SASSI Comment Statement – Synthetic Amorphous Silica (SAS) as a "Nanomaterial" as per the *Policy Statement on Health Canada's Working Definition for Nanomaterial*[1]

01 September 2023

Synthetic Amorphous Silica (SAS) is a form of silicon dioxide (SiO_2) that is intentionally manufactured. Common forms of SAS include precipitated silica, silica gels and colloidal silica (CAS #112926-00-8) as well as pyrogenic or fumed silica (CAS #112945-52-5). 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. They are used in a multitude of industrial applications including coatings, tires, adhesives, and sealants. In addition, SAS is approved to be used in food/feed, cosmetics and pharmaceuticals. **The purpose of this Comment Statement is to provide the Synthetic Amorphous Silica and Silicates Industry Association's ("SASSI's") current interpretation that SAS is a nanomaterial under the provisions of the Policy Statement on Health Canada's Working Definition for Nanomaterial (06 October 2011).**

It is important to note, there is no globally-accepted, harmonized definition for "nanomaterials". The status of a substance as a "nanomaterial" is dependent on the definition offered by the respective Regulatory Authority and recognized standards organization.

Health Canada's Working Definition for Nanomaterial

Health Canada considers any manufactured substance or product and any component material, ingredient, device, or structure to be nanomaterial if:

a. It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or;

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[1] https://www.canada.ca/en/health-canada/services/science-research/reports-publications/nanomaterial/policy-statement-health-canada-working-definition.html (06 October 2011)

b. It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties/phenomena.

For the purposes of this definition:

i. The term "nanoscale" means 1 to 100 nanometers, inclusive;

ii. The term "nanoscale properties/phenomena" means properties which are attributable to size and their effects; these properties are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and,

iii. The term "manufactured" includes engineering processes and the control of matter.

Morphology of SAS

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 covalently bond to form indivisible units, called aggregates. 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 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

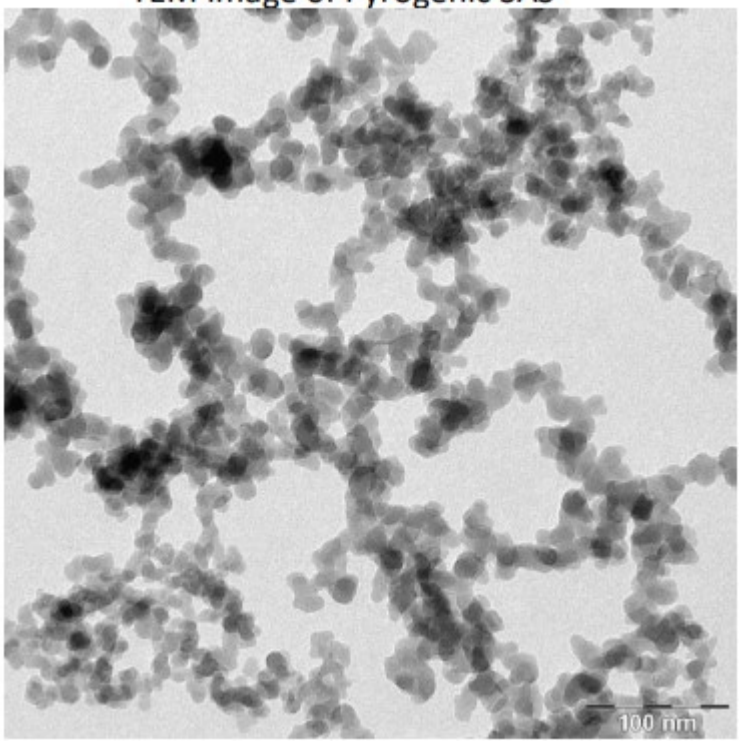
comprise nano-objects and nanostructured materials. Nano-objects possess one, two or three external dimensions in the nanoscale (size range from approximately 1 nm to 100 nm). The identifying feature of nanostructured materials is that their internal or surface structure is in the nanoscale, but their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

Health Canada's Working Definition of a Nanomaterial is based on the size of the constituent particles of the nanomaterial or the material exhibiting nanoscale properties/phenomena which are distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material. Please note that this working definition is without regard to hazard or risk".

There are no nanoscale properties/phenomena associated with the forms of SAS commercially available. However, SAS in powder form can be defined as a nanostructured material given that the constituent primary particle sizes are within the nanoscale (1-100 nanometers).

Therefore, SASSI's interpretation is, that SAS is considered a nanomaterial under the Health Canada's working definition of a nanomaterial. TEM image analyses confirm this conclusion.

TEM Image of Pyrogenic SAS



Important Considerations:

- 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.

About SASSI

The Synthetic Amorphous Silica and Silicate Industry Association (SASSI) is a forum that addresses industry-wide questions arising during production-related activities as well as ecotoxicity, toxicology and regulatory matters concerning the use of synthetic amorphous silica and silicates. SASSI is a non-profit corporation (IRS 501(c)(6) corporation) with 7 members representing the major synthetic amorphous silica and silicate producers in the US and Europe.

SASSI came together as an association of manufacturers in 1993, commensurate with the 1992 formation of the Association of Synthetic Amorphous Silica Producers (ASASP), a Sector Group within Cefic one of the leading European trade associations with offices in Brussels