AEROSIL® SIPERNAT® SPHERILEX® ULTRASIL® ZEODENT® ZEOFREE®

Silica and STOT RE 1 – FAQ

EVONIK
Leading Beyond Chemistry

Contents

Glossary


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CA:
Competent Authorities

CLH:
Harmonized classification and labelling

CLP:
Regulation on Classification, Labelling and Packaging of Substances and Mixtures

ECHA:
European Chemicals Agency

GHS:
Globally Harmonized System

RAC:
Committee for Risk Assessment within the European Chemicals Agency

REACH:
Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

SAS:
Synthetic Amorphous Silica

STOT RE 1:
Specific Target Organ Toxicity, hazard category 1

Questions regarding the **CLH process**

WHY WAS SYNTHETIC AMORPHOUS SILICA (SAS) 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 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").

WHAT DOES STOT RE 1 (H372) MEAN?

STOT means "specific target organ toxicity" and is a hazard class of chemicals for which Regulation (EC) No. 1272/2008 of December 16, 2008 (CLP Regulation) prescribes specific labeling and packaging.

STOT RE consists of two hazard categories: STOT RE 1 (H372, signal word "Danger") and STOT RE 2 (H373, signal word "Warning").

Substances with a classification of STOT RE 1 or STOT RE 2 (inhalation) must be labeled with the GHS hazard symbol 08 and the corresponding signal word "Danger" or "Warning."

The reference H372 means: Causes damage to respiratory tract/inhalation through prolonged or repeated exposure if inhaled.

WHAT DOES "HARMONIZED CLASSIFICATION AND LABELING" (CLH) MEAN?

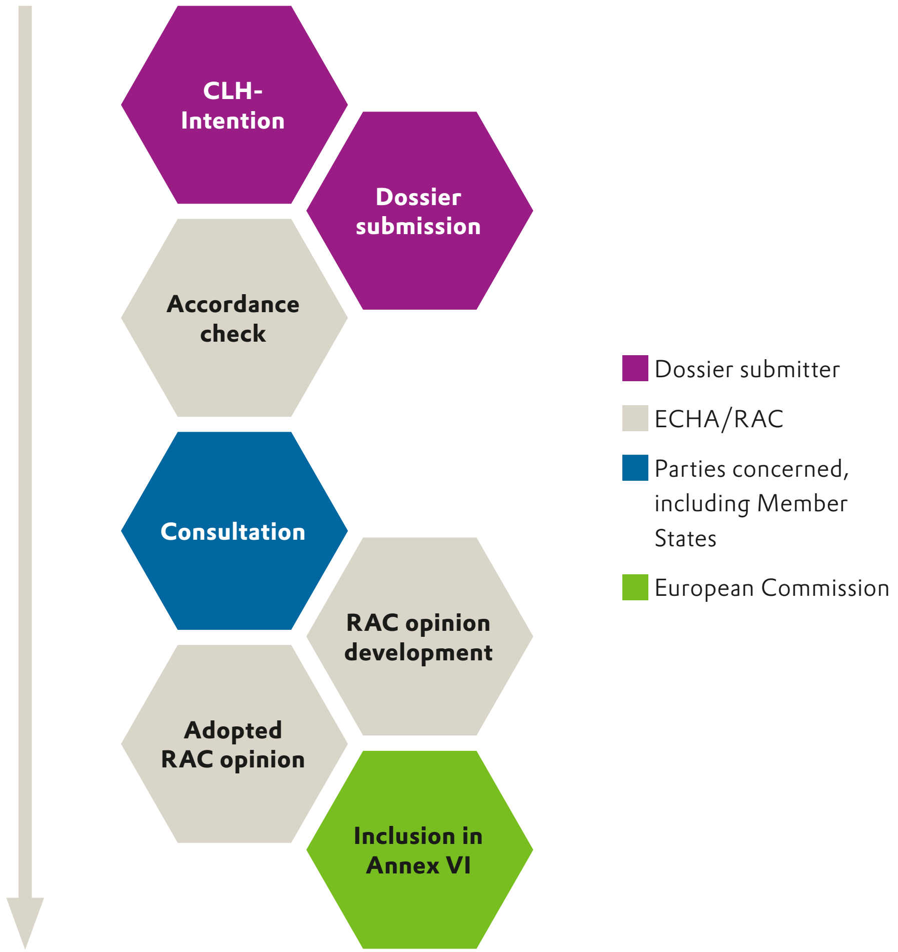
Harmonized classification and labeling may be proposed for substances not currently listed in Annex VI of CLP and for substances for which a harmonized classification exists but requires modification due to new information, new scientific or technical developments, changes in classification criteria or re-evaluation of existing data.

The respective competent authority (CA) of EU Member States, manufacturers, importers and downstream users can submit a proposal for the harmonized classification and labeling (CLH proposal) of a substance to the European Chemicals Agency (ECHA). This can be done in three different situations:

- if the substance is either carcinogenic, mutagenic, toxic for reproduction or an inhalation allergen,
- if there is a justification that the classification of a substance in other hazard classes is necessary at EU level,
- if one or more new hazard classes need to be added to an existing entry under the above conditions.

More information can be found on the ECHA website.

STEPS OF THE CLH PROCESS



WHAT DO "GHS" AND "CLP" MEAN?

GHS stands for Globally Harmonized System.

CLP stands for the Regulation on Classification, Labeling and Packaging of substances and mixtures.

The CLP Regulation governs the classification, labeling and packaging of chemicals and implements the internationally valid Globally Harmonized System (GHS) of the United Nations in the EU. The GHS serves as an internationally uniform basis for classification, labeling and packaging.

The main aim of the CLP Regulation is to inform stakeholders in the supply chain about the potential harmful effects of substances and mixtures by classifying and labeling them accordingly.

Questions regarding **silica in general**

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. It gives horsetail grass its stability, for example.

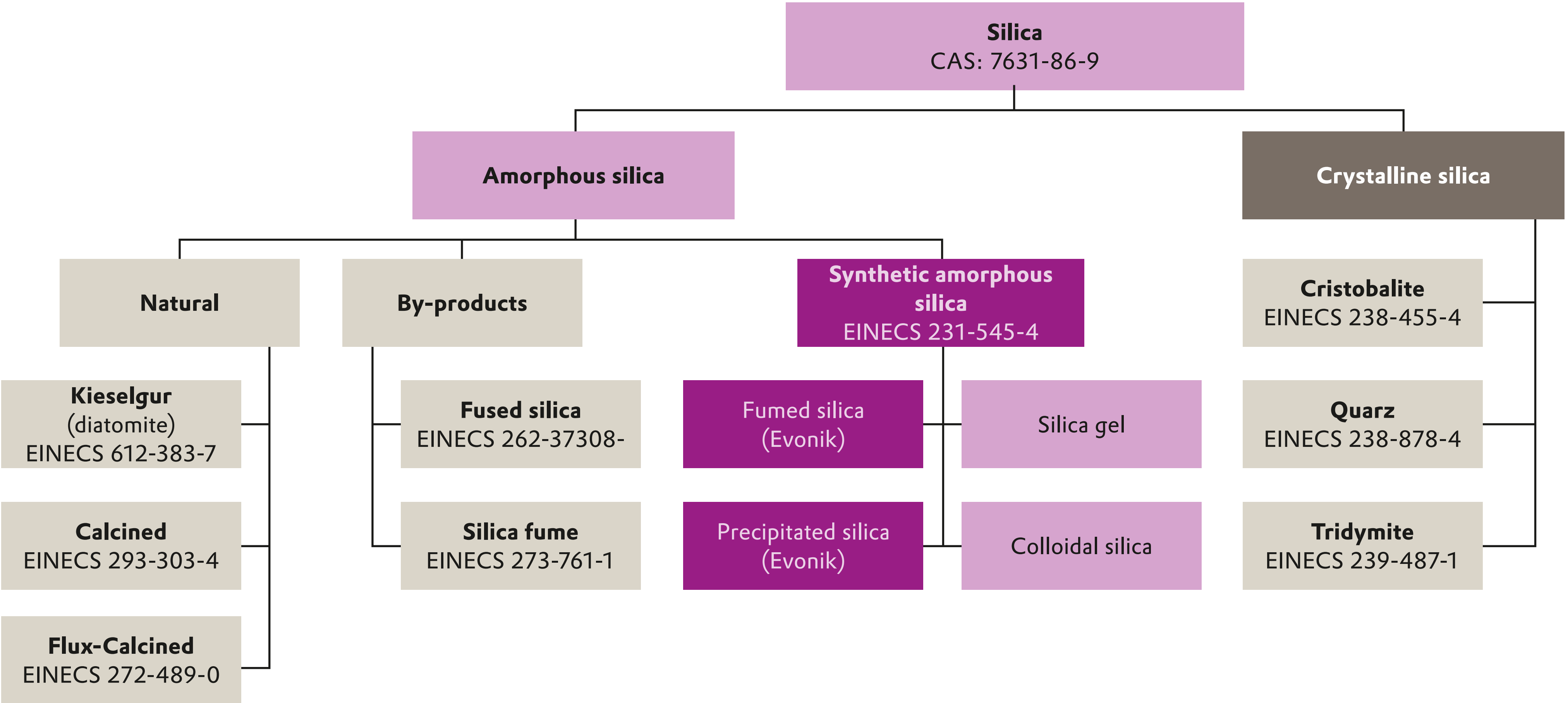
By the way: The two components in this compound, oxygen and silicon (approx. 27%), are among the most common elements in the Earth's crust when measured by weight.

The industry can produce silicon dioxide synthetically through different processes. The rather inhomogeneous natural raw material is converted into silica products with a constantly high purity and quality for a wide spectrum of specific applications in numerous industries. In simple terms, sand is turned into a valuable high-purity material. Only in this pure form is synthetic amorphous silica an essential additive for countless industrial applications.

Evonik produces only **synthetic amorphous silica**, or SAS.

The various SAS types produced by Evonik differ in terms of their physicochemical features, such as particle size, density or surface treatment. That's why Evonik offers tailor-made silica products with specific properties for many different applications.

SILICA (SILICON DIOXIDE) AND ITS VARIOUS MANIFESTATIONS



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WHAT IS SAS?

SAS is the abbreviation for synthetic amorphous 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.

Synthetic amorphous silica is recognized as a nature-identical, sustainable and safe material that plays an important role in many different applications.
Evonik produces only synthetic amorphous silica. This distinction is very important to set it apart from crystalline silica.

The industry predominantly uses two different routes to produce SAS product groups with specific properties: Precipitated silica and silica gels are produced from an aqueous solution, while fumed silica is created in a hydrogen flame. Both product groups – precipitated silica and fumed silica – belong to the amorphous silica types.

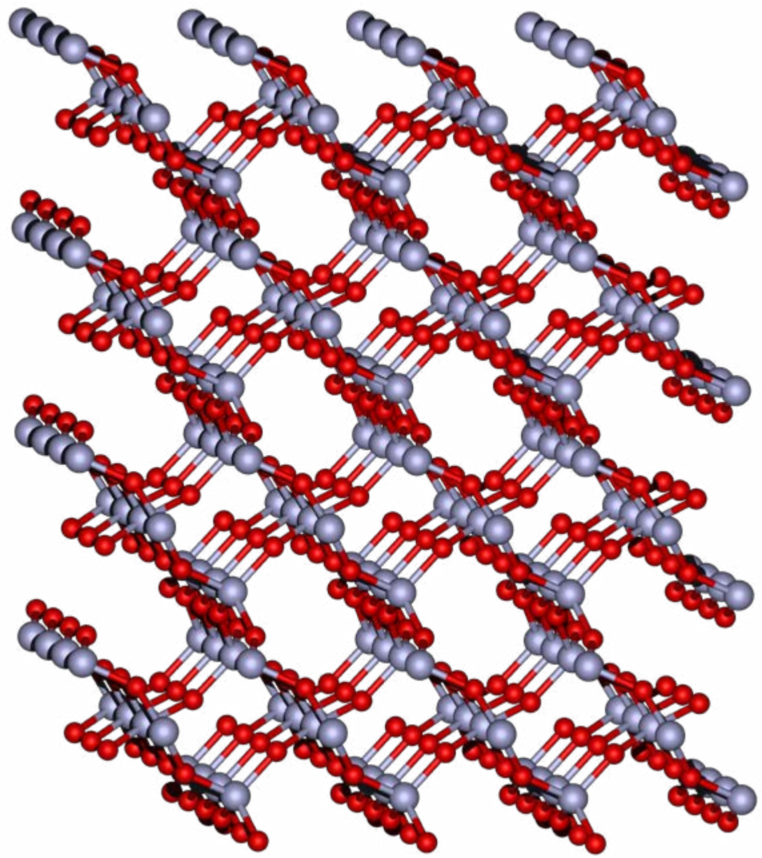
Evonik markets its fumed silica under the brand name AEROSIL® and precipitated silicas under the SIPERNAT®, SPHERILEX®, ULTRASIL®, ZEODENT® and ZEOFREE® brands.

WHAT IS THE DIFFERENCE BETWEEN AMORPHOUS SILICA AND CRYSTALLINE SILICA?

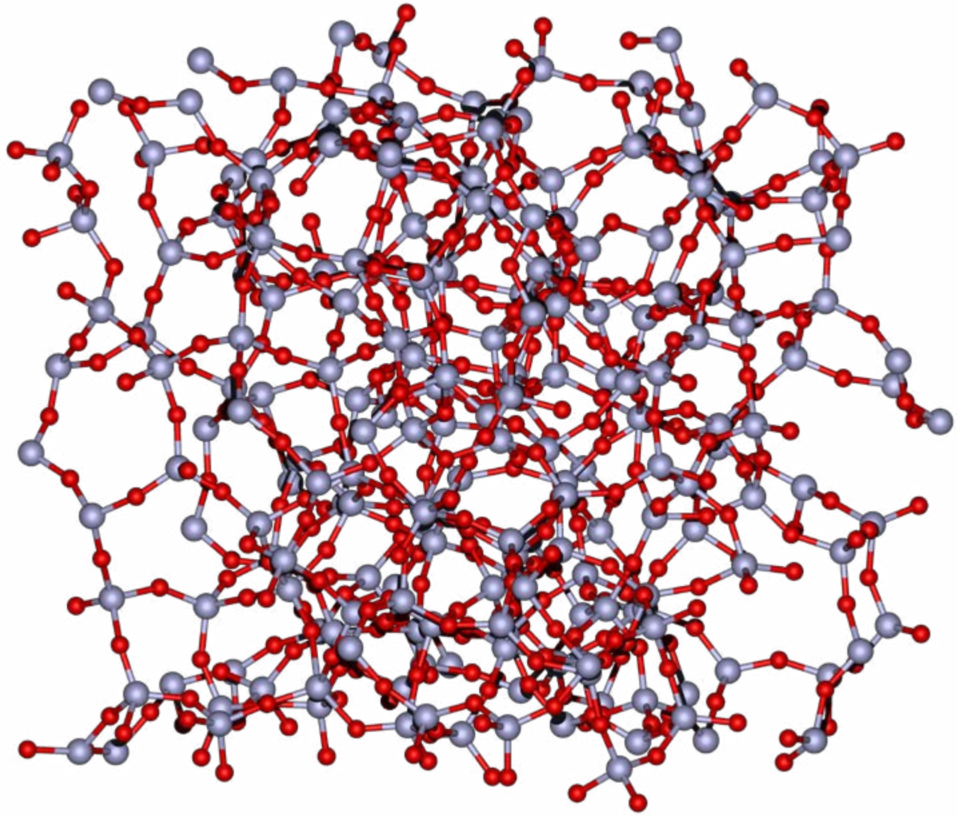
When talking about silica or silicon dioxide in general, it is important to understand the difference between amorphous and crystalline silica. Both types occur in nature: Quartz rock, for example, is a primary form of crystalline silica whose structure resembles a regular lattice framework. Silica is also incorporated in plants such as horsetail (image) and rice. his type is called amorphous silica because it has an irregular structure. Synthetic amorphous silica (SAS) created in an industrial process has an identical structure to that of amorphous silica in plants.

Consequently, it differs from crystalline silica not only in physical terms but also regarding its toxicological properties: Breathing in dust of crystalline silica, for example in mining, stonemasonry, and sandblasting, can cause the lung disease silicosis, which leads to irreversible damage of the lung tissue. On the other hand, it has been proven that amorphous silica and synthetic amorphous silica do not cause silicosis.

HORSETAIL



CRYSTALLINE SILICA:
The atoms are arranged in a regular lattice structure



AMORPHOUS SILICA:
The atoms are connected in a loose, irregular structure

WHAT IS SYNTHETIC AMORPHOUS SILICA USED FOR?

Synthetic amorphous silica is a highly innovative substance that improves countless everyday consumer goods and high-tech products. As an additive, it gives products certain properties. As a processing aid, it ensures that manufacturing processes run smoothly and resource-efficiently.

For example, certain types of silica act as free-flow and anti-caking agents and prevent powders from clumping together. Other types of silica act as carriers for other ingredients, and some can absorb liquids to such an extent that they can be further processed in powder form.

More information about silica functions and solutions:
www.silica-specialist.com/en/our-solutions

WHICH PRODUCTS CONTAIN SYNTHETIC AMORPHOUS SILICA?

- The food industry needs synthetic amorphous silica to ensure the consistent quality of powdered food products.
- As cleaning particles in toothpastes, silica ensures that teeth are cleaned thoroughly but gently. Silica also serves as a carrier for fluoride.
- Highly porous grades are used, for example, to absorb liquid vitamins and other nutrients and thus allow homogeneous distribution of valuable additives in animal feeds.
- Silica is essential for the automotive industry because it contributes to safe, fuel-saving and long-lasting tires.

These are our markets:
www.silica-specialist.com/en/our-markets

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.

In many applications, there are no equivalent alternatives, or developing substitutes and adapting formulations would involve considerable effort, resource consumption and costs.

In many cases, SAS even fulfill several functions at once thanks to their versatile profile of properties: For example, adhesives achieve a firm bond, but do not drip or dry during processing. And in car tires, they increase driving safety, extend durability and reduce fuel consumption. In numerous applications, silicas contribute to sustainability by reducing the waste of resources or extending the service life of products.

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.

Questions regarding **silica and safety**

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.

At no point in the value chain do people come 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. 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.

Synthetic amorphous silica (SAS) is used in many products and processes. There are no indications of any effects that could damage organs, tissues or genetic material if SAS is breathed in once or repeatedly, even in high doses. No damaging effects on reproduction or development or damage to the immune or nerve system have been reported. As a result, no maximum amounts have been defined for the acceptable daily intake (ADI).

In inhalation studies, SAS caused no long-term changes in the lung or progressive damage comparable to silicosis. In epidemiological studies on employees with long-term exposure, there were also no signs of silicosis; no damage is to be expected under realistic exposure conditions. The available data also contains no indications of lung cancer or other permanent respiratory diseases.

Synthetic amorphous silica can be handled safely when good occupational hygiene and the national or regional applicable maximum allowable concentration are complied with. If this limit value cannot be guaranteed, local extraction equipment must be operated, or dust masks must be worn.

Applicable guiding values at the workplace can be found in the respective safety data sheets of our silica products.

In Germany, for example, a maximum allowable concentration (MAC) of 4 mg/m^3 (inhalable) dust must not be exceeded.

WHAT IS THE ASSUMPTION BEHIND THE CLASSIFICATION OF SYNTHETIC AMORPHOUS SILICA AS "HARMFUL TO THE RESPRATORY TRACT THROUGH PROLONGED OR REPEATED EXPOSURE BY INHALATION"?

This classification is based on tests with rats that led to isolated cases of inflammatory processes in the lung tissue. However, the animals were exposed to disproportionately high amounts of dusts from synthetic amorphous silica (SAS) over a longer period. But the concentration and duration of exposure do not correspond to the real conditions in the production and processing of SAS.

It has also been medically proven that dusts in high concentrations and certain particle sizes generally pose a health risk and are harmful to the respiratory tract. For this reason, general upper limits apply to dusts in workplaces, even if they have no specific toxic effect.

WHY DOES EVONIK REJECT THIS CLASSIFICATION?

Evonik believes that this classification of synthetic amorphous silica (SAS) as STOT RE 1 is not justified, given that it is the dust particles that may create an adverse effect in the respiratory system and not the chemical (synthetic amorphous silica) itself. Moreover, Evonik is of the opinion that the amount and exposure assumed in the study do not correspond to the real conditions in the handling, industrial processing and any consumer use of SAS.

The proposed classification of synthetic amorphous silica as "harmful to the respiratory tract through prolonged or repeated exposure by inhalation" only refers to one extraordinary case: the inhalation of SAS dusts in high concentrations over long periods of time. Consumers do not come into contact with such dusts at all because all consumer products contain silica in bound form only. Safety at workspaces and health of employees is guaranteed by national occupational health and safety regulations.

WHAT MUST BE OBSERVED WHEN PROCESSING SYNTHETIC AMORPHOUS SILICA, AND WILL THIS CLASSIFICATION CHANGE ANYTHING?

All necessary instructions for the safe handling and processing of Evonik's silica products can be found in the respective safety data sheets. Even after a STOT RE 1 classification, the occupational safety regulations do not have to be amended.

In Germany for example, the Technical Rules for Hazardous Substances (TRGS) correspond to the latest standards in occupational medicine and hygiene as well as other established scientific findings for handling hazardous substances, including their classification and labeling.

For amorphous silicas, TRGS 900 sets binding occupational exposure limits for inhalable dust and not the labeling obligation that follows from chemicals legislation.

More information: www.baua.de/EN/Service/Technical-rules/TRGS/TRGS.html

HOW CAN THE USE OF SILICA-CONTAINING PRODUCTS BE HARMLESS TO HEALTH IF THE EU CLASSIFIES SYNTHETIC AMORPHOUS SILICA (SAS) AS POTENTIALLY HARMFUL TO THE RESPIRATORY TRACT?

SAS is only classified as potentially harmful to the respiratory tract in the form of particulate matter. However, there would only be a health risk if dusts were inhaled in large quantities and over a longer period of time without protection.

Safety in production is guaranteed by occupational health and safety regulations. At no stage in production or processing do people come into contact with silica dust in hazardous concentrations.

WHAT MEASURES DOES EVONIK TAKE TO ENSURE THE SAFETY OF EMPLOYEES DURING THE PRODUCTION OF SILICA?

Exercising environmental responsibility and protecting the health of employees, industrial customers and consumers are integral components of Evonik's business culture. We only produce and market materials if we can manufacture and use them in a safe, environmentally sound manner using our current technology. As part of these efforts, Evonik adheres to the international principles of Responsible Care.

When manufacturing materials, we provide the best possible protection for people and the environment by using closed production systems and additional technical tools, such as filters, vacuum equipment and, when necessary, personal protective equipment. To ensure that these efforts are effective in the workplace, we perform particle counts at regular intervals and provide routine medical care by site physicians.

Questions regarding **nanomaterials**

WHAT DOES NANO ACTUALLY MEAN?

The term comes from the Greek word for dwarf: nanos or nannos. Like the prefixes centi-, milli- or deci-, nano- simply describes an order of magnitude: A nanometer (nm) is a billionth of a meter, i.e., 0.000000001 meters. By way of comparison: A human hair is 50,000 nm thick, an atom is just 0.1 to 0.3 nm and the human genetic substance DNA (desoxyribonucleic acid) has a diameter of approximately 2 nm.

Things as small as this cannot be seen with the human eye and even conventional optical microscopes are not sufficient. Instead, you need special microscopes, such as scanning electron microscopes or transmission electron microscopes (SEM and TEM).

WHAT IS NANOMATERIAL?

Several different approaches and suggestions could be used to answer this question. A very basic definition is that nanotechnology is concerned with structures and objects of a size between 1 nm and 100 nm in at least one dimension. However, many institutions, researchers and authorities specify different sizes, and no single uniform and universally applicable definition currently exists.

WHAT DOES NANOSTRUCTURED MEAN?

Nanostructured materials are those with a nanoscale structure within the material or at its surface.

ARE NANOMATERIALS DANGEROUS?

Nanomaterials are not dangerous in themselves but are under particular scrutiny in the European Union's substance evaluation.

The scientific risk assessment of the German Federal Institute for Risk Assessment (BfR) focuses on purposefully manufactured nanomaterials. The basic principles of health risk assessment also apply to nanomaterials: Both potential health hazards (harmful effects) and actual exposure must be considered.
Due to the wide range of applications of nanomaterials in different products, the uptake pathways via the respiratory tract (inhalation), via the digestive tract (oral) and via the skin (dermal) are considered.

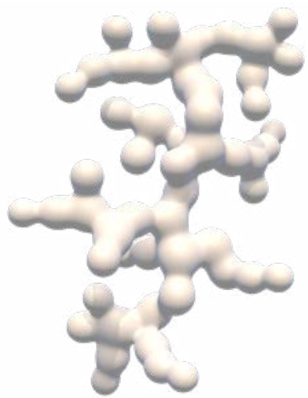
More information:
www.bfr.bund.de/en/health_assessment_of_nanomaterials-30439.html

IS SILICA A NANOMATERIAL?

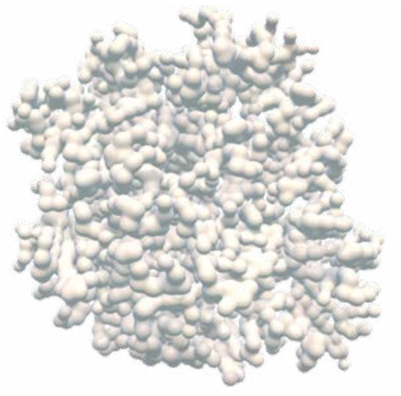
In the EU, most silica products must be labeled as nanomaterials by definition in the product safety data sheet. Some EU countries maintain nano registers in which nanomaterials and their applications must be listed. In some applications and workplace guidelines, other regulations apply that do not define silica products as nanomaterials.

Evonik SAS does not contain isolated nanoparticles; it consists of nanostructured agglomerates. These agglomerates need to be in a specific size range for SAS to fulfill its technical functions as an anti-caking agent and as a flow aid. The nanostructured SAS agglomerates, in turn, are made up of SAS aggregates. These aggregates are formed by inseparably bound nanoparticles.

AEROSIL® (LEFT) AND SIPERNAT® (RIGHT) AGGREGATES



Aggregates are the smallest structural units in silica products from Evonik. They consist of inseparably merged primary particles.



ARE NANOMATERIALS APPROVED FOR USE IN FOOD?

In the EU there are currently different nanomaterial definitions for different areas of law. The relevant definition of "engineered nanomaterials" for food can be found in the Regulation on Novel Foods (EU) 2015/2283, which came into force on January 1, 2018.

The silica used in food as additive E 551 and approved in Regulation (EC) 1333/2008 has been produced and used with the same production processes and product specifications for many decades.

E 551 is not produced to show novel nano properties in food. Rather, silica acts as a spacer between the particles of the powdered food and is therefore approved as an anti-caking agent in Regulation (EC) 1333/2008. Unbound silica primary particles would be too small to act as an anti-caking agent. It is aggregates that fulfill this function. Aggregates normally have dimensions in the micrometer range. No individual primary particles of E 551 have been found in commercially available silica products. Therefore, according to the Food Information to Consumers Regulation (EU) 1169/2011, E 551 does not have to be labeled with the affix "(nano)."

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WHAT HAPPENS TO SAS IN THE BODY?

Synthetic amorphous silica (SAS) can enter the body through breathing or with food. However, the body excretes natural amorphous silica and also SAS completely and in an unchanged form.

Dust particles containing silica are caught in the nose when you breathe and are discharged with nasal secretions. Two mechanisms prevent smaller particles from entering the bloodstream: Firstly, the particles are transported out by mucus and cilia, and secondly, the phagocytes continuously clean particles from the lung tissue. Only a very small, negligible part actually gets into the bloodstream, but this is then discharged via the kidneys.

SAS with the classification E 551 is added to food. When this food is eaten, a small part of the silica can be dissolved and get into the bloodstream – this is discharged via the kidneys. The body excretes the remainder normally. No accumulation of SAS in the body has been discovered with any of the ingestion paths.

Most SAS consumed with food is excreted in the stool. Only a very small part is reabsorbed into the bloodstream via the gut in the form of soluble silica and is then discharged again quickly with urine. If silica (E 551) is added to food, in an aqueous environment and depending on the pH, soluble silica can form which can be reabsorbed by the body.

In the mouth cavity and stomach this is not a relevant mechanism for the absorption of silica, even if E 551 is "freely" available after its carrier substance (e.g., salt) has dissolved. The mucous layer in the mouth cavity, which is much thicker (70–100 µm) than the silica particles, creates an effective barrier and protects the oral epithelium; consequently, appreciable resorption via the mouth cavity is practically impossible. Even with a very acidic pH, as found in the stomach, E 551 is not decomposed; soluble silica can only be released and reabsorbed in the small intestine. This small amount is integrated into the body silicon pool.

It is likely that silicon plays a structural role in the formation of connective tissue, including bones and skin. The highest silicon concentrations are found in bones and connective tissue and are higher in a growing organism than in old age. The silicon level in blood is kept constant by resorption and excretion. No accumulation of SAS in the body has been discovered, regardless of how it enters the body.

CAN SAS ENTER THE BODY THROUGH THE SKIN?

The cosmetic industry is an important area of application for Evonik's silica products. They get onto the skin with creams and powders, for example. The skin, however, is a very effective barrier to solid particles such as synthetic amorphous silica (SAS). SAS cannot penetrate the top layer of skin.

Skin is a natural barrier that prevents absorption of solid particles such as SAS. Particles applied to the skin have to penetrate several horny layers or, if they bypass this barrier, hair follicles or gland outlets before they could reach living cells in the dermis and get into the systemic circulation. All the information and studies that are available support the view that SAS remains on the skin surface or in the hair follicles and gland outlets and does not penetrate the top layers of skin.

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