September 2012

Factsheet:

Synthetic Amorphous Silica (SAS)

Introduction

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 physicochemical properties. SAS as white dry powders or dispersions is used in a multitude of industrial applications. In addition, it is approved for use in food, cosmetics and pharmaceutical applications. All historic physicochemical and toxicology data remain valid for SAS manufactured today.

SAS is produced by thermal route (pyrogenic/fumed) or wet route (precipitated, gel, colloidal) processes. In the initial particle formation step, primary particles with dimensions less than 100 nm are formed by nucleation, coagulation and coalescence. By covalent bonding, these particles form indivisible units, the aggregates, with external dimensions typically above 100 nm; they are fused together with no clear physical boundaries among them. These aggregates combine to form agglomerates in the micron size range by physical attraction forces (van der Waals) and H-bridges. An identifying feature of SAS powder is that it is put 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.

Particle size data for SAS

Image analysis by electron microscopy (TEM) of SAS show fractal structures where covalently bonded primary particles in aggregates 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 is the smallest indivisible unit upon dispersion - as determined by granulometric methods.

Standard granulometric methods for the analysis of dry particles in air have been utilized, primarily dry-sieving and laser light diffraction to assess the real particle size distribution of SAS as delivered. These two methods are non-destructive, i.e. the agglomerates are mostly preserved and the particle aerosol concentration is sufficiently high to reflect real technical handling conditions. SAS, as delivered to downstream users, is typically in the micron size range.

Applications

SAS has been safely used in a wide variety of industrial and consumer applications for many decades.

In consumer applications, SAS is used in cosmetics (e.g., as abrasion additive in toothpastes, thickener in pastes, formulation aid in creams), pharmaceuticals (e.g., as free-flow additive, carrier, or retardant agent) and food (as E 551 e.g. to introduce free-flow properties into powder or seasonings).

In industrial applications, SAS is used as a reinforcement agent (e.g., in rubber (“Green Tyre”) and silicones), as matting agent or rheological additive (e.g. in paints, lacquers, and varnishes), to prevent plastic films from sticking, and in thermal insulations. Colloidal silica is widely used in coatings, ink receptive papers, metal casting, refractory products, catalysts, and as a filter aid in food production, where it is removed completely at the end of the process.

Hazard Assessment

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

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, REACH Dissemination Report 2012). In addition, SAS has been selected for the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials and for the Cefic Long-range

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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 projects are consistent with existing data and confirm the relevance of existing toxicological data on SAS; that is, the substance is of low toxicity and does not meet any classification criteria of a hazardous material under European Regulation (EC) No 1272/2008 (i.e. CLP Regulation) and the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals.

Emission and Exposure

Emission to the environment

The rate of SAS released into the environment during its life cycle can be considered negligible in comparison with the natural presence of silica within the environment.

Occupational exposure

In SAS production the highest exposure has been measured during packaging and loading operations, with highest mean values of up to 3 mg/m^3 inhalable dust and up to 1 mg/m^3 respirable dust. In 2006, Germany established a legally binding occupational exposure limit of 4mg/m^3, TWA (inhalable fraction) for “silica, amorphous”, i.e. SAS.

Consumer exposure:

SAS is typically incorporated into a product matrix where it is tightly bound such as in paints, plastics, and rubber, therefore consumer exposure to SAS by the inhalation route is expected to be very low.

Oral intake of SAS is regulated and permitted under specific conditions when used in food (E551) and pharmaceuticals. Skin contact in cosmetics applications is a longstanding practice without indication of any health effects.

Exposure to “nano-silica” (which is different from Synthetic Amorphous Silica described in this document) via food is under investigation by Competent Authorities of EU Member States. ASASP/Cefic is involved in this process by data sharing.

Literature Search

In the last few years numerous papers under the key words “nano-silica”, “nano toxicity” have been published. ASASP has implemented a literature search process to identify and evaluate relevant publications in this field. This includes direct communications with the authors, when necessary. One of the essential criticisms of many of these publications is the poor substance characterization and the invalid link to SAS.

For a comprehensive review of SAS data see: “The toxicological mode of action and the safety of synthetic amorphous silica — A nanostructured material”, C. Fruijtier-Polloth, *Toxicology*, 294 (2012) 61–79.

Overall Conclusion

ASASP Members have been conducting comprehensive safety and health studies on SAS which demonstrate our SAS products are safe for use in industrial applications, as well as in life science applications such as food, pharmaceuticalsand personal care formulations.

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