Industry Consortium SAS FOR REACH

**Information Letter 2 b** 

# Substance Identity Profile for Synthetic Amorphous Silica (SAS) [EC no.: 231-545-4; EC name: silicon dioxide, chemically prepared] Surface treated (silanized)

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# Contents

1.	Introduction	.3
2.	Available information for Synthetic Amorphous Silica	.4
2.1	General Information	.4
2.2	Substance Composition	.4
2.3	Impurities that affect Classification and Labelling	.4
3.	Analytical Data	.4

#### 1. Introduction

This report is the substance identity profile (SIP) for nanostructured Synthetic Amorphous Silica (EC no. 231-545-4, EC name: Silicon Dioxide, chemically prepared), which is surface treated by silanization (SAS Silanized). SAS Silanized exists as a nanostructured material consisting of agglomerates and aggregates which are composed of primary particles fused together; except for mono- and polydisperse nanoparticles of colloidal silica in dispersions. The surface treatment agents are alkoxy- or chlorosilanes, silazanes, and/or siloxanes and have been generally registered under REACH as relevant. The use as surface treatment agents is described in the REACH dossiers and exposure scenarios of specific alkoxy- or chlorosilanes, silazanes and/or siloxanes. The carbon content at the surface of SAS Silanized is maximum 20 wt-% and typically less than 10 wt-%.

Surface treatment means the process of chemically treating the surface of with synthetic amorphous silicon dioxide (the substrate) chlorosilanes. alkoxysilanes, silazanes and/or siloxanes for changing certain physico-chemical properties of the surface or to alter chemical reactivity (i.e. to functionalize the surface chemistry). The surface-treatment substance (chlorosilanes, alkoxysilanes. silazanes and/or siloxanes) reacts with the surface forming covalent Si-O-Si bonds. Modification of the silica surface by such chemical reaction, thereby introducing a material onto the outermost layer of the silica, is mostly carried out to achieve the property of hydrophobicity of the silica without changing other properties. This type of reaction is usually not stoichiometric. The report contains general information of the substance and compositional data in order to ensure the sameness of samples from different suppliers (manufactures or importers). Individual companies are responsible for providing their own analytical data and appropriate method descriptions as part of their registration submission (IUCLID Section 1.4). The lead registrant will not provide the analytical data. Each company is responsible for the detailed description of the surface treated agents (if relevant) in their own legal entity composition (IUCLID Section 1.2).

## 2. Available information for SAS silanized

#### 2.1 General Information

Generic name: Silica, reaction or hydrolysis products with chlorosilanes, alkoxysilanes, silazanes and/or siloxanes

Table 1: General Information of SAS S	Silanized
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Type of C	composition	mono constituent substance
Substance O	Drigin	Inorganic
CAS number of the	e particle	7631-86-9
Reference EC n	umber of the	231-545-4
particle		
EC name of the pa	rticle	Silicon Dioxide, chemically prepared
Molecular formula	of the particle	SiO <sub>2</sub>
Structural formula of the particle		$O \equiv Si \equiv O$
Molecular weight	[g/mol] of the	60.084
particle		
Optical activity		no optical activity
Specific surface area		≥ 4 ≤ 1000 m²/g (BET)
Surface treating agents*		Alkoxysilanes, chlorosilanes, silazanes or siloxanes
Surface treatment property		hydrophobization/functionalization

\* Each company is responsible for the detailed description of the surface treating agents (if relevant) in their own legal entity composition (IUCLID Section 1.2).

#### 2.2 Substance Composition

Table 2: Substance Composition of SAS silanized

Substance Composition*		Remark	S		
Purity	≥ 95.0 % (w/w)				
Impurities		Remark	S		
Disodium sulphate or chloride	≤ 5.0 % (w/w)	Only	for	the	wet
		manufacturing route			

If hazardous impurities are present, any impact on safe use, PBT assessment and classification and labelling relating to impurities must be evaluated by the registrants in its own company-specific part of the registration dossier.

\* Guidance Document "identification and naming under REACH" (Version 2.1, 2017) page 55: <<No differentiation is made between technical, pure or analytical grades of the substance. This means that the "same" substance may have a different purity/impurity profile depending on its grade. However, well defined substances should contain the same main constituent(s) and the only impurities allowed are those derived from the production process (for details see Chapter 4.2) and additives which are necessary to stabilize the substance.

#### 2.3 Impurities that affect Classification and Labelling

Table 3: Other impurities	that affect Classification and	Labelling of SAS silanized
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EC number	EC name	Typical Concentration	comment
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None of the impurities contribute to the classification and labelling of the substance.

### 3 Analytical Data

SAS Silanized is predominantly characterized through the following methods of identification:

- Amorphous structure: X-ray diffraction (XRD)
  X-ray diffraction diagrams of SAS, show only a broad halo, revealing an X-ray amorphous structure. The detection limit for crystallinity by X-ray is in the maximum order of 0.3% by weight or below.
- Infrared spectroscopy (IR drift unit)
- Magnetic Resonance spectroscopy solid state NMR Si<sup>29</sup>
- Constituent Particle Size Distribution SAS is a nanomaterial according to European Commission recommendation 2011/696/EU and the status should be determined according to methods given in the latest JRC science for policy report (An overview of concepts and terms used in the European Commission's definition of nanomaterial, 2019)
- Carbon content: ISO 3262-20

The detection limit of  $\leq$  0.3 % by weight is the limit for the crystalline part of the registered silicon dioxide, including impurities.