

ASASP position on the proposed harmonised classification of Synthetic Amorphous Silica (SAS) in the EU

ASASP is the European Association of Synthetic Amorphous Silica Producers and is a Sector Group of Cefic, formed in 1992. It consists of nine member companies which account for approximately 85% of SAS production in the EU. ASASP calls on the responsible authorities to pause the SAS CLH classification process until an appropriate framework has been developed that addresses both scientific and regulatory complexities surrounding particulate materials.

Overview of SAS and its applications

Synthetic Amorphous Silica (SAS) is a manufactured, highly pure, crystalline-free, nano structured material consisting of aggregates and agglomerates. It is a specialty chemical that has been produced and marketed for more than 80 years, without changes in physicochemical properties.

SAS is an extremely versatile material, essential across strategic sectors, including automotive, defence, renewable energy (including batteries and wind turbines), electronics / semiconductors, insulation, construction, paints, technological adhesives, cosmetics and personal care, food, animal feed, packaging, pharmaceuticals. SAS is the “*hidden champion*” in countless applications.

Why is SAS important ?

The strategic importance of SAS is significant and cannot be underestimated. Because of its unique technical characteristics, SAS fulfils multiple functions in the products it is used in, and there are no one-to-one substitutes that provide the same combination of properties. Notable applications include its use in green tyres to help reducing energy consumption and CO₂ emissions, while improving safety by enabling shorter braking distances. It is also a critical reinforcing filler in medical-grade silicone tubing, ensuring strength, toughness, and durability. In toothpaste, it serves as a gentle cleaning abrasive, a thickener for the desired texture and an efficient carrier for fluoride.

In the EU, SAS plays a major role in achieving the EU’s strategic objectives, such as defence and strategic autonomy as well as decarbonisation. Europe accounts for 20% of global production of SAS and is a net exporter on the international market. It is also a world leader in innovation and stands out as the main worldwide manufacturer of high-quality technical products.

The SAS industry secures over 10,000 jobs across Europe and is an integral part of a value chain worth over EUR 300 billion annually (Eurostat, 2022).

Classification Proposal of SAS in the EU

The European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC) has proposed an EU harmonised classification of SAS as “Specific Target Organ Toxicity following Repeated Exposure, Category 1” (STOT RE 1). However, RAC’s proposal relies on numerous assumptions and

interpretations of scientific data that lack sufficient substantiation. Additionally, the definitions of substance identity and scope of validity remain insufficiently clear. Furthermore, relevant literature and information provided during the public consultation were not adequately considered. Notably, comprehensive human epidemiological studies demonstrating no adverse health effects were excluded without clear justification. It is essential that all available data are evaluated, with the weight of evidence process conducted in a scientifically justified and transparent manner.

The RAC opinion on SAS clearly underscores the on-going confusion around particulate materials and CLP.

ASASP Position and Asks

The RAC opinion on SAS is fundamentally flawed, calling into question its validity and suitability. In light of this, ASASP calls for the core issues surrounding particulate materials to be addressed before any classification proceeds. Establishing an appropriate framework to address the scientific and regulatory complexities related to particulate materials is, in our view, the most effective approach to move forward on this matter. This request aligns with the recommendations of the Particles Platform* that include the creation of an expert group on particles under the auspices of ECHA, comprising of representatives from ECHA, academia, and industry.

This is particularly critical as the proposed classification has significant regulatory and socio-economic impacts. It would cause uncertainty and concerns within the supply chain, potentially leading to significant loss in demand for SAS and adversely affecting exports. This increased pressure on the industry could result in production relocating outside the EU, thereby undermining competitiveness and strategic autonomy.

ASASP and its members will continue to engage with all key authorities and stakeholders to advocate for a pause in the SAS classification process until a thorough evaluation can be conducted to ensure informed and effective classification decisions.

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ASASP aims to provide a platform for an open and constructive dialogue throughout the value chain, between manufacturers, downstream users and key regulators at European level. ASASP works closely with leading scientists and academics to continually support research related to synthetic amorphous silica, its uses, health and safety.

* The Particles Platform is an informal alliance of EU industry associations that deals with issues related to particle classification in the EU. (www.particlesplatform.eu)

