aSASp Association of Synthetic Amorphous Silica Producers

Synthetic Amorphous Silica – ASASP's current interpretation as a nanomaterial

Synthetic Amorphous Silica (SAS), EINECS No. 231-545-4, is a form of silicon dioxide (SiO_2) that is intentionally manufactured. SAS has been produced and marketed for decades without significant changes in its physical-chemical properties. SAS is in the form of white dry powders or dispersions of these powders are used in a multitude of industrial applications. In addition, it is approved to be used in food, cosmetics and pharmaceuticals.

SAS is affected by the evolving nanotechnology/nanomaterial discussions between stakeholders, researchers, regulators, Non-Governmental Organizations and industry.

The purpose of this statement is to provide the current interpretation of the Cefic Sector Group Association of Synthetic Amorphous Silica Producers ("ASASP") with respect to the substance SAS concerning two definitions of the term "nanomaterial":

- The scientific-based definition of the term nanomaterial as developed by the ISO Technical Committee (TC) 229, "Nanotechnologies"; and
- The regulatory driven Recommendation 2011/696 of the EU Commission (published on 18 October 2011) intended to be applied as an overarching framework with regard to other EU regulatory definitions.

It is important to note, there is no harmonized definition for "nanomaterials". The status of a substance as a "nanomaterial" is dependent on the specific definition. Thus, ASASP may have position statements for different regulations such as the EU Cosmetic Regulation 1223/2009 or Food information Regulation 1169/2011 (See in particular ASASP statement on Cosmetics Regulation, April 11, 2012).

SAS is produced by thermal (pyrogenic/fumed) or wet (precipitated, gel, colloidal) processes. In the initial particle formation step, primary particles with dimensions below 100 nm are formed by nucleation, coagulation and coalescence. These primary particles convalently bond to form indivisible units, called aggregates, which have no physical boundaries among them. The aggregates have external dimensions typically above 100 nm (pyrogenic, precipitated, gel). The aggregates combine to form agglomerates in the micron size range by physical attraction forces (van der Waals) and H-bridges. SAS powder is placed on the market as micron-sized agglomerates with an internal structure in the nanoscale. This fact is true for all currently known SAS products in powder form, independent of manufacturer, process and trade name. Colloidal silica is placed on the market as aqueous preparations of nanoparticles.

Image analysis by electron microscopy (TEM) of SAS shows fractal structures where the aggregates formed from covalently bonded primary particles can be identified. The size of the conceptual primary particle is in the nanoscale range, however, it typically does not exist in isolation. Hence, the aggregate in SAS is the smallest indivisible unit upon dispersion – as determined by granulometric methods.

Standard test methods for the analysis of dry particles in air have been applied, primarily, dry-sieving and laser light diffraction to assess the actual size/distribution. These two methods are non-destructive, that is, the agglomerates are mostly preserved and the particle aerosol

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concentration is sufficiently high to reflect actual technical handling conditions. SAS powder as delivered to downstream users is typically in the micron size range.

In accordance with ISO/TC 229 "Nanotechnologies" nanomaterials comprise nano-objects and nanostructured materials. Nano-objects possess one, two or three **external** dimensions in the nanoscale (size range from approximately 1 nm to 100 nm). The identifying feature of nanostructured materials is that their **internal** or surface structure is in the nanoscale, but their external dimensions are typically greater than the nanoscale range (ISO/TS 80004-1:2010 on terminology for nanoscale, nanomaterial, nanoparticle and nanostructured materials).

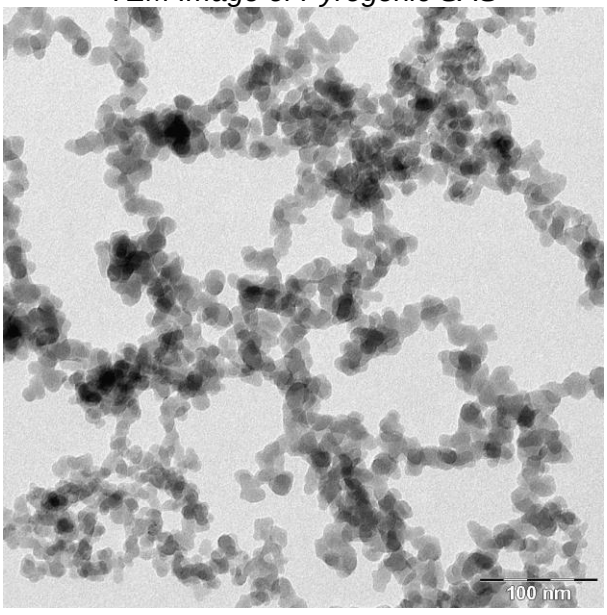
The EU Commission Recommendation is based "solely on the size of the constituent particles of the nanomaterial, without regard to hazard or risk". Furthermore the EU Commission acknowledges that "there is no consistent causal link between nano size alone and hazards" (EU Commission's Question & Answer, October 18, 2011). Per the definition, a nanomaterial is "natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm" Paragraph 12 of the 'Whereas' section of the Recommendation also includes particles in agglomerates or aggregates whenever the constituent particles are in the size range 1 nm – 100 nm'.

The EU Commission Recommendation does not explicitly refer to an analytical measurement method(s) to determine the number size distribution whereas the threshold limit value can be derived. This is a significant limitation of the Recommendation and must be considered in further evaluations.

In conclusion SAS in powder form is a nanostructured material according to the technical specification of ISO TS 80004-1. The aggregate is the smallest indivisible unit upon dispersion.

ASASP's interpretation is that SAS is considered a nanomaterial under the current EU Commission Recommendation definition TEM image analyses confirm this conclusion.

TEM Image of Pyrogenic SAS



Additionally, other important facts:

- As SAS is a nanostructured material, no bulk/macroform of SAS exists. Today's production processes are based on technologies established since 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; aggregates are distributional in nature with a size range typically above 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 Dissemination Report 2012).
- SAS has been selected for the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials and for the Cefic Long-range Research Initiative (LRI) Projects N1: Tiered approach to testing and assessment of nanomaterial safety to human health and N3: Testing and Assessment of Reproductive Toxicity of Nanomaterials. As of the date of this statement, results of the OECD & Cefic LRI are consistent with existing data and confirm the relevance of existing SAS toxicological data; that is, the substance is of low toxicity. Therefore, we continue to believe our SAS products are safe for use in industrial applications, as well as in life science applications such as food, pharmaceuticals or personal care formulations.

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