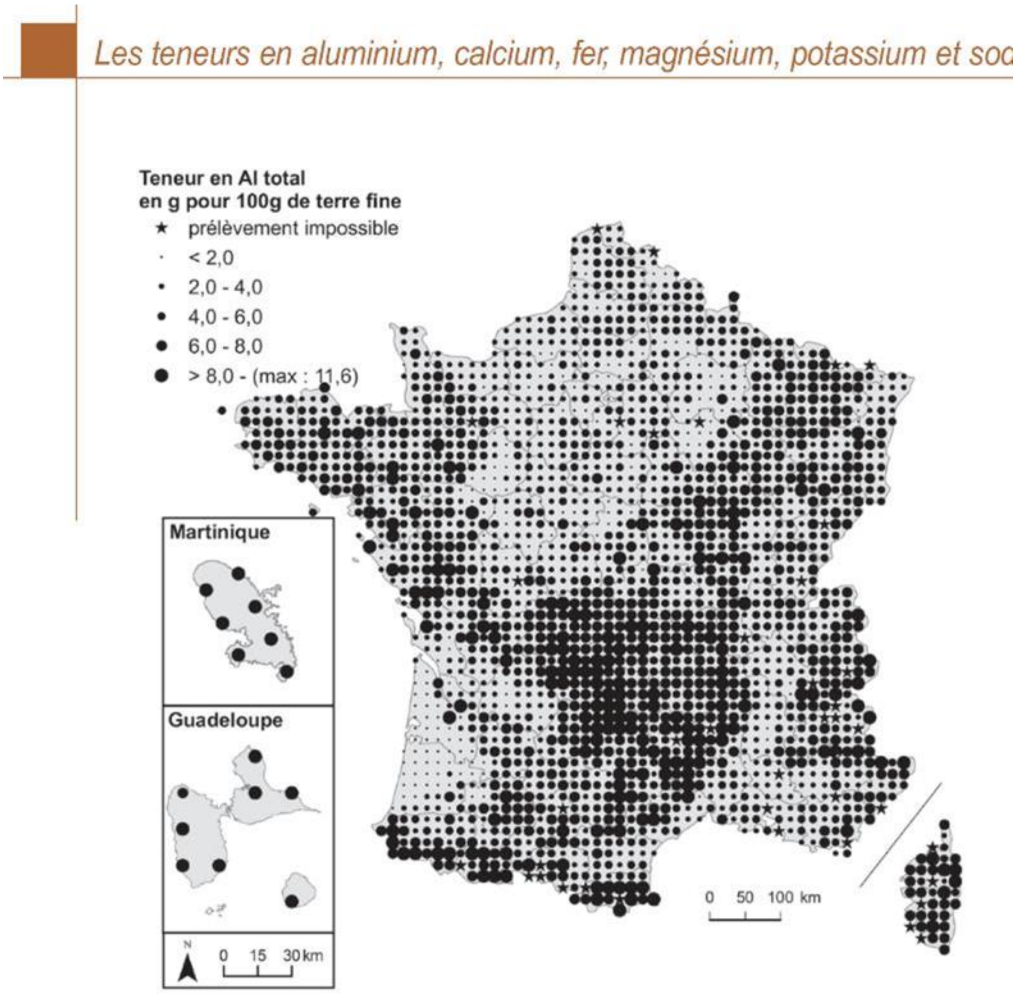

Figure 2: GISSOL aluminium data in French topsoil (g per 100 g of fine soil) – p.67 of 192 - https://www.gissol.fr/publications/rapport-sur-letat-des-sols-de-france-2-849

An important factor to note is that aluminium silicate (kaolin clay), either calcined or hydrous, is not soluble in any naturally occurring solvents, and it does not readily form ions in nature. In fact, it remains inert in the environment, for example in soils and clay deposits, for millions of years. These characteristics explain most of the properties of kaolin-type clays in the natural environment: kaolin clays are insoluble, stable and the aluminium in its crystal structure is not bioavailable. Kaolin clays are inert to biological mechanisms, which is a reason why they are routinely used as medical drug carrier agents. Kaolin clays are distinctive from zeolites, also

[2] Groupement d'intérêt scientifique Sol (Gis Sol)

known as sodium aluminium silicates, which have different properties than kaolin, and in particular are capable of ion exchange, which kaolin clay is not capable of.

In summary, the amount of aluminium added to soils by an application of Surround® at 30 kg/ha will add an insignificant amount of aluminium to the aluminium already naturally occurring in the soil, and furthermore the aluminium in kaolin clay is locked away in the crystal structure of the clay mineral because it is not soluble in any naturally-occurring solvents and therefore is not bioavailable.

CP 8.2 Fate and Behaviour in Water and Sediment

Not applicable.

Surround® WP Crop Protectant contains 95% calcined aluminium silicate. Aluminium silicate is extremely stable. 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. Since aluminium silicate is a non-degradable natural component of the environment a waiver is requested for all environmental fate studies.

CP 8.2.1 Aerobic mineralisation in surface water

Not applicable.

CP 8.2.2 Water/sediment study

Not applicable.

CP 8.2.3 Irradiated water/sediment study

Not applicable.

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})

Not applicable. Based on the characteristics of aluminium silicate, standard FOCUS calculations are impossible and meaningless.

Surround® WP Crop Protectant contains 95% kaolin. Kaolin is not soluble in water, but forms suspended particles in water. Therefore, Surround® WP Crop Protectant 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 kaolin, 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 kaolin from Surround® WP Crop

Protectant 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$_{SW}$)

Table Σφάλμα! Χρησιμοποιήστε την καρτέλα "Κεντρική σελίδα", για να εφαρμόσετε το Titre 3 στο κείμενο που θέλετε να εμφανίζεται εδώ.**-1: Application pattern**

Crop	Application rate	Max number of Applications	Min Interval	Application period
Vine	30 kg/ha	4	7 days	Up to BBCH 65

The application of aluminium silicate is not expected to increase significantly the natural kaolin content of natural water bodies.

Two PECsw approaches have been conducted and are presented below.

The initial worst-case PEC$_{Surface\ Water}$ for kaolin has been calculated for vines taking into consideration spray drift only, for one application at the maximum dose and also assuming total accumulation of kaolin between applications. PEC$_{SW}$ are calculated as follows:

$$PEC_{SW}\ (mg/L) = \frac{\text{Application rate (g/ha) x drift (decimal)}}{300\ L/m^2 \text{ x } 10 \text{ (conversion factor)}}$$

Table Σφάλμα! Χρησιμοποιήστε την καρτέλα "Κεντρική σελίδα", για να εφαρμόσετε το Titre 3 στο κείμενο που θέλετε να εμφανίζεται εδώ.**-2: Worst case PECsw for kaolin in surface waters with 3 m buffer zone – use in vines – late treatment**

	Max single spray	**Total season**
Application rate (vines)	30 000 g/ha	120 000 g/ha*
Spray drift** (%)	8.02	8.02
Spray deposit (mg/m^2)	240.6	962.4
Water volume (L)	300	300
PEC$_{SW}$ (mg/L)	**0.802**	**3.208**

* based on a maximum application rate of 4 x 30 kg/ha

**Late season vines, 3 m from water body, SANCO/4145/2000

Aluminium silicate is not soluble in water. Therefore, aluminium silicate will either settle in a slow-moving water body or be dispersed until settling can take place.

Following a request from the RMS, PEC_{SW} calculations were conducted using the FOCUS STEPS 1-2 model as per co-RMS feedback.

The following input values were used:

All possible scenario combinations were modelled:

- North and South Europe
- Early application (minimal crop cover)
- Late application (full canopy)
- Treatment in October to February, March to May and June to September
- Single application rate: 30 000 g/ha
- 4 applications, 7-day interval
- 0,000001 mg/L water solubility (lowest value accepted by model for an insoluble substance)
- Koc = 1 000 000 L/g (highest value for a natural soil component)
- DT50 = 1000 days in soil, surface water and sediment (default worst case)

Results are presented in the table below.

Table 8.2.5-3: PEC_{SW} and PEC_{SED} for SURROUND as calculated by FOCUS STEPS1-2

STEP 1-2	**Vine Early**					
			PECsw (µg/L)		PECsed (µg/kg)	
STEP1			1.11E+03		~~30000~~ 3.08E+05	
			PECsw Mult App	PECsw Single App	PECsed Mult App	PECsed Single App
STEP2	North EU	Oct - Feb	250.8474	269.9	96400	24400
		Mar - May	250.8474	269.9	43000	11000
		Jun - Sep	250.8474	269.9	43000	11000
	South EU	Oct - Feb	250.8474	269.9	78600	19900
		Mar - May	250.8474	269.9	78600	19900
		Jun - Sep	250.8474	269.9	60800	15500
STEP 1-2	**Vine Late**					
			PECsw (µg/L)		PECsed (µg/kg)	
STEP1			3240		~~30000~~ 3.24E+05	
			PECsw Mult App	PECsw Single App	PECsed Mult App	PECsed Single App
STEP2	North EU	Oct - Feb	665.6138	**802.8***	~~79000~~ 1.09E+5	20900
		Mar - May	665.6138	802.8	~~43400~~ 5.53E+5	12000

		Jun - Sep	665.6138	802.8	~~43400~~ 5.53E+5	12000
	South EU	Oct - Feb	665.6138	802.8	~~67100~~ 9.08E+4	17900
		Mar - May	665.6138	802.8	~~67100~~ 9.08E+4	17900
		Jun - Sep	665.6138	802.8	~~55300~~ 7.3E+4	15000

*: Value used for aquatic ecotoxicology risk assessment

In any case, it shall be pointed out that RMS considers both current approaches acceptable, due to the nature of the compound and the FOCUS model restrictions.

Predicted environmental concentrations in sediment (PEC_{SED})

Aluminium silicate will naturally settle provided water currents are slow enough to permit deposition. Once settled, aluminium silicate will be completely undistinguishable from naturally-present clay particles and become part of the sediment. Since aluminium silicate is not soluble in water, we consider 100% of the product entering waterways will transfer to the sediment.

Considering the first approach, PEC_{SED} are calculated as follows:

$$PEC_{SED}\ (mg/kg) = \frac{\text{Application rate (g/ha) x drift (decimal)}}{\text{Sed. volume (cm}^3\text{) x sed. density (g/cm}^3\text{) x 10 (conversion factor)}}$$

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} for kaolin in surface waters with 3 m buffer zone – use in vines – late treatment**

	Max single spray	Total season
Application rate (vines)	30 000 g/ha	120 000 g/ha*
Spray Drift**	8.02	8.02
Spray deposit (mg/m^2)	240.6	962.4
Sediment weight (1 m^2 x 5 cm depth x 1.3 g/cm^3)	65 kg	65 kg
Transfer to sediment	100 %	100 %
PEC_{SED} (mg/kg)	**3.70**	**14.81**

* based on a maximum application rate of 4 x 30 kg/ha
** Late season vines, 3 m from water body, SANCO/4145/2000

For the FOCUS approach, PEC_{SED} have been calculated with the FOCUS STEPS1-2 tool and presented in Table CP 8.2.5-3 above.

RMS comments on the PECsw/sed calculations

Input parameters and application patterns are considered acceptable and in line with the proposed GAP. Calculations were repeated by the RMS considering minimal cover as worst case also for late applications, and some amendments on PECsed calculations, were made directly in Table 8.2.5-3

CP 8.3 Fate and Behaviour in Air

Not applicable.

Surround® WP Crop Protectant contains 95% calcined aluminium silicate. Aluminium silicate is extremely stable and has no vapour pressure. Therefore, evaporation of aluminium silicate from soil or plant surfaces is not possible.

Aluminium silicate can only be observed in air as particles in suspension, similar to natural dust suspended in air and cannot be distinguished from naturally present dust particles

A waiver is requested for all environmental fate studies in air.

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

Not applicable.

CP 8.4 Estimation of Concentrations for Other Routes of Exposure

Not applicable.

Aluminium silicate is a natural form of clay that is present the world over. Exposure to clay particles is ubiquitous in the form of dust, suspended particles in water, sediment or soil. Estimating exposure to one of the most common mineral substances on Earth is meaningless.

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