SOCIO-ECONOMIC ANALYSIS

Of the Impacts of the Potential Re-Classification of Synthetic Amorphous Silica (SAS) as STOT RE 1

SUBSTANCE: Synthetic Amorphous Silica (SAS)
CAS: 112945-52-5, 112926-00-8, 7631-86-9
FROM: Association of Synthetic Amorphous Silica Producers (ASASP), a Sector Group within Cefic
DATE: 19 April 2023

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CITATION:

EPPA, '*Socio-economic analysis of the Impacts of the Potential Re-Classification of Synthetic Amorphous Silica (SAS) as STOT RE 1*', Report for Cefic, April 2023

DISCLAIMER:

TABLE OF CONTENTS

1. SUMMARY OF SOCIO-ECONOMIC ANALYSIS

Main findings

Synthetic Amorphous Silica (SAS) is a highly versatile substance providing multiple functions. It is used in multiple highly innovative applications in key economic and strategic sectors. From the automotive industry to renewable energy (e.g., batteries), construction insulation, from cosmetics, food & pharmaceuticals to paints & coatings, adhesives & sealant, including plastics and rubber, paper and packaging and several other industries whose finished products are used on a daily basis by millions of European consumers. The downstream user sectors, using SAS as a high-performance additive, have a combined estimated added value of more than 300 billion EUR per annum.[1]

The European industry is a global leader in the production of SAS and a net exporter of SAS. The silica industry is strategically important for the European market and vice versa the European market represents a considerable portion globally (20% of the world's production of SAS is originated from the EEA).

In July 2021, the evaluating Member State Competent Authority (eMSCA) of the Netherlands issued an evaluation report on SAS under REACH Art. 48.2 In the report, the eMSCA concludes that there is sufficient ground to start the process for harmonised classification and labelling for the endpoint specific target organ toxicity - repeated dose toxicity (STOT RE) (lung/respiratory tract). The RIVM announced in March 2022 that the proposal will be Cat 1 for the substance (CAS: 7631-86-9).[3]

In view of a potential STOT RE 1 classification, this socio-economic analysis (SEA) focuses on the value of synthetic amorphous silica and SAS-based products on the European market[4] and aims to provide **strong evidence-based findings on the expected social and economic impacts of such a harmonised classification.** The SEA has been performed by EPPA[5] at the request of the Association of Synthetic Amorphous Silica Producers (ASASP), a Sector Group within CEFIC.

The results of this SEA demonstrate that the STOT RE 1 harmonised classification for SAS would result in **severe social and economic impacts for the manufacturers and suppliers of the substance, on the downstream users of SAS in a diverse range of industry sectors, on the marketing and use of a vast array of industrial, professional and consumer products and ultimately also on society and citizens overall.**

[1] Eurostat, 2022. Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E). Retrieved on 7 October 2022 from: https://ec.europa.eu/eurostat/databrowser/view/SBS_NA_IND_R2__custom_3557579/default/table?lang=en (NACE codes = "C109", "C17", "2030", "C21", "C221", "C222", "C2361", "C272"; Geographical entry = "EU27"; Time = "2019"; Economic indicator = "Value added at factor cost").

[2] https://echa.europa.eu/documents/10162/5f238e67-e159-1fba-1f7f-23df7c25a4fb

[3] https://echa.europa.eu/nl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1809d3513

[4] It has been conducted in accordance with the existing official guidance from ECHA under other EU regulatory processes (in particular REACH), in a spirit of cross-sectorial coherence and methodological consistency.

[5] www.eppa.com

In most downstream-user sectors, there is no equivalent alternative to SAS which is of the same quality and performance level. Therefore, a substitution of SAS would require costly investments by downstream user sectors to convert a significant portion of product portfolios and would take considerable time (more than 10 years). Invariably this would be a case of regrettable substitution.

The classification of the SAS as STOT RE 1 would imply for companies producing and using the substance, additional re-labelling requirements for all plant and storage parts related to SAS products, re-labelling of packaging, re-design/adaptations to the safety data sheets, and integration of additional workplace safety measures on top of those already put in place by the sector and individual companies.

Additional regulatory requirements would increase re-localization of the industry out of the EU, in a similar dynamic to the one we are currently witnessing in many other market segments of industry. Furthermore, SAS manufacturers anticipate a **significant loss in demand of SAS** as a result of the classification. This will **impact both industrial and end-consumer applications of SAS** (food, cosmetics, pharma). In the latter, regulatory requirements are stricter, the impact will be direct and immediate.

In quantitative terms, the **total direct impact of a classification for the EEA is monetized as reaching over 840 million EUR,** consisting of:

- > 144 million EUR of economic impacts (EBIT loss) on active substance suppliers;
- > 90 million EUR of social impacts (i.e., unemployment in the EU-27);
- > 219 million EUR of economic impacts (loss in sales) on downstream users and end-users;
- > 195 million EUR of public health impacts for the society;
- > 192 million EUR of economic impacts from direct expenditures for consumers.

<u>This estimate should be considered as a minimum (lower boundary) of the expected impacts of a classification in the EEA silica supply chain.</u>[6] The above estimate covers only a small part of the value chain that would be impacted. In fact, apart from the producers of SAS, the downstream users of the substance who participated in the survey are only a fraction of the total number of impacted users. The latter underlie a combined estimated added value of more than 300 billion EUR per annum.

From a broader EU macroeconomic standpoint, a STOT RE 1 classification of SAS would undermine the confidence in the long-term performance of many formulations relying on SAS and significantly affect the ability for a wide range of products in high technologies industries to compete against non-EEA (mostly Asian) competition.

The exports outside the EEA represent a very significant share of the EEA based production. A CLP classification of SAS as STOT RE 1 in the EEA would not only disadvantage European markets in their trade and competition with the rest of the world, but also would hand over a dominant position in this important European-based market to the Asian competitors.

[6] Potential gains for suppliers of other ingredients have been already taken into account.

Thus, a STOT RE 1 classification of SAS would pave the way to an **increased imports from Asia and the Americas, and greater EU dependence on external actors in high-tech industries**. The EU is a worldwide technological leader in the application of SAS in energy-efficient "green" tyres, batteries, renewable energies. One of main drivers for innovation in the silica business is the rapid technological advancement motivated by strong and growing demand for lightweight, functional, robust highly functional materials in electronics, automotive, energy, food packaging, construction, and other industries. A STOT RE 1 classification of SAS would compromise **sustainability and innovation goals in a wide range of strategically vital sectors, including automotive, energy production and consumption.**

Based on the above evidence-based considerations, this report concludes that a CLP classification of SAS as STOT RE 1 would have disproportionate negative impacts on the European economy, innovation, and society overall.

SENSITIVITY IMPACT ANALYSIS[7]

The results of this report are based on a potential re-classification of SAS as STOT RE 1. Based on data collected as part of this study and assumptions presented in this report, it is assumed that a decline in demand for SAS combined with adverse effects on consumer and user perceptions would mean the loss of sales for downstream users. This loss is assumed to be minimum 10% (**conservative assumption**).[8]

However, a **classification of SAS as STOT RE 1 could also be a pre-cursor of even more serious consequences over time in the light of the EU Chemical Strategy for Sustainability (CSS)**, and in particular in the context of the extension of the Generic Risk Approach (GRA).[9] According to the CSS Communication, changes in the GRA will result in the banning of certain substances in consumer and professional uses. Once substances have been through the process of harmonised classification, substances, mixtures and possibly articles containing the CLP-classified substances will be affected by generic restrictions. A STOT RE 1 classification may not immediately lead to bans. However, if the GRA would effectively be implemented, **multiple products which utilize SAS could indeed be subject to generic restrictions and bans in the short to medium-long term**.

In the light of these far-reaching consequences, we need to take into account more extensive impacts to reflect a restriction scenario rather than a 'mere' classification. In consideration of the potential restrictions connected to the implementation of the Generic Risk Approach under the CSS, higher percentages are used for the estimation of the monetised socio-economic impacts. Notably, **the economic fallout of a partial restriction would rather fall within the spectrum of a 20%, if not 30% or 50% reduction in current SAS/SAS-based products demand.**[10] **The total economic impacts would therefore be: 1.68 billion EUR, 2.5 billion EUR or 4.2 billion EUR** respectively**.**

Evidently, these are still conservative estimates of the potential impacts for the SAS-based supply chain. The largest impacts would be suffered downstream in the supply chain, at the level of the manufacturers of finished products. The survey we have conducted cover only a smaller fraction of those, and the results downstream are rather presented as a descriptive statistic of the consequences of this regulatory process for the surveyed companies.

[7] Sensitivity analyses are best defined as "*the study of how the uncertainty in the output of a model can be apportioned to different sources of uncertainty in the model input*". (Saltelli, A., 2002. Sensitivity analysis for importance assessment. *Risk analysis*, *22*(3), 579-590). In other words, sensitivity analysis determines how different values of an independent variable (in this case, the 10% loss in demand assumption) affect a particular dependent variable (i.e., the economic impacts).

[8] The academic economic literature lacks studies on the impact of harmonised classifications on the economy. Therefore, to estimate the economic impacts of this policy option (viz., the potential harmonised classification of SAS as STOT RE 1), we made reference to two previous studies (Ricardo Energy & Environment, 2021; RPA, 2017). With the understanding that the conclusions of such studies (particularly the so-called 10% assumption) are downward estimates in this particular case, given the widespread use of SAS in strategically important industries. Hence the need to show what would happen in our economic model if this 10% assumption were enlarged.

[9] European Commission, 2023. https://ec.europa.eu/docsroom/documents/53078

[10] The GRA concept would be implemented through REACH Restrictions, in particular under Article 68(2) of REACH, and sectoral legislation. Thus, even certain applications would be excluded from a restriction, which is the reason why it is not possible to say with certainty that 100% of the demand for SAS-based products would be lost, the potential economic impacts for the SAS-based value chain would still be extensive. Given the lack of specifics, the assumption for this sensitivity analysis is that up to a maximum of 50% of the turnover of companies operating in the value chain would be lost.

2. AIMS AND SCOPE OF THE SEA

2.1. Purpose, scope, and methodology of SEA under CLP

In July 2021, the evaluating Member State Competent Authority (eMSCA) of the Netherlands issued an evaluation report on Synthetic Amorphous Silica (SAS) under REACH Art. 48.[11] In the report, the eMSCA concluded that there is sufficient ground to start the process for harmonised classification and labelling for the endpoint specific target organ toxicity - repeated dose toxicity (STOT RE) (lung/respiratory tract). The RIVM announced in March 2022 that the proposal will be Cat 1 for the substance CAS 7631-86-9.[12]

This ex-ante Socio-Economic Analysis (SEA) aims to identify and to assess in both qualitative and (when feasible) quantitative terms the socio-economic impacts that are expected to occur in case of a CLP classification of SAS as STOT RE 1.

This SEA provides information and estimates, by *ex-ante* describing the main potential socio-economic consequences expected along the relevant supply chains connected to SAS as well as society at large in the event of a classification for SAS as STOT RE 1, as compared to the baseline scenario.

This SEA focuses on the EEA market, and on the relevant downstream supply chain connected to use of SAS. The results are based on information and data gathered from manufacturers and suppliers of the substance (SAS), as well as downstream user manufacturers, operating in several key industries for SAS.

An extensive survey has been conducted along the supply chain in the EU, by providing a detailed questionnaire to gather information and data from multiple key actors likely to be affected by a STOT RE 1 classification of SAS in the EU. Complementary to the questionnaire, an online survey and targeted interviews were performed with users of SAS based products in key target industries such as automotive (especially tyre manufacturers), construction, food, animal feed, pharmaceuticals, electronics, and personal care (hereafter ‘downstream users’).

The participating companies have provided socio-economic data in view of extrapolating, where possible, the impacts for the whole market in a conservative approach, as further detailed below. **The estimates reported in this socio-economic analysis should therefore be considered as a minimum (lower boundary) of the expected impacts of a CLP classification of SAS as STOT RE 1.**

[11] https://echa.europa.eu/documents/10162/5f238e67-e159-1fba-1f7f-23df7c25a4fb

[12] https://echa.europa.eu/nl/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1809d3513

The assessment has been conducted in accordance with the existing official guidance from ECHA under REACH.[13] ECHA has already developed a solid methodology for conducting socio-economic assessments in the context of the REACH Regulation, with the support of a dedicated committee (Socio-Economic Assessment Committee – SEAC). More specifically, this methodology is consistently applied for REACH applications for authorization, and REACH restrictions for Substances of Very High Concerns (SVHC) with a view of forecasting through the SEA the impacts of the different regulatory options. Despite being different regulatory frameworks, in practice, a STOT RE 1 classification of SAS under the CLP would trigger similar socio-economic consequences along the supply chain, that can be assessed using the same methodology developed by ECHA for REACH authorizations and restrictions.

In the spirit of consistency between EU regulatory processes, bridging ECHA's methodology of socio-economic assessments between REACH and CLP seems to be the most logical, scientific, and comprehensive approach to assess the socio-economic consequences of this regulatory process (CLP).

From a geographical perspective, this analysis focuses on the European Economic Area (EEA) territory, comprising the European Union (EU-27), Iceland, Liechtenstein, and Norway. A specific time horizon needs to be set for this SEA. For the purposes of estimating economic impacts, it has been decided to use a 4-year time horizon, starting from the year 2024, which is a time period suggested by SEAC when there is no alternative available in general (SAGA).[14, 15]

Future monetary values have been estimated by using the concept of net present value (NPV), adopting a 3% annual discount rate, which is the standard discount rate, adopted by the European Commission and European agencies (e.g., ECHA) in impacts assessments.[16] All monetized values have been adjusted to a base year, assumed to be 2022. Information and data have been aggregated and anonymized. Statements and estimations from the participating companies are as close to real data or perception of future changes as possible.

2.2. Overview and importance of SAS in the EEA

2.2.1. General overview of SAS sectorial applications

Silicon dioxide (SiO_2) is an important material solid in the Earth's crust, and comprises the two most abundant elements in Earth's crust, silicon, and oxygen. SiO_2, as such, is by far the most abundant component of Earth's crust, mostly found as crystalline quartz. It is estimated that almost 59% of the mass of Earth's crust – the layer which extends about 30 to 40 km below the surface – is made of

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[13] The ECHA Guideline for an SEA to be used in REACH Application for Authorization is available at: https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e.

[14] ECHA, 2021. SEAC's approach to assessing changes in producer surplus. Available at https://echa.europa.eu/documents/10162/0/afa_seac_surplus-loss_seac-52_en.pdf/5e24c796-d6fa-d8cc-882c-df887c6cf6be?t=1633422139138

[15] https://echa.europa.eu/documents/10162/13637/ec_note_suitable_alternative_in_general.pdf/5d0f551b-92b5-3157-8fdf-f2507cf071c1

[16] European Commission, 2021. Better Regulation Guidelines and Toolbox. https://commission.europa.eu/document/download/9c8d2189-8abd-4f29-84e9-abc843cc68e0_en?filename=br_toolbox-nov_2021_en.pdf

silicon dioxide, which is the main constituent of more than 95 percent of the known rocks on Earth.[17] Not to mention the wide presence of SiO_2 in the deserts, the soil and in the atmosphere.

While crystalline quartz is a common mineral found in the Earth's crust, amorphous silica is also present in nature, although in quantities smaller than the crystalline quartz. As such, amorphous silica is a key structural element in many plants such as rice, wheat, or barley, and in diatoms, whose fossil remnants are behind the most abundant natural amorphous silica, diatomaceous earth or diatomite.

Synthetic amorphous silica (SAS) is the manufactured amorphous form of SiO_2. SAS in the solid form of pyrogenic (fumed), precipitated, gel or, in the liquid form of colloidal silica, have been produced and marketed for decades without significant changes in its physicochemical properties.

SAS represents a group of nanomaterials (NMs) manufactured either by thermal (pyrogenic silica) or wet route (includes precipitated silica, silica gel and colloidal silica). In the initial particle formation step, primary particles with dimensions less than 100 nm are formed by nucleation, coagulation and coalescence.[18] By covalent bonding, **these particles form indivisible units**, also known as aggregates, with external dimensions typically above 100 nm. These aggregates, composed of particles which are bound together via strong chemical links, combine to form agglomerates in the micron size. The agglomerates are characterised by reversible weak forces (i.e., attraction forces and hydrogen bridges) between the different particles/aggregates.[19]

Based on the method of production, different forms of SAS products with diverse functions and applications are produced. There are two main production routes: the so-called "thermal route" producing the pyrogenic type of silica, commonly known also as **fumed silica**, and the wet route producing **precipitated silica, silica gel** and **colloidal**.

SAS powders are placed on the market as micron-sized agglomerates with an internal structure in the nanoscale. This is true for all currently known SAS products in powder form, independent of manufacturer, process and trade name. The only exception is colloidal silica, which is traded as aqueous preparations of nanostructured material.[20]

These four main SAS products account for the vast majority of the applications of silica in the EEA as well as worldwide. Other process technologies exist (e.g., natural source) but represent a very marginal part of the silica business.[21]

[17] Encyclopædia Britannica. Retrieved September 29, 2022, from https://www.britannica.com/science/silica

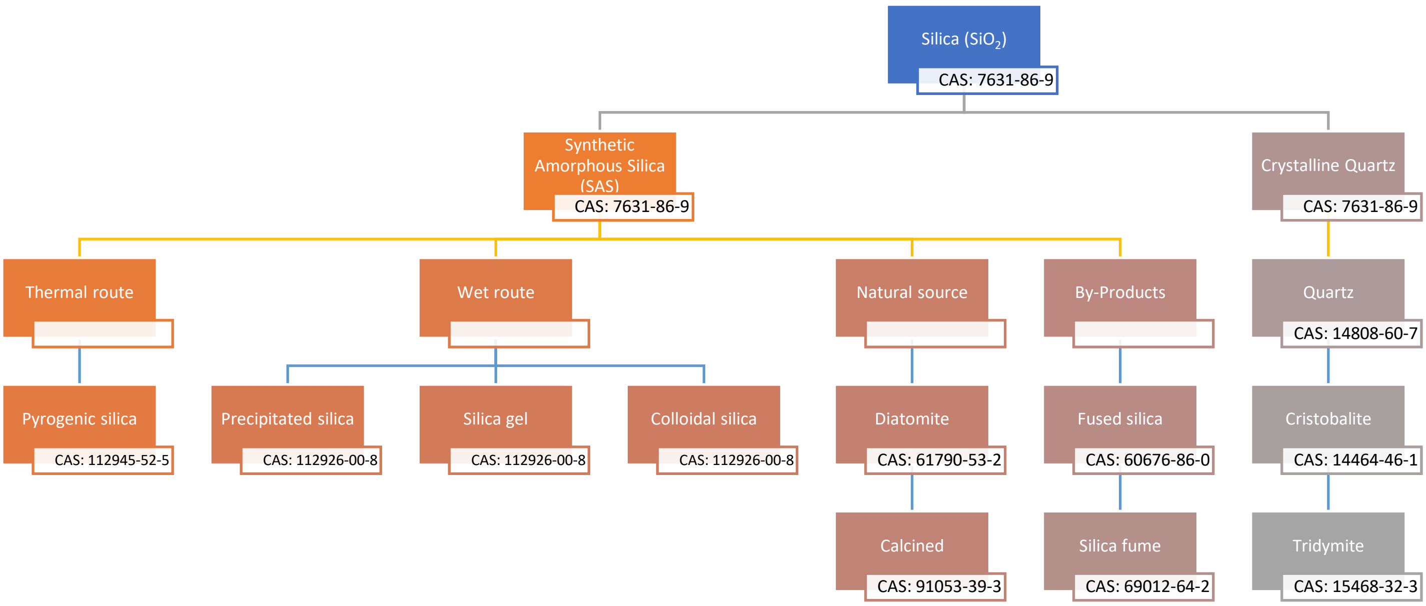
[18] See https://www.asasp.eu/index.php/about-silica/manufacture.

[19] Walter, D., 2013. Primary particles–agglomerates–aggregates, in DFG (ed.). *Nanomaterials*, 9-24.

[20] See https://www.asasp.eu/index.php/about-silica/manufacture.

[21] For the purpose of this report, only the SAS and its by-products (pyrogenic, precipitated, colloidal silicas and silica gels) are investigated.

Picture 1. Overview of silica types and CAS numbers[22]



Thermal route

Pyrogenic silica, or fumed silica, (CAS: 112945-52-5) is produced via the so-called thermal route, by combustion of a chlorosilane in an air-hydrogen flame at temperature between 1200-1600 °C in a continuous operating process. Properties are controlled by varying process parameters, such as feedstock, flame composition and flame temperature.[23] As the particles cool down, they form three-dimensional aggregates.[24, 25]

Wet route

Precipitated silica (CAS: 112926-00-8) is produced by reaction of alkali metal silicate solutions (such as sodium silicate solution) with mineral acids in water. The reaction characteristics are varied to precipitate silicas of different particle sizes, porosity, and surface characteristics. The suspension generated from precipitation is filtered. Precipitated silica is washed and dried, and can be subsequently milled and granulated.

Silica gel (CAS: 112926-00-8) is similarly produced by the reaction of alkali metal silicate solutions and a mineral acid at higher concentrations. The process is ending in a solid form which is washed, aged then dried and typically milled to the targeted particle size. Reactant concentration, temperature, pH, electrolyte concentration, time of aging, atmosphere, and mechanical pressure affect the final

[22] Fruijtier-Pölloth, C., 2012. The toxicological mode of action and the safety of synthetic amorphous silica—A nanostructured material. *Toxicology*, *294*(2-3), 61-79.

[23] OECD, 2016. Silicon dioxide: summary of the dossier. Series on the Safety of Manufactured Nanomaterials No. 71. Available at https://one.oecd.org/document/ENV/JM/MONO(2016)23/en/pdf

[24] Encyclopædia Britannica. Retrieved September 29, 2022, from https://www.britannica.com/science/silica.

[25] See https://www.asasp.eu/index.php/about-silica/manufacture

product. Gels can also be produced from colloidal silica or by the hydrolysis of silicon compounds such as silicon tetrachloride or ethyl silicate. In the latter case, pure, dense gels can be formed.

Finally, the *colloidal silica* (CAS: 7631-86-9) is a dispersion of amorphous silicon dioxide (silica) particles in water. These amorphous silica particles are produced by polymerizing silica nuclei from silicate solutions under alkaline conditions to form nanometre sized silica sols with high surface area. There is no danger from inhalation toxicity because the substance is sold and used in liquid form (in water).

As mentioned above, different methods of production (e.g., precipitation, high temperatures) produce different sets of product properties. For example, precipitated silica is used as a reinforcement and free flow additive, pyrogenic silica has better thermal stability and chemical purity, and thus performs better as a rheology control agent, while colloidal silica is more versatile and highly tailored to the customers' end use foreseen for the product.

At present, the use of silica is increasingly important in synthetic resins, plastics, lacquers, vinyl coatings, varnishes, adhesives, paints, printing inks, silicone rubber, fillers in the rubber industry, tyre compounds, insulation material, additive to coatings, as free-flow and anti-caking agents in powder materials including food, as toothpaste additives, cosmetics, pharmaceuticals, as liquid carriers particularly in the manufacture of agrochemicals and animal feed, and foods.[26] Moreover, SAS is increasingly used in strategic fields such as diagnostic and biomedical research such as cancer therapy, DNA delivery, and enzyme immobilization.[27] This multitude of downstream user sectors potentially impacted by a CLP classification of SAS as STOT RE 1 represent a value of over 300 billion EUR per annum. The overall impact of a classification on this 300 billion EUR market will be very significant (cf. Section 4.3 of this report).[28]

2.2.2. Market trends

More than 70 years have passed since the first introduction of SAS on the market. Nevertheless, the demand for SAS is still growing at a consistent rate.[29] The reason for this consistent growth in demand (and use) lies in the wide range of functions delivered by silica and its specific structural appearances as SAS. The data on the usage show that the substance is not at the end of its product life cycle, but rather its use is increasingly important for a number of strategically or economically important and emerging industries.

[26] Fruijtier-Pölloth, C., 2012. The toxicological mode of action and the safety of synthetic amorphous silica—A nanostructured material. *Toxicology*, *294*(2-3), 61-79.

[27] Barik, T.K., Sahu, B., Swain, V., 2008. Nanosilica—from medicine to pest control. *Parasitology research*, *103*(2), 253-258.

[28] Eurostat, 2022. Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E). Retrieved on 7 October 2022 from: https://ec.europa.eu/eurostat/databrowser/view/SBS_NA_IND_R2__custom_3557579/default/table?lang=en (NACE codes = "C109", "C17", "2030", "C21", "C221", "C222", "C2361", "C272"; Geographical entry = "EU27"; Time = "2019"; Economic indicator = "Value added at factor cost").

[29] Estimates in this section are based on aggregated data from the survey, SAS producer companies' Intelligence gathering, interviews with interested market players, and desk research.

Overall, the silica market can be sorted into two categories. On the one hand, SAS products benefit from the high demand in high volume markets in consumer-far applications. This is, for example, the case for precipitated silica in the automotive segment. More than half precipitated silica is found in the automotive industry. Its reinforcement and elongation properties make SAS indispensable for the manufacturing of energy-efficient long-lasting tyres. As a result, the demand for silica from the rubber industry has experienced a boost in the last 20 years.

On the other hand, pyrogenic silica, colloidal silica, and silica gels, are lower in volume but provide high value specialties. These three SAS products cannot be defined as commodities, but rather they are highly specialised raw materials which can be tailor-made to the end use foreseen for the product (customers' needs) and used in a wide range of chemical manufacturing processes. Thus, **the high value (and price) derives from tailored high-end applications**.

For example, silica gels are typically used in the food industry for beverage clarification (e.g., in beer and wine), as a desiccant and as an anti-caking agent. Typical applications range from industrial scale (e.g., silica gels used as a matting agent in paints and coatings) to highly sophisticated uses in the pharmaceutical industries, such as purification agent in the manufacturing process of vaccines, including COVID-19 vaccines' production.

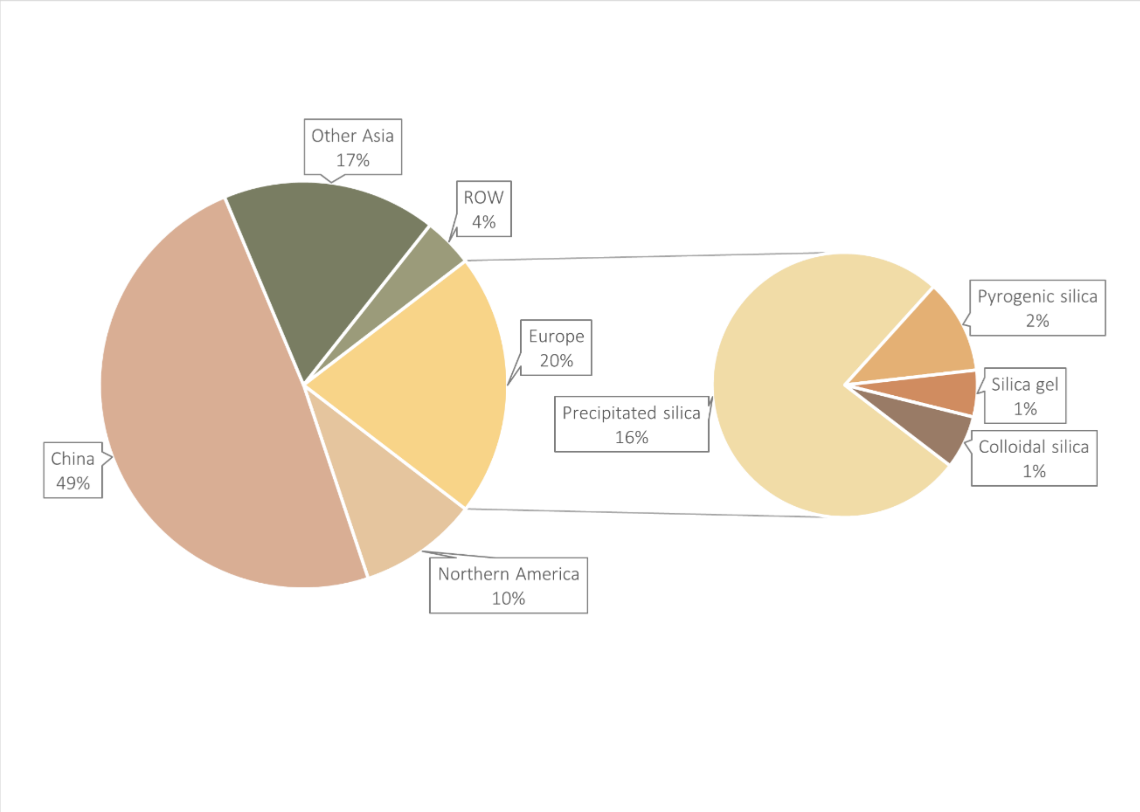
Given the specialty characteristics of these types of silica, they are smaller in volume compared to the high-volume market for precipitated SAS, but relatively high in value. This is because customers using these high-performing raw materials are willing to pay a higher price to tailor them to their needs in terms of function delivered, performance, and compatibility with other ingredients.

Overall, the European market is paramount for SAS production. Around 840,000 tons are produced every year in the EEA (2022 estimates). Picture 1 presents both the global and European level breakdown of the SAS production. Europe accounts for 20% of the world's production of SAS. As such, **the European market is the second largest in the world** behind China.

This makes the European region a **net exporter** of SAS products, especially precipitated and pyrogenic silicas. Even if imports into the EEA are equal to about one third of domestic production (32%), the EEA produces high quantities of SAS and exports to non-EEA countries are a significant business for SAS suppliers. It is estimated that almost half of the EEA production (45%) is exported outside the EEA.

The sections below describe the market trends and applications for the four SAS products. Each section focusing on a different SAS product. Figures and estimates in this section are based on a combination of aggregated data from the survey, SAS producer companies' Intelligence gathering, interviews with interested market players, and desk research.

Fig. 1. Global SAS production breakdown by volume[30]



Precipitated silica

Precipitated silica covers the higher share of the EEA market. In 2022, the total EEA production was estimated in the range of 640,000 to 685,000 tons. This is equal to approximately 22% of world's demand (note China alone covers almost one third of the global demand for precipitated silica). Thus, **SAS is strategically important for the European market and vice versa the European market represents a considerable portion of the silica market**. The demand for precipitated silica experienced an average growth rate of 3% in the last five years, and it is expected to grow consistently over the next five years.[31] This estimation is in accordance with public market studies.[32]

[30] Estimates based on aggregated data from the survey, SAS producer companies' Intelligence gathering, interviews with interested market players, and desk research. Data have been processed by the authors of this report and presented in the graph.

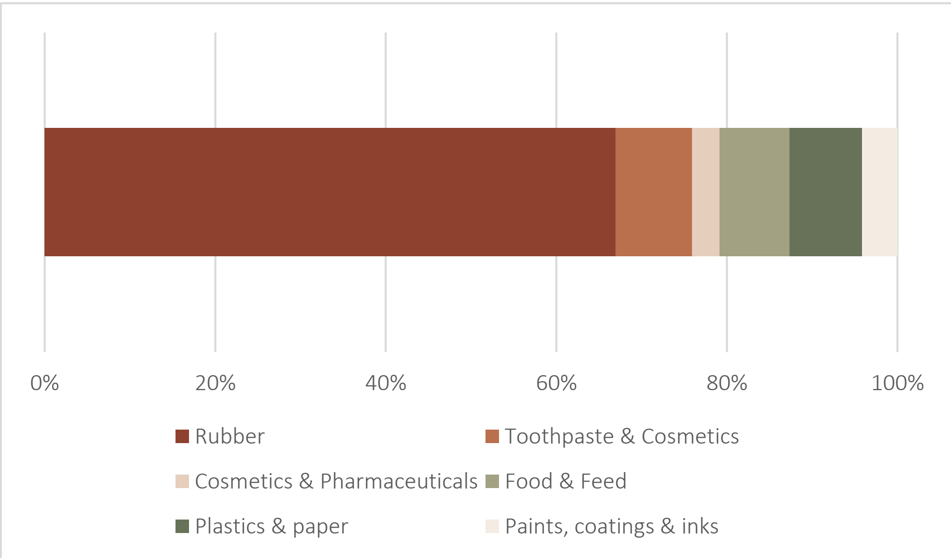
[31] Estimates based on aggregated data from the survey, SAS producer companies' Intelligence gathering, interviews with interested market players, and desk research. Data have been processed by the authors of this report.

[32] See, for example, S&P, 2021. Chemical Economics Handbook – Silicates and Silicas. Available from https://www.spglobal.com/commodityinsights/en/ci/products/silicates-chemical-economics-handbook.html.

As further detailed below, the reinforcement performance is the main driver for the global demand for precipitated silica. Within the rubber industry, which alone accounts for 67% of the EEA demand for precipitated silica (i.e., the darkest blue coloured area in Fig. 2), the tyre manufacturers drove most of the demand for the production of energy efficient tyres.[33] The remainder is covered by other non-tyre rubber uses. Typically, these include but are not limited to footwear and silicone-based magnetorheological grease (MRG), a new type of smart magnetorheological materials that experiences a high off-state viscosity, and thus with huge engineering and industrial application prospect, from paints and coatings to seismic controllable dampers.

These figures showcase the growing interest and use of SAS in the EEA as well as worldwide. Breaking down these figures by the relevant markets and applications, the resulting picture highlights the importance of precipitated silica for the rubber market, and in particular tyres, the cosmetics, notably the toothpaste market, and for the nutrition & health industry, consisting of food, agricultural feed and pharmaceutical markets. Other industrial applications include paper, plastics, paint, coatings, adhesives and inks, as well as a wide variety of other industrial processes where silicas are mainly used as a high-performance additive (i.e., carrier, free flow, anti-caking, anti-static agent).

Fig. 2. Precipitated silica European demand by end user market



Pyrogenic silica (fumed silica)

The world pyrogenic silica consumption was estimated at approximately 300,000 tons (rounded) in 2021, with growth forecast at 2.3% annually between 2021 and 2026. **The EEA represents the market leader for the production of pyrogenic silica.** Approximately 100,000 tons of pyrogenic silica is produced in the EEA every year. As such, the EEA accounts for one third of the global production of pyrogenic silica.

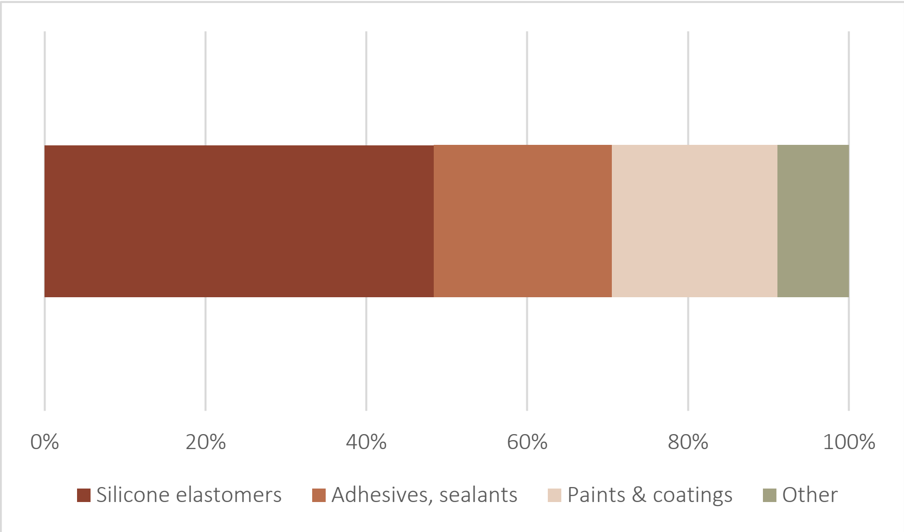
[33] Ibid.

Hence, **the EEA is a net exporter of pyrogenic silica**. Approximately 20% of the EEA production of pyrogenic silica is exported outside the EEA, not counting the growingly important export of pyrogenic silica contained in silicone polymers.

In 2021, the EEA consumption was estimated at 78,000 tons. As visually demonstrated in Fig. 3, almost half of the demand is driven by silicone elastomers, where pyrogenic silica is mainly used for its excellent elastomer reinforcement properties. Indeed, pyrogenic silica is perfect for reinforcement of rubber, especially silicone rubber.

The remaining market demand is covered by adhesives, sealants, paint, and coatings applications, where pyrogenic silica is mainly used as a thickening agent and for its rheology control technical performance because of its fractal structure.

Fig. 3. Pyrogenic silica European demand by end user market[34]



Silica gel

The global market for silica gels is estimated at approximately 550,000 metric tons with an average annual growth forecast at 3% over the next five years. The steep growth in demand for silica gels is primarily owing to China's growing demand for low-cost adsorbents and desiccants. About 60% of the global demand is driven by the use of silica gels as desiccants and as adsorbent in cat litter markets. The low value market is mainly dominated from Asian suppliers. China is the largest producer and exporter of silica gel, followed by South Korea and other Asian key markets.

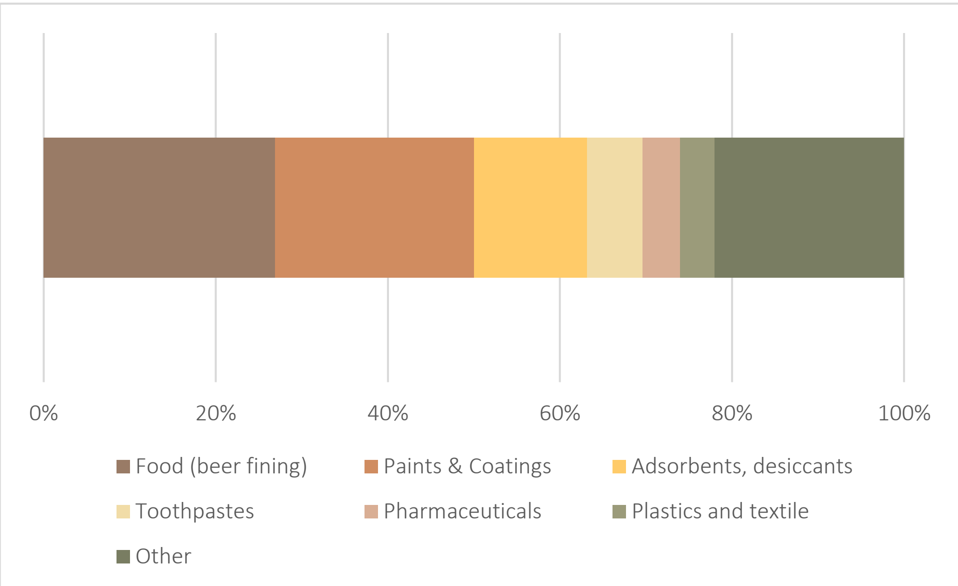
[34] SAS industry estimation.

The EEA production represent only a minor share of the global demand (<10%). The reason is that silica gel produced and consumed in Europe is significantly different to the one produced and imported from Asia. Despite the low volume of the substance, **silica gel is a major driver for specialty silica growth**. **The silica gel produced in the EEA is a high value specialty used in a wide range of high-end applications** (Fig. 4). As mentioned above, the high price for this substance derives from highly specialised tailored applications. Indeed, silica gels produced in the EEA are mainly highly specialised raw materials which can be tailor-made for the end use foreseen for the product and used in a wide range of chemical manufacturing processes.

Globally, the three largest end-use markets, namely paints and coatings, plastics films, and beverage, adsorb between 100,000 to 120,000 metric tons every year. As visually shown in Fig. 4, in the EEA, there is no one market segment that stands out above the others. About 25-30% of the demand is driven by the use of silica gels in food, especially in beer processing applications. Beer stabilising silica gels comprise highly selective adsorbents that are specifically manufactured for breweries to reduce the level of haze forming ingredients in finished beer.

The remaining demand is driven fairly equally by a wide range of other specialised tailored applications that range from industrial scale high end market with very specific requirements (e.g., silica gels used in toothpastes, as a matting agent in paints and coatings, antiblocking agent and adsorbent in plastics) to sophisticated industrial applications with special technical know-how (e.g., anti-corrosion agent in coatings, pharmaceutical tableting applications, specialty desiccants in biodiesel).

Fig. 4. Silica gels European demand by end user market[35]



<u>Colloidal silica</u>

[35] SAS industry estimation.

Colloidal silica is the only form of SAS which is sold in highly purified liquid form. As a consequence, the market for colloidal silica is extremely regionalised. In other words, transportation costs are extremely high for these SAS products and both imports and exports represent a minor fraction of the production worldwide, and accordingly in the EEA.

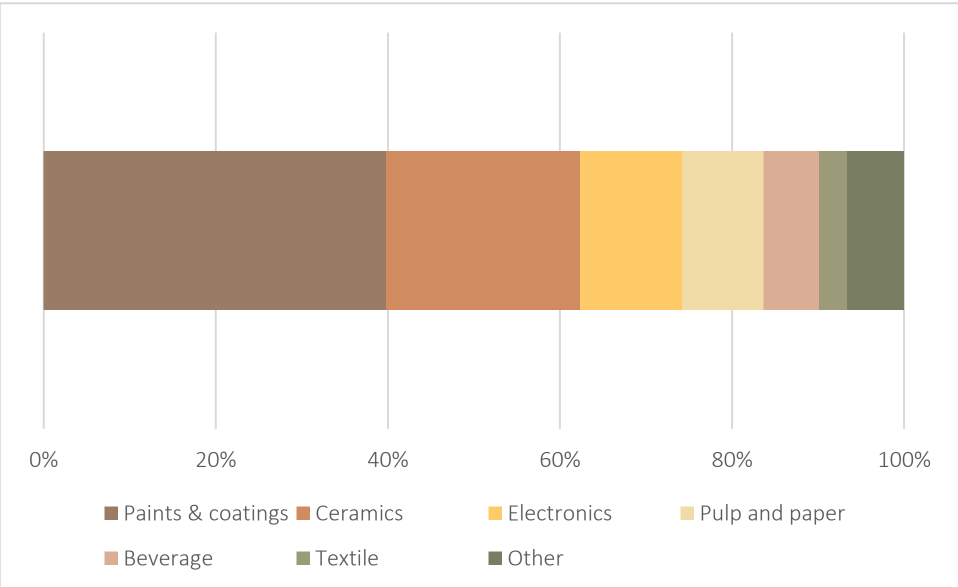
The EEA production nearly equals its consumption, which is mainly driven by the paint and coatings, and ceramics applications. Indeed, colloidal silica act efficiently as a binder agent.

In paints and coatings, it helps reduce alkalinity, lowering the pH and solubility of the binder, hence improving the weather resistance of the paint. In ceramics applications, colloidal silica is a liquid binder used with aggregates to create a ceramic shell in the casting process of a wide range of metal alloys. Indeed, colloidal silica systems allows to form a long-life ceramic slurry with a large range of refractory materials due to their stability and versatility.

Colloidal silica consumption is also growing in pulp and paper mills as part of a retention/drainage aid system with a polymer. Nevertheless, the leading growth market is in the electronics/semiconductor industry as a polishing agent. Colloidal silica has a much smaller particle size and a lower tendency to clump. Given its chemical structure, it is the optimal solution for chemical mechanical planarization (CMP) slurries, mainly used by the electronics industry for the production of chips and printed circuit boards (PCB). These two segments are the main driver for colloidal silica accelerating growth in the past ten years.

Although due to the limited amount of colloidal silica required for the manufacture of chips and PCBs, electronics is one of the most interesting and growing segments. In the next few years, it is expected that the market share of electronics within the of colloidal silica market will grow considerably, especially in the light of the efforts of the European Commission and the EU Member States to reinforce the whole EU chips value chain (e.g., EU Chips Act).

Fig. 5. Colloidal silica European demand by end user market



2.2.3. Policy trends

The transition towards a sustainable and circular economy is the first political priority of the European Commission in the 2019-2024 period.[36] This includes in particular the gradual reduction of GHG emissions (-55% net in 2030 compared to 1990 and net-zero in 2050),[37] the transition towards a circular model ("take-make-use-reuse") with longer product life cycles,[38] and a more sustainable use of chemicals at large.[39] Those policy objectives are being translated into new regulatory obligations and financial incentives as part of the European Green Deal strategy.[40]

The use of the SAS contributes to the achievement of all these goals. In fact, SAS products are underlying a number of strategically important industries for the reduction of CO2 emissions and the achievement of a green and digital transition.

Typical examples are the uses of SAS, particularly SAS-based silicone elastomers in the production of energy from renewable sources. In this context, and in line with the objectives set out by the European Commission in the EU Green Deal, **the role of silica in renewable energies is paramount to achieve a transition to a climate-neutral society**.

<u>Green policy trends for the automotive industry</u>

The transport sector is under the spotlight of the EU Green Deal with the general objective to achieve a 90% reduction of transport GHG emissions by 2050.[41] The increase in the number of vehicles on the road and the growing demand for transportation services has led to a significant increase in the emission of greenhouse gases from the transport sector.

Transportation is currently the second-largest source of GHG emissions in the EU. Greenhouse gas emissions from the transport sector account for 27% of total EU domestic emissions.[42] In this respect, road transport constitutes the highest proportion of overall transport emissions: up to 77% of all EU transport GHGs in 2020 were emitted by the road transport.[43]

Among other things, the green transition in the automotive industry is also driven by the rapid technological advancement in the tyre industry. Innovation in this field led to a whole new breed of

[36] Ursula von der Leyen, *Political Guidelines for the next European Commission 2019-2024*, 2019.

[37] Regulation of the European Parliament and of the Council establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law').

[38] European Commission, *A new Circular Economy Action Plan*, COM(2020) 98, 11 March 2020.

[39] European Commission, *Chemicals Strategy for Sustainability*, COM(2020) 667, 14 October 2020.

[40] European Commission, *The European Green Deal*, COM(2019) 640, 11 Dec. 2019.

[41] See, for example, the EU Green Deal Communication https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF

[42] European Environment Agency (EEB), 2020. https://www.eea.europa.eu/data-and-maps/indicators/transport-emissions-of-greenhouse-gases/transport-emissions-of-greenhouse-gases-12

[43] European Environment Agency (EEB), 2022. https://www.eea.europa.eu/ims/greenhouse-gas-emissions-from-transport

SAS-based energy-efficient tyres which allow to reduce significantly fuel consumption and therefore CO2 emissions.[44, 45]

In addition, SAS also help preserving the integrity of the rubber, which can be reused or recycled over time, hence extending tyres' service life and further reducing the need for new primary raw materials. Thus, the deployment of SAS-based tyres allows to cut down the overall energy consumption of the global tyre production. **Overall, SAS can help reduce the climate and environmental footprint of the automotive industry both in the EU and globally. This objective is in line with the goal of transitioning to a more sustainable and low-carbon economy (green mobility), as outlined in the European Union's Green Deal and other EU climate policies.**

This is only one of the different ways silicas are contributing to the decarbonisation of the automotive sector. The other major contribution of SAS to the decarbonisation of the automotive sector is through batteries.

In the context of the EU Green Deal, the European Commission has shared its intent to ensure that batteries placed on the EU market are more sustainable, high-performing, and safe all along their entire life cycle. According to the European Commission, this means that batteries should be produced with the lowest possible environmental impact, using materials obtained in full respect of human rights as well as social and ecological standards.[46]

Batteries are the key component of (e.g.,) electric cars and vans. Since transport still is heavily reliant on fossil fuels and one of the main pollution sources, with an associated major impact on economy and the environment, low- and zero- emission vehicles can have a positive impact on Europe's decarbonisation efforts.[47]

SAS is extremely important for batteries used in electric vehicles (EV) and energy storage in general.[48] The production of batteries in Europe is paramount for the Electric Vehicle (EV) deployment in the European Union (EU). The latter the cornerstone of the 'Fit for 55' package, a set of proposals presented by the European to make the EU's climate, energy, land use, transport and taxation policies fit for reducing net GHG emission by at least 55% by 2030.[49]

<u>Other policy trends</u>

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[44] See, for example, OECD, 2014. *Nanotechnology and Tyres: Greening Industry and Transport*, OECD Publishing, Paris, https://doi.org/10.1787/9789264209152-en.

[45] See, for example, European Commission Consumer's Guide to Energy-Efficient Tyres https://ec.europa.eu/energy/sites/ener/files/documents/FIN%20User%20guide%20-%20tyres.pdf

[46] See, for example, European Commission's press release of 10 December 2020. Green Deal: Sustainable batteries for a circular and climate neutral economy. Available at https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2312

[47] Tsakalidis, A., Thiel, C., 2018. *Electric vehicles in Europe from 2010 to 2017: is full-scale commercialisation beginning? An overview of the evolution of electric vehicles in Europe*, EUR 29401 EN, Publications Office of the European Union, Luxembourg, ISBN 978-92-79-96719-1, doi: 10.2760/8053, JRC112745

[48] See, for example, Rolison, D.R., Dunn, B., 2001. Electrically conductive oxide aerogels: new materials in electrochemistry. *Journal of Materials Chemistry*, *11*(4), 963-980.

[49] These include more ambitious targets for reducing the CO2 emissions of new cars and vans, a 55% reduction of emissions from cars by 2030; a 50% reduction of emissions from vans by 2030; and 0 emissions from new cars by 2035.

Other uses of SAS that help achieving sustainability goals include plastics, paint and coatings, pulp and paper, and textile. **As part of the EU Circular Economy Action Plan**, the European Commission is taking regulatory measures to **increase plastic recycling** and **the overall lifetime of plastic materials and products**.[50]

The use of SAS can help improve the toughness, strength and water resistance, as well as reduce thermal degradation and increase product durability for plastics and polymerised materials.[51] Therefore, **SAS can help mitigating the growing consumption for plastics products by preventing the degradation of the plastic's physical properties**.

Similarly, for the paint and coatings industry, the use of SAS as a rheology control agent helps increase product durability during storage. Water-based formulations, such as paints, must be stable during the entire preparation, storage, and transport phase so as to **avoid waste** and to **optimize energy consumption and the use of raw material resources**. Without the function delivered by silicas, a great amount of paint and coatings would be wasted.

Overall, there is a clear policy trend to expand product life duration in a growing number of sectors, so as to limit waste losses and primary raw material consumption, while decreasing the environmental and climate footprint of the manufacturing processes.

In this context, many of the industries that could be impacted by a potential STOT RE 1 classification play a pivotal role in the sustainability goals outlined by the European Union. In this sense, **the continued use of SAS is one of the contributors to the reduction of CO2 emissions and a transition to a more sustainable economy in a number of strategically key sectors. A potential STOT RE 1 classification is likely to impact innovation and sustainability goals in these sectors.**

[50] European Commission, *A new Circular Economy Action Plan*, COM(2020) 98, 11 March 2020.

[51] Ismail, H., Zaaba, N. F. 2014. The mechanical properties, water resistance and degradation behaviour of silica-filled sago starch/PVA plastic films. *Journal of elastomers & plastics*, *46*(1), 96-109.

3. OVERVIEW OF ALTERNATIVES

A comprehensive assessment of the status of the alternatives to SAS was performed as part of the SEA and data collection. Data and qualitative statements from 9 companies, producers of SAS in the EEA, have been aggregated and cross-checked with additional sources, including academic peer-reviewed studies, and reports.

The sections below provide a general overview of the alternatives (or lack thereof) to SAS in the market, including technical considerations, the EHS profile of potential alternatives, the functions delivered by SAS, and the challenges of substitution with alternatives.

3.1. Function and technical performance of SAS

3.1.1. Functions

SAS is not just a raw material used as a filler, but it is widely used as a high-performance additive in most of the applications. Depending on the reference processing system, i.e., whether it is powder processing or liquid systems, different functions are obtained.

Process additives for powder processing

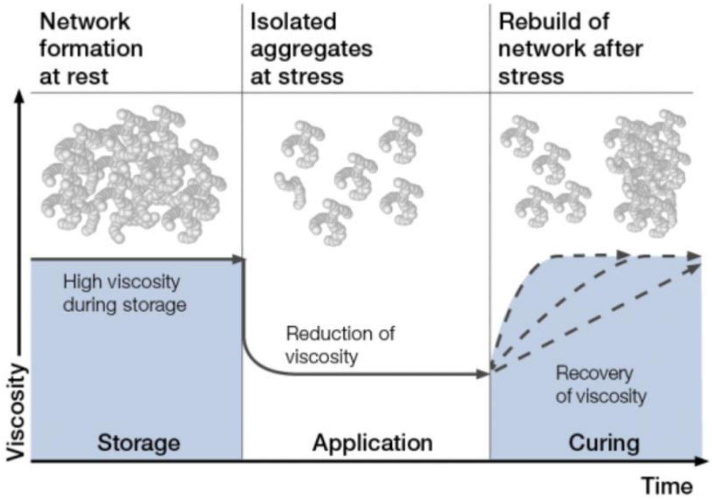
One of the main functions for which silicas are used is as a **free flow agent**. SAS is used as a process additive to facilitate the free flow as well as the distribution of dry powders. Many industry processes highly depend on this type of technical function delivered by SAS, including food, feed, pharmaceuticals, cosmetics, plastics.

At the same time, SAS products are also used as **anti-caking agents** and as an **anti-static agent**. Most of the technical powders (e.g., plastic powders) are non-conductive and thus take up charge. Indeed, when a powder flows, the contacts between the particles with the conveying material (such as pipes, blades, machine parts) create electric charges which lead to an electric charge build-up that strengthens the electrostatic cohesive interactions and significantly decreases the powder processability. Anti-static agents, such as SAS, are used to either manage static charges during various stages of processing or to provide long-term static protection based on end-use applications. The charge control of non-conductive powders is extremely important for toner applications (e.g., printers) where the charge powder electric charge build-up could be potentially very dangerous for consumers.

Process additives for liquid systems

On the other hand, silicas, especially *pyrogenic silica*, are also used as process additives for liquid systems. The use of SAS as a **rheology control agent** is key for (e.g.,) paint and coatings applications. The rheology describes the deformation and flow behaviour of all kinds of material. Thus, controlling the rheological properties is expressed in practical terms as workability of the liquid system. In other words, the structure viscosity impact of SAS in liquid coating formulations is key to retain an optimum rheology profile throughout their product life cycle (as show in Fig. 6). Indeed, during storage (at rest), settling is prevented because of the rheology control (the anti-settling effects help the uniform distribution of pigments in paints), while, in the application phase (when agitated), levelling and sagging behaviour are balanced. Once applied, the paint returns to its static phase and sticks to the surface.

Fig. 6. Structure viscosity impact of SAS in paints and coatings[52]



The rheology control is one of the main reasons why silica is also used, for example, in toothpaste. The rheological behaviour of consumer products like toothpastes is critical for stability, quality control, and sensory properties.[53] Hydrated silica helps increase the viscosity of the paste and ensure the shape retention of toothpaste ribbon on the toothbrush. Without rheology control, toothpaste would be unusable (i.e., it would be too liquid to remain on the toothbrush).

SAS is also used as a filler for the **reinforcement of polymers**. Additives such as SAS are widely used to reinforce polymers and improve properties like dimensional stability and scratch resistance. Indeed, without fillers, rubber or polymers would have no 'strength' and would behave more like a liquid. Typical application is the use of pyrogenic silica in the production of silicone elastomers.

In this context, fillers like carbon black increase the strength of the materials (for example, tyres). Unfortunately, carbon black is only used for reinforcement. On the other hand, SAS combines excellent elastomer reinforcement performance with very good elongation properties, which make it the number one solution to produce highly performing, more sustainable rubber products. The practical applications for this type of function provided by SAS include more sustainable tyres.

In the construction industry, pyrogenic silica is used as a reinforcement agent in high-performance concretes. Because of its chemical and physical properties, **pyrogenic silica ensures high strength and long-term durability by densifying the microstructure, reducing concrete permeability and**

[52] Source: https://www.wacker.com/cms/en-us/products/applications/industrial-coatings/rheology-control/rheology-control.html (Accessed on 14 February 2023).

[53] Ahuja, A., & Potanin, A., 2018. Rheological and sensory properties of toothpastes. *Rheologica Acta*, *57*(6), 459-471.

enhancing the cement paste bond to the aggregates, and thereby resulting in strength betterment.[54] High-strength concrete is a very economical material for carrying vertical loads in high-rise structures. Moreover, the reaction between pyrogenic silica and calcium hydroxide, released as the cement hydrates, offers a dense impermeable pore-like structure. As a result, the presence of SAS, in the form of pyrogenic silica, ensures permeability of the concrete, preventing concrete deterioration and corrosion in harsh environmental conditions, such as, for example, marine salts.[55] Silica containing concrete ensures high resistance to penetration by chloride ions. For these reasons, the use of pyrogenic silica in concrete for construction and the maintenance of existing infrastructures, such as bridges, is increasingly important.

An overview of the main industries and applications for silica is visually presented in Table 1.

Table 1. Summary overview of main applications and industries[56]

Pyrogenic silica End Market	Reinforcement	Rheology / Thickening	Thermal Insulation	Free Flow / Anti caking	Abrasion / Polishing	Carrier	Defoaming	High-temp. resistance	Purification	Adsorption	Transparency / Matting	Haptics/ Feel
Construction	X	X	X	X				X				
Automotive	X	X						X			X	X
Electronics	X	X			X			X			X	
Toothpaste		X			X							
Pharma		X		X		X						
Cosmetics		X		X	X	X						
Food & Feed				X		X	X		X			
Paint & Coatings		X									X	
Adhesives & Sealants		X					X					
Plastics	X	X		X				X		X		X
Pulp & Paper Industry							X					
Batteries	X	X	X					X				
Renewable Energy & High voltage industry	X	X	X					X				
Industrial processes		X		X			X					
Appliances	X	X	X	X		X		X				X
Textile	X	X					X					X
(Bio)Fuels									X	X		

[54] Oertel, T., Helbig, U., Hutter, F., Kletti, H., Sextl, G., 2014. Influence of amorphous silica on the hydration in ultra-high-performance concrete. *Cement and Concrete Research*, *58*, 121-130.

[55] Zhu, N., Jin, F., Kong, X., Xu, Y., Zhou, J., Wang, B., Wu, H., 2018. Interface and anti-corrosion properties of sea-sand concrete with fumed silica. *Construction and Building Materials*, 188, 1085-1091.

[56] Based on the data gathered and the results of the survey conducted in the context of this Socio-Economic Analysis.

As visually demonstrated in Table 1, SAS is also used for its **transparency** properties. A typical example of a SAS based finished products used by consumers in their daily life is rubber nipples for baby bottles. The transparency of these (and several other) products is ensured by SAS.

Further effects include chemical driven technical functions, such as **purification** (e.g., in beverages, including beer and wine, but also fuels), **absorptivity** (e.g., in plastics, biofuels, and natural gas), **catalytic activity**, **hydrothermal stability**, **surface energy**. In addition, SAS is also used for **anti-blocking** (e.g., in films for food packaging), **matting and flatting agent** (e.g., in paints and coatings), **thermal conductivity**, **heat resistance**, **electrical resistance**, **carrier capacity, anti-caking agent, excipient** (e.g., in feed & food, pharmaceuticals) and many other effects.[57]

The significant advantage of SAS with respect to potential alternatives is that SAS is typically able to cover several effects at the same time, providing a high-level performance and compatibility with other ingredients that other substances cannot provide.[58]

3.1.2. The Environment, Health, and Safety (EHS) profile of SAS

One of the typical raw materials for SAS production is sand, which corresponds to 27% of the earth crust building material, and thus the cheapest raw material source without reasonable shortness of supply or long transportation cost. Furthermore, the density of silica is low compared to most possible alternatives and the material mass contribution in the application is low. Thus, SAS as such does not lead to an increase in environmental emissions, beyond energy related ones.

Moreover, as highlighted in previous sections, **a significant proportion of silica in the EEA market is used in bound form and therefore does not generate exposure to people, animals or the environment**. In terms of workers exposure, occupational exposure limits and monitoring are already in place. The workplace exposure is negligible as all SAS based processes are mainly closed with the exceptions of the filling and dosing procedures. Also, the waste streams and by-products in the manufacturing process are limited.

Further, it is currently impossible to replace SAS with non-particulate (i.e., non-dusty) materials.[59] Even without considering the comparison of the differing technical performance, potential (less performing) alternatives for SAS products are generally powders or fillers which share similar physical properties. As shown by many animals' inhalation experiments and human experience,[60] all dusts carry the same principal risks (which is being managed by safety measures and risk management measures in workplaces). Therefore, the use of these alternatives in the place of SAS would not lead

[57] For further information, see, for example, Wohlleben, W., Punckt, C., Aghassi-Hagmann, J., Siebers, F., Menzel, F., Esken, D., Drexel, C.P., Zoz, H., Benz, H.U., Weier, A. and Hitzler, M., 2017. Nanoenabled products: categories, manufacture, and applications. *Metrology and Standardization of Nanotechnology: Protocols and Industrial Innovations*, 409-464.

[58] Based on the data gathered and the results of the survey conducted in the context of this Socio-Economic Analysis

[59] Ibid.

[60] See, for example, Tsuji, J.S., Maynard, A.D., Howard, P.C., James, J.T., Lam, C.W., Warheit, D.B., Santamaria, A.B., 2006. Research strategies for safety evaluation of nanomaterials, part IV: risk assessment of nanoparticles. *Toxicological sciences*, *89*(1), 42-50.

to real benefits to society, but a significant reduction of the technical performance (e.g., toothpastes, tyres, paint and coating, animal feed).

3.2. The Current Status of the Alternatives to SAS – Overall Lack of Alternatives Reported

Surveyed companies highlighted the lack of technically and economically feasible alternatives to SAS in the market that delivers the same performance at a competitive price.

Examples of a lack of viable alternatives

Specifically, in >95% of the applications, the versatility of the used silica is the key enabler for the application itself, either as processing additive or the performance additive that enables the performing properties. In this regard, alternatives can only serve as second-best options. Therefore, for performance properties in the application, the substitution with alternatives will always lead to a second-best solution that will not be competitive, neither in performance, nor in price.

For example, SAS is used in **tyres** to help reducing the rolling resistance. Carbon black can be used in tyres in substitution to SAS but does not offer the same product performance which is achieved by SAS. The reason is that while carbon black offers comparable reinforcement properties, SAS deliver a far better elongation performance making tyres more efficient in terms of rolling resistance and the energy loss as the tyre deforms against the road. Specifically, energy conservation improves fuel efficiency while rolling resistance accounts for 10-15% of fuel consumption in passenger cars but jumps up to 30% in heavy trucks. As tyres account for 20 to 30% of a vehicle's fuel consumption, choosing energy efficient tyres results in fuel cost savings.[61] All alternatives to SAS, including carbon black, would likely lead to an increase in fuel consumption and less safety performance of motor vehicles. Moreover, innovation in the tyre sector has led to the launch of energy-efficient tyres (sometimes called "green tyres"). These tyres currently cannot be viably produced without SAS. Therefore, sustainability goals in tyre production would be further compromised.[62]

In other sectors, such as **battery** production, SAS (in particular, precipitated silica) is a key component of Polyethylene Envelope (PE) type battery separators used in lead-acid batteries for automotive, industrial, and recreational applications. Battery separators are silica-filled polyolefin material, typically polyethylene, whose main function is to keep positive and negative electrodes apart to prevent electrical short circuits while at the same time allowing charge transfer. In this regard, precipitated silica is used for its ability to enable production of microporous battery separators with good electrolyte wettability and low electrical resistance, which are critical to battery performance. In addition, pyrogenic silica is used in the production of gel electrolytes in stationary lead batteries to increase the lifetime of the battery.

[61] https://ec.europa.eu/energy/sites/ener/files/documents/FIN%20User%20guide%20-%20tyres.pdf

[62] As part of the efforts of the European Commission under the umbrella of the Green Deal and subsequent strategies and policy implementation to make the EU's climate, energy, transport and taxation policies fit for reducing net greenhouse gas emissions by at least 55% by 2030, compared to 1990 levels.

Overall, it is expected that less performing alternatives to SAS would lead to a decrease in battery life and thus an increase in battery waste. Furthermore, there is no suitable alternative to SAS for battery separators. Batteries and battery separators are the key component of (e.g.,) electric cars, designated to help achieve the key goals of the Green Deal.[63]

Another example of the essential use of SAS is in **toothpaste**. SAS in the form of hydrated silica is currently used as cleaning agent in most of the fluoride and non-fluoride toothpastes in Europe. The primary function of hydrated silica in cosmetic toothpaste is to provide effective removal of dental biofilm and consequently reduce plaque formation, with minimal tooth damage, high compatibility, and flexibility, especially with fluoride compounds such as sodium fluoride (NaF), stannous fluoride (SnF2), sodium monofluorophosphate (SMFP) and amine fluoride (AmF). Hydrated silica also acts as a thickening agent (viz., it provides body and bulk to the toothpaste). For all these reasons, hydrated silica is key component for the majority of toothpastes: around 80% of toothpastes in the EU use silica as their cleaning agent.[64]

The majority of potential alternatives such as alumina, kaolin, perlite, phosphates such as dicalcium phosphate dihydrate (Dical), calcium pyrophosphate, sodium metaphosphate, and carbonates (e.g., calcium carbonate (chalk), sodium bicarbonate)[65] have significant compatibility issues with fluoride compounds (e.g., ionic fluoride and/or sodium fluoride) or stannous and/or zinc salts. In this context, SAS plays an important rule for teeth health and the prevention of caries, pain as well as sequelae resulting from the loss of teeth, as detailed further below (cf. Chapter 4.2). Likewise, it helps to save significantly on medical treatment costs to patients and countries' public spending.

Examples with potential substitutes for SAS

SAS is widely applied to processed foods and registered by the EU as a food additive with the code E 551.[66] It is used by the food industry to prevent poor flow, or "caking" (i.e., anti-caking agent), especially in powdered products. In food, SAS particles are also used as thickening agents in pastes, as a carrier of flavours, as well as for purification of beverages, the control of foaming or for other purification.[67]

SAS is used as a processing aid (filtering aid) for purification in beer and wine. Processing aids are defined as substances which are typically removed after treating the food or beverage except for technological unavoidable traces.

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[63] These include more ambitious targets for reducing the CO2 emissions of new cars and vans, a 55% reduction of emissions from cars by 2030; a 50% reduction of emissions from vans by 2030; and 0 emissions from new cars by 2035.

[64] Mintel, 2021. 10 Year Overview of the Toothpaste Market. Retrieved in August 2021 from Mintel database: https://www.mintel.com

[65] See, for example, Lippert, F., 2013. An introduction to toothpaste-its purpose, history and ingredients; in van Loveren C. (ed.), 2013. Toothpastes. Monographs in Oral Science. Basel, Karger 23, 1-14.

[66] European Union. Comission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. Off J Eur Union. 2012;2012(83):1–295.

[67] Winkler, H.C., Suter, M., Naegeli, H., 2016. Critical review of the safety assessment of nano-structured silica additives in food. *Journal of nanobiotechnology*, *14*(1), 1-9.

For food additives and processing aids, several nano-scaled materials could act as substitutes, but may lead to higher processing cost. However, in several of the uses, replacing the SAS with an alternative would lead to a significantly altered product for downstream users. Overall, **the expected impact is not only an increase in production costs (and eventually in the price paid by end consumers) but also potential loss of performance and thus overall business for a wide range of industries relying on SAS.**

For example, colloidal silica is used for purification in beer and wine. Potential alternatives are not as efficient as colloidal silica. Hence, more concentration of the substance needs to be used to achieve the same performance with more losses in beer.

In the **animal feed sector**, many of the current antibiotic replacements use SAS as an additive. In this context, most of the alternatives would decrease the shelf-life and require significant recipe changes, with high price effects and costs. However, no valid alternative to SAS for these materials is available on the market and the producers are currently unable to replace the SAS with an alternative.[68]

Overall, SAS is the most viable and, in most cases (i.e., applications), **the only solution available to achieve the required level of product performance**. However, in some limited applications, a classification of SAS as STOT RE 1 may lead to the replacement of SAS with the listed alternatives.

3.3. Typical innovation cycle in the sector and challenges with substitution

Overall, innovation in the nanomaterials (NM) market is mainly driven by rapid technological advancement, which is in turn motivated by the increased demand for lightweight, functional, and robust materials.[69] These are all aspects that NMs, and specifically SAS, can offer. SAS is a highly versatile material that covers multiple functions at the same time, as demanded by the customers. Customers typically demand a specific function or set of functions that companies should target in the formulation process. In addition to that, customers may have compatibility requirements (e.g., in toothpaste, compatibility with fluoride compounds), sustainability requirements, such as biodegradability or renewably sourced raw materials, as well as safety requirements that need to be met. Producers of SAS must ensure that the products they supply deliver the desired functions, are safe for their intended uses and comply with applicable regulations and laws. Therefore, the clients' needs (and eventually the consumers' expectations) steer innovation and technological advancement in the SAS segment.

Typical reformulation process

[68] Based on consultation with stakeholders.

[69] ECHA, 2022. Study of the EU market for nanomaterials, including substances, uses, volumes and key operators. http://dx.doi.org/10.2823/680824. Available at: https://euon.echa.europa.eu/documents/2435000/3268573/eumarketstudy.pdf/3a9daabf-eef9-9294-1e1a-2273bd219dc4?t=1667820390467

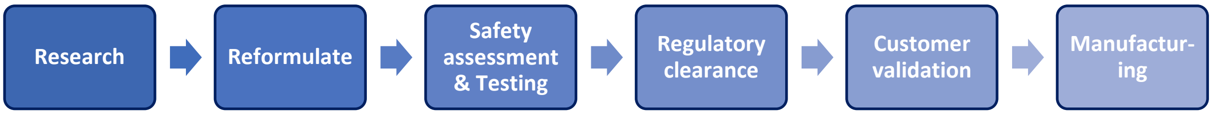
In general terms, a reformulation cycle in the sector is a multi-year process. Timelines vary greatly depending on the complexity of the substitution: for example, a filler is easier to replace than a high-performance additive encompassing multiple functions at the same time.

The typical cycle starts with the identification of a new substance that covers the desired function(s). After that, the development phase follows, including (eco)toxicological assessments and testing. Next, the toxicological evaluation starts after lab development and prior to sampling to potential customers. Overall, testing depends on the application and can take several months. Subsequently, the new substance needs to undergo regulatory compliance (e.g., REACH registration typically would take at least 1-2 years), and customer validation, including R&D, stability testing, performance review, as well as significant investment in product development to design modifications to end products. On average, at the end of the whole process, **depending on the complexity of the case, time to market from conception to final launch ranges between four years up to more than ten years**, depending on the application.

As explained in the following section, market players operating in sensitive and highly regulated sectors, such as pharmaceuticals, food and feed, might consider the reformulation of their products should SAS be classified. However, in the vast majority of cases a replacement is not technically feasible because of the lack of alternative substances that match SAS' technical performance, as shown in the previous section.

For a smaller share of the applications where a potential less performing alternative exists, it is reasonable to expect that timelines would be much closer to the second range, if not higher, due to its unique properties as described previously and the wide range of applications.

From a regulatory standpoint, downstream users would require several years to adapt their products to new formulations and place their products on the market due to additional mandatory regulatory approvals from authorities being required for new substances and formulations. For example, in the pharmaceutical and food segments, new formulations require even longer timelines because new material certification from the national authorities would be ultimately required.



3.4. Conclusion

Overall, SAS is a highly versatile substance that provides multiple functions. It is used in multiple highly innovative applications in a wide and diverse range of sectors. As such, SAS is the most viable and, in most cases applications the only, solution available to achieve the required level of product performance. The significant advantage of SAS with respect to potential alternatives is that SAS is typically able to cover several effects at the same time, providing a high-level of performance and compatibility with other ingredients that other substances cannot provide.

In most of these sectors, there is no direct equivalent alternative to SAS on the same quality and performance level including in market segments such as food, feed, or cosmetics. Some applications can be replaced but using alternative materials that require much higher doses and with decreased quality.

Furthermore, potentially suitable alternatives, if inorganic, are not likely to be significantly different to SAS with regard to their EHS profile but would nonetheless deliver worse performance, as highlighted by surveyed companies operating both at the upstream (SAS manufacturers) and downstream levels in the value chain. Furthermore, many other similar substances, both natural and synthetic, may eventually be classified as well, using the same arguments. This is the case for example for natural silicates, other insoluble powder materials, and metal oxides.

Therefore, **a substitution of SAS products would require costly investment by all companies to convert a significant portion of companies portfolios and take considerable time (more than 10 years) and invariably be a case of regrettable substitution.**

4. ANALYSIS OF IMPACTS

4.1. Economic impacts

The sections below provide a general overview of the social and economic impacts, considering business impacts (i.e., at different stages of the value chain), market impacts (i.e., on the product market), substitution costs, and broader macroeconomic consequences resulting from a potential STOT RE 1 classification of SAS.

4.1.1 General socio-economic impacts

A survey over the EU upstream silica industry has been run for the preparation of this report. **Data from nine companies, including suppliers and producers of SAS in the EEA,** among the biggest players in the silica market, **have been received and aggregated**.

As expressed during the surveys and interviews that have been conducted in the context of this report, the main challenge highlighted by participating companies is that market uncertainty is extremely high. **The actual impact of a classification of SAS highly depends on the market reaction by downstream users of the substance**.

This perception is in line with the result of a study on the EEA market for nanomaterials commissioned by the ECHA's European Union Observatory for Nanomaterials (EUON). The study found that **the main market barriers include the regulatory landscape, which is stricter in the EU/EEA than in other regions**.[70]

Similarly, according to the results of the survey, the current regulatory landscape, and in particular the current market uncertainty, is perceived as the main barrier for growth because it does not allow an easy commercialisation of SAS-containing products.

Producers of SAS anticipated a significant loss in demand of SAS (and in turn in sales) as a result of the classification. Most of the economic impacts are expected on the sale of products in those more sensitive industries and highly regulated sectors where the likelihood of triggering a negative consumer reaction is the highest: food, feed, cosmetics, pharmaceuticals, technical aids. In these industries, the regulatory requirements are stricter and consumers are more careful and risk-averse about the substances used in the production of consumer products.

Customers and downstream users operating in these sectors could stop using the substance pre-emptively, driven by negative consumer and industrial/professional user perceptions, thus leading to

[70] ECHA, 2022. Study of the EU market for nanomaterials, including substances, uses, volumes and key operators. http://dx.doi.org/10.2823/680824. Available at: URL: https://euon.echa.europa.eu/documents/2435000/3268573/eumarketstudy.pdf/3a9daabf-eef9-9294-1e1a-2273bd219dc4?t=1667820390467

market losses for manufacturers of SAS and SAS-containing products and their downstream supply chains.

Unless the introduction of the new hazard classification for SAS in the EEA would be eventually emulated by other non-EEA jurisdictions, it is reasonable to expect that the non-EEA SAS-based business will continue to growth and prosper as usual. In other words, industries/producers based outside of the EEA will continue to use and develop SAS-based applications, and may likely take over European markets, not only by technical advantage, but also by cost: European based manufacturing would cope with costly investments for (e.g.,) developing alternate replacements, while non-EEA producers would not do so.

Moreover, **the classification may trigger in the medium long term generic restrictions in the light of the EU Chemical Strategy for Sustainability**. As the overarching major pieces of chemicals legislation, REACH and CLP Regulations establish various regulatory management measures for substances, mixtures, and articles with hazardous properties. These measures are more stringent for those substances that are considered to pose the greatest risk.

In this context, the so-called generic risk approach (GRA) has been introduced and utilised by a number of pieces of EU chemicals legislation in order to ensure a high level of protection to human health and the environment. This approach is reflecting the precautionary principle,[71] and is well defined as: '*an automatic trigger of pre-determined risk management measures (e.g., packaging requirements, restrictions, bans, etc.) based on the hazardous properties of the chemical and generic considerations of their exposure (e.g., widespread uses, uses in products destined to children, difficult to control exposure). It is applied in a number of pieces of legislation on the basis of specific considerations (e.g., characteristics of the hazard, vulnerability of certain population groups, non-controllable or widespread exposure).'.*[72]

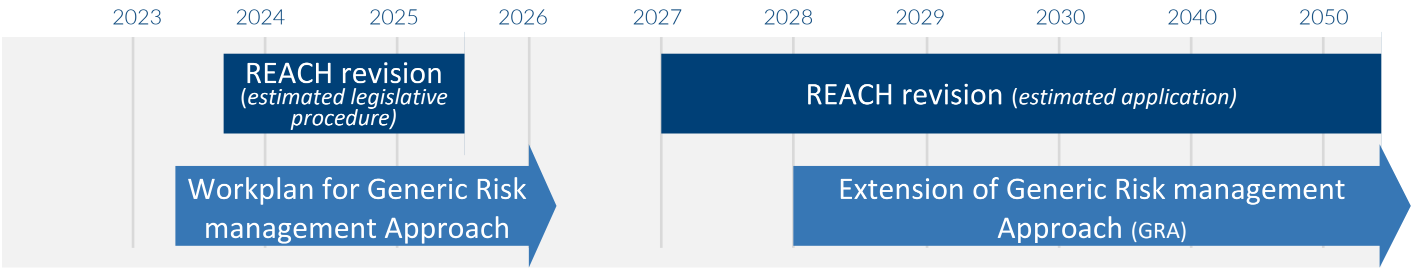
In the EU, the GRA is applied to certain REACH Restrictions, in particular under Article 68(2) of REACH, and through sector specific legislation.

As visually presented in Fig. 7, starting from 2028, the date of the potential application of the extended GRA concept, **a potential CLP classification of SAS as STOT RE 1 could lead to more serious consequences in the context of the upcoming extension of the GRA under the EU Chemical Strategy for Sustainability (CSS).** According to the CSS Communication, **the GRA will result in the banning of certain hazard classes in consumer and professional uses**. Once substances have been through the process of harmonised classification, substances, mixtures and possibly articles containing the CLP-classified substances will be affected by generic restrictions. The impact will occur as a result of implementation through REACH Restrictions, in particular under Article 68(2) of REACH, and sectoral legislation.

[71] See European Parliament Think Tank, 2015. *The precautionary principle: Definitions, applications and governance for definition and applications*. Available at https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA(2015)573876

[72] European Commission, 2019. Commission Staff Working Document Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries SWD/2019/199 final/2. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2019:199:FIN

Fig. 7. Timeframe for the estimated development and adoption of GRA proposal.[73]



In this context, **high-tech industries may suffer for the high production standards and eco-requirements that would be required in case SAS is classified as STOT RE 1**. These requirements include re-labelling requirements – namely all plant and storage parts related to SAS products, as well as SAS-based products' packaging would need to be re-labelled, and the safety data sheets (SDS) re-designed – as well as the additional workplace safety measures. As a consequence, SAS suppliers highlighted the increased risk that some downstream users in key industries such as automotive, high end industrial processes, lacquering and paint industry, may decide to substitute SAS with second-best options to avoid these costly investments and cumbersome requirements to comply with these requirements.

Depending on the severity of the legislative impact, producer companies expect partial plant closures (worst case scenario) or severe financial distress (best-case scenario) caused by the expected market reaction, result of the increasing NGO, media and stakeholder pressure rather than from regulatory requirements to comply with the stricter production standards and eco-requirements associated with a STOT RE classification of the SAS.

4.1.2 Business impacts on active substance suppliers

Overall, the total EEA market for SAS products (all forms) is estimated at approximately 850,000 tons produced every year by the EU silica industry.[74] Surveyed companies cover most of this volume: nearly 650,000 tons of SAS every year (all silica forms included).

Based on the volumes produced by the producers of SAS, **the market share covered by this survey is >75% of the whole EEA market for SAS**, including >95% of the market for precipitated silica and >90% of the production of pyrogenic silica. **The assessment is, therefore, highly representative of the upstream SAS industry.** This large share can be used to obtain reliable estimates for the EU market via extrapolation, as detailed below for the assessment of the economic impacts.

[73] European Commission, 2023. https://ec.europa.eu/docsroom/documents/53078

[74] Estimates based on aggregated data from the survey, SAS producer companies' Intelligence gathering, interviews with interested market players, and desk research. Data have been processed by the authors of this report.

The SAS market is currently growing and there is a high demand for high performance additives with multiple functions and excellent compatibility. According to surveyed companies, the demand for SAS is to increase over time with a potential growth in the range of 3% to 6%, depending on the silica type.

In total, the SAS suppliers employ more than 10,000 workers in the EEA, including more than 4,500 FTEs directly involved in the production of SAS in the EEA (e.g., Germany, France, Spain, Italy, Netherlands, Belgium, Poland, Finland). The SAS produced by these companies is supplied to manufacturers of treated articles. Notably, SAS (active substance) is supplied to more than 4,200 EU industrial customers. A significant share of these customers are SMEs (>35%) producing the finished consumer products.

SAS is extremely important for these companies and their business. An important share of their overall company turnover in the EEA depends on activities which depend on the production of SAS. Therefore, a CLP classification of SAS as STOT RE 1 would have significant impacts on their business and customers.

Consequently, the SAS suppliers would lose business in the EEA. The direct cost for the EEA society is represented by the loss of the contribution to the EEA economy. The relevant economic measure to quantify this economic impact is given by Earnings Before Interest and Taxes (EBIT). The monetization (net present value, NPV, with 3% discount rate) of this economic impact (lost EBIT) is reported below.

In this context, companies participating to the survey have been asked to consider how their revenues for the year 2022 were impacted under the assumption that a CLP classification for SAS as STOT RE 1 were to be fully adopted with immediate effect (i.e., in 2023).

As mentioned in the previous section, supplier companies anticipated a significant reduction in sales caused by a drop in demand from industrial customers (market response). Especially, in highly sensitive regulated markets. This loss in demand would in turn lead to the shrinking of EEA's SAS manufacturing base and the likely shutdown of an uncertain number of production lines.

In the absence of specific market studies on how consumers, or indeed retailers, would respond to a STOT RE 1 label for SAS-based products under the CLP Regulation, a reasonable assumption of the economic impacts upstream in the chain would be that 10% of current total SAS demand in the EEA might be lost because of a STOT RE 1 classification of the substance.

This assumption is in line with the main results of two previous studies. The first study is the socio-economic analysis of the impacts of a harmonised classification for titanium dioxide (TiO2) as Carc Cat 2.[75] The study found that "*a Carc Cat 2 classification would lead to 10-15% of current demand for TiO2 being lost due to adverse effects on the downstream uses of the substance*". Despite the different scope of the analysis conducted by RPA, the economic impacts of a STOT RE 1 harmonised classification of SAS are assumed to be in the same order of magnitude. Moreover, this estimate is in line with the main findings of a study conducted by Ricardo for the European Chemicals Industry Council (CEFIC) on the impacts of the European Commission's Chemicals Strategy for Sustainability.[76] In particular, the business impacts of the extension of the Generic Risk Approach (GRA). The study found that the changes to CLP and GRA could lead to a reduction in turnover of around 12% for businesses operating upstream and downstream in the relevant supply chains.

Based on the above, companies provided the expected loss in EBIT and these data have been anonymised and aggregated in the report using a conservative approach. Hence, if SAS were classified as STOT RE 1, it is estimated that **producers of SAS would face a net EBIT loss of approximately 29M EUR/year**,[77] not accounting for the growing market and the growing interest in SAS, driven by its high performance and the multiple applications.

Over four years (the time frame suggested by ECHA to assess changes in producer surplus when no alternative is available), the total impact is expected to be approximately **108M EUR** (NPV, 3% d.r.) for SAS producers.[78]

One can use the market share of SAS to extrapolate **the total economic impact in the EEA across all suppliers.** The market share covered by this survey is more than 75% of the whole EEA market. This figure is used for the extrapolation of the impacts for the whole EEA market in a conservative approach. **The total impact for the EEA market (upstream) would therefore be at least**: 108M EUR x 1/0.75 = **144M EUR (rounded).**

<u>This estimate should be considered as a minimum (lower boundary) of the expected impacts of a STOT RE 1 classification upstream in the EEA silica supply chain</u>. It does not take into account the high investment costs for the suppliers to comply with the higher production standards, and the new labelling obligations.

To be conservative in the approach, the estimate derived above reflects purely the economic impacts of a classification of SAS as STOR RE 1. Nevertheless, it ought to be highlighted that should the extension of the GRA under the CSS be implemented, substances, mixtures and possibly articles containing SAS will be affected by generic restrictions through Article 68(2) of REACH and sector

[75] Zarogiannis, P., Cockcroft, L.J., Halliday, R., 2017. *Analysis of the socio-economic impacts of a harmonised classification of Carcinogen Category 2 for titanium dioxide (TiO2)*. Risk & Policy Analysts Limited (RPA). Available at: https://rpaltd.co.uk/uploads/report_files/titanium-dioxide-918.pdf [Accessed on 12 December 2022].

[76] Ricardo Energy & Environment, 2021. *Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability – Phase 1 Report*. Final Report for European Chemicals Industry Council (Cefic). Ref: ED 14790.

[77] Aggregated estimate based on data from nine producers of SAS among the biggest players in the market.

[78] Using the Excel function =PV(3%,4,- 29000000,0,0).

specific legislation. Thus, the economic impacts on suppliers of the substances would be much higher and closer to the economic impacts under broad REACH restrictions.

4.2. Social impacts: unemployment

In general, it is difficult to estimate the unemployment because this depends on whether the end user market will accept a STOT RE 1 harmonized classification of SAS. In the context of the survey, companies have been asked to consider how their workforce for the year 2022 were impacted under the assumption that a CLP classification for SAS as STOT RE 1 were to be fully adopted with immediate effect (i.e., in 2023). Based on the above, companies provided the expected unemployment effect and these data have been anonymised and aggregated in the report using a conservative approach.

In the STOT RE 1 classification scenario, at least 10% of the workforce in the companies participating to the survey is assumed to face layoff in the EU. This is equivalent to 480 people. Here we report the monetization of the likely social costs of unemployment for these workers.

For the purpose of this SEA, the weighted average annual salary across these European workers (including the employer's social security contributions) reported by the surveyed companies is 80,000 EUR (rounded).[79]

A well-known guideline in monetizing the social impact of unemployment has been developed by the European Chemicals Agency (ECHA) for evaluating such impact in different regulatory processes.

Estimates have been made in accordance with the ECHA document on the evaluation of unemployment (SEAC/32/2016/04)[80] and the paper of Dubourg (2016)[81] endorsed by ECHA. Therefore:

- Using Table A7 (column G, considering the gross wages including the employer's social security contributions) in Dubourg's paper, the total social cost of unemployment in EU is equal to 2.16 times the annual gross salary.[82]
- Table 3 in Annex I presents the statistics from Eurostat (data for 2021-Q4) on the average duration of unemployment for both men and women in the age of 15-64 years in EU-27.[83]
- Only 75% of the average duration of employment is considered, to reflect the fact that some affected workers are highly skilled and could find employment sooner.

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[79] The number of affected workers per company is used as weights.

[80] ECHA, 2016. The Social Cost of Unemployment. Available at: https://echa.europa.eu/documents/10162/13555/seac_unemployment_evaluation_en.pdf/af3a487e-65e5-49bb-84a3-2c1bcbc35d25

[81] Richard Dubourg, 2016. Valuing the Social Costs of Job Losses in Applications for Authorization. The Economics Interface Limited.

[82] This value is greater than 1 because it takes into account the following components: lost wage, costs of job searching, recruitment costs, the impact of unemployment status on future wages (scarring effect) and employment possibilities, and leisure time (which is a benefit and therefore subtracted from the previous components).

[83] Data extracted from http://appsso.eurostat.ec.europa.eu/nui/show.do?wai=true&dataset=lfsq_ugad

The social costs of unemployment would therefore be equal to:

80,000 EUR x 480 people x 2.16 x 14.826475584/12 x 75% = 77M EUR.

Although companies along the supply chain would face a reduction in sales over the years, we assume for simplicity that the entire workforce will continue working for another three years. Therefore, we discount the monetized impact derived above by three years due to the assumed delay in the layoff, using discount rate of 3% per year, as follows: 77M EUR x $(1 + 0.03)^{-3}$ = 70.5M EUR.

As reported above, one can use the tonnage (proxy for market share) of SAS to extrapolate the total social impact of the unemployment (best-case scenario) in the EU across all SAS suppliers. The market share covered by this survey is approximately 75% of the whole EEA market for SAS. Therefore,

70.5M EUR x 1/0.75 = **90M EUR (rounded)**

One can affirm with a high likelihood that the total social impact of a STOT RE 1 classification of SAS used along *the whole supply chain* would be larger than 90 million EUR, once one considers all other economic operators having business linked to silica. Note that this is an estimate in the best-case scenario (only 5% of workforce will face layoff).

The following elements should be noted:

- All occupation groups (i.e., both high-skilled and low-skilled workers) are expected to be affected. As such, job losses are expected across the whole EU.
- Overall, some companies have reported that their profitability could be affected, and this will have a negative impact also on the wages paid to their workers (more likely in a worst-case scenario) as well as to the working conditions and satisfaction.
- If manufacturers producing competitive products to SAS will suddenly face new business, it is likely they will be able to increase selling prices. Hence, a loss in consumer/end-user surplus should also be taken into account.

4.3. Business impacts on downstream users

At the downstream level, a survey was utilized in preparation of this report. **Data from downstream companies have been received and aggregated. These companies are manufacturers of finished goods in a wide variety of key industries for SAS, including automotive, construction, cosmetics and oral care, food & feed, pharmaceutical, and electronics industries.**

In addition, a series of structured interview and inputs on the importance of SAS in the value chain have been conducted. The aggregated replies from large players in the market for silicone elastomers, automotive tyres and toothpaste manufacturers have been taken into account and presented in three case studies on these key markets for SAS.

The data received from the downstream users does not allow to make an extrapolation of the whole EEA market, but the results of the survey are rather presented as a **descriptive statistic** of the consequences of this regulatory process for the surveyed companies.

Should SAS be classified as STOT RE 1, downstream users would incur substantial loss in sales. Nevertheless, the quantification of the impacts from a classification of STOT RE 1 for SAS is fraught by high uncertainty. In other words, as for the social impacts on SAS producers, it is difficult to estimate the loss in sales for these companies because this depends on whether the end user market, namely the companies more downstream in the chain, the distributors and, ultimately the end consumers, will accept a STOT RE 1 harmonised classification of SAS.

Downstream users supply their products to more than 1,300 customers in the EEA, one-third of which are SMEs. According to the results of the survey, SAS is extremely important for downstream users' businesses. A significant portion (i.e., 38%) of the company turnover of the companies participating to the survey is based on products and/or articles containing SAS as a high-performance additive.[84]

Downstream users recognized the potential risks of a reduced performance linked to some alternatives on the market. Indeed, most of the manufacturers participating to the survey agree that **the technical performance of alternative substances is likely be less effective than that offered by SAS**. As a consequence, these companies expect a cost impact on the final price of the finished goods they produce should they substitute SAS. This cost impact has been estimated at approximately +6% across all downstream users.[85]

Downstream users have been asked to anticipate the impacts on their businesses should SAS no longer be available to use in their products (due to the extension of the GRA concept under the EU CSS) or limited in use because of the potential classification of SAS as STOT RE 1. **The income generated through the sale of SAS-based and/or SAS containing products, likely to be affected by a CLP classification of SAS as STOT RE 1, is estimated in the range of approximately 1.5 billion EUR/year and 1.75 billion EUR/year for the downstream users participating to the survey.**[86] Not counting for the growing demand for SAS. Annual sales of SAS-based products are projected to grow at 3% over the next few years.

Based on data collected as part of this study and assumptions presented in this report, it would be reasonable to expect that a decline in demand for SAS combined with adverse effects on consumer and user perceptions would mean the loss of sales for downstream users can be tentatively estimated at 10-15%. To be conservative in the estimates, one takes the lower boundary (i.e., 10%). Again, this estimate is in line with what has been found by Ricardo in 2021 in the context of the extension of the GRA under the EU CSS.[87]

[84] Weighted average of the share of the product portfolio based on activities where SAS or SAS-based products are used.

[85] Weighted average of the effect on the price if using an alternative to SAS.

[86] The monetisation includes the extrapolated economic impact from manufacturers of silicone elastomers.

[87] Ricardo Energy & Environment, 2021. *Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability – Phase 1 Report*. Final Report for European Chemicals Industry Council (Cefic). Ref: ED 14790.

Considering the conservative estimate on the loss of sales caused by a STOT RE 1 classification, the total impact of a CLP classification of SAS as STOT RE 1 on sales is monetised in the range of 271M EUR/year and 324M EUR/year. Therefore, a CLP classification of SAS as STOT RE 1 would have significant business impacts on downstream users. Consequently, manufacturers would lose an important part of their business in the EEA.

As for the economic impacts upstream, the direct cost of a CLP classification as STOT RE 1 is represented by the loss of the contribution to the EEA economy of the EBIT generated by downstream user manufacturers using SAS within their products.

Therefore, if SAS is classified as STOT RE 1, it is estimated that downstream manufacturers would face an EBIT loss of approximately 49M EUR to 59M EUR/year (rounded).[88] **Over four years, the total impact on the EBIT for downstream manufacturers and distributors that participated to the survey** amounts to about **182M EUR to 219M EUR** (NPV, 3% d.r.; rounded) for downstream users.[89, 90]

It ought to be highlighted that **this estimate should be considered as a minimum (lower bound) of the expected impacts of a STOT RE 1 classification downstream in the EEA silica supply chain**. Indeed, the impacts derived above are presented as a descriptive statistic of the impacts for the surveyed companies. It is expected that the impacts downstream in the chain would be much larger than that. In fact, the socio-economic impacts typically follow a magnification effect along the supply chain so that the (downstream) manufacturers of finished products are expected to have larger impacts.

Moreover, as mentioned above, the economic impacts of generic restrictions under the CSS have not been conservatively considered.

4.3.1 Case studies

A series of structured interviews on the importance of SAS in the value chain have been conducted.

<u>Silicone elastomers</u>

The primary market for pyrogenic silica is silicone elastomers applications. Pyrogenic silica is widely used in silicone elastomers as a cross-linking reinforcement agent and filler additive. At present, silicone elastomers are behind nearly half of the demand/consumption of pyrogenic silica produced in Europe. Even though in the long-term it is expected that downstream users relying on pyrogenic silica as a high-performance additive will gradually replace it with colloidal silica, nevertheless, pyrogenic silica is not currently replaceable.

Pyrogenic silica remains the dominant substance for this application. Notably, pyrogenic silica is used both in room-temperature-vulcanizing (RTV) silicone and in High Temperature Vulcanizing (HTV) silicone rubber, also known as heat-cured rubber elastomers. Silicone adhesives, sealants and caulks

[88] Based on the conservative assumption that EBIT = 10% sales (where an EBIT margin has not been provided).
[89] Using the Excel function =PV(3%,4, -49000000,0,0).
[90] Using the Excel function =PV(3%,4, -59000000,0,0).

are also compounded from these elastomers. The reason for the use of pyrogenic silica, in place of silica and non-silica alternatives, is that perfect reinforcement of rubber, especially silicone rubber, is provided by the pyrogenic type. Along with the reinforcement and filling properties, pyrogenic improves the free flow properties during processing and significantly extend the shelf-life of HTV silicone rubber. Moreover, as regards the silicone adhesives and sealants, pyrogenic silica offers optimal thickening effects in finished products, but it is also used as thixotropic agents.

Beyond these typical silicone elastomers applications, pyrogenic silica is also used in other filled silicone resins, particularly in silicone resins used in electronic applications, where it is historically the preferred option because of the optimal particle size and high level of purity. The latter is considered as a niche, mature market segment.

Downstream users using pyrogenic silica in silicone elastomers applications have been asked to anticipate the impacts on their businesses in two scenarios. In the event of a CLP classification as STOT RE 1, major investments would be required should the silica powder be classified, including investments in adapting production plants and processes (e.g., labelling and safety data sheets). This would certainly divert important resources from other projects, including R&D.

In case of a STOT RE 1 harmonized classification for SAS, without any ban associated with other legislation (e.g., CSS), the loss in sales for manufacturers of silicone elastomers would be significant, up to 10% of sales, but it would allow the European industry to stay in business.[91]

Nonetheless, should, via implementation of the GRA, pyrogenic silica no longer be available to use in the finished products, the silicone elastomers downstream industry would be particularly hard hit. There is currently no alternative to pyrogenic silica in silicone elastomers applications. Thus, the industry heavily relies on the use of pyrogenic silica, which is the reason why it accounts for almost half of both the global and the European demand. In this scenario, manufacturers of silicone elastomers declared that there would no other option than to move the business outside the EEA. The consequent economic impact, as measured by the added value generated by the industry would be in the order of magnitude of billions of EUR.

Public health impacts: the case of SAS in toothpastes

A survey has been run across the European toothpaste industry, and data from the major players in the market have been aggregated. The findings are based on information and aggregated data from the toothpaste industry, representing approximately 80% of this market.

The toothpaste manufacturers highlighted the importance of SAS, in particular in the form of hydrated silica, a high purity product used by toothpaste manufacturers for its multiple functions. The main function of hydrated silica in toothpastes is as an abrasive agent, helping with the removal of plaque bacteria (key for cavity and gum issue prevention), stains and food particles during the act of tooth brushing. Hydrated silica is historically used as an abrasive agent in the vast majority of the fluoride

[91] The associated economic impacts for manufacturers of silicone elastomers have been aggregated and reported in the previous section.

toothpastes marketed in the EEA. It is estimated that, in the European Economic Area (EEA), approximately 80% of effective fluoride toothpastes are currently formulated with SAS (hydrated silica).

The reason for the wide-spread use of hydrated silica is to be found in the combination of several essential characteristics that are sought by manufacturers to make toothpastes as effective as possible against dental cavities (caries). Indeed, hydrated silica, as a versatile abrasive agent, combines effective cleaning ability (reducing plaque formation in teeth) with an exceptional level of compatibility with fluoride compounds and all main functional ingredients in toothpaste formulations, as compared to alternative abrasives. Moreover, the flexibility of hydrated silica allows manufacturers to control/modulate the level of abrasiveness of hydrated silica and make the toothpaste optimal for the target users (i.e., toothpastes with a whitening and anti-stain effect, as well as products meant for children and individuals at risk of dental erosion and dentine hypersensitivity).

To a lesser but certainly relevant extent, hydrated silica is also utilised for its rheology control properties as a thickening agent (i.e., increase the viscosity without substantially changing its other properties) to give toothpastes their traditional consistency, which is key to secure the expected consumer experience, driving adherence to a daily use regime of toothbrushing.

The information from the downstream toothpaste producers also indicates the lack of suitable alternatives that could be able to replace hydrated silica in the vast majority (80%) of toothpastes in the market. At present, no alternative abrasive agent is able to provide comparable performances in terms of combined cleaning ability, versatility and notably compatibility with fluoride ingredients (e.g., sodium fluoride, stannous fluoride, amine fluoride).

Accordingly, a transition to hydrated silica free toothpastes would not only undermine toothpastes' anti-caries performance but it would also not be viable in the short term, as companies would need time to overcome to these compatibility issues with potential alternatives. Based on the inputs received from the toothpaste industry, manufacturers would need high investments in the development and validation of alternative abrasive agents in their toothpastes in order to ensure the safety and effectiveness of the product. This process is highly time consuming and cost intensive without any certainty on the efficacy level of the final outcome. Clinical studies are notably an important part of this development and validation process. to ensure that the toothpaste is effective and meets the necessary safety standards. As a result, more than eight years would be required to reformulate toothpaste manufacturers' product portfolio, which are currently based on hydrated silica, to ensure a status-quo equivalent to what is available today.

In the intermediate time, toothpaste would not be able to deliver the same level of performance they currently deliver. Thus, a potential STOT RE 1 classification of hydrated silica and the related impacts regarding market uncertainties is expected to have considerable health consequences on society in the EEA. In particular, it would potentially result in both direct and indirect negative impacts on the public health in the EEA.

Daily oral hygiene is paramount to achieve and maintain a good oral health. In this context, the pivotal role of fluoride toothpastes is well known, and it has been recently reiterated and strongly highlighted by the WHO.[92] On the basis of the information gathered by the industry, we have attempted to estimate the order of magnitude of the health loss because of a CLP classification as STOT RE 1 in a conservative fashion. In line with the WHO guidelines for the evaluation of human health impacts, the concepts of Quality-Adjusted Life Years (QALYs) and Disability-Adjusted Life Years (DALYs) are utilised.

Hence, taking into account that:

- SAS-based toothpastes represent 80% of the EEA toothpaste market;[93]
- 60% of EEA citizens brush their teeth twice daily;[94]
- The price adjusted GDP per capita of 28 370 EUR;
- The Global Burden of Disease Study (GBD) estimates on epidemiological values of DALY associated with caries in permanent teeth and periodontal diseases;[95]
- Assuming a 6.4% decrease in toothpaste efficacy against dental cavities.[96, 97]

The human health impact is estimated in the order of magnitude of 526M EUR/year. **Over four years, the total monetised health impact for the society is therefore equal to 1.95 billion EUR** (NPV, 3% d.r).[98]

The negative consequences for downstream users derived above are estimated at 10% in order to reflect the impacts of a STOT RE 1 classification in a conservative approach. Therefore, **the total monetised health impact for the EEA society is estimated at 195M EUR** (1.9 billion EUR x 10%).

Using a similar approach to estimate the economic impact on EEA consumers caused by increased dental expenditure, we found a comparable order of magnitude estimate. The direct cost for consumers is estimated at 517M EUR/year. **Over four years, and accounting for the conservative 10% assumption, the total direct cost for EEA consumers would amount to approximately 192M EUR** (NPV, 3% d.r).[99]

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[92] See, for example, WHO, 2021. Oral health: achieving better oral health as part of the universal health coverage and noncommunicable disease agendas towards 2030: report by the Director-General. World Health Organization. https://apps.who.int/iris/handle/10665/359533

[93] Estimates based on aggregated data from the survey, toothpaste companies' Intelligence gathering, interviews with interested market players, and desk research. (See, for example, http://www.oralhealthplatform.eu/wp-content/uploads/2021/11/Platform-for-Better-Oral-Health-in-Europe-Potential-ban-for-silica-Public-Health-perspective.pdf).

[94] See, for example, Carvalho, J.C., Schiffner, U., 2019. Dental caries in European adults and senior citizens 1996–2016: ORCA Saturday Afternoon Symposium in Greifswald, Germany–part II. *Caries research*, *53*(3), 242-252.

[95] GHDx, 2020. Global Burden of Disease Study 2019 Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2020. Retrieved on 7 September 2021 from GHDx: http://ghdx.healthdata.org/gbd-results-tool

[96] Sodium monofluorophosphate (SMFP) is the only source of fluoride which is fully compatible with alternatives abrasives to hydrated silica. Thus, it is reasonable to assume that, in the absence of numerous clinical studies among all the different alternatives with SAS, then a comparison between NaF (the most used fluoride source) and SMFP can be used as a proxy for the difference between hydrated silica and all other commercial alternative abrasives (which necessarily contain SMFP). This is confirmed by toothpaste companies' Intelligence gathering. Stookey et al (1993) found the difference in clinical efficacy between NaF and SMFP at least 6.4% over a 2-to-3-year clinical period.

[97] Stookey, G.K., DePaola, P.F., Featherstone, J.D.B., Fejerskov, O., Möller, I.J., Rotberg, S., Stephen, K.W. and Wefel, J.S., 1993. A critical review of the relative anticaries efficacy of sodium fluoride and sodium monofluorophosphate dentifrices. *Caries research*, *27*(4), 337-360.

[98] Using the Excel function =PV(3%,4,- 526000000,0,0).

[99] Using the Excel function =PV(3%,4,- 517000000,0,0).

The impact would disproportionately affect lower socio-economic groups (e.g., low-income population). Indeed, reduced toothpaste performance would result in higher oral care costs. This would eventually contribute to widening the social inequalities, as access to affordable oral healthcare is an important factor in overall health and well-being. Additionally, poor oral health is already shown to have important negative impacts on an individual's ability to work and participate in society. This is particularly concerning during times of crisis, when access to healthcare and other essential services may be limited.

Animal feed

Data from five major feed manufacturers have been received and aggregated. Manufacturers of feed additives, premixes, and concentrates highlighted the importance of SAS for the feed industry where the alternatives are considered inadequate in terms of efficacy. Indeed, SAS provide technical performance that alternatives can hardly match in terms of absorptions of vitamin E and liquid organic acids next to anti-caking effects, improved adhesion, and free flow.

Animal feed producers declared that the use of SAS results in a better digestibility of vitamins and proteins. More generally, the main benefits of using SAS in animal feed products include higher feed efficiency, higher average daily gain and final weight, enhanced action of antibiotics and acidifiers. SAS allows to reduce production of ammonia and other odorous gases. As a result, the use of SAS as an additive allows to improve the feed conversion rate (the conventional measure of livestock production efficiency).

The benefits associated with the SAS are not limited to those listed above, but also include the reduction of oxidative stress in fish and shrimp. Together with an improved absorption of calcium and phosphorus, the use of silica in feed also yields important results in terms of survival rate in aquaculture.

In this context, manufacturers have stressed that no real equivalent solution exists on the market. Replacing SAS would be very difficult for some animal feed products, but impossible for the most of them. Therefore, relocation to outside the EEA cannot be disregarded.

Case study: the importance of SAS for electronics

Electronics has become increasingly important in recent times due to the rising reliance on technology in all aspects of modern life. From communication and entertainment to healthcare and transportation, electronics play a vital role in the way we live and work. In addition, the development of new technologies such as the Internet of Things (IoT) and artificial intelligence (AI) is driving the demand for more advanced electronics. As a result, the electronics industry is constantly evolving and growing, and the importance of electronics is only set to increase in the future.

Amid the recent global semiconductors' shortages, the EU's security of supply resilience and technological leadership in semiconductor technologies and applications have gained importance in the political priorities of EU governments and the European Commission.

In this context, **the use of SAS in electronics in the EEA is of particular importance in the framework of the European Commission's proposed European Chips Act**. The goal of the European regulators is to ensure that the EU has the necessary tools, skills, and technological capabilities to become a leader in the field of semiconductors, in design, manufacturing and packaging of advanced chips, to secure its supply of semiconductors and to reduce its dependencies.[100]

Electronics is one of the drivers of continued growth in the demand for SAS, in particular pyrogenic and colloidal silica. Because of their ideal chemical structure, these SAS products have been increasingly adopted by the electronics industry as an optimal solution for chemical mechanical polishing (CMP).

CMP is a key technology in semiconductor fabrication for highly integrated circuits and memory disks. This technology uses both chemical and mechanical forces for material removal from surfaces (planarization). Planarization is a crucial step in semiconductor manufacturing as it ensures that the surface of the semiconductor substrate is smooth and flat. This is essential for the proper functioning of the devices that are built on the substrate. In fact, if the surface is not flat, it can cause issues with the alignment of the various layers and components that are placed on the substrate, leading to faulty devices. Additionally, a smooth surface allows for better control over the movement of electrons, which is crucial for the performance of the devices. Thus, planarization is important in semiconductor manufacturing as it ensures the proper functioning of the devices and enhances their performance.

In CMP, the planarization is achieved by a synergistic combination of chemical and mechanical forces using slurries containing different chemical reagents and abrasives.[101] SAS particles act as abrasives. SAS can be highly tailored to use in electronics applications. For this reason, the semiconductor industry has been increasingly relying on SAS for the production of chips and PCBs.

4.4. Wider economic impacts

It is also important to consider the wider macroeconomic impacts and consequences on the EU society at large, by focusing on the expected consequences for the EEA market. In particular, there are concerns on the overall EU trade balance (increase of imports from outside the EEA), on the competitiveness of EEA market, the innovation and the sustainability goals in the EEA.

<u>Impacts on the market – Trade and competitiveness</u>

The silica industry is strategically important for the European market and vice versa the European market represents a considerable portion globally.[102] The EU/EEA is one of the global leaders in the production of SAS. As mentioned above, the European market is the second largest in the world, after China. This makes the EEA a net exporter of SAS products, especially precipitated and pyrogenic silicas.

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[100] See, for example, Communication from the European Commission: A Chips Act for Europe. Available at: https://ec.europa.eu/newsroom/dae/redirection/document/83086

[101] Coutinho, C.A., Gupta, V.K., 2011. Chemical mechanical polishing: role of polymeric additives and composite particles in slurries. In *Applied Plastics Engineering Handbook* (pp. 519-532). William Andrew Publishing.

[102] See Fig. 1 for a global SAS production breakdown. Europe account for 20% of the global production of SAS.

A CLP classification of SAS as STOT RE 1 in Europe would hinder competition in the global market, contributing to increase the gap with the Asian markets. As a crosscut classification would concern and affect all EEA-based market players, the risk is that **a STOT RE 1 classification would advantage non-EEA competitors in their competition with the EEA-based industry**.

Unless the introduction of the new hazard classification for SAS in the EEA would be eventually emulated by other non-EEA jurisdictions, it is reasonable to expect that the non-EEA SAS-based business will continue to growth and prosper as usual. Thus, EEA businesses would become less competitive both domestically and overseas and, over time, some parts of the value chains might consider relocating outside the EEA, unless a similar hazard classification was also adopted by non-EEA jurisdictions.

Indeed, while the EU industry would cope with labelling requirements and high production standards that would require heavy investment costs for all companies dealing with SAS, if not a complete substitution with second-best options in more sensitive markets, such as cosmetics, food, feed and pharmaceuticals, non-EEA players and importers of SAS and/or SAS-based products would be less regulated in that sense (e.g., they would not be required to comply with more stringent rules and safety standards in production, as this would take place outside the EEA). Thus, EEA producers would find it cost prohibitive to continue to produce in EEA over the longer term.

As a result, surveyed companies expect the imports from non-EEA markets to increase over the long-term because of a CLP classification of SAS as STOT RE 1. Especially from Asia, whose exports have been increasing over the last decade driven by precipitated silica and especially low-quality silica gels.

At present, China is top exporter of silicon dioxide, followed by Germany and the European Union as a whole. Therefore, **a STOT RE 1 classification to SAS would pave the way to an increased importance of imports from the Asia-Pacific region and the Asian global leading position in the silica market**.

At the same time, the exports from the EEA would also be particularly hard hit by a potential STOT RE 1 classification. At present, the European region a **net exporter** of SAS products, especially precipitated and pyrogenic silicas. It is estimated that almost half of the EEA production (45%) is exported outside the EEA.

The surveyed companies have stressed that should the GRA concept be extended and implemented as currently proposed in the EU CSS, products containing substances classified as STOT RE 1 could not be exported outside the EU. Thus, the classification of SAS would dramatically reduce the exports of SAS based product to non-EEA markets. As a result, **the overall EU trade balance would be adversely impacted**.

<u>Impacts on the market – Quality and costs</u>

With higher imports of SAS-based products from outside the EEA, and the use of less performing alternatives to SAS in highly sensitive markets, the risk is of seeing the quality of these product to drop.

For example, as presented above, in oral health, the use of alternatives to hydrated silica does not ensure compatibility with fluoride compounds and other components of the formulation such as flavors, which are included in most of the toothpastes produced and marketed in the EEA. As a result, without hydrated silica, toothpastes would not be able to deliver the same optimal efficacy in addressing a large spectrum of oral conditions, from dental cavities to tooth decay and gum diseases.

Based on the results of the survey, it is likely that in the case of a CLP classification as STOT RE 1, certain highly sensitive industries would be forced to substitute SAS, to the extent possible. In these market segments, consumers would face a reduction in product availability and choice, increased market prices, loss of performance. In sum, this policy option would result in a loss of several functions that are currently delivered by SAS.

Impacts on the market – Competition in the EEA

A potential STOT RE 1 classification could lead to certain market distortions. Producers of alternative substances would benefit from a CLP classification of SAS as STOT RE 1, and gain market share. At the same time, the number of available solutions on the market will decrease. Therefore, the demand for potentially alternative substances, such as calcium carbonate or carbon black, would jump, and the prices would consequently increase in a typical supply-demand market dynamic.

The major impact of a potential increase in prices will likely be on SMEs, which represent most of the companies operating in the market segments potentially affected by a classification, including a significant share of the industrial customers of SAS producers as well as the end user markets that rely on SAS.

Indeed, while overseas markets are more accessible for Multinational Enterprise (MNE) producers, downstream SMEs in the EEA may have a more regional focus and less capability of becoming competitive exporters and thus they could be particularly vulnerable to a drop in the demand for SAS-based products in the EEA (market response), and/or the loss of a critical raw material or articles that depend on it (reformulation).

According to the EUON report on nanomaterials, the uncertain regulatory landscape represents the main market barrier for SMEs.[103] A CLP classification for SAS as STOT RE 1 would be a major source of uncertainty for market players, and an insurmountable market barrier that is likely to principally affect the competitive landscape as it makes harder for SMEs and start-ups to compete with well-established players, notably from the Asia-Pacific region, which may affect the EU SAS producers in the mid- to long- term.[104]

[103] ECHA, 2022. Study of the EU market for nanomaterials, including substances, uses, volumes and key operators. http://dx.doi.org/10.2823/680824. Available at: URL: https://euon.echa.europa.eu/documents/2435000/3268573/eumarketstudy.pdf/3a9daabf-eef9-9294-1e1a-2273bd219dc4?t=1667820390467

[104] Ibid.

The high production costs caused by stricter re-labelling requirements as well as the additional workplace safety measures, may limit scaling up and introducing high entry barriers into the market. As a consequence, it is reasonable to expect that a STOT RE 1 classification would lead to a market concentration in the EEA, which would inevitably push prices up for all products where SAS is currently used.

Impacts on the market – Innovation in the EEA

SAS is a high-performance additive and processing aid, which is part of many innovative products currently marketed in Europe. One of main drivers for innovation in the silica business is the rapid technological advancement motivated by strong and growing demand for lightweight, functional, robust highly functional materials in electronics, automotive, energy, food packaging, construction, and other industries. Typically, customers' expectations are related to the technical effects, i.e., customers demand a specific set of technical performance that companies should target in the formulation process. Additionally, customers (downstream users) may have compatibility or sustainability requirements that need to be met.

In this context, being an extremely versatile substance, there is room for continued innovation around SAS. The European industry is one of the leading markets for silica and SAS. R&D activities of SAS producers are located in the EEA and so does the innovation and know-how around SAS. These companies invest between 2% to 4% of the company turnover of silica sales in R&D.

To this end, public (EU and national) funding has significantly boosted the progress of the SAS market, which is expected to continue, considering the needs of the market and investment in the development of innovative materials. This boost has led over time in the development of more advanced and highly functional manufacturing lines and standardised manufacturing processes, which have substantially reduced the cost of SAS, making such products a lot more affordable to the EU market.

All the progress that has been made in this regard, which was based on formulas where SAS are extensively used, would be considerably undermined should companies be forced to either reformulate their product portfolios to replace SAS or redirect important economic and human resources to cope with re-labelling requirements and stricter workplace safety measures. Thus, **these financial efforts would therefore come at the cost of innovation.**

5. CONCLUSIONS

Synthetic Amorphous Silica (SAS) is used as a high performance, versatile additive in a wide variety of applications in key economic and strategic sectors. As such, **SAS can be considered as one of the contributors to the overall evolution and innovation of the EEA society**, including via its use in oral care, energy-efficient tyres, food & feed, as well as many high-tech applications ranging from solar cells, windmill blades, medical tubes, prothesis, coatings, vaccine thermal insulation, chips and highly integrated circuits, electrical insulation.

This SEA focuses on the value of synthetic amorphous silica and SAS-based products on the European market and identifies the main potential negative consequences that the EU society at large would face in the framework of the potential CLP classification of SAS as STOT RE 1. It has been performed in line with existing ECHA guidance under REACH, in a conservative approach. The results are based on a survey focused on the EU SAS industry, with market share coverage of approximately 75% of the EU market. It therefore provided sufficiently reliable data for a representative extrapolation of the EU upstream SAS market.

<u>Overall, the results of the SEA demonstrate that a STOT RE 1 harmonised classification would have disproportionate negative impacts on the European economy, innovation, and society overall.</u>

The total monetized impact of a classification of SAS as STOT RE 1 represents more than 840 million EUR, including: economic impacts (EBIT loss) on active substance suppliers; social impacts (i.e., unemployment in the EU-27); economic impacts on downstream users and end-users; public health impacts for the society; economic impacts from direct expenditures for consumers.

It ought to be noted that the above estimate covers only a small part of the value chain that would be impacted. In fact, apart from the producers of SAS, the downstream users of the substance who participated in the survey are only a fraction of the total number of impacted users. The latter underlie a combined estimated added value of more than 300 billion EUR per annum. Thus, **this estimate should be considered as a minimum (lower bound) of the expected impacts of a STOT RE 1 classification in the EEA silica supply chain.**

Furthermore, SAS manufacturers anticipate a **significant loss in demand of SAS** as a result of the classification. This will **impact both industrial and end-consumer applications of SAS** (food, cosmetics pharma). In the latter, regulatory requirements are stricter, the impact will be direct and immediate.

In terms of **wider economic impacts**, a CLP classification of SAS as STOT RE 1 would advantage non-EEA competitors, paving the way to an **increased importance of imports from Asia and the Americas, and greater EU dependence on external actors in high-tech industries**. Moreover, the role of SAS in renewable energies and the decarbonization is paramount to achieve a transition to a climate-neutral society. A classification of SAS would compromise **sustainability goals in a wide range of strategically vital sectors, including automotive, energy production and consumption and jeopardise innovation in many sectors.**

SENSITIVITY IMPACT ANALYSIS

The results of this report are based on a potential re-classification of SAS as STOT RE 1. Based on data collected as part of this study and assumptions presented in this report, it is assumed that a decline in demand for SAS combined with adverse effects on consumer and user perceptions would mean the loss of sales for downstream users. This loss is assumed to be minimum 10% (**conservative assumption**).[105]

However, a **classification of SAS as STOT RE 1 could also be a pre-cursor of even more serious consequences over time in the light of the EU Chemical Strategy for Sustainability (CSS)**, and in particular in the context of the extension of the Generic Risk Approach (GRA).[106] According to the CSS Communication, changes in the GRA will result in the banning of certain substances in consumer and professional uses. Once substances have been through the process of harmonised classification, substances, mixtures and possibly articles containing the CLP-classified substances will be affected by generic restrictions. A STOT RE 1 classification may not immediately lead to bans. However, if the GRA would effectively be implemented, **multiple products which utilize SAS could indeed be subject to generic restrictions and bans in the short to medium-long term**.

In the light of these far-reaching consequences, we need to take into account more extensive impacts to reflect a restriction scenario rather than a 'mere' classification. In consideration of the potential restrictions connected to the implementation of the Generic Risk Approach under the CSS, higher percentages are used for the estimation of the monetised socio-economic impacts. Notably, **the economic fallout of a partial restriction would rather fall within the spectrum of a 20%, if not 30% or 50% reduction in current SAS/SAS-based products demand.**[107] **The total economic impacts would therefore be:**

- **1.68 billion EUR**
- **2.5 billion EUR**
- **4.2 billion EUR** respectively**.**

Evidently, these are still conservative estimates of the potential impacts for the SAS-based supply chain. The largest impacts would be suffered downstream in the supply chain, at the level of the manufacturers of finished products. The survey we have conducted cover only a smaller fraction of those, and the results downstream are rather presented as a descriptive statistic of the consequences of this regulatory process for the surveyed companies.

[105] The academic economic literature lacks studies on the impact of harmonised classifications on the economy. Therefore, to estimate the economic impacts of this policy option (viz., the potential harmonised classification of SAS as STOT RE 1), we made reference to two previous studies (Ricardo Energy & Environment, 2021; RPA, 2017). With the understanding that the conclusions of such studies (particularly the so-called 10% assumption) are downward estimates in this particular case, given the widespread use of SAS in strategically important industries. Hence the need to show what would happen in our economic model if this 10% assumption were enlarged.

[106] European Commission, 2023. https://ec.europa.eu/docsroom/documents/53078

[107] The GRA concept would be implemented through REACH Restrictions, in particular under Article 68(2) of REACH, and sectoral legislation. Thus, even certain applications would be excluded from a restriction, which is the reason why it is not possible to say with certainty that 100% of the demand for SAS-based products would be lost, the potential economic impacts for the SAS-based value chain would still be extensive. Given the lack of specifics, the assumption for this sensitivity analysis is that up to a maximum of 50% of the turnover of companies operating in the value chain would be lost.

2 ANNEX I

Table 3. Duration of unemployment in EU-27 in 2021Q4[108]

Duration Grouping	Thousand units	Proportion (A)	Assumed duration (B)	Weighted average (A*B)
Less than 1 month	1673.7	0.12415159	0.5	0.062075795
From 1 to 2 months	2463.6	0.182744732	1.5	0.274117097
From 3 to 5 months	1975.2	0.146516234	4.5	0.659323052
From 6 to 11 months	1794.7	0.133127119	8.5	1.131580509
From 12 to 17 months	1501.1	0.11134848	14.5	1.614552967
From 18 to 23 months	939.0	0.06965307	20.5	1.427887932
From 24 to 47 months	1618.9	0.12008664	35.5	4.263075713
48 months or over	1514.9	0.112372136	48	5.393862519
Total	13481.1	1		14.826475584

[108] Data extracted from https://ec.europa.eu/eurostat/web/products-datasets/-/lfsq_ugad

ABBREVIATIONS

AI	Artificial Intelligence
AmF	Amine Fluoride
ASASP	Association of Synthetic Amorphous Silica Producers
CAGR	Compound Annual Growth Rate
CAS	Chemical Abstracts Service
CEFIC	European Chemicals Industry Council
CLP	Classification, Labelling and Packaging
CMP	Chemical Mechanical Planarization
CSS	Chemical Strategy for Sustainability
DALY	Disability-Adjusted Life Years
EBIT	Earnings Before Interest and Taxes
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EHS	Environment, Health & Safety
eMSCA	Evaluating Member State Competent Authority
EU	European Union
EUON	European Union Observatory for Nanomaterials
EUR	Euro (currency)
EV	Electric Vehicle
FTE	Full Time Equivalent
GBD	Global Burden of Disease
GHS	Globally Harmonised System
GRA	Generic Risk Approach
HPV	High Production Volume
HTV	High Temperature Vulcanizing
IHME	Institute for Health Metrics and Evaluation
IoT	Internet Of Things
MNE	Multinational Enterprise
MRG	Magnetorheological Grease
NaF	Sodium fluoride
NM	Nanomaterials
NPV	Net Present Value
OECD	Organization for Economic Co-operation and Development
PCB	Printed Circuit Board
PE	Polyethylene Envelope

PV	Photovoltaic
QALY	Quality-Adjusted Life Years
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Mitigation Measures
ROW	Rest of the World
RTV	Room Temperature Vulcanizing
SAGA	Suitable Alternative Generally Available
SAS	Synthetic Amorphous Silica
SDS	Safety Data Sheet
SEA	Socio-Economic Analysis
SEAC	Committee for Socio-Economic Analysis
SiO_2	Silicon dioxide
SME	Small and Medium Enterprise
SMFP	Sodium Monofluorophosphate
SnF2	Stannous fluoride
STOT RE	Specific Target Organ Toxicity Repeated Exposure
SVHC	Substance of Very High Concern
TiO2	Titanium Dioxide
WHO	World Health Organization

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