Association of Synthetic Amorphous Silica Producers

Update - Brussels, April 2013

Statement for Synthetic Amorphous Silica regarding the definition of 'nanomaterials' for cosmetic use in the European Union by the Association of Synthetic Amorphous Silica Producers (ASASP), an Industry Sector Group of Cefic

The purpose of this statement is to provide the position of the Association of Synthetic Amorphous Silica Producers ("ASASP") with respect to the substance Synthetic Amorphous Silica ("SAS") under the definition of "nanomaterial" provided in Regulation (EC) No 1223/2009 on cosmetic products ("the EU Cosmetics Regulation").

According to ASASP, SAS does not fulfil the criteria of insolubility or biopersistence included in the definition of nanomaterial provided by the Cosmetics Regulation and, therefore, should not be considered as a nanomaterial under that Regulation for the reasons explained below.

Background:
Currently two regulatory definitions of nanomaterial coexist in the EU in the field of cosmetics:

- The specific definition included in the EU Cosmetics Regulation 1223/2009; and
- The definition provided by Commission Recommendation 2011/696/EU on the definition of nanomaterial.

This statement refers to EU Cosmetics Regulation and the legally binding definition of a "nanomaterial" that it contains.

ASASP understands that Member States, EU agencies and economic operators are invited to use the definition of nanomaterial provided in the Commission Recommendation. This, however, should not prejudge or reflect the scope of application of specific EU legislation providing additional requirements, nor constitute an obligation for the Commission to substitute the existing EU Cosmetics Regulation definition with the definition of the Commission Recommendation for "nanomaterial" in the Cosmetics Regulation.

Specifically, Article 2(1)(k) of the EU Cosmetics Regulation defines "nanomaterial" as:
"*an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*".

However, the EU Cosmetics Regulation does not provide definitions for the two key terms included in the nanomaterial definition – "insoluble" and "biopersistant". Although not legally binding, objective criteria for insolubility and/or biopersistence of nanomaterials under use conditions have to be applied for interpretation. ASASP recommends using the following objective criteria:

- **Insolubility:**

Within the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008, "poorly soluble substances" are defined as substances of water solubility < 1 mg/l (Note 3 under Table 4.1.0 of the CLP Regulation). Furthermore, Cosmetics Europe (formerly Colipa)[1] and the European Federation for Cosmetic Ingredients (EFfCI)[2] have provided guidance defining the lower limit of substance solubility as 1 mg/l.
Additionally, the solubility of synthetic amorphous silica was determined under OECD Guideline 105 on arbitrarily selected samples in a range of 40 – 200 mg/l.

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- **Biopersistence:**

  To the best of our knowledge, no definition for "biopersistence" is provided in other pieces of EU legislation. However, Annex XIII of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) provides criteria for the identification of persistent, bioaccumulative and toxic substances, but specifies that it only applies to organic substances. Therefore, the criteria for "persistence" should not apply to inorganic chemical substances. Consequently, by analogy and given the similarity of intent, since SAS is an inorganic chemical substance, it should not be considered as biopersistent.

Additionally, the following points can be made:

- Today's production processes are based on technologies established in the 1940's. These processes have been optimized and improved since that time while maintaining the same technological principles.
- The aggregate is the smallest indivisible unit upon dispersion and typically has a size > 100 nm.
- SAS has been widely investigated over decades of its production and use in numerous toxicological and epidemiological studies. It is considered a non-hazardous substance (OECD HPV, ECETOC JACC Report No. 51 and REACH Dossier 2009 by Lead Registrant Evonik Degussa GmbH).

The results of existing toxicological studies remain valid for these products. Furthermore, we have no indications which would lead us to assume that our products do not continue to be safe for use in life science applications such as food, pharmaceuticals, personal care formulations, and others.

This statement represents the ASASP's current understanding of the Cosmetics Regulation. The Association will continue to monitor this evolving regulatory matter and will update this statement as appropriate.

References:

[1] *Colipa Discussion Paper on interpretation of the definition of the term "nanomaterial" according to the EU Cosmetic Regulation 1223/2009 (14-04-2011)*
[2] *EFfCI Guidance Paper on Nanomaterials in Cosmetics (01-2012)*