

Silica and STOT RE 1 – Media Guide



Information about the possible classification of synthetic amorphous silica as STOT RE 1

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Introduction

ESSEN, GERMANY.

The European Chemicals Agency ECHA published a proposal for the harmonized classification and labeling of all types of synthetic amorphous silica (SAS) in June 2024. This also applies to silica from Evonik. Therefore, Evonik's silica business line has compiled an information package for customers, media and the public, explaining the company's position and the consequences of a possible classification of SAS as STOT RE 1. This is a hazard class of chemicals for which the European Union prescribes specific labeling and packaging, according to the substance evaluation process (CLH). The proposed classification as STOT RE 1, H372 stands for "endpoint specific target organ toxicity – repeated dose toxicity" and refers to the lung / respiratory tract.

Evonik rejects this proposal with the conviction that synthetic amorphous silica (SAS) is safe. SAS created in an industrial process has an identical structure to that of naturally occurring amorphous silica in plants, and in animal and human organisms. SAS is not distinguishable from biogenic silica. Evonik's synthetic amorphous silica is recognized as a nature-identical, sustainable and safe material. Furthermore, Evonik is convinced that a STOT RE 1 classification of SAS is neither scientifically justified nor in terms of health policy. It may lead to disproportionate, far-reaching and negative impacts on producers, processors and consumers: Countless products containing SAS as an additive would have to be labeled with a warning (symbol GHS08). If processors were to dispense with silica, this would massively impair the quality and properties of countless high-tech and everyday products.



Please find comprehensive information on the safety of Evonik's silica in this media guide and on our website:

- Evonik's positioning statement on the proposed classification of silica as STOT RE 1
- Explanation of the CLH process and consequences
- Extract of our FAQ about synthetic amorphous silica
- Silica infographic and explanatory video Evonik Silica as a part of the natural geological cycle of silica

More detailed information, including a comprehensive FAQ section, silica technical data and scientific studies, is available on our webpage Silica is safe:

www.silica-specialist.com/en/service-center/silica-safety



Evonik's position on the classification of silica as STOT RE 1

We reject a classification of synthetic amorphous silica (SAS) as STOT RE 1 because we are convinced that SAS is safe for producers, processors and consumers. Furthermore, we are convinced that this hazard class for SAS is neither scientifically justified nor in terms of health policy as it is not based on intrinsic properties of the substance.

The proposed STOT RE 1, H372 classification is based on inhalation tests that led to isolated cases of inflammatory processes in lung tissue. But the concentration and duration of exposure during these tests did not correspond to the real conditions when producing and processing SAS.

At no point in the value chain do people get into contact with dust of SAS in hazardous concentrations.

OUR MAIN ARGUMENTS AGAINST THE CLASSIFICATION OF SAS

SAS is safe in compliance with the applicable occupational health and safety regulations – during production, processing, transport and storage. In the processed product, silica occurs in bound form only and is safe for consumers.

In most downstream user sectors, there is no equivalent alternative to silica that offers the same level of quality and performance. This would invariably be a case of regrettable substitution.

If processors were to dispense with silica, this would massively impair the quality and properties of countless high-tech and everyday products. Important EU export goods would no longer meet their previous quality standards and would be harder to sell globally. Some products could even disappear from the market.



FAQ: Silica and STOT RE 1 (extract)

WHAT IS SILICA?

Silica is the common name for silicon dioxide (SiO_2). SiO_2 is very common in nature, for example, as crystalline silica in quartz or grains of sand. Another form of silica, amorphous silica, is found in human and animal organisms as well as in plants. The two components in this compound, oxygen and silicon (approx. 27 %), are among the most common elements in the Earth's crust when measured by weight.

The industry can produce silicon dioxide synthetically through different processes. In simple terms, sand is turned into a valuable high-purity material which is an essential additive for countless industrial applications.

Evonik produces only synthetic amorphous silica (SAS). This distinction is very important to set it apart from crystalline silica.

"Synthetic" means that the silica was produced in an industrial process. "Amorphous" means that the atoms are not organized in a regular lattice pattern, but in irregular shapes. In terms of its structure, synthetically produced silica is indistinguishable from natural amorphous silica. SAS is recognized as a nature-identical, sustainable and safe material.

The various SAS types produced by Evonik differ in terms of their physicochemical features, such as particle size, density or surface treatment – tailor-made for many different applications.

WHY WAS SYNTHETIC AMORPHOUS SILICA SUBJECTED TO A SUBSTANCE EVALUATION?

In the European Union, all substances or mixtures that are manufactured or imported in quantities of above one metric ton a year must be registered with the European Chemicals Agency (ECHA) according to Art. 6 REACH Regulation. Part of the procedure is a substance evaluation (CLH), which aims to clarify whether a substance constitutes a risk to human health or the environment.

A substance evaluation of synthetic amorphous silica (SAS), a type of silicon dioxide (SiO_2), was initiated in 2013. The final report, published in 2021, left doubts as to the complete safety of the substance based on inhalation studies. This led to a review of SAS synthetic amorphous silica in the CLH process. Subsequently, the competent authorities (CA) recommended a harmonized classification for synthetic amorphous silica as STOT RE 1 (H372, signal word "Danger").

FAQ: Silica and STOT RE 1 (extract)

WHY IS EVONIK CONVINCED THAT SYNTHETIC AMORPHOUS SILICA IS SAFE?

The synthetic amorphous silica (SAS) types produced by Evonik are safe for everyone involved in production, processing, transportation, and storage, as well as for consumers of the end products.

SAS is being proposed for classification based on adaptive, unspecific inflammatory effects in rat repeated dose inhalation toxicity studies, which are generic to all particles regardless of the substance.

This means that there would only be a health risk if dusts were inhaled in large quantities and over a longer period of time without protection.

But at no point in the value chain do people get into contact with silica dust in hazardous concentrations. Evonik (including its predecessor companies) has been producing SAS since the 1940s. It is one of the most rigorously tested substances regarding potential risks to humans or the environment. SAS is a substance with no intrinsic toxicity. Toxicological and ecotoxicological tests and decades of experience in its manufacture and use have resulted in no indications of risks to health or the environment through SAS when the substance is handled appropriately. Safety in production and processing is guaranteed by occupational health and safety regulations.

WHY IS SYNTHETIC AMORPHOUS SILICA HARD TO REPLACE?

Silica is everywhere: Almost every industry – from consumer goods such as toothpaste to high-tech components including microchips – uses synthetic amorphous silica (SAS) as a process aid or functional additive. It is a versatile substance with a wealth of properties. In 95 percent of all applications, silica plays a key role in the function and/or properties of the end product. And it contributes to sustainability by reducing the waste of resources or extending the service life of products. In many applications, there are no equivalent alternatives, or developing substitutes and adapting formulations would involve considerable effort, resource consumption and costs. Many everyday products, as well as future technologies, would function worse or not at all without silica. In technical terms, the replacement of a proven chemical with a non-equivalent substitute is referred to as a "regrettable substitution." As a consequence, end consumers will receive products of a poorer quality, while important EU export goods will no longer meet their previous high quality standards and will be harder to sell globally. Some products could even disappear from the market.



Do you have any further questions? Then visit our comprehensive FAQ section with more than 40 answers, including scientific details for experts, on our Silica is Safe webpage:

www.silica-specialist.com/en/service-center/faq-silica-and-stot-re-1



Published Media

VIDEO

Watch this video to see how silica makes everyday life easier, safer and more sustainable:



FAQ

Questions and answers on silica in general, silica and safety, various applications, the CLH process, and potential economic consequences

Silica and STOT RE 1 – FAQ



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SILICA IS SAFE AND IMPROVES YOUR DAILY LIFE

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Super-strong and durable adhesives and sealants with excellent processing properties for green energy applications such as solar modules and rotor blades for wind turbines



Toothpaste with smooth consistency, nature-identical cleaning agents for white teeth, and effective anti-cavity ingredients



Baby bottles' silicone teats remain transparent and elastic, heat-resistant and tear-proof – therefore safer for babies



Fire extinguishers work reliably because the fine powder inside does not cake



Highly energy-efficient refrigerators with more storage space, thanks to ultra-flat vacuum insulation panels



Electric vehicle starter batteries with increased performance and durability



Free-flowing spices that do not clump in the shaker



Easy-to-use, low-dose detergents that do not contain microplastics. Powders do not cake, liquids are convenient to dispense, pods do not stick together



Highly durable tires with reduced rolling resistance save fuel, or extend the range of electric vehicles. Improved wet grip increases driving safety

Evonik's synthetic amorphous silica (SAS) is a highly innovative substance that improves countless consumer goods and high-tech products. These are just a few examples. Sand is the starting point for SAS production. If Evonik's silica were released into the environment, it would not be distinguishable from naturally occurring silica in minerals or plants. It would re-integrate into the natural geological cycle of silicon dioxide (SiO₂).

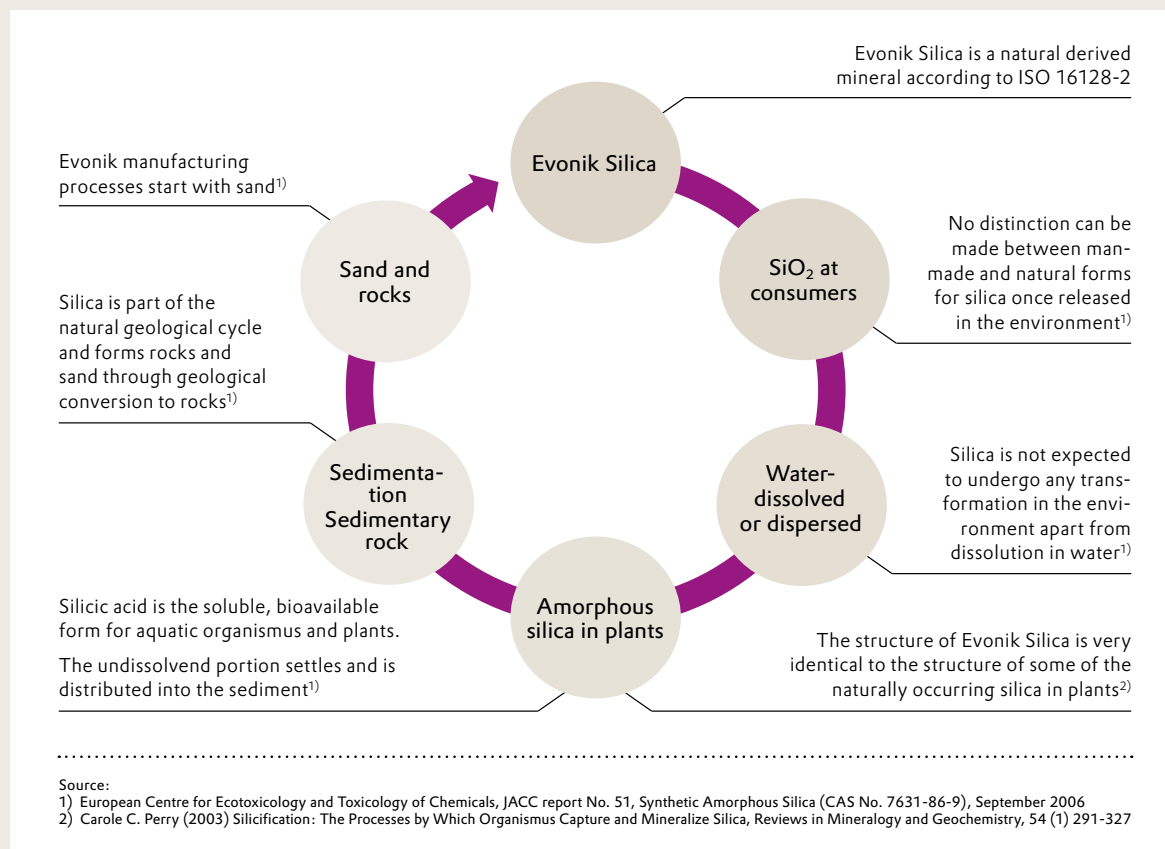
Would you expect minerals to be biodegradable?

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Evonik Silica – part of the natural geological cycle of silica

Evonik Silica has been produced for decades and is a sustainable and resource efficient raw material for various applications. Evonik uses either precipitation methods or flame processes to manufacture tailor-made, amorphous silica of high and constant quality for a broad range of applications and it all starts with the natural source sand! Hence, Evonik Silica is a natural derived mineral ingredient according to ISO 16128. If it is released from consumer products like personal care, oral care, food etc. into the environment, it is not distinguishable from naturally occurring silica in minerals. Evonik Silica integrates again into the natural cycle of silica and at the end, it will sediment as sand and forms rocks.



COMPANY INFORMATION

Evonik is one of the world leaders in specialty chemicals. The company is active in more than 100 countries around the world and generated sales of €15.3 billion and an operating profit (adjusted EBITDA) of €1.66 billion in 2023. Evonik goes far beyond chemistry to create innovative, profitable, and sustainable solutions for customers. More than 33,000 employees work together for a common purpose: We want to improve life today and tomorrow.

ABOUT SMART MATERIALS

The Smart Materials division includes businesses with innovative materials that enable resource-saving solutions and replace conventional materials. They are the smart answer to the major challenges of our time: environment, energy efficiency, urbanization, mobility and health. The Smart Materials division generated sales of €4.46 billion in 2023 with more than 8,100 employees.

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