

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).

In January 2018, the Association of Synthetic Amorphous Silica Producers (ASASP) submitted a dossier to the European Commission demonstrating that amorphous silica 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 amorphous silica is soluble in water. In 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 20 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 20-21 June 2019, the SCCS published an Opinion on the "*Solubility of Synthetic Amorphous Silica (SAS)*". In this Opinion, the SCCS concluded that "*in regard to the nanomaterial definition in the Cosmetic Regulation, none of the SAS materials (hydrophilic or hydrophobic) included in the dossier can be regarded as soluble.*"

This Opinion is not legally binding. It only 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.

ASASP is actively participating in and monitoring this decision-making process, and is continuing to work with the SCCS and the EU Commission. We believe based on our scientific study supporting the ASASP dossier that SAS is soluble and should not be regarded as a nanomaterial according to the Cosmetic Regulation nanomaterial definition. We also believe there to have been legal and procedural flaws in the

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.



evaluation of the dossier which have been brought to the attention of the SCCS and the European Commission.

This statement will be updated following any new developments.

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 cosmetic products is considered safe.

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. www.asasp.eu