

Update – Brussels, 21 September 2020

Status of Synthetic Amorphous Silica (SAS) according to the ISO standard 16128 - Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products.

SAS is produced by 2 processes:

- **Thermal route (pyrogenic/fumed):**
Pyrogenic SAS is made by hydrolysis of volatile chlorosilanes or methylchlorosilanes in an air-hydrogen flame at temperature between 1200-1600 °C in a continuous operating process
- **Wet route (precipitated, gel, colloidal):**
Precipitated SAS is produced via a wet production route, which is based on a reaction of alkali metal silicate solutions with mineral acids.
Silica gel is produced in a comparable process but not in a water suspension. The process ends in a solid form which is ground before being washed and processed further.

The ISO standard 16128 – Part 1 defines natural ingredient, derived natural ingredient, derived mineral ingredient, derived organic ingredient and non-natural ingredient. Part 2 defines the criteria to determine the natural origin index of cosmetic ingredients.

The aim of this paper is to determine to which one of these categories SAS material belongs and what the natural origin index is, if any.

1. **Natural ingredients** are “cosmetic ingredients obtained only from plants, animals, micro-organisms or minerals”

Sand (silicon dioxide – SiO₂) and amorphous silicas such as diatomaceous earth, are naturally occurring and qualify for the definition of natural mineral ingredient.

2. **Derived natural ingredients** are cosmetic ingredients of greater than 50 % natural origin, by molecular weight, by renewable carbon content, or by any other relevant methods, obtained through defined chemical and/or biological processes with the intention of chemical modification.

ASASP synthetic amorphous silica does not qualify for “Derived natural ingredient” criteria.

3. **Derived mineral ingredients** are cosmetic ingredients obtained through chemical processing (an informative list of such processes is provided in Annex B) of inorganic substances occurring naturally in the earth, which have the same chemical composition as natural mineral ingredients. Annex A gives information on solvents in relation to ingredient manufacturing.



An informative list of derived mineral ingredients is included in Annex D of the ISO standard where SILICA [natural analogue identified is quartz] and HYDRATED SILICA [no natural analogue listed] are both identified as 'Derived mineral ingredients.

Chemical Identity:

While from a pure chemical composition standpoint, SAS is chemically identical to Quartz [CAS number 7631-86-9], the natural analogue cited in annex D of the ISO standard; there is a difference in crystallinity and associated safety profile of both substances. SAS is crystalline-free while Quartz is 100% crystalline, with well-known inhalation risk associated. SAS is considered a much safer alternative to any naturally occurring silicon dioxide species for use in cosmetic application.

Process-related question:

Pyrogenic SAS is produced by hydrolysis of chlorosilanes at high temperature in an air-oxygen flame. Annex B clearly states, that "The use of halogenated non-mineral derivatives is not recommended during the processing of derived natural organic and mineral ingredients."

ASASP Assessment: The intermediate products SiCl_4 or MeSiCl_3 used in pyrogenic silica synthesis can be seen as halogenated mineral derivatives (i.e. of sand SiO_2) because of the defining Si-Cl structure. Our understanding of the term "halogenated non-mineral derivatives" means "halogen-organic moieties" (e.g. chloroform as extraction agent). In addition, dimethyldichlorosilane used as hydrophobization agent can be interpreted as halogenated mineral derivative (because there is no C-Cl bond but only Si-Cl bonds).

In addition, the use of chlorinated hydrocarbons is not forbidden per annex B, only 'not recommended'. Per our knowledge of the process, there will be no chlorosilane (halogenated compound) left at the end of the process. The by-product of the thermal route production is HCl and only chloride ions, because of the total hydrolysis of the (inorganic) Si-Cl bond, may remain attached at SAS surface. Therefore, neither halogenated mineral nor non-mineral derivatives will contaminate pyrogenic SAS product.

Precipitated/Gel SAS is manufactured using processes permitted in the Annex B list and with raw materials of natural origin. The products are produced by dissolving sand then either precipitating or gelling the solution to give an amorphous silica. No chemical modification is made to the mineral composition.

Conclusion:

ASASP believe **untreated SAS** can be considered a " **derived mineral ingredient**" per ISO Standard 16128. Since "silica" and "hydrated silica" are explicitly named with their INCI names in annex D, a discussion about how they are produced should be rendered obsolete. In case a substance is named, the standard applies. **Surface treated SAS** do not qualify for the derived mineral ingredient definition and are, therefore considered "**non-natural ingredients**" due to the chemical modification applied on the SAS surface (surface treatment such as dimethyldichlorosilane) that render them hydrophobic.



Naturality indices per ISO16128 standard Part 2

The 'index' is a value indicating the extent to which a cosmetic ingredient meets the ISO 16128-1:2016, Part 2 definitions of

- natural ingredient
- derived natural ingredients
- organic ingredients
- derived organic ingredients

INCI NAME	Naturality indices			
	Natural	Natural origin (derived)	Organic	Organic origin (derived)
SILICA	0	1	0	0
HYDRATED SILICA				
SILICA SILYLATE		0		
SILICA DIMETHICONE SILYLATE				
SILICA DIMETHYL SILYLATE				

