

Synthetic Amorphous Silica (SAS) industry response to the opinion of the Scientific Committee on Consumer Safety (SCCS)

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 Silica, Hydrated Silica, and Silica Surface Modified with Alkyl Silylates (nano form) in cosmetic products of 20 March 2015 and the revision of 28 September 2015.

In April 2012, ASASP issued a statement informing its customers that Synthetic Amorphous Silica (SAS) does not fulfil the criteria of insolubility or biopersistence included in the definition of nanomaterial provided by the Cosmetics Regulation (EC No 1223/2009) and, therefore, SAS should not be considered as a nanomaterial under that Regulation and cosmetic products containing SAS do not require a nano labelling on their packaging nor an Article 16 nanomaterial notification.

Despite this determination, the Commission received 172 nanomaterial notifications from one applicant. Subsequently, the Commission requested the SCCS to provide a safety assessment of four types of silica. Within this context, a public call for data was launched by the Commission in February 2014 to all interested parties to submit available information on the subject.

ASASP submitted to this public consultation a dossier on the Safety of Nanostructured and Colloidal SAS used in cosmetic products which includes comprehensive studies on the physical-chemical properties and safety of SAS used in cosmetic products and demonstrates no adverse health effects in humans, even after many decades of use in cosmetic, food, personal care, and industrial applications.

In its Opinion including the revision of 28 September 2015, the "SCCS found no proof that nano-silica penetrates the skin or is toxic, but also SCCS did not find enough evidence to rule out those possibilities". The Opinion states, the evidence "is inadequate and insufficient to allow drawing any firm conclusion either for or against the safety of any of the individual SAS materials, or any of the SAS categories that are intended for use in cosmetic products".

ASASP believed SCCS may not have considered the information in the ASASP dossier during the development of its opinion and therefore brought this oversight to the attention of SCCS during the recent public consultation. Nevertheless, SCCS is still considering the SAS information as not sufficient to make a final conclusion and remains with the same opinion.

The SCCS did not take into consideration many of the studies showing SAS to be safe as it cannot link the studies to specific product grades. ASASP believe this is unreasonable as the dossier included information showing the properties of all SAS products to be very similar.

ASASP, in close collaboration with Cosmetics Europe, the Association representing companies in the cosmetics and personal care industry, is working with the SCCS and the European Commission to address the points raised in the Opinion and to demonstrate that SAS is safe in these applications.

The health and safety of employees, consumers and the wider community are of the upmost 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.

ASASP Member Companies include Cabot, Evonik Resource Efficiency, Grace, J.M. Huber, IQESIL, PPG, PQ, Solvay, Wacker Chemie and Zeochem.

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