

14th February 2020

Synthetic Amorphous Silica (SAS) industry response to the opinion of the Scientific Committee on Consumer Safety (SCCS) on silica in cosmetics with regard to solubility

The purpose of this statement is to provide the position of the Association of Synthetic Amorphous Silica Producers (ASASP) with respect to the recently published Opinion of the European Commission's Scientific Committee on Consumer Safety (SCCS) on solubility of Synthetic Amorphous silica (SAS) and the associated corrigendum.

In January 2018, the Association of Synthetic Amorphous Silica Producers (ASASP) submitted a dossier to the European Commission demonstrating that Synthetic Amorphous Silica (SAS) is not a nanomaterial according to the definition of Article 2(1)(k) of the Cosmetics Regulation (EC) No 1223/2009, on the basis that Synthetic Amorphous Silica is not insoluble in water. According to Cosmetics Regulation (EC) No 1223/2009, a nanomaterial is "*an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*".

Following receipt of the dossier, on 20th March 2018 the European Commission issued a mandate to the Scientific Committee on Consumer Safety ("SCCS"¹) in the form of a "*Request for a scientific opinion on Solubility of Synthetic Amorphous Silica (SAS)*".

On December 6th, 2019, the SCCS published a Corrigendum Opinion on the "Solubility of Synthetic Amorphous Silica (SAS)" after an initial publication of the opinion on June 21, 2019. In this Opinion, the SCCS concluded that (1. Abstract, page 3): "*The hydrophilic and hydrophobic SAS materials can therefore be regarded as "insoluble" (i.e. below 100 mg/L) to very slightly soluble" (i.e. 100 mg/L to 1000 mg/L) by the SCCS based upon the terminology used in USP38 and USP 38 NF33.*"

This Opinion is not legally binding. It constitutes an advisory opinion within the framework of a decision-making process. The European Commission will itself decide whether or not SAS qualifies as a nanomaterial according to the definition of Article 2(1)(k) of the Cosmetics Regulation (EC) No 1223/2009.

We do not agree with the interpretation of SCCS as we believe, based on our scientific studies supporting the ASASP dossier, that SAS is not insoluble, as the typical solubility of hydrophilic and

¹ SCCS is an independent scientific committee managed by the Directorate-General for Health and Consumer Protection of the European Commission, which provides scientific advice to the European Commission.

hydrophobic SAS is above 100 mg/L. The SCCS in its opinion itself stated that materials with a solubility of more than 100 mg/L are not insoluble, as established above. Therefore, according to ASASP, SAS should not be regarded as a nanomaterial according to the current Cosmetics Regulation nanomaterial definition.

ASASP is actively participating in and monitoring this decision-making process and is continuing to work with the SCCS and the European Commission. This statement will be updated following any new developments.

About ASASP

The Association of Synthetic Amorphous Silica Producers is a sector group of the European Chemical Industry Council (Cefic) and represents the major producers of synthetic amorphous silica (SAS) in Europe. ASASP is a non-profit organisation established in 1992 dedicated to promoting the safe use and benefits of SAS to society.

The health and safety of employees, consumers and the wider community are of the utmost importance to ASASP members. ASASP continues to be convinced that based on the available information, the use of SAS in consumer products is considered safe.

www.asasp.eu

Legal disclaimer:

The information contained in this document is intended for guidance only and whilst the information is provided in utmost good faith and has been based on the best information available currently, it is to be relied upon at the user's own risk. No representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted by ASASP nor any of its members for damage of any nature whatsoever resulting from the use of this information. The only valid and current document is stored on <http://www.asasp.eu/>. Any other source contains an uncontrolled version which may be modified and/or outdated, and which may not correctly reflect ASASP's actual position on the subject.