United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances

Document Type:

☐ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☒ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

Silicon Dioxide

Handling/Processing

Identification

Chemical Names:
dioxosilane; silanedione; silicic oxide; silicon (IV) oxide; silicon dioxide.

Other Names:
amorphous silicon dioxide; anhydrous silica; colloidal silica; fumed silica; hydrolyzed silica; precipitated amorphous silica; pyrogenic silica; silica; silica, amorphous; silica, precipitated; synthetic amorphous silica (SAS).

Trade Names:
Aerosil; Cab-O-Sl; Flo-Gard; HDK; Hi-Sil; Levasil; Neosil; Perkasil; Sipernat; Sorb-it; StripPax; Zeosil.

CAS Numbers:
7631-86-9 (general);
112926-00-8 (precipitated; gel; colloidal);
112945-52-5 (fumed; pyrogenic);
63231-67-4 (gel).

Other Codes:
EC Numbers: 231-545-4; 601-214-2; 643-045-7.
INS: 551; E 551.
UNII: ETJ7Z6XBU4.

Summary

This full-scope technical report provides updated information to the National Organic Standards Board (NOSB) to support the sunset review of silicon dioxide, listed at 7 CFR 205.605(b)(29). This report focuses on uses of silicon dioxide in organic processing and handling as a defoamer, and for other uses when organic rice hulls are not commercially available.

In 1995, the NOSB discussed adding colloidal silica (a form of silicon dioxide) to the National List of Allowed and Prohibited Substances (hereafter referred to as the "National List") for use as a processing aid. However, the NOSB ultimately did not recommend it. However, silicon dioxide was included on the National List on December 21, 2000 in its first iteration (65 FR 80548, December 21, 2000; 66 FR 15619, March 20, 2001). The NOSB has continued to recommend its renewal in 2010, 2016, and 2021(NOSB, 2011, 2016a, 2021) with an annotation change effective on November 03, 2013 (78 FR 31815, May 28, 2013).

The last silicon dioxide technical report was published in 2010 (USDA, 2010). A petition filed that year requested the removal of silicon dioxide from the National List and claimed a rice-hull-based substitute could replace silicon dioxide in a 1:1 ratio (RIBUS, Inc., 2010). In December 2011, the NOSB's Handling Subcommittee found the data presented in the petition to be limited and insufficient to remove silicon dioxide from the National List; however, they felt that the natural alternative should be acknowledged (NOSB, 2011).

In response to the petition, the NOSB recommended adding the following annotation to silicon dioxide: "For use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available." In 2013, the NOP implemented the recommendation with the following changes: "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available." (78 FR 31815, May 28, 2013). The annotation has remained since.

Terminology describing silicon dioxide and substances composed of silicon dioxide changes depending on the context and source. "Silicon dioxide" is the IUPAC name of the chemical formula SiO_2. Substances made from SiO_2 are commonly referred to as "silica." This technical report focuses on substances known as synthetic amorphous silica (SAS) because these are the silica substances that food processors typically use as processing aids. Additionally, SAS is the broadest subset of silica used in food production and has been the focus of previous NOSB discussion. SAS is subcategorized as:

- fumed or pyrogenic silica
- precipitated silica
- silica gel
- colloidal silica

These are the specific forms described by the Food Chemicals Codex (United States Pharmacopeial Convention, 2025), the scientific literature summarized in this technical report, and the marketing materials for food additives with the CAS number 7631-86-9. SAS chemical purity is higher than that of other forms of silica.

Many international guidelines and regulations use the terms “silicon dioxide (silica),” “silicon dioxide,” or “silica” to refer to one or more SAS forms. Unless otherwise specified, we refer to:

- the chemical formula SiO_2 as “silicon dioxide”
- substances composed of SiO_2 as “silica”
- synthetic amorphous silica (and the substances described by the term) as “SAS”

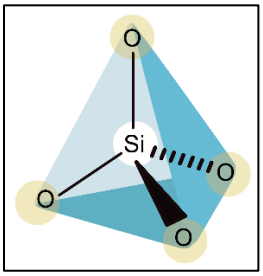
As “silicon dioxide” is listed at § 205.605(b), synthetic forms are allowed. Diatomaceous earth contains silicon dioxide (SiO_2) and can be nonsynthetic. However, diatomaceous earth is included separately on the National List at § 205.605(a). As it is listed separately, we consider diatomaceous earth to be distinct from the silicon dioxide National List annotation at § 205.605.

Characterization

Composition of the Substance

Silicon dioxide is a stable oxide of silicon (Agency for Toxic Substances and Disease Registry, 2019). It comprises one silicon atom (Si) with a formal charge of +4 and two oxygen atoms (O), each with a formal charge of -2, yielding a neutral structure (McLean & Yarovsky, 2024). By mass, it is 46.75% silicon and 53.26% oxygen (Royal Society of Chemistry, 2025). Silicon dioxide has the molecular formula SiO_2, regardless of source or structural variation (Agency for Toxic Substances and Disease Registry, 2019; Housecroft & Sharpe, 2005). Although silicon dioxide’s molecular formula is SiO_2, materials composed of silicon dioxide are structured as SiO_4 tetrahedral units (see *Figure 1*) (Khouchaf et al., 2020; Videira-Quintela et al., 2021; Zou et al., 2008).

Figure 1: Silicon dioxide tetrahedral unit structure.



Silica materials are variations of bonded SiO_4 unit networks, in which the oxygens at the corners connect to two neighboring tetrahedra in three dimensions (Fruijtier-Pölloth, 2012; Housecroft & Sharpe, 2005; Khouchaf et al., 2020). Particles are covalently bonded at the corners of the molecules, creating a structural bridge through oxygen atoms (Fruijtier-Pölloth, 2012; Housecroft & Sharpe, 2005; Khouchaf et al., 2020). Each silicon atom is bonded to four oxygen atoms; however, each oxygen is bonded to two silicon atoms. The result is that structurally, silicon dioxide is structured as a tetrahedron (SiO_4), but these structures are also bonded to adjacent neighbors; therefore chemically, the substance overall is SiO_2.

At the edges of these networks, the structure is different. The networks of these tetrahedra (or the “bulk”) terminate with surfaces composed of (Agency for Toxic Substances and Disease Registry, 2019; McLean & Yarovsky, 2024; Videira-Quintela et al., 2021):

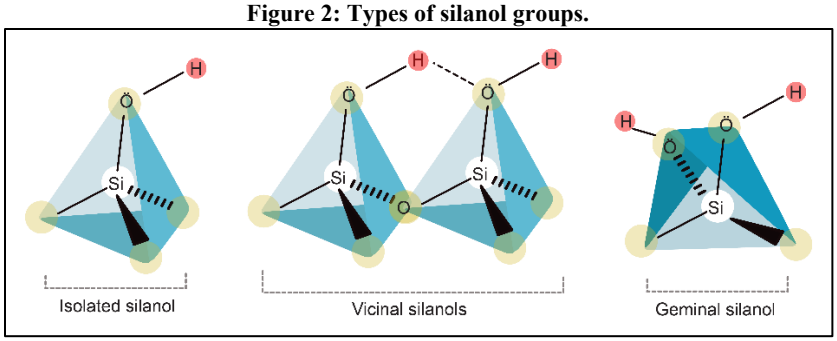
- siloxane groups (silicon and oxygen atoms covalently bonded as Si−O−Si)
- silanol groups (Si−OH)

It is these siloxane and silanol groups at the surface of the bulk that give silica many of its important characteristics.

The concentration and arrangement of silanol groups at the surfaces of the silica bulk vary from substance to substance, and are the main indicators for surface activity (see *Action of the Substance*) (Khouchaf et al., 2020; Videira-Quintela et al., 2021; Zou et al., 2008). Researchers classify the arrangement of silanol groups into three distinct types (see *Figure 2*) (Videira-Quintela et al., 2021; Zou et al., 2008):

- isolated: a standalone silanol group, dangling at the surface of the bulk
- vicinal: silanol groups formed at adjacent silicon atoms, interacting through hydrogen bonding
- geminal: silanol groups with two -OH groups bonded to the same silicon atom

Figure 2: Types of silanol groups.



Different manufacturing processes produce different surface silanol concentrations and arrangements [see *Evaluation Question #1(B)*].

Materials composed of silicon dioxide occur in regularly ordered (crystalline) and irregularly ordered (amorphous) structural arrangements (Agency for Toxic Substances and Disease Registry, 2019; Khouchaf et al., 2020; Videira-Quintela et al., 2021). The type of arrangement depends on the pattern of the SiO_4 tetrahedral units (or lack of pattern) and surface groups (Videira-Quintela et al., 2021), and the bond angles throughout the network (Khouchaf et al., 2020). Pressure and heat affect the form of silica produced (West, 2014).

Generically, silica is described with CAS Registry Number (CAS RN, or CAS number) 7631-86-9. This CAS number represents three types of SiO_4 tetrahedral arrangements (Fruijtier-Pölloth, 2012):

- crystalline silica
- naturally occurring amorphous silica
- synthetic amorphous silica (SAS)

In addition to its generic CAS number, silica materials have additional CAS numbers that identify more specific forms (Agency for Toxic Substances and Disease Registry, 2019; ECHA, 2024; Fruijtier-Pölloth, 2012). For example, SAS forms are assigned specific CAS numbers based on the manufacturing process. The specific CAS numbers for food-grade forms are noted in *Identification*.

Amorphous forms of silica

Amorphous silica is defined by its irregularly arranged SiO_4 tetrahedral units (McLean & Yarovsky, 2024). A contrasting feature between crystalline and amorphous forms is the Si−O−Si bond angles (Khouchaf et al., 2020; McLean & Yarovsky, 2024). Unlike crystalline forms with repeating bond angles, amorphous forms have varying bond angles throughout the structure's network, giving varying pore sizes between the tetrahedral units (Khouchaf et al., 2020; McLean & Yarovsky, 2024). As a result, amorphous forms contain channels that allow small positively charged ions (*e.g.,* sodium) to migrate into the bulk (Drees et al., 1989; Fruijtier-Pölloth, 2012). For further information about these pore sizes, see *Properties of the Substance*.

Amorphous silica is found in a variety of natural substances, including (Agency for Toxic Substances and Disease Registry, 2019; Housecroft & Sharpe, 2005; West, 2014):

- diatomaceous earth
- vitreous silica (silica glass, such as obsidian)

Some types of opal may also include an amorphous structure (Drees et al., 1989); however, purely amorphous opal is uncommon in soils.

Sedimentary deposits, as diatom fragments, are more common sources of amorphous silica (Drees et al., 1989). The term "diatomite" describes sedimentary deposits where silicon dioxide comprises at least 50% of the bulk sediment (*e.g.,* diatomaceous earth) (Flower, 2013). Diatomites contain large quantities of natural amorphous forms (Flower, 2013; Napierska et al., 2010). These amorphous silica substances also include other minerals consisting of elements like iron, titanium, calcium, and sodium. Amorphous sources may also contain crystalline structures before processing (Napierska et al., 2010; Nattrass et al., 2015).

Commercial diatomite processors typically convert some of the amorphous silica into a crystalline form, depending on the desired end product (Nattrass et al., 2015).

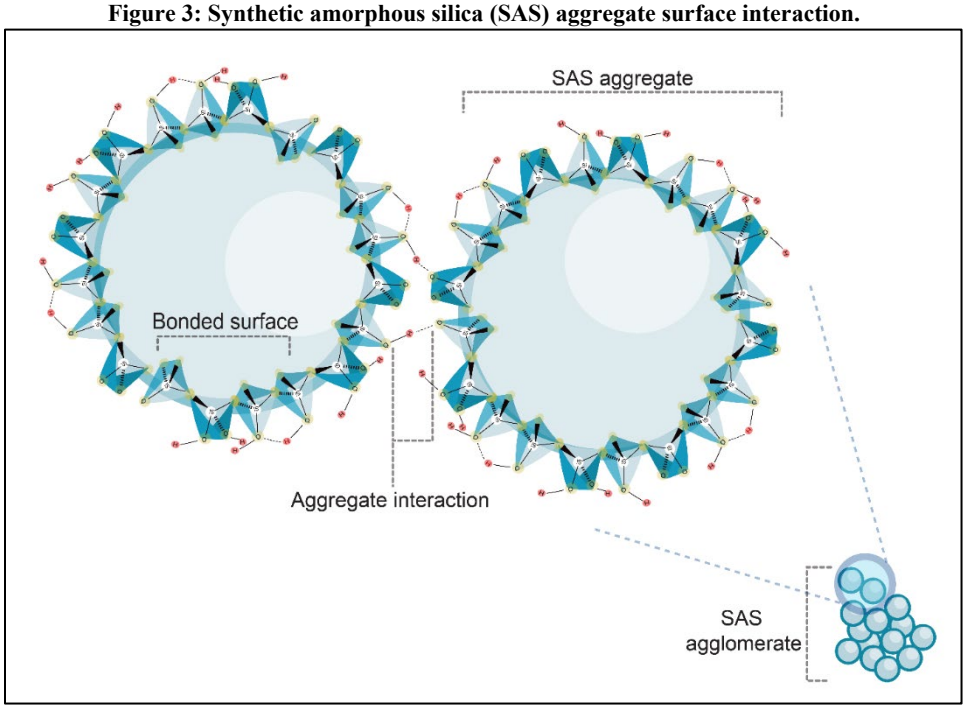
Food-grade amorphous silica varieties used as additives in food are categorized as synthetic amorphous silica (SAS) (Thakur & Singh, 2018). SAS products contain less than 1% impurities and no detectable amounts of crystalline silica because of their manufacturing processes (Fruijtier-Pölloth, 2012). Forms include (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018; Fruijtier-Pölloth, 2012; United States Pharmacopeial Convention, 2008):

- fumed or pyrogenic silica
- precipitated silica
- silica gel
- colloidal silica

SAS "primary particles" bond together and create aggregates (Zou et al., 2008). The bonds between primary particles that form an aggregate remain intact even under strong mixing conditions (Zou et al., 2008). Multiple aggregates in turn interact through weak interactions like van der Waal forces and hydrogen bonds, and form grape-cluster like agglomerates (see *Figure 3*) (Fruijtier-Pölloth, 2012; Zou et al., 2008). The surface silanol groups of one aggregate interacts with adjacent groups on another aggregate in order to create the agglomerate (Fruijtier-Pölloth, 2012; Zou et al., 2008). This leads to agglomerates being only loosely bound together (Fruijtier-Pölloth, 2012).

Forms of SAS that contain a higher number of silanol groups are more likely to agglomerate (Zou et al., 2008). Fumed silica has the lowest incidence of silanol groups per square nanometer, while silica gel has the highest. Silica gel's overall pore arrangement can be described as ring-like (Ciriminna et al., 2013).

Figure 3: Synthetic amorphous silica (SAS) aggregate surface interaction.



Crystalline forms of silica

Unlike amorphous forms, the SiO_4 tetrahedra in crystalline silica are linked together in a well-ordered lattice structure, with defined Si-O-Si bond angles (Housecroft & Sharpe, 2005). Most crystalline silica forms at temperatures below the melting temperature of silicon dioxide (1700 °C), at standard atmospheric pressure (Napierska et al., 2010; West, 2014). SiO_4 crystalline structures change from one arrangement to another under varying temperature and pressure (West, 2014). For example, tridymite is formed from quartz at 870 °C at standard atmospheric pressure. The number of known crystalline structures is limited (Napierska et al., 2010), but a few examples of crystalline silica are the minerals (Videira-Quintela et al., 2021; West, 2014):

- quartz
- cristobalite
- tridymite

Crystalline arrangements are less surface active than amorphous arrangements because of their ordered structure (Khouchaf et al., 2020). We did not find evidence of crystalline silica being used in food.

Source or Origin of the Substance

After water, silicon dioxide is the most common oxide in the Earth's crust (West, 2014). Materials composed of silicon dioxide are structured in a wide variety of ways (see *Composition of the Substance*). The term "silica" is used as the common name for materials composed of silicon dioxide (Napierska et al., 2010). Most bioavailable silicon is continuously recycled through biomineralization and dissolution in water, both in fresh and marine bodies (Dixit & Van Cappellen, 2002). Although many substances include silicon dioxide, two of the forms that are most applicable to food processing are:

- synthetic amorphous silica
- diatomaceous earth

The cell walls of diatoms, a group of single-celled algae, are made of hydrated silica (Nattrass et al., 2015). When fossilized in large quantities, these diatoms form diatomite sediments. Manufacturers mine these sediments (referred to as diatomaceous earth) as a source of amorphous silica (Nattrass et al., 2015). Sediments, though silica-rich, are interspersed with contaminant minerals such as clays and carbonates (Nattrass et al., 2015). In the food industry, diatomaceous earth is used primarily as a filtering aid and as an insect pest control agent (Flower, 2013). All food-grade, pure, amorphous silica used in the handling context as a component in food products can be described under the "synthetic amorphous silica" (SAS) categorization (Fruijtier-Pölloth, 2012; Napierska et al., 2010). For further information about nonsynthetic sources, see *Evaluation Question #9*.

SAS is manufactured through the chemical reaction of a silicon source and either an acid, water, and/or an alcohol (wet processes), or molecular oxygen (thermal processes) [see *Evaluation Question #1(B)*] (Barthel et al., 2005; Fruijtier-Pölloth, 2012; Zou et al., 2008). Strong acids, bases, or high-energy flames are needed to create SAS because of silicon's inert nature (Zou et al., 2008). SAS precursor materials are primarily synthetic and include:

- silicon tetrachloride and oxygen gas; or
- sodium silicate, sodium hydroxide, and sulfuric acid

Wet processes yield (Barthel et al., 2005; Fruijtier-Pölloth, 2012):

- precipitated silica
- silica gel
- colloidal silica

The thermal process yields fumed (pyrogenic) silica (Barthel et al., 2005; Fruijtier-Pölloth, 2012; Zou et al., 2008).

The wet and thermal processes are described in further detail in *Evaluation Question #1(B)*.

Properties of the Substance

Synthetic amorphous silica (SAS) appears as a white solid that is commercially available in different particle sizes and porosity variations (see *Table 1*) (Agency for Toxic Substances and Disease Registry, 2019; Thakur & Singh, 2018). Colloidal dispersions are also commercially available and appear as milky white suspensions (ECETOC, 2006b). Primary particles are below 1 micrometer and generally spherical (De Temmerman et al., 2012). However, SAS functions and primarily exists in larger aggregates and agglomerates.

Silica melts when heated over 1700 °C, regardless of structural organization (Napierska et al., 2010).

SAS is hydrophilic and hygroscopic, but sparingly soluble in water and organic solvents (*e.g.,* ethanol) (Fruijtier-Pölloth, 2012; United States Pharmacopeial Convention, 2008; Zou et al., 2008).[1] Its hydrophilic and hygroscopic properties are a result of the silanol and siloxane groups on the surface of the material (Zou et al., 2008). Its solubility in water is affected by its surface structure (*i.e.,* silanol and siloxane group availability) and overall surface area (Fruijtier-Pölloth, 2012). SAS dissolves in hydrofluoric acid and hot, concentrated alkali solutions. Silicon dioxide's solubility increases as (Agency for Toxic Substances and Disease Registry, 2019; Housecroft & Sharpe, 2005; West, 2014):

- particle size decreases
- temperature increases
- pH increases
- surface area increases

[1] Hygroscopic: able to absorb or adsorb water from air.

SAS surfaces carry an overall negative charge (Barthel et al., 2005).[2]

SAS may be surface hydrated or non-hydrated (anhydrous) (Fruijtier-Pölloth, 2012). Fumed silica (also known as pyrogenic silica) is a white, fluffy, non-gritty powder and is anhydrous because of its manufacturing process (United States Pharmacopeial Convention, 2008). SAS produced from wet processes contains three types of water that can be removed by heating the material at different temperatures (Wypych, 2021):

- free water, removed at 105 °C
- adsorbed water (hydrogen-bonded to the surface), removed at 105 - 200 °C
- constitutional water, removed at 700 - 900 °C

These types of SAS can also be white, fluffy powders, but can also appear as white, microcellular beads or granules (United States Pharmacopeial Convention, 2008).

Silicon dioxide is relatively inert and, as a result, silica materials do not readily react with acids other than hydrofluoric acid (Housecroft & Sharpe, 2005; Wypych, 2021). When silicon dioxide units react with hydrofluoric acid, it forms aqueous hexafluorosilicic acid (H_2SiF_6) (Housecroft & Sharpe, 2005). Oxides of alkali metals (*e.g.,* sodium and potassium) also react with silica (Pratsinis, 1998; West, 2014). Alkali oxides can interrupt the silicon dioxide network (SiO_4) and form silicates (Housecroft & Sharpe, 2005; Pratsinis, 1998).

SAS is resistant to shear stress because it tends to aggregate and agglomerate (Barthel et al., 2005; Dultz, 1971).

Table 1: Properties of SAS.

Property	Value
Physical state and appearance	Fluffy powder, granules, microcellular beads, or gel
Odor	Odorless
Taste	Tasteless
Color	White
Molecular weight (g/mol)	60.08
Density (g/cm^3 at 25 °C)	2.196
pH	5-8
Solubility (in water at 20 °C)	Insoluble to slightly soluble
Boiling point (°C)	2230
Melting point (°C)	1710
Vapor pressure (mmHg)	Negligible at 20 °C
Stability	Stable
Reactivity	Reacts with hydrofluoric acid and alkaline solutions

Sources: (Agency for Toxic Substances and Disease Registry, 2019; CAS Common Chemistry, n.d.; ECHA, 2024; Thakur & Singh, 2018; United States Pharmacopeial Convention, 2008; Zou et al., 2008)

Compared to crystalline silica, SAS has a larger surface area-to-mass ratio (Barthel et al., 2005; Thakur & Singh, 2018); in other words, it is less dense. The increased surface area is attributed to SAS's internal porosity (Raschpichler et al., 2020; Wypych, 2021). SAS pore size is generally classified as (Napierska et al., 2010; Raschpichler et al., 2020):

- microporous: pore diameters less than 2 nanometers (nm); or
- mesoporous: pore diameters between 2 and 50 nm

SAS types can also contain macropores (pore diameter greater than 50 nm), but these are less common (see *Table 2*) (Napierska et al., 2010). In contrast, colloidal silica from the Stöber growth process is nonporous [see *Evaluation Question #1(B)*].

Silica pores are uniform in size throughout the bulk network (Fruijtier-Pölloth, 2012). Manufacturers can adjust the pore diameter, distribution, and available surface area by controlling the washing, aging, and drying conditions (Fruijtier-Pölloth, 2012; Napierska et al., 2010; Wypych, 2021).

[2] This negative charge is localized, as an atom's individual dipole charge effect, and does not refer to the net charge of the molecule.

Table 2: SAS porosity and moisture adsorption properties. Data from ECETOC (2006b), Fruijtier-Pölloth (2012), Wypych (2021), and Zou et al. (2008).

SAS	Adsorbed moisture at 50% RH* and 25 °C (%)	Pore diameter (nm)	Maximum silanol groups (1/nm^2)	Bulk density (BET, m^2/g*)	Mean pore classification
Pyrogenic	6	< 2	2	50-400	Microporous
Precipitated	7-20	30	6	30-500	Mesoporous
Gel	23-27	2-50	8	250-1000	Meso- or macroporous

**Relative humidity (RH), square meters per gram (m^2/g)*

Specific Uses of the Substance

Synthetic amorphous silica (SAS) can be found as silica gel, fumed silica, and precipitated silica powders. These may be used interchangeably for the purposes described in this section. However, as noted below, colloidal silica (another type of SAS) and silica gel beads or granules have more specific applications. We found no evidence of crystalline silica being used in food production.

Food manufacturers typically utilize SAS powders at levels up to 2% by weight for various purposes, including their use as (ECETOC, 2006b; Evonik, 2025; Lawrence Industries, 2025):

- flow agents
- thickening agent
- anticaking agents
- grinding aids
- adsorption agents
- carriers
- dispersion agents

SAS manufacturers offer a variety of products marketed for specific uses, depending on the nature of the food being processed and the size of its particles (CHEMPOINT, 2025; Evonik, 2025; HIFULL, 2023; Lawrence Industries, 2025). For example, if a food manufacturer wants to improve flowability and reduce caking in a dry, hard powder, precipitated silica or fumed silica would be the recommended option among SAS products (Lawrence Industries, 2025). In contrast, if a food processor works with a wet powder and aims to reduce cake and improve flowability, a highly porous precipitated silica would be the suggested choice.

SAS powders are commonly found in a range of food products, such as (ECETOC, 2006b):

- beverage mixes
- salad dressings
- sauces
- gravy mixes
- seasoning mixes
- soups
- spices
- snack foods
- sugar substitutes
- desserts

More specifically, organic food manufacturers use SAS as (NOSB, 2016a; OTA, 2016a):

- a flow agent in syrups, oligodextrins, fruit snacks, and cheese powders
- an anticaking agent in foods, specifically spice blends and organic seed pellets
- a stabilizer in beer production (filtered out of the beer prior to final processing)
- an adsorbent in tableted foods
- a carrier
- a defoaming agent

Additionally, beverages such as wine, beer, and fruit juices can be clarified using colloidal silica (Agency for Toxic Substances and Disease Registry, 2019), which most often consists of SAS particles dispersed in a liquid, such as water (Fruijtier-Pölloth, 2012). Colloidal silica is also mixed with essential oils for craft beer and jam production (Peña-Gómez et al., 2020). Manufacturers combine silica with thymol, vanillin, and eugenol as an alternative to

pasteurization, since pasteurization compromises quality characteristics (Villacreces et al., 2022). This combination is not used in wine (Ruiz-Rico et al., 2021).

In the pharmaceutical industry, SAS is employed as an anti-caking agent and as an excipient in various drug and vitamin preparations (Agency for Toxic Substances and Disease Registry, 2019). Silica gel beads are also used in food storage containers (ECHA, 2024), food packaging, and cosmetics (Agency for Toxic Substances and Disease Registry, 2019)as an atmospheric control product (*e.g.*, moisture absorber, desiccant) (Chen, 2017; Karate et al., 2024). The granules are placed inside packages to help keep the products dry by absorbing excess moisture.

Approved Legal Uses of the Substance

The Code of Federal Regulations at § 172.480(a) indicates that "silicon dioxide" (*i.e.,* silica) food additive is "manufactured by vapor-phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect. "Vapor-phase hydrolysis produces SAS, not crystalline silica. The allowed uses of the silica include serving as an anticaking agent, a stabilizer in beer production, and an adsorbent.

We found no instances in which crystalline silica serves that function in food processing. SAS has a larger surface area-to-mass ratio (Raschpichler et al., 2020; Wypych, 2021) and increased porosity (Barthel et al., 2005; Thakur & Singh, 2018) than crystalline silica. These properties are why SAS functions effectively as a processing aid in the food industry. Crystalline silica could not function effectively in any of the ways indicated in the Code of Federal Regulations (anticaking agent, stabilizer, and adsorbent) due to its physicochemical composition (less active surface, less porosity, organized and regular crystalline structure, etc.). In addition, breathing in crystalline silica dust can lead to silicosis, a lung disease (Agency for Toxic Substances and Disease Registry, 2019). This makes crystalline silica hazardous and inappropriate for food production.

Due to these reasons, "silicon dioxide" as described at § 172.480(a) and by the FDA, appears to refer specifically to SAS. The FDA notes that "silicon dioxide" (*i.e.,* SAS) is used as (US FDA, 2025):

- an anticaking agent or free-flow agent
- an antioxidant
- a coloring agent or color adjunct
- a drying agent
- an emulsifier
- a flavoring agent or adjuvant
- a formulation aid
- a humectant
- a lubricant or release agent

The FDA lists silicon dioxide (SAS) as an ingredient in the production of other products (21 CFR 172.480), such as:

- An adjuvant in microcapsules for flavoring substances (§ 172.230);
- A beer stabilizer, if it is removed from beer by filtration before final processing [§ 172.480(c)]; and
- An adsorbent for Dl-α-tocopheryl acetate and pantothenyl alcohol in tableted foods for special dietary use [§ 172.480(d)].

Standard of identity for silicon dioxide, under FDA

The FDA describes the standard of identity for silicon dioxide as follows (21 CFR 172.480):

> *The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.*

The description of silicon dioxide produced from vapor phase hydrolysis is consistent with fumed silica, a form of SAS.

GRAS affirmation for silicon dioxide, under FDA

The FDA considers silicon dioxide to be GRAS as a food additive, provided it is used in accordance with good manufacturing practices (21 CFR 172.480). Silicon dioxide as an anticaking agent in food should not exceed 2% by weight of the food (§ 172.480).

Specifications for silicon dioxide in the Food Chemicals Codex

The current version of the Food Chemicals Codex (United States Pharmacopeial Convention, 2025) specifies the following for "silicon dioxide" (SAS):

> *Description:*
> *Silicon Dioxide occurs as an amorphous substance that shows a noncrystalline pattern when examined by X-ray diffraction. It is produced synthetically, either by a vapor-phase hydrolysis process, yielding fumed silica, or by a wet process, yielding precipitated silica, silica gel, colloidal silica, or hydrous silica. Fumed silica is produced in an essentially anhydrous state, whereas the wet-process products are obtained as hydrates or contain surface-adsorbed water. Fumed silica occurs as a white, fluffy, non-gritty powder of extremely fine particle size and is hygroscopic. The wet-process silicas occur as white, fluffy powders or as white, microcellular beads or granules and are hygroscopic or absorb moisture from the air in varying amounts. All of these forms of Silicon Dioxide are insoluble in water and in organic solvents, but they are soluble in hydrofluoric acid and in hot, concentrated solutions of alkalies.*
>
> *Function:*
> *Anticaking agent; defoaming agent; carrier; conditioning agent; chillproofing agent in malt beverages; filter aid*
>
> *Identification:*
> *A. Procedure*
> *Sample:5 mg*
> *Analysis: Place Sample into a platinum crucible, mix with 200 mg of anhydrous potassium carbonate, and ignite over a burner at a red heat for about 10 min. Cool, dissolve the melt in 2 mL of freshly distilled water, warming if necessary, and slowly add 2 mL of ammonium molybdate TS.*
> *Acceptance criteria: A deep yellow color appears.*
> *B. Procedure*
> *Sample: Solution remaining from Identification test A*
> *Analysis: Place 1 drop of Sample from Identification test A on a filter paper, and evaporate the solvent. Add 1 drop of a saturated solution of o-tolidine in glacial acetic acid, and place the paper over ammonium hydroxide.*
> *Acceptance criteria: A green-blue spot develops.*

[Various test descriptions then follow in the monograph, which we have omitted here.]

TTB

The Alcohol and Tobacco Tax and Trade Bureau (TTB) regulates the use of filtering aids used to produce wine and juice. The TTB regulations describing the use of "silicon dioxide" (no forms specified) include 27 CFR 24.246. In short, the TTB states that silicon dioxide can be used to treat wine and juice, but it must be completely removed by filtration, and that the amount of silicon remaining in the wine must not exceed 10 ppm (10 mg/L). The TTB also allows for the use of silicon dioxide as a defoaming agent and specifies the following limitations:

> *Defoaming agents which are 100 percent active may be used in amounts not exceeding 0.15 pounds per 1000 gallons (18 mg/L) of wine. Defoaming agents which are 30 percent active may be used in amounts not exceeding 0.5 pounds per 1000 gallons (60 mg/L) of wine.*

Silica gel (colloidal silicon dioxide) is also specifically permitted as a clarifier for wine and juice by the TTB with the following limitation:

> *Use must not exceed the equivalent of 20 pounds colloidal silicon dioxide at a 30 percent concentration per 1000 gallons (2.4 g/L) of wine. Silicon dioxide must be completely removed by filtration.*

Action of the Substance

Synthetic amorphous silica's (SAS) action relates to its surface activity and large surface area (see *Composition of the Substance*) (Barthel et al., 2005; Zou et al., 2008). Additionally, SAS commonly forms hydrogen bonds. The surface of SAS particles are covered with siloxane and silanol groups that are capable of participating in chemical reactions (McLean & Yarovsky, 2024). This differs from the interior of SAS networks (the "bulk"), which are inert (McLean & Yarovsky, 2024). The functional groups act as partially negative charge sites that can interact with positively charged substances (McLean & Yarovsky, 2024; Zou et al., 2008). The specific interaction sites are oxygen atoms in the surface groups (McLean & Yarovsky, 2024). Because the surface of SAS is negatively charged, it can be incompatible with other negatively charged substances (Videira-Quintela et al., 2021).

As described previously in *Composition of the Substance*, there are different types of silanol groups. These are defined by the number and orientation of hydroxide groups at the surface of each SiO_4 tetrahedron. Silanols are isolated, vicinal, or geminal. These silanol groups exhibit different abilities to adsorb substances and have different chemical activities (see *Figure 2*) (Napierska et al., 2010). For example, vicinal silanol groups interact strongly with water molecules and therefore are better adsorbers than isolated or geminal silanol groups (Napierska et al., 2010). Silica forms with a low silanol group density (of any type) have a comparatively reduced sorbent (adsorbent and absorbent) effect. As a result, manufacturers choose different types of SAS for their specific applications. See *Specific Uses of the Substance* for complete use information.

Fumed (pyrogenic) silica

Fumed silica's surface is primarily composed of siloxane and isolated silanol, and it does not have internal silanol groups (Barthel et al., 2005). Fumed silica is a wettable powder that does not swell (Barthel et al., 2005; Napierska et al., 2010). Due to the number of siloxane and isolated silanol groups, fumed silica readily forms hydrogen bonds with adjacent aggregates or other substances (Fruijtier-Pölloth, 2016; Wypych, 2021)**.** Under high rates of shear stress (*i.e.*, mixing, shaking, sonicating), the hydrogen bonds are broken, which causes the powder or liquid to thin out (Barthel et al., 2005; Khan et al., 2024). As the shear stress decreases, aggregates rearrange and form new bonds (Barthel et al., 2005). The effect of these interactions is that fumed silica gets between food particles and prevents powder from clumping. In liquids, fumed silicon behaves similarly, leading to an increase in viscosity (Barthel et al., 2005; Fruijtier-Pölloth, 2012).

Precipitated silica

As discussed in *Specific Uses of the Substance*, fumed silica and precipitated silica are used interchangeably. We did not find specific action information regarding precipitated silica's unique function.

Silica gel

Silica gel is used as a desiccant in food packaging (Karate et al., 2024). The highly porous network allows surface adsorption of water and capillary condensation, keeping excess moisture away from dry foods (Chen, 2017; Karate et al., 2024).[3] Silica gel works well at ambient temperature, but may have decreased adsorption rate and equilibrium moisture content at higher temperatures (Chen, 2017). Manufacturers do not intend for silica gel desiccant products to come into contact with food (Janjarasskul & Suppakul, 2018; Yildirim et al., 2018).

Silica gel's adsorption properties and pore size is also exploited in cold-sterilization of beer (Peña-Gómez et al., 2020). Compared to other filtering aids like diatomaceous earth and sand, silica gel has a smaller pore size (see *Evaluation Question #10*) (Peña-Gómez et al., 2020). The relatively small pore size and adsorptive action function together to reduce the pathogen load, without affecting antioxidants or altering amino acids and proteins (Peña-Gómez et al., 2020). Silica gel does not affect the color, flavor, and foam of beer.

Colloidal silica

As a fining (clarifying) agent in wine production, it removes gelatin and is known to wine producers as kieselsol (Marchal & Waters, 2010; Orhan Dereli et al., 2023).[4] The negatively charged surface of colloidal silica interacts with the positively charged gelatin (Marchal & Waters, 2010). Colloidal silica binds to gelatin, causing it to flocculate and then settle out of the wine. Colloidal silica is sometimes used as an anti-caking agent in bentonite, another flocculating agent used to remove gelatin (Marchal & Waters, 2010).

[3] Mesoporous structures arranged in layers can retain fluid when adsorbed by silanol groups at pore surfaces (Lyklema, 1995). The fluid enters the structure as a vapor. This is known as capillary condensation (Lyklema, 1995).

[4] Gelatin is used in the fining process to remove polyphenols (Marchal & Waters, 2010). Phenolic compounds are a cause of turbidity (Orhan Dereli et al., 2023). Gelatin use also occurs in the cold-clarification process in juices.

Combinations of the Substance

Synthetic amorphous silica (SAS) is generally sold as a single, high-purity substance (Videira-Quintela et al., 2021). Precipitated silica and silica gel may contain small amounts of sodium sulfate as an impurity formed during manufacturing at no more than 1.5% (Wypych, 2021). The impurity comes from the acid-base reaction in wet processes and is not an intentionally added substance [see *Evaluation Question #1(B)*]. The Food Chemicals Codex (2008) notes an acceptance criteria equivalent of no more than 5.0%.

Commercial colloidal solutions require stabilizing agents to suspend colloidal silica from the base-catalyzed Stöber method and to resuspend SAS from indirect preparation methods (see *Colloidal silica*). These suspensions contain potassium hydroxide, sodium hydroxide, ammonia, or hydrochloric acid at up to 10% by weight (ECETOC, 2006b; Fruijtier-Pölloth, 2012) and may also contain aluminum oxide (alumina) at around 0.2% by weight (Dultz, 1971; ECETOC, 2006b). We discuss ancillary substances in *Evaluation Question #1(E)*.

Silica gel is commercially available as a moisture absorber for food packaging and is contained in a permeable container, like a sachet, microporous bag, or pads (Janjarasskul & Suppakul, 2018; Yildirim et al., 2018).

Status

Historic Use

We found sparse details on how the specific food applications of SAS evolved in the food industry. Authors of recent research note that SAS was used for anti-caking, thickening, stabilizing, and clarifying "decades" ago (ECETOC, 2006b; Fruijtier-Pölloth, 2012; Thakur & Singh, 2018).

Modern commercial production of diatomaceous earth (DE) began in northern Germany as early as 1840, and in the United States in 1884, after its filtering capacity gained recognition (Seckbach & Gordon, 2019). It has since remained a standard filtering aid for beer, cooking oils, and wine (dos Santos Bernardi et al., 2019; Seckbach & Gordon, 2019). Calcination and grading technologies were developed in the 1920s, and applications expanded to include absorbents, fillers, and insulators (Seckbach & Gordon, 2019).

The first patents for silica gel technologies were awarded in the early 1900s (Ciriminna et al., 2013), including a production process invented by chemistry professor Walter A. Patrick (1919). The gel form had remained largely a curiosity to scientists from as early as 1640 (Feldman & Desrochers, 2003). Its absorbent properties made it useful in gas masks during World War I. Little development occurred before World War II (Feldman & Desrochers, 2003), although Davison Chemical Company began selling silica gel in 1923 (W. R. Grace & Co., n.d.). In 1963, the successor company to Davison introduced pelletized silica gel for pharmaceutical desiccants (W. R. Grace & Co., n.d.). Samuel Kistler secured a patent for aerogel (using silica gel as the precursor material) in 1931 (Ciriminna et al., 2013; Dhua et al., 2022).

Most silica polymorphs were described and named (in the European-origin scientific community) by the 1920s (Rogers, 1928). In the 1930s, the risk to workers of developing silicosis from exposure to crystalline silica and diatomaceous earth began to emerge from previously conducted research (Hughes et al., 1998).

In 1942, Harry Kloepfer, a chemist at Degussa AG, invented a high-temperature hydrolysis process for producing an extremely fine silica. He was searching for an alternative to carbon black for reinforcing car tires (Wypych, 2021). Now known as fumed silica, the substance has been sold under the name Aerosil since 1943 (Evonik, n.d.; Pratsinis, 1998). Researchers developed processes for fumed silica in part to utilize byproducts from the manufacture of other silicon products, such as silicones and purified silicon for semiconductors (Wacker Chemie Ag, 2014). The high-purity powders of small particle size, high specific surface area, and controlled particle size distribution (Pratsinis, 1998) quickly gained widespread industrial use as thickeners and fillers (Barthel et al., 2005). Manufacturers soon added it to cake mixes, toothpaste, and ketchup as a flow agent (Ulrich, 1984). Industry began using SAS in the 1950s for paint, plastics, and surface coatings (ECETOC, 2006b), and the material began appearing in food and pharmaceutical products in the 1960s (Thakur & Singh, 2018).

Organic Foods Production Act, USDA Final Rule

OFPA (1990) does not include any reference to silicon dioxide.

Silicon dioxide is listed at 7 CFR 205.605(b). Silicon dioxide was included in the first publication of the NOP Final Rule (65 FR 80548, December 21, 2000).

RIBUS, Inc. filed a petition in 2010, requesting the removal of silicon dioxide from the National List and claimed a rice-hull-based substitute could replace silicon dioxide in a 1:1 ratio (RIBUS, Inc., 2010). In December 2011, the Handling Committee found the data presented in the petition to be limited and insufficient to remove silicon dioxide from the National List; however, they felt that the natural alternative should be acknowledged and suggested a change to the annotation (NOSB, 2011). In response to the petition, the NOSB proposed adding the following annotation to silicon dioxide: "For use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available." In 2013, the NOP accepted the recommendation with the following changes: "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available." (78 FR 31815, May 28, 2013). The annotation has remained since.

Diatomaceous earth contains silicon dioxide (SiO_2) and can be nonsynthetic. Diatomaceous earth is included separately on the National List at § 205.605(a).

Nonsynthetic silicon dioxide (such as from diatomaceous earth) is also permitted as a livestock feed additive in organic production under § 205.237(a). Additionally, crystalline-free forms of silicon dioxide are allowed as inert ingredients in pesticide formulations according to the 2004 EPA List 4.

International

Internationally, SAS is referred to as:

- silicon dioxide
- silicon dioxide (amorphous)
- silica
- silica powder
- silica gel
- colloidal silica
- hydrous silica

In many regulations, "silicon dioxide" is synonymous with E551 or INS 551, which are the codes the European Food Safety Authority and the International Numbering System for Food Additives assigned to it, respectively. Both codes refer to the same material: SAS. The EFSA Panel on Food Additives and Nutrient Sources notes that silicon dioxide used as E551 is SAS and includes fumed silica and hydrated silica (precipitated silica, silica gel and colloidal silica) (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018). SAS is generally allowed under other international standards (see below).

International Organic Food Standards: CODEX Alimentarius Commission—Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)

Silicon dioxide (amorphous) is included as INS No. 551 and is listed under CODEX guidelines specifically in Annex 2, Table 3.1. This table lists additives permitted for use under specified conditions in certain organic food categories or individual food items. Amorphous silicon dioxide is allowed in "herbs, spices, seasonings, and condiments," such as seasonings for instant noodles. However, it is not permitted in foods of animal origin under these guidelines. Additionally, silicon dioxide is permitted in the form of a gel or colloidal solution, as outlined in Table 4 of the CODEX guidelines. This table details processing aids that may be used in the preparation of products of agricultural origin, as specified in Section 3 of the guidelines, but their use is limited to plant products only.

International Organic Agriculture Standards: IFOAM – Organics International (International Federation of Organic Agriculture Movements)

Silicon dioxide (amorphous) is included as INS 551 and is listed under IFOAM guidelines Appendix 4–Table 1: Approved additives and processing/post-harvest handling aids. It is allowed without limitation.

Canada: Organic production systems-General principles and management standards (CAN/CGSB-32.310), Organic production systems-Permitted substances list (CAN/CGSB-32.311)

Silicon dioxide (silica) is allowed with no restrictions on sources or uses except for maple syrup production, at CAN/CGSB-32.311 Permitted Substances List Table 6.3-Ingredients classified as food additives, and Table 6.5-Processing Aids. CAN/CGSB-32.310 7.2.12.6 allows silica powder in organic maple syrup production only for simple filtration with a filter press to remove suspended solids.

Europe and United Kingdom (Northern Ireland): European Economic Community (EEC) Council Regulation (EC No. 2018/848 and 2021/1165)

Silicon dioxide (E551) is permitted as outlined in Annex V, Section A1, which covers food additives, including carriers. It can be used in cocoa, herbs, spices in dried powdered form, flavorings, and propolis. However, there are specific conditions and limits for cocoa; it is only allowed for use in automated dispensing machines.

Annex V, Section A2 pertains to processing aids and other products that may be used to process ingredients of agricultural origin from organic production. It also permits "silicon dioxide gel or colloidal solution," albeit with a restriction on plant origin.

Furthermore, Annex V, Part D, concerning authorized products and substances for the production and conservation of organic grapevine products in the wine sector, allows "silicon dioxide gel or colloidal solution."

Japan: Japan Agricultural Standard (JAS) for Organic Production

Silicon dioxide (INS Number 551) is permitted as outlined in Annex A, Table A.1, for additives in organic processed foods, excluding organic alcoholic beverages. Its use is limited to processed products derived from plant sources, where it can be utilized as a gel or colloidal solution.

Additionally, these standards allow silicon dioxide as listed in Appendix B, Table B.1, for additives in organic alcoholic beverages, with no specific annotations regarding its use.

Korea: Republic of Korea (ROK) Korean Organic Act

We were unable to access the specific ROK standards that detail the allowance of silicon dioxide in organic food handling.

Switzerland: Federal Office for Agriculture (FOAG), Switzerland Organic Ordinances, Organic Farming Ordinance (SR 910.18), EAER Ordinance on Organic Farming (SR 910.181), FOAG Ordinance on Organic Farming (SR 910.184)

Silicon dioxide (E 551) is permitted in the form of a gel or colloidal solution, as outlined in Annex 3, Section A, which lists authorized food additives, including carriers. According to the specific restrictions set forth in these standards, silicon dioxide is allowed for products of plant origin, specifically dried powdered herbs, spices, and flavorings. For animal-origin products, it is only permitted for flavorings.

Additionally, silicon dioxide in gel or colloidal solutions is permitted in Annex 3, Section B, which covers directly used technical aids and other products that may be used to process organically produced agricultural ingredients, only for plant-origin products. Lastly, in Annex 7, Part B, which discusses feed additives for animals, colloidal silicon dioxide is also allowed as a binder and/or release agent, with no special conditions or restrictions.

Taiwan: Organic Agriculture Regulations

Silicon dioxide is permitted without specific conditions in Chapter 2, entitled "Substances Allowed for Production, Processing, Packaging, Distribution, and Sale," as shown in Table 3, which lists food additives permitted for use.

United Kingdom (Great Britain): Organic Products Regulations (2009), Retained Council Regulations (EC) (834/2007, 889/2008, and 1235/2008)

Silicon dioxide (E 551) is permitted as detailed in Annex VIII, Section A, which pertains to food additives, including carriers. Specifically, it can be used for dried powdered herbs, spices, flavorings, and propolis. This standard also allows silicon dioxide to be included in preparations of foodstuffs derived from both plant and animal origins.

Additionally, Annex VIII, Section B covers processing aids and other products that may be used to process ingredients of agricultural origin from organic production. It permits the use of silicon dioxide gel or colloidal solution solely in preparations of foodstuffs from plant origins without any specific conditions or restrictions.

Evaluation Questions

Classification of the Substance

Evaluation Question #1(A): Describe if this substance is extracted from naturally occurring plant, animal, or mineral sources.

The different types of synthetic amorphous silica (SAS) are not extracted from naturally occurring plant, animal, or mineral sources. They are produced by the reaction of a synthetic silicon source (such as silicon tetrachloride) and another reactant (such as oxygen). SAS forms that we will discuss below are:

- fumed or pyrogenic silica
- precipitated silica
- silica gel
- colloidal silica

Diatomaceous earth is a natural source of amorphous silica, but it is listed as a separate material at 7 CFR 205.605(a)(10). Other natural and synthetic forms of silica, such as quartz, cristobalite, tridymite, etc., are crystalline and are not used in organic handling or processing. For these reasons, we are excluding discussion of these other forms of silica for the Evaluation Questions.

Evaluation Question #1(B): Describe the most prevalent processes used to manufacture or formulate this substance. Include any chemical changes that may occur during manufacture or formulation of this substance.

SAS manufacturing processes are classified into two main pathways (Barthel et al., 2005; Fruijtier-Pölloth, 2016):

- thermal process
- wet processes

The thermal process yields pyrogenic silica, commonly known as fumed silica (Fruijtier-Pölloth, 2012). The thermal process forms silicon dioxide (SiO_2) through high-temperature fusion (see *Thermal process: fumed or pyrogenic silica*).

Wet processes form silicon dioxide (SiO_2) through silicic acid polymerization (see *Wet processes: acid-base precipitation and the Stöber method*). Wet processes yield (Barthel et al., 2005; Fruijtier-Pölloth, 2012):

- precipitated silica
- silica gel
- colloidal silica

Below, we first discuss the processes used to make the precursor materials. Then, we discuss the thermal and wet processes themselves.

SAS precursor production: thermal process

Silicon dioxide (SiO_2) synthesized by the thermal process is sourced from oxygen from a flame and silicon tetrachloride:

1. Metallurgical silicon is commercially produced by reducing quartz sand in a submerged arc furnace at temperatures above 1800 °C.
2. Silicon tetrachloride is produced through a reaction between silicon and hydrochloric acid (see *Equation 1*) (Xia et al., 2023).

$$Si + 4\,HCl \rightarrow SiCl_4 + 2\,H_2$$

(silicon) + (hydrochloric acid) → (silicon tetrachloride) + (hydrogen gas)

Equation 1

SAS precursor production: wet processes

SAS produced through wet processes involve multiple synthetic reagents and processing aids, including:

- sodium silicate
- tetraethylorthosilicate (TEOS)
- sulfuric acid
- sodium hydroxide
- potassium hydroxide

- hydrochloric acid

Silicon atoms originate from synthetic sodium silicate or TEOS. Most sodium silicate is a product of a high heat (1100 – 1400 °C) furnace reaction between quartz sand and sodium carbonate (Matinfar & Nychka, 2023; NOP, 2025d). Sodium silicate can also be produced in a high-pressure environment using quartz sand and sodium hydroxide. See the 2025 *Sodium Silicate* technical report for more information on the production of this material (NOP, 2025d). TEOS (tetraethoxysilane) (Ciriminna et al., 2013) is synthesized from silicon tetrachloride (see *Equation 4*) (PubChem, 2025).

Thermal process: fumed (pyrogenic) silica

Fumed silica is manufactured by flame pyrolysis (Barthel et al., 2005; Zou et al., 2008). It is a highly disordered substance due to its rapid high-temperature preparation and subsequent cooling (Dann, 2000; Wypych, 2021). Fumed silica is the purest form of the SAS (Videira-Quintela et al., 2021). To make fumed silica via the thermal process, manufacturers do the following (Barthel et al., 2005; Pratsinis, 1998; Zou et al., 2008):

1. First, they hydrolyze volatile silicon tetrachloride in an oxygen and hydrogen-containing flame.
2. Then, they remove hydrogen chloride gas with cyclone separators or filters, steam, and air treatment in fluidized beds. This leaves silicon dioxide aerosol particles in the flame.
3. Finally, they cool the resulting aggregated silica and collect it.

The reaction between the starting material (silicon tetrachloride) and the flame produces silicon dioxide (in the form of fumed silica) and hydrogen chloride (see *Equation 2*) (Pratsinis, 1998). Though the flame temperature is between 1200 and 1600 °C (Fruijtier-Pölloth, 2012), the reaction is exothermic (releases heat) and the reaction reaches about 1800 °C (Pratsinis, 1998; Wypych, 2021). The small "primary particles" leave the burner in a molten state and grow as they fuse with other fumed silica particles (Barthel et al., 2005; Pratsinis, 1998; Wypych, 2021). The high temperature environment is required for primary particle growth (Barthel et al., 2005). Primary particles adhere to each other as they collide (Barthel et al., 2005). Cooler flames (below ~1200 °C) only result in a partial primary particle fusion.

Manufacturers collect the fumed silica as the aerosol stream leaves the high-temperature zone and cools down (Pratsinis, 1998). This begins the cooling stage. Primary particles continue to collide and fuse at this lower temperature stage, forming larger primary particles (Barthel et al., 2005; Pratsinis, 1998). However, aggregate formation is the main interaction at lower temperatures. Silica aggregates are then removed from the flame to complete their cooling (Barthel et al., 2005). Aggregates continue to collide to form agglomerates.

Primary particles may exist in the final commercialized fumed silica product [see *Evaluation Question #1(D)*].

$$SiCl_4 + 2\,H_2 + O_2 \rightarrow SiO_2 + 4\,HCl$$

(silicon tetrachloride) + (hydrogen) + (oxygen) → (silicon dioxide) + (hydrogen chloride)

Equation 2

Wet processes: acid-base precipitation and the Stöber method

SAS forms such as precipitated silica, silica gel, and colloidal silica, are produced from an acid-base precipitation method using a sodium silicate solution, and the Stöber method (Napierska et al., 2010). These are referred to generically as wet processes.

The silica produced from the wet process contains three types of water that can be removed by heating the material at different temperatures (Wypych, 2021):

- free water, removed at 105 °C
- adsorbed water (hydrogen-bonded to the surface), removed at 105 - 200 °C
- constitutional water, removed at 700 - 900 °C

Acid-base precipitation process to produce precipitated silica

This process can be summarized as a destabilization of sodium silicate and subsequent precipitation (see *Equation 3*) (De Temmerman et al., 2012). Manufacturers have also adapted this process to manufacture precipitated silica and other SAS forms (*e.g.*, silica gel or colloidal silica) (Fruijtier-Pölloth, 2012; Videira-Quintela et al., 2021).

$$Na_2SiO_3 + H_2SO_4 \rightarrow SiO_2 + Na_2SO_4 + H_2O$$
(sodium silicate) + (sulfuric acid) → (silicon dioxide) + (sodium sulfate) + (water)

Equation 3

Precipitated silica is manufactured by treating soluble silicates with mineral acids (Barthel et al., 2005; Zou et al., 2008). The silicate and mineral acid source materials vary (Fruijtier-Pölloth, 2012); however, the most common commercial process involves the reaction of sodium silicate solutions and sulfuric acid (Fruijtier-Pölloth, 2012; Videira-Quintela et al., 2021). Manufacturers use the following steps to produce precipitated silica (Videira-Quintela et al., 2021):

1. First, they pre-heat an alkaline sodium silicate solution.
2. Then, they acidify the solution with sulfuric acid until the pH reaches 8 – 10.
3. Lastly, they filter, wash, dry, and mill the resulting precipitated silica. The milling size depends on the intended application.

A small percentage of sodium sulfate may remain in the final product (up to 1.5%) as an impurity (Wypych, 2021). Commercial precipitated silica is generally sold as a 98–99% pure substance (Videira-Quintela et al., 2021).

Stöber method

The Stöber method is the primary method used to specifically manufacture silica gel and colloidal silica suspensions (Videira-Quintela et al., 2021). Stöber et al. (1968) developed this method to control silicon dioxide particle growth by creating a silicic acid nucleation site. The approach, as described by Stöber et al. (1968), is to hydrolyze tetraethylorthosilicate (TEOS) or tetramethylorthosilicate (TMOS) using a base as a catalyst, and produce a solution of uniform silicon dioxide particles. Manufacturers also use this method to create silica gel using an acid catalyst (Videira-Quintela et al., 2021).

Silica gel

Manufacturers specifically use a two-step sol-gel process to create silica gel (Ciriminna et al., 2013; Fruijtier-Pölloth, 2012; Videira-Quintela et al., 2021). The term sol-gel describes the following two processes used to synthesize the gelatinous substance (Ciriminna et al., 2013; Matinfar & Nychka, 2023; Noppari et al., 2025):

- solution ("sol"): a process that hydrolyzes sodium silicate or TEOS in a solution at pH 2 to < 7
- gelation ("gel"): a process that condenses (or links monomers together to form a polymer) the hydrolyzed products

The gelatinous silica precipitate produced from the sol-gel process is also referred to as a hydrogel or silica polymer (Ciriminna et al., 2013).

$$Si(OR)_4 + 2\,H_2O \xrightarrow{H_3O^+} SiO_2 + 4\,ROH$$
acid catalyst

(sodium silicate or TEOS) + (water) → (silicon dioxide) + (water or alcohol)

Equation 4

The two processes described above can happen sequentially or simultaneously (Ciriminna et al., 2013), and involve the following steps:

1. Sodium silicate or TEOS is hydrolyzed by water in the presence of an acid catalyst (*Equation 4*) (Zou et al., 2008). The acid is typically sulfuric acid (ECETOC, 2006b); however, hydrochloric acid may also be used (ECETOC, 2006b; Noppari et al., 2025).
2. The reaction produces silicic acid, $Si(OH)_4$, as an intermediate (Matinfar & Nychka, 2023). This serves as the monomer unit.
3. Silicic acid units form chains and networks to produce the silica gel polymer material.
4. Water or alcohol is released (syneresis), depending on the solvent and silicon atom source (Matinfar & Nychka, 2023; Zou et al., 2008).
5. The gel precipitate is filtered, washed, dehydrated, and milled (Fruijtier-Pölloth, 2012). Any surfactants used are completely removed in either the washing or dehydrating steps (Fruijtier-Pölloth, 2012; West, 2014). Manufacturers can alter the washing, aging, and drying conditions to produce different porosities.

In contrast to precipitated silica, manufacturers conduct the sol-gel process at room temperature (Ciriminna et al., 2013). The process is slower and very sensitive to the reaction medium because the silica product is not water-

soluble. Manufacturers may include an alcohol solvent (*e.g.,* ethanol) in addition to water and amphiphilic surfactants to maximize the rate of hydrolysis (Ciriminna et al., 2013; Fruijtier-Pölloth, 2012; Zou et al., 2008).[5] In all manufacturing variations, the rate of hydrolysis must be larger than the rate of condensation to form the gel (Ciriminna et al., 2013). Manufacturers vary certain conditions to optimize the reaction kinetics, including (Matinfar & Nychka, 2023; Noppari et al., 2025; Zou et al., 2008):

- pH, adjusted with acid or sodium hydroxide
- ratio of sodium silicate (or TEOS) to solvent
- time, ranging from a few seconds to several hours

Silica gel manufacturers do not use one precise parameter combination for optimal gel formation (Matinfar & Nychka, 2023).

Unless otherwise specified, scientific literature refers to silica gel (hydrogel) as "silica gel." As a hydrogel, silica gel contains water within its structure (Manzocco et al., 2021). Aerogels are a type of highly porous, low density network of interconnected particles (*i.e.,* SiO4 units) where all liquid present in the material (*i.e.,* water in the silica hydrogel) is removed (Dhua et al., 2022; Manzocco et al., 2021). Further drying steps can produce these silica gel derivative substances (aerogels) with alternate physical features (Dhua et al., 2022; Manzocco et al., 2021). The following special drying steps remove solvents from the gel to create a matrix of large, air-filled pores (Manzocco et al., 2021):

- supercritical carbon dioxide assisted drying: solvents in the pores are dissolved in the liquid carbon dioxide and sublime out of the matrix.
- oven-drying, using solvents with low surface tension (*e.g.,* hexane, pentane, ethanol, acetone); the drying conditions may require modification of the gel surface to prevent cracking and pore damage.

Other methods of aerogel preparation are possible and are currently under investigation for potential use in food applications (Dhua et al., 2022; Manzocco et al., 2021). Aerogel material development is decades old. However, development and commercialization of food-grade aerogels is very slow and food-grade edible silica aerogels have not yet been commercialized (Dhua et al., 2022; Manzocco et al., 2021).

Colloidal silica

Colloidal silica solutions consist of aqueous dispersions of polymerized $Si(OH)_4$ units (Ciriminna et al., 2013).[6] Manufacturers produce colloidal silica through the Stöber method under alkaline pH conditions (7 to 10) (Matinfar & Nychka, 2023; Noppari et al., 2025; Zou et al., 2008). The higher pH conditions favor a higher condensation rate and a lower hydrolysis rate (Ciriminna et al., 2013); in other words, the opposite conditions that lead to the formation of silica gel. To make colloidal silica, manufacturers use a base instead of an acid to hydrolyze sodium silicate, tetramethyl orthosilicate (TMOS), or tetraethylorthosilicate (TEOS) (Matinfar & Nychka, 2023; Noppari et al., 2025; Zou et al., 2008). The resulting silicon compound then condenses into silicon dioxide while remaining suspended in solution (Ciriminna et al., 2013; Fruijtier-Pölloth, 2012). The solvent is water or a mixture of water and an alcohol, typically ethanol (Fruijtier-Pölloth, 2012; Noppari et al., 2025). Colloidal silica production consists of (Ciriminna et al., 2013; Videira-Quintela et al., 2021):

1. sodium silicate, TMOS, or TEOS hydrolysis
2. silicon dioxide condensation
3. particle stabilization to prevent precipitation

In base-catalyzed hydrolysis, bonds in the sodium silicate, TMOS, or TEOS precursor material break, creating a hydroxylated silicon compound and releasing a water or alcohol molecule (Ciriminna et al., 2013; Videira-Quintela et al., 2021). Often, manufacturers use ammonia as the alkali catalyst (Fruijtier-Pölloth, 2012) because SAS particles created in the absence of ammonia are irregularly shaped (Stöber et al., 1968).[7] A silicon atom of one molecule and oxygen atoms from the hydroxide groups of other molecules then react, creating silicic acid in what is called a condensation reaction (Videira-Quintela et al., 2021). The condensation reaction produces at least two silicic acid units ($Si(OH)_4$), equivalent to a proportional number of silicon dioxide units (SiO_2) and additional solvent (Chen et al., 1996; Videira-Quintela et al., 2021). A balanced equation describing the condensation of the final silicon dioxide particles (SiO_2) is not available due to the variation in starting materials and solvent.

Although sodium silicate or TMOS can be used as reactants, manufacturers typically use TEOS (Napierska et al., 2010; Noppari et al., 2025). The result of the TEOS hydrolysis and condensation reaction is spherical colloidal silica

[5] The amphiphilic surfactants are composed of hydrophilic and hydrophobic ends, increasing the solubility of silica.
[6] $Si(OH)_4$ is SiO_4 in the aqueous solution (*e.g.,* water). Also referred to as silicic acid.
[7] Unlike sodium silicate, TEOS decomposes in neutral water (PubChem, 2025).

particles of uniform size (Fruijtier-Pölloth, 2012). Manufacturers can decrease the ratio of water to TEOS to promote particle growth, giving a rough particle surface with micropores (Napierska et al., 2010). Using higher water to TEOS ratios produce smooth, nonporous particle surfaces.

The growth of particles between 1 – 5 nm is gradual because the silica created is unstable (Ciriminna et al., 2013; Fruijtier-Pölloth, 2012). When SAS is unstable, it does not remain suspended in solution. Suspended silica (SiO_4) interacts in the solution forming chains and a stable silica gel product. Chain formation are the result of (Ciriminna et al., 2013; Fruijtier-Pölloth, 2012):

- any addition of salts
- a pH below 7
- a colloidal silica concentration above 10 to 15%, at the particle growth stage

Manufacturers prevent colloid particles from interacting with each other by adding potassium hydroxide, sodium hydroxide, ammonia, or hydrochloric acid at up to 10% by weight in order to neutralize the negative charges at the surface (ECETOC, 2006b; Fruijtier-Pölloth, 2012). This neutralization is known as stabilization. Alternatively, manufacturers can stabilize the colloidal suspension by substituting some of the silicon atoms with aluminum atoms (Fruijtier-Pölloth, 2012). Manufacturers sometimes add aluminum oxide (alumina) at around 0.2% by weight (Dultz, 1971; ECETOC, 2006b). Substituting silicon with aluminum neutralizes the surface charge of the resulting colloidal silica (now a mixture of silicon dioxide and aluminum oxide), which stabilizes them (*i.e.,* allows them to remain suspended in solution).

Manufacturers can indirectly prepare SAS aqueous solutions by dispersing precipitated silica or silica gel (ECETOC, 2006b). Fumed silica can also be dispersed, but this is not common. The existing SAS is diluted then the suspension is stabilized, and commercialized as colloidal silica (ECETOC, 2006b; Fruijtier-Pölloth, 2012). If the suspended SAS contains sodium ions (*i.e.,* precipitated silica), the SAS product may first be diluted and passed through an ion exchange column to exchange sodium ions for hydrogen. Silica solutions ("silica sols" or "SAS sols") from this process are redispersed SAS aggregates (ECETOC, 2006b).

Once stabilized, the suspensions are concentrated by evaporation (Napierska et al., 2010). Depending on SAS particle size, the final concentration of suspended SAS ranges between 30 and 50% by weight (Ciriminna et al., 2013; Fruijtier-Pölloth, 2012). Suspensions above 50% concentration do not remain in solution. Commercial colloidal silica solutions are stable for at least six months (Ciriminna et al., 2013). Eventually, hydrogen ions from the surface of the colloidal silica dissociate in the aqueous solution, resulting in a net negative charge on colloidal silica and a lower solution pH (Fruijtier-Pölloth, 2012). The low pH is favorable for the formation of silica gel.

Evaluation Question #1(C): Discuss whether this substance is agricultural or nonagricultural. If the substance is nonagricultural, is it synthetic or nonsynthetic (natural) [7 U.S.C. 6502(22); NOP 5033-1 (Decision Tree for Classification of Materials as Synthetic or Nonsynthetic); NOP 5033-2 (Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production of Handling)]?

Agricultural or nonagricultural classification

Evaluation of synthetic amorphous silica (SAS) against Guidance NOP 5033-2 *Decision Tree for Classification of Agricultural and Nonagricultural Materials for Organic Livestock Production or Handling* (NOP, 2016b) is discussed below.

1. *Is the substance a mineral or bacterial culture as included in the definition of nonagricultural substance at section 205.2 of the USDA organic regulations?*

While crystalline forms of silica such as quartz or cristobalite are minerals, these forms are not used in food production. To be a mineral, a substance must have both a well-defined chemical composition, and a specific crystalline structure. Synthetic amorphous silica (SAS) is not crystalline and therefore is not a mineral (and neither is it a bacterial culture).

2. *Is the substance a microorganism (e.g., yeast, bacteria, fungi) or enzyme?*

No. SAS is not a microorganism or enzyme.

3. *Is the substance a crop or livestock product or derived from crops or livestock?*

No. SAS is not a crop or livestock product or derived from crops or livestock.

Therefore, SAS should be classified as a nonagricultural substance.

Synthetic or nonsynthetic classification

Evaluation of SAS against Guidance NOP 5033-1 *Decision Tree for Classification of Materials as Synthetic or Nonsynthetic* (NOP, 2016a) is discussed below.

1. *Is the substance manufactured, produced, or extracted from a natural source?*

No. SAS is manufactured from chemical reactions between synthetic substances.

Fumed silica is manufactured from a chemical reaction between silicon tetrachloride and oxygen from a flame (Pratsinis, 1998). Silicon tetrachloride is the product of a reaction between metallurgical silicon and hydrochloric acid (Xia et al., 2023) and thus, not a natural source.

SAS from wet processes (*i.e.,* precipitated silica, silica gel, and colloidal silica) are manufactured from chemical reactions using sodium silicate, synthetic sulfuric acid, or tetraethyl orthosilicate (TEOS) (see *Wet processes: acid-base precipitation and the Stöber method*). Sodium silicate is typically a product of a high heat reaction between quartz sand and sodium carbonate (Matinfar & Nychka, 2023; NOP, 2025d) and thus, not a natural source. TEOS is synthesized from silicon tetrachloride (PubChem, 2025).

Thus, SAS is synthetic according to the decision tree.

Evaluation Question #1(D) Does this substance in its raw or formulated forms contain nanoparticles?

According to NOP Policy Memo 15-2, *Nanotechnology*, nanotechnology is "conducted at the nanoscale, which is about 1 to 100 nanometers" (nm) (NOP, 2015). However, many researchers studying SAS use a different size range than the NOP when calling something "nanosized." Researchers often refer to anything under one micrometer (µm) as nanosized. This definition includes sizes that are one order of magnitude larger than what the NOP defines as a nanomaterial. This means that readers cannot simply rely on what authors call a nanomaterial, nanosized, nanoscale, etc., when determining whether something is or is not a nanomaterial under NOP definitions.

NOP uses the term "incidental nanomaterials" to refer to substances that are byproducts of other manufacturing (*e.g.*, homogenization, milling) or that occur naturally. Additionally, NOP uses the term "engineered nanomaterials" to refer to substances manufactured to have unique properties or behaviors as a result of their particle size.

We are unable to definitively classify SAS according to the definitions in NOP Policy Memo 15-2, *Nanotechnology*, based on SAS structure and the available analytical measurement data (NOP, 2015). Current measurement technology limits how accurately researchers can measure or even estimate the particle size of SAS. We discuss this further, below. However, the Organic Federation of Canada's Standards Interpretation Committee recently evaluated whether fumed silica was a product of nanotechnology under Canadian regulations (Organic Federation of Canada, 2026). They determined that it was not a product of nanotechnology.

Classification of SAS is dependent on what the smallest unit of the substance is. All sources of amorphous silica measure under 1 µm or 1000 nm at the primary particle level, regardless of origin (Barik et al., 2008). However, individual SAS particles combine to form aggregates and agglomerates (see *Composition of the Substance*). Functionally, this structure is analogous to a raspberry, where many drupelets are connected to make the overall compound (aggregate) fruit that you eat. A single SAS aggregate is composed of thousands of silicon dioxide (SiO_2) units (Wypych, 2021). SAS aggregates are no smaller than 100 nm and cannot be separated once formed (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018; Fruijtier-Pölloth, 2016).

Researchers agree that SAS properties and functional behavior are a result of the substance surface activity, as aggregates and agglomerates (see *Action of the Substance*). To function as an anticaking agent, adsorbent, or thickener, SAS particles must be larger than 100 nm (Fruijtier-Pölloth, 2016). Researchers do not currently understand SAS to be intentionally engineered under 100 nm for functional purposes. In other words, SAS aggregates and agglomerates do not meet the NOP nanomaterial definitions. However, the primary particles that form aggregates could be classified as nanomaterials, depending on which measurement estimates are considered. It is not clear if commercial SAS contains isolated, primary particles.

Researchers disagree about the size of primary SAS particles and the prevalence of isolated, primary particles in commercially available SAS. Fruijtier-Pölloth (2012, 2016) states that commercial products do not contain isolated

primary particles.[8] Additionally, they state that analytical limitations make individual particle (those that combine to form aggregates and exist as a part of aggregates) size estimations impossible. However, Khan et al. (2024) state that particles between 1 and 100 nm are likely included in commercial products. Particle sizes are not uniform and researchers' estimates vary (Thakur & Singh, 2018). Conservative estimates that account for analytical limitations place primary particle sizes in a range from 1 to 200 nm (Thakur & Singh, 2018). Primary particle estimates range from 1 to 100 nm when analytical limitations are not considered.

Manufacturing processes influence how uniform primary particles are in size (De Temmerman et al., 2012). For example, researchers propose that the thermal process produces greater size variability compared to the precipitated process (De Temmerman et al., 2012). The lack of consensus comes from analytical method limitations. We detail these limitations below.

Analytical limitations

SAS particles are difficult to measure because of analytical constraints (Khouchaf et al., 2020; Thakur & Singh, 2018). Measurements vary depending on the analytical method (Barthel et al., 2005) and preparation techniques (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018; Khan et al., 2024).

The most widely used methods for estimating the size of silica particles are transmission electron microscopy (TEM) and scanning electron microscopy (SEM) (Khan et al., 2024; Wypych, 2021; Zou et al., 2008). TEM provides information about the inner structure of SAS materials (Khan et al., 2024; Zou et al., 2008). SEM provides information about surface characteristics (Khan et al., 2024). Recent discussions consider TEM- and SEM-only measurement methods for SAS to be incomplete (Fruijtier-Pölloth, 2016; Khan et al., 2024). Electron microscopy images do not provide complete information about three-dimensional structures (*e.g.,* particle sphere thickness, non-spherical aggregate diameter) because the depth dimension is not accounted for (Fruijtier-Pölloth, 2016). Researchers reporting on primary particle estimates using TEM and SEM typically do not attempt to identify isolated primary particles (De Temmerman et al., 2012). Primary particle sizes are calculated from aggregate particle data.

In addition to electron microscopy, researchers must use several other techniques to accurately estimate silica particle size (Fruijtier-Pölloth, 2016; Khan et al., 2024). The European Commission's 2018 re-evaluation of silicon dioxide discussed this limitation. Size data accounting for TEM and SEM constraints is limited (Khan et al., 2024).

Preparation techniques can also affect the measured particle size because agglomerates randomly form and/or separate due to surface interactions (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018; Khan et al., 2024). Khan et al. (2024) measured commercial food-grade SAS using various analytical methods and preparation techniques. The researchers could not measure individual particles using TEM because of aggregate and agglomerate crowding. Aggregates ranged from 20 to 1000 nm in shaken dispersions and 50 to 500 nm in sonicated dispersions. Calculated average aggregate sizes were reported between 117.9 and 233.5 nm in diameter, while average agglomerate sizes were between 300 and 500 µm.

Colloidal silica

Colloidal silica from the Stöber process are prepared and sold as intentionally isolated, monodispersed spheres that may be under a micrometer in size (Fruijtier-Pölloth, 2012; Zou et al., 2008). Colloidal silica particles are sold as electrostatically stabilized suspensions in water, in concentrations between 30 and 50% by weight [see *Evaluation Question #1(B)*]. Particle sizes are accepted to be between 10 and 100 nm in diameter, with a broader consideration range of 5 nm to 2 µm (Fruijtier-Pölloth, 2012; Zou et al., 2008). As discussed above, size estimates are limited by analytical methods, and there is wide variance in reported values. Raschpichler et al. (2020) created colloidal silica suspensions under different conditions (*i.e.,* different mixing conditions, redispersion techniques, growth techniques) and reported diameters ranging from 130 nm to 371 nm. The samples measured were synthesized using commercial methods. However, the samples themselves were not commercial samples. Colloidal silica particles gradually aggregate out of the aqueous solution (Fruijtier-Pölloth, 2012).

[8] The terms "engineered nanomaterial" and "incidental nanomaterial," as defined by NOP, can only be applied if particles meet the size range of 1–100 nm. The present lack of research consensus regarding both the size and prevalence of primary particles prevents clear classifications between engineered or incidental nanomaterials.

Evaluation Question #1(E) Does this substance in its raw or formulated forms contain ancillary substances?
In 2016, the NOSB formally recommended that the NOP adopt their *Ancillary Substances Procedure Proposal* (NOSB, 2016b). According to the proposal, ancillary substances are:

> *Additives intentionally added to a non-organic substance on the National List that are not removed and have a technical or functional effect on the non-organic substance, not on the final organic product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only in insignificant amounts. Ancillary substances fall under the FDA definition and labeling regulations for "incidental additives," which do not need to be declared on the label of the final food (including organic product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3 i to iii4).*

As described in *Evaluation Question #1(B)*, colloidal silica products contain stabilizing agents like aluminum oxide (~0.2%). Colloidal silica is suspended in water or a mixture of water and ethanol. Stabilizing agents and solvents are intentionally added to products commercially sold as colloidal silica in order to keep the SAS suspended in solution for a minimum of six months (Ciriminna et al., 2013). These substances do not appear on the National List for use as an ingredient in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Evaluation Question #1(F): Is this substance created using excluded methods?
We found no instance in which SAS is produced through excluded methods. The substance is not manufactured from agricultural raw materials or biological raw materials.

Evaluation Question #2: Specify whether this substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices [7 CFR 205.600(b)(5)]. If not categorized as GRAS, describe the regulatory status.
The FDA considers "silicon dioxide" (*i.e.,* silica) to be Generally Recognized as Safe (GRAS) without limitations other than current good manufacturing practice (21 CFR 172.480). The FDA notes that its use as an anticaking agent in food should not exceed 2% by weight of the food. It can also be used as a beer stabilizer and as a microcapsule and tableted edibles (*e.g.,* supplements) processing aid. See *Approved Legal Uses of the Substance* for more information.

It is unclear whether all forms of silica are considered GRAS or if only amorphous silica is, according to FDA regulations and GRAS notification. The Code of Federal Regulations at § 172.480(a) indicates that "silicon dioxide" (*i.e.,* silica) food additive is "manufactured by vapor-phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect. "Vapor-phase hydrolysis produces fumed silica, a type of Synthetic Amorphous Silica (SAS). Crystalline silica has long been linked to silicosis, a progressive lung disease, which is also associated with an increased risk of developing lung cancer in humans. Amorphous silica has not been associated with silicosis (GRN No. 321). This makes crystalline silica hazardous and inappropriate for food production.

The most recent GRAS notification for "silicon dioxide" (FDA, 2010), emphasizes the properties of SAS (pyrogenic silica, precipitated silica and silica gel and colloidal silica) but considers that "all silicas are silicon dioxide" and states that the notifier (Cabot Corporation) intends to use "silicon dioxide in all of its forms for both direct and indirect uses."[9] Therefore, it is unclear if the notifier also considered crystalline silica GRAS within the GRAS notice. Due to the physical and chemical limitations of crystalline silica compared to SAS (lower surface area-to-mass ratio and reduced porosity), we assume that "silicon dioxide" mentioned in § 172.480(a) and by the FDA implicitly refers to SAS. We did not find any cases of crystalline silica used as an anticaking agent in food, as a beer stabilizer, or as a microcapsule or tableted processing aid.

Purpose and Necessity of the Substance

Evaluation Question #3: Describe whether the primary technical function or purpose of this substance is a preservative [7 CFR 205.600(b)(4)].
The FDA defines a preservative as a substance that slows product spoilage caused by mold, air, bacteria, fungi or yeast (FDA, 2024). When used in organic production, silicon dioxide does not work as a preservative. The primary

[9] A notifier is the company, individual, or entity that submits information to the FDA, concluding that a substance is GRAS under certain conditions of use.

technical function of silicon dioxide is to serve as an anticaking agent, texture improver, and fining agent for beer, wine, juices and edible oils, as outlined in *Approved Legal Uses of the Substance*. Moreover, silicon dioxide can help preserve various commodities and extend their shelf life by adsorbing moisture, as mentioned in *Action of the Substance*.

Evaluation Question #4: Will this substance primarily be used to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? If so, describe how [7 CFR 205.600(b)(4)].
Yes, synthetic amorphous silicon dioxide (SAS) is primarily used to improve the texture of foods and enhance the color and clarity of wine, beer, and juice. Powdered forms of SAS are generally used as a thickener or anticaking agent (see *Approved Legal Uses of the Substance*).

Silica gel or colloidal silica solutions serve as fining (clarifying) agents in the production of wine, beer, and juice.

SAS thickens, prevents caking, and clarifies food commodities (see *Action of the Substance*). SAS acts as an anticaking agent because it readily forms hydrogen bonds (that are weak) with adjacent molecules. These bonds break under high shear loads, such as when a substance is mixed. Similarly, SAS serves as a thickener because when liquids are under low shear loads (*i.e.,* not being mixed or otherwise disturbed), it forms hydrogen bonds between adjacent molecules, decreasing viscosity. Colloidal silica serves as a fining agent by removing impurities from wine, juices, and other liquids. It works by binding to positively charged impurities due to its negatively charged surfaces, which allows these impurities to flocculate and settle out of the liquid.

Evaluation Question #5: Describe any effect or potential effect on the nutritional quality of the food or feed when this substance is used [7 CFR 205.600(b)(3)].
Silicon dioxide is inert and does not affect the levels of nutrients (*e.g.,* proteins, carbohydrates, fats, vitamins, and minerals) commonly found in food products. We found no instance in which synthetic amorphous silica (SAS) is added to food as a nutrient source. Dietary silica is primarily derived from plants and plant-based foods (Farooq & Dietz, 2015). Though some forms of SAS may be consumed, these are not considered a primary source of silicon (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018; Farooq & Dietz, 2015).

Environment and Human Health Effects

Evaluation Question #6: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in this substance [7 CFR 205.600(b)(5)].
The FDA establishes “action levels” for poisonous or deleterious substances that are unavoidable in human food and animal feed (U.S. FDA, 2000). These include aflatoxin, cadmium, lead, polychlorinated biphenyls (PCBs), and many other substances. The FDA uses different action level tolerances for these substances, depending on the commodity. Commodities are largely food items; however, the FDA also includes tolerances for ceramic items, such as eating vessels and utensils. ”Silicon dioxide” (*i.e.,* silica) is not included in their list of commodities (U.S. FDA, 2000).

The current version (as of July 1, 2025) of the Food Chemicals Codex specifies that silicon dioxide (synthetic amorphous silica) should not contain more than 5 mg/kg of lead (United States Pharmacopeial Convention, 2025). The current version of the Food Chemicals Codex does not provide specific limit values for other heavy metals or contaminants; however, it does note that soluble ionizable salts (as Na_2SO_4) in precipitated silica, silica gel, and hydrous silica should not exceed 5%, and that insoluble substances should be limited to no more than 1%. The third edition of the Food Chemicals Codex specifies that silicon dioxide should contain no more than 10 parts per million (ppm) of lead and no more than 3 ppm of arsenic (National Research Council, 1981)

Evaluation Question #7: Discuss and summarize findings on whether the manufacture and use of this substance may be harmful to the environment or biodiversity [7 U.S.C. 6517(c)(1)(A)(i) and 7 U.S.C. 6517(c)(2)(A)(i)].
While SAS can negatively affect aquatic organisms, it is unlikely to have negative effects on the environment or biodiversity at the concentrations used in food processing.

Silicon dioxide in the environment

Silicon is the second most abundant element in the Earth's crust and is found in a wide range of minerals (Schaller et al., 2021). Silica and silicate minerals are the most abundant minerals in the Earth’s crust. Silica primarily exists in its crystalline form as quartz, which is very stable and insoluble in water (Agency for Toxic Substances and Disease Registry, 2019).

Most primary minerals are formed from silicon dioxide and silicates (Nanzyo & Kanno, 2018).[10] When these primary minerals undergo weathering—through physical and chemical processes—they produce secondary minerals (Barton, 2002). The fundamental structural units of these secondary minerals are an extended sheet of SiO_4. Ultimately, the silica particles of the secondary minerals settle into soil and sediments, and to a lesser extent, into water (Agency for Toxic Substances and Disease Registry, 2019). These silica particles are a common component of soils and are abundant on the Earth's surface in the forms of clay, silt, and sand (Smalley et al., 2005).

In its amorphous form, silica is also widespread in nature, with biogenic forms occurring in diatomaceous earth, radiolarians, and various plants, particularly grasses (Agency for Toxic Substances and Disease Registry, 2019). This biogenic amorphous silica is released into the soil through processes such as burning or normal decay (Agency for Toxic Substances and Disease Registry, 2019). Additionally, amorphous silica particles can form during the chemical weathering of minerals (Agency for Toxic Substances and Disease Registry, 2019). The ocean contains a vast reservoir of silica and silicates, which various marine organisms utilize to build their skeletons, including diatoms, radiolarians, and sponges (Agency for Toxic Substances and Disease Registry, 2019). The concentration of amorphous silica in various regions ranges from a minimum of 2.5 mg per gram of soil to a maximum of 7.3 mg per gram of soil (Sferratore et al., 2006).

Synthetic amorphous silica (SAS), has been used as a direct food additive for decades (Fruijtier-Pölloth, 2016). After ingestion, part of the SAS (synthetic amorphous silica) will dissolve quickly in the body to form silicic acid and ultimately be expelled via the kidneys, through urine. SAS aggregates and agglomerates may be eliminated mostly through the fecal and biliary routes (Lee et al., 2017) and bioaccumulation is not expected (Fruijtier-Pölloth, 2012).[11]

All SAS agglomerates and aggregates are expected to degrade into nanoparticles. Naturally occurring SAS nanoparticles may be one of the most abundant nanoparticles on Earth (Croissant et al., 2020).[12] Fumed silica dissolves over a timescale of months to years, while SAS produced through the wet methods (precipitated silica, silica gel, and colloidal silica) is expected to dissolve over weeks to months.

The predicted median concentrations of SAS nanoparticles in surface water vary; estimates range from 0.12 µg/L (Wang et al., 2016) to 1 µg/L (Michel et al., 2013). The average concentration of total dissolved amorphous silica in outgoing water from a wastewater treatment plant near Paris was approximately 2.3 mg/L (Sferratore et al., 2006). Other reported average dissolved silica concentrations are (Tréguer et al., 1995):

- 9 mg/L in rivers
- 4 mg/L in lakes
- 17 mg/L in groundwater
- 4.2 mg/L in ocean waters (nearly exclusively in monosilicic acid form)
- 0.12–6 mg/L ocean waters at the surface
- 0.6- 10.8 mg/L ocean in deep and bottom waters.

Ultimately, all SAS degrades to monosilicic acid in the biosphere (Croissant et al., 2020). Silicic acid is non-toxic and serves as a soluble silica source to provide essential silica to the animal and plant kingdoms (Croissant et al., 2020). We did not find studies that discussed whether the concentration used in food would contribute to toxic conditions in soil, air, or water. The percentage of foods labeled as containing silicon dioxide ranged from less than 0.1% in many subcategories to 24.5% in specific vitamins and dietary supplements, with an overall average of 1.0% (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018).

Ecotoxicity of SAS

The toxicity of SAS particles is not always the same; it depends on the way the SAS particles were manufactured and several interrelated factors, including (Croissant et al., 2020):

- physicochemical properties
- particle size
- particle morphology
- surface charge (positive vs. negative)
- stability

[10] A primary mineral is a mineral that has not been altered chemically since its crystallization from molten lava and deposition (Nanzyo & Kanno, 2018).

[11] The biliary system refers to bile production, storage, and secretion via the liver, gallbladder, and bile ducts (Dave et al., 2025).

[12] Nanomaterials can occur naturally, for example in volcanic ash and ocean spray, and may also be incidental byproducts of human activity, such as homogenization or milling (NOP, 2015).

The chemical aspects of these variations are explained in *Evaluation Question #8*.

Colloidal silica is a product from a wet process; the different types of SAS produced through the wet processes (colloidal silica, precipitated silica and silica gel) share a similar toxicological profile (Croissant et al., 2020). Many studies assessing the toxicology of SAS utilize colloidal silica. Book et al. (2019) conducted an ecotoxicity screening of seven different types of commercial colloidal silica and concluded that these materials generally exhibit low ecotoxicity. The results indicated that colloidal silica is not toxic at concentrations up to several hundred mg/L for:

- bacteria
- algae
- daphnids (a small aquatic invertebrate animal)

According to Book et al. (2019), colloidal silica particles tend to adsorb to the cell walls of bacteria and algae, but there are no studies showing its cellular internalization. However, at a concentration of 294.7 mg/L, nano-sized (17 nm) colloidal silica particles inhibited the growth of the algae *Raphidocelis subcapitata* by 20% (Book et al., 2019).

Additionally, the same researchers found that colloidal silica particles are toxic to fish cell lines at specific concentrations (Book et al., 2019). However, Book et al. (2019) noted that the toxicity of colloidal silica particles to fish cell lines does not necessarily indicate higher toxicities in whole organisms. Duan et al. (2013) manufactured colloidal silica particles in their laboratory using the Stöber method. They then conducted a toxicological study using zebrafish embryos and discovered that significant malformations occurred when the embryos were exposed to concentrations of 25 mg/L of their lab-made colloidal silica particles. After 96 hours of constant exposure to this concentration, approximately 25% of the zebrafish embryos exhibited malformations. In contrast, the control group showed about 12% of deformed embryos.

Ale et al. (2021) summarized the known ecotoxicity of silica nanoparticles in aquatic organisms. They indicated that the toxicity of SAS nanoparticles varies based on multiple environmental factors. While there is some evidence that SAS has toxic effects on aquatic organisms, researchers do not understand the specifics of these effects well, which vary in different species depending on multiple variables (*e.g.,* pH, UV light incidence, temperature, and co-exposure to other pollutants). For instance, one study cited by Ale et al. (2021) reported that *Daphnia magna,* when exposed to low concentrations of colloidal silica for 21 days, showed no toxic effects. In contrast, exposure of the nematode *Caenorhabditis elegans* to 10 mg/L of fumed silica resulted in genotoxic effects, specifically a reduction in reproductive ability.

SAS manufacturing process

Both thermal and wet methods described in *Evaluation Question #1* use precursors (silicon tetrachloride and sodium silicate), which are manufactured from silica sand (Errington et al., 2023). The extraction of sand has significant environmental consequences (Gavriletea, 2017). Mining sand can lead to deforestation, biodiversity loss, soil erosion, and acid drainage, among other environmental impacts. However, most of the extracted sand (about 73 %) is used for hydraulic fracturing or for well packing and cementing (Dolley, 2019), not for SAS production. To put this into perspective, in 2014, 75 million metric tons of industrial sand and gravel were mined in the United States (USGS, 2015); however, only a small portion of that sand was utilized to produce SAS precursors. In 2015, the aggregate production volumes specifically reported for fumed silica and silica gel ranged from 1,000,000 to 10,000,000 pounds (Agency for Toxic Substances and Disease Registry, 2019). For precipitated SAS, national aggregate production volumes were 498,843,155 pounds in 2011 (Agency for Toxic Substances and Disease Registry, 2019).

The manufacturing of SAS's silicon tetrachloride and sodium silicate precursors is the most environmentally detrimental part of its life cycle (Errington et al., 2023). The thermal and wet methods are the most relevant manufacturing processes for SAS production (see *Evaluation Question #1*).

The most common thermal, or dry, method of producing fumed silica utilizes silicon tetrachloride. The production of the silicon tetrachloride precursor requires chlorine and carbon black (Errington et al., 2023). Chlorine contributes significantly to the environmental impact of fumed silica production due to the energy needed to obtain it via electrolysis and the aquatic implications of the chemicals used during its manufacture (Errington et al., 2023). For more information regarding the environmental impact of chlorine production, refer to *Evaluation Question #5* in the 2025 Potassium Hypochlorite technical report (NOP, 2025a). Carbon black is sometimes derived from petrochemical sources, significantly impacting the environment on multiple levels (Errington et al., 2023). The raw

silicon used to produce silicon tetrachloride is obtained from smelters, which require significant energy in the form of heat. This process emits greenhouse gases and substances harmful to the ozone layer.

In the wet method, sodium silicate is the primary precursor to obtain precipitated silica, silica gel, or colloidal silica. Large amounts of energy are also required to produce sodium silicate because the furnace and hydrothermal process used to manufacture the raw silicon, as well as the reaction to form the sodium silicate, require heat from electricity, gas, or other sources (Errington et al., 2023). The hydrothermal method requires about 30% of the energy needed by the furnace method; however, in the United States, the furnace method is currently the primary process used to obtain sodium silicate (NOP, 2025d).

Another reactant used in the manufacture of sodium silicate is sodium carbonate. The production of sodium carbonate also has environmental impacts. For more information on these impacts, refer to the 2025 Sodium Bicarbonate technical report (NOP, 2025b).

Evaluation Question #8: Describe and summarize any reported effects upon human health from use of this substance [7 U.S.C. 6517(c)(1)(A)(i), 7 U.S.C. 6517(c)(2)(A)(i), and 7 U.S.C. 6518(m)(4)].

Surface chemistry determines the toxicity of SAS

Evaluating the toxicity of synthetic amorphous silica (SAS) particles is inherently complex due to the numerous variables that influence their behavior.

In their review article, Croissant et al. (2020) propose a helpful framework for understanding SAS toxicology. This framework distinguishes between two primary "pedigrees" of synthesis: SAS produced through thermal processes and SAS produced through wet processes (see *Evaluation Question #1*).

SAS generated via wet processes (silica gel, precipitated silica, and colloidal silica) tends to exhibit similar toxicological profiles. In contrast, SAS obtained through thermal processes (fumed silica) displays significantly higher toxicity in experiments using cells and living animals (Croissant et al., 2020).

The distinct toxicity of fumed silica is attributed to the surface chemistry of the aggregates and agglomerates. The surface of fumed silica contains more reactive chemical groups, particularly three-membered siloxane rings and silanol groups. SAS obtained through the wet processes contains only reactive silanol groups (Croissant et al., 2020).[13] Under physiological conditions, the covalent bonds (chemical bonds in which electron pairs are shared between atoms) within these three-membered rings break. When these chemical bonds interact with cellular membranes and break, reactive oxygen species (ROS) are generated. ROS are known to induce oxidative stress and cellular damage (Croissant et al., 2020).[14] These chemical reactions do not occur with silica gel, precipitated silica, or colloidal silica, since these materials lack three-membered siloxane rings.

In terms of silanol groups, generally, SAS particles will interact less with cell membranes and be less toxic when environmental or processing conditions allow silanol groups to bond with hydrogen atoms fully, or when the overall concentration of silanols is reduced (Croissant et al., 2020). For SAS obtained through wet processes, toxicity is primarily dependent on the particle size and the density and configuration of silanol groups (See *Figure 2*). For SAS derived from wet processes, a decrease in particle size correlates with increased toxicity in intravenous injection experiments. For instance, colloidal silica particles measuring 300 nm were non-toxic when injected into rodents at 200 mg/kg, whereas 70 nm particles were lethal at 45 mg/kg, and 30 nm particles proved lethal at doses as low as 12 mg/kg (Croissant et al., 2020).

Studies exploring the inhalation and direct injection of different types of SAS show conflicting evidence regarding their potential toxicity. Croissant et al. (2020) argue that such inconsistencies stem from the misconception that all SAS materials possess equivalent toxicological profiles, without considering their synthesis method, exposure conditions, and material specifications (*e.g.,* surface modification, coating presence, or degree of aggregation). Moreover, few studies conduct a comprehensive SAS characterization, which is required to establish reliable structure–activity relationships and to elucidate the precise mechanisms underlying SAS-induced toxicity (Croissant et al., 2020).

[13] A chemical structure with a ring shape made of six atoms: three silicon atoms alternatively bonded to three oxygen atoms.
[14] A type of unstable molecule that contains oxygen and that easily reacts with other molecules in a cell.

Toxicity of SAS Particles

Many recent researchers have assessed the toxicity of food-grade SAS, including fumed silica and hydrated silica (such as precipitated silica, silica gel, and colloidal silica). These researchers have not found conclusive evidence that SAS produces toxicity or harmful effects on human health when used as a food additive (Agency for Toxic Substances and Disease Registry, 2019; Bartucci et al., 2021; EFSA Panel on Food Additives and Flavourings et al., 2024; EFSA Panel on Food Additives and Nutrient Sources added to Food, 2009; Fruijtier-Pölloth, 2012, 2016; Yoo et al., 2022). Recent studies evaluating the oral toxicity of food-grade SAS in living animals have not shown adverse toxicological evidence (Bartucci et al., 2021; EFSA Panel on Food Additives and Flavourings et al., 2024; EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018; Lee et al., 2017; Yoo et al., 2022). All studies published before 2022 indicate that oral exposure to SAS is safe (Croissant et al., 2020).

Fruijtier-Pölloth (2012) performed an extensive scientific literature review of SAS's toxicological mode of action and concluded that there are no reports of adverse reactions from exposure to oral and topical pharmaceutical and cosmetic products; and anti-caking agents in food.

In 2016, Fruijtier-Pölloth conducted a second comprehensive review to assess the safety of nanostructured SAS (Fruijtier-Pölloth, 2016). They concluded once again that no adverse effects have been found in any of the core areas defined by the European Food Safety Authority (EFSA) for evaluating the toxicity of food additives, including:

- genotoxicity
- subchronic toxicity
- chronic toxicity
- carcinogenicity
- reproductive toxicity
- developmental toxicity
- neurotoxicity
- endocrine-mediated effects

After reviewing the toxicological literature available before 2017, the EFSA Panel on Food Additives and Nutrient Sources concluded that food grade SAS is not toxic when used as a food additive at current use levels (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018).

Recent discussions among stakeholders in the food industry have raised concerns about the potential hazards and risks associated with SAS nanoparticles and their toxicity (EFSA Panel on Food Additives and Flavourings et al., 2024; EFSA Panel on Food Additives and Nutrient Sources added to Food, 2009; Fruijtier-Pölloth, 2012; Khan et al., 2024). Due to the nature of these materials, nanoparticle exposure could occur if they disaggregate and deagglomerate at some point in the digestive process (Peters et al., 2012).

Some researchers suggest that SAS nanoparticles (particles ranging from 1 to 100 nm) may not persist in living organisms after consumption (Yoo et al., 2022). SAS particles (described in *Evaluation Question #1D*) tend to form aggregates and agglomerates, which do not easily break down in the stomach (Fruijtier-Pölloth, 2012, 2016), or, in the case of colloidal silica, quickly polymerize to bigger aggregates under physiological conditions. Fruijtier-Pölloth (2016) suggested that SAS nanoparticles may not be able to cross the mucous layer of the intestine. Zaiter et al. (2022) performed an *in vitro* (outside of a living organism) evaluation of SAS nanoparticles and their potential toxicity using a simulation of an intestinal barrier and found that nanoparticles were not internalized by the intestinal cells, even in mucus-free models. They also found that the digested SAS nanoparticles did not induce any toxic effect on the intestinal barrier model. From these studies, Zaiter et al. (2022) concluded that the interactions of SAS nanoparticles with intestinal cells were limited. In contrast, other researchers, such as Schmidt (2024), note that bioaccumulation of SAS particles in tissues—including the liver, placenta, and umbilical cord—can occur. Based on studies performed in rats, the overall absorption rates for SAS nanoparticles and bulk SAS are relatively low (around 4% and 3%, respectively) when administered orally (Lee et al., 2017). Furthermore, after acute oral exposure to SAS, the accumulation of these nanoparticles in tissue diminishes over time (Lee et al., 2017). For instance, the concentration of SAS that accumulates in rat lungs returns to normal within two days after a single oral administration of 500 mg/kg of body weight. In contrast, the SAS levels in the kidneys, liver, and spleen return to normal three days after administration (Lee et al., 2017).

SAS inhalation

Inhalation of crystalline silica can cause silicosis, a disease characterized by lung inflammation that may lead to cancer (Agency for Toxic Substances and Disease Registry, 2019). Occupational exposure studies show no evidence of adverse pulmonary effects from SAS exposure (Agency for Toxic Substances and Disease Registry, 2019).

Workers in SAS manufacturing industries did not exhibit fibrosis of the lungs (silicosis) or any other permanent respiratory ailments (Agency for Toxic Substances and Disease Registry, 2019).

Recently, Zhou et al. (2023) found that after introducing high doses of SAS nanoparticles (5-20 nm) into the mice trachea via a tube, the levels of collagen fibers in the lungs of mice increased significantly. The most notable elevation in collagen fibers, which indicates pulmonary fibrosis and potential long-term tissue damage, was observed in a group exposed to 35 mg/kg. It is important to note that this dose is much higher than what a typical worker would experience through occupational exposure. In contrast, 7 mg/kg doses did not significantly increase collagen fibers (a damage indicator) compared to the control groups.

SAS oral ingestion

We were unable to find recent studies that use humans as models for researching the oral toxicology of SAS. Many toxicological studies are conducted using rodents. While rodents are mammals and share physiological similarities with humans, caution should be exercised when extrapolating results from rodent models to the human toxicology of SAS.

Researchers have fed rats and mice high doses of silica gel, up to 7000 mg/kg of body weight for up to 21 months, without finding negative impacts on the rodents' health; the only noticeable effect was a decrease in the growth of the rodents (Fruijtier-Pölloth, 2012). Kim et al. (2014) fed colloidal silica at doses of up to 2000 mg/kg body weight for 90 days, with no observed effects. Other researchers have fed precipitated silica at concentrations of up to 4000 mg/kg of body weight for as long as 90 days without any detectable toxic effects (ECETOC, 2006a).These studies are summarized in the EFSA documents (EFSA Panel on Food Additives and Flavourings et al., 2024; EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018). More recent studies did not indicate toxicity at doses as high as 5000 mg/kg of body weight per day for up to 90 days, for standard food-grade fumed silica (Fruijtier-Pölloth, 2016). Researchers observed the following results of studies on mice and rats when fed 1000 mg/kg body weight of SAS daily for 28 days:

- no specific target organs identified (fumed silica)(van der Zande et al., 2014)
- no adverse effects; metabolomics changes were below the threshold of effects (colloidal silica)(Buesen et al., 2014)

SAS toxicology under specific conditions

Some recent studies suggest that SAS may be toxic under specific conditions.

Kim et al. (2014) found that specifically engineered silica nanoparticles caused immunotoxicity, with negatively charged particles being the most potent for inducing immunotoxicity *in vivo*. However, this study used silica nanoparticles that were produced differently from food-grade SAS. For example, some particles were coated with citrate, while others had their surfaces modified with an amino acid. Therefore, it is unclear whether these findings would apply to food-grade SAS, as the physicochemical properties of these engineered particles seem to differ, and agglomeration was prevented in this experiment using ultrasonication.

Isoda et al. (2013) observed dose-dependent liver damage in rodents when suspensions of SAS particles with diameters of 30, 50, and 70 nanometers were injected. The smallest particles (30 and 50 nanometers) caused the most damage. However, this experiment used intravenous administration at concentrations of up to 40 mg/kg of animal body weight, which does not reflect the blood levels that could be achieved through ingesting food-grade SAS, given its very low absorption rate when taken orally.

Bartucci et al. (2021), performed an ex vivo (outside of a living body) exposure experiment using mouse liver samples and found no significant alterations in inflammation and fibrosis markers after exposure to SAS nanoparticles. The exposure lasted for 72 hours, and only the highest (100 µg/mL) concentration caused mild decay in the liver's viability.

Ingesting SAS could be detrimental to individuals with existing stomach conditions. For instance, Iwasaki et al. (2024) exposed mice to strong chemicals to simulate conditions that lead to ulcers. In ulcerated mouse stomachs, SAS particles were associated with delayed healing and excessive fibrosis; however, the researchers did not observe these negative effects in mice with healthy stomachs.

Schmidt (2024) notes a possible association between high levels of dietary SAS and Celiac disease, and suggests that SAS particles may accumulate over time and cause low-grade gut inflammation sufficient to trigger an autoimmune response. However, this conclusion is drawn from studies that use mouse models, and human

physiology may differ. More research is needed to study the association between food-grade SAS and the incidence of food sensitivity in humans.

Alternatives

Evaluation Question #9: Are there alternative nonsynthetic (natural) source(s) of the substance [7 CFR 205.600(b)(1)]?

The forms of silicon dioxide used in food handling typically cannot be obtained from nonsynthetic sources without substantial processing. Synthetic amorphous silicon dioxide (SAS) food additives contain less than 1% impurities and no detectable amounts of crystalline silica (Fruijtier-Pölloth, 2012). Synthetic manufacturing processes yield specific particle sizes, surface areas, and purity for specific applications (Fruijtier-Pölloth, 2012; Stöber et al., 1968; Videira-Quintela et al., 2021). For example, fumed silica's large surface area makes it effective at adsorbing polar compounds such as methanol, glycerol, and free fatty acids from vegetable oils (Wang et al., 2022). The Food Chemicals Codex (United States Pharmacopeial Convention, 2008) specifies that silicon dioxide used in food is amorphous and produced synthetically, to include fumed, precipitated, colloidal, gel, and hydrous forms. And although other forms may be legally allowed as food additives, the EU specifications likewise limit the definition of food additive E551 to synthetic amorphous silica (EFSA Panel on Food Additives and Nutrient Sources added to Food, 2018).

In contrast, nonsynthetic silica occurs most commonly in the crystalline state (USDA, 2010). These forms are unsuitable for food applications because they lack the high surface activity, surface area, and porosity that enable the desirable defoaming, anti-caking, and sorbing functions of SAS.

Natural forms of amorphous silica, including diatomaceous rocks, opal, sand, and vitreous silica (silica glass) also contain some crystalline silica (Agency for Toxic Substances and Disease Registry, 2019; Nattrass et al., 2015). Unprocessed diatomaceous earth is used as a filtering aid (see next section) and contains small amounts of crystalline silica (Nattrass et al., 2015); however, food processors generally require amorphous silica at higher purity. As noted in *Silicon dioxide in the environment*, over 90% of the volume of the earth's crust consists of silica and silicates (IARC, 1997; Schaller et al., 2021; Wypych, 2021). However, silica cycles through the environment in various ways, including weathering of rocks, volcanic activity, and biogenic processes (Agency for Toxic Substances and Disease Registry, 2019). Over time silica leaches into and from soil during rainfall and irrigation; silicon also competes with other elements for binding sites on soil mineral surfaces (Schaller et al., 2021). It is abundant, but rarely in the pure forms that food processors use.

Quartz sand is the source of the mineral feedstocks used to produce most SAS (see *Composition of the Substance*) (Errington et al., 2023); however, very pure quartz is rare (IARC, 1997). The specialized uses of quartz include electronics, fiber optic cables, components for photovoltaic cells and semiconductors, high-temperature lamp tubing, and specialty glass (U.S. Geological Survey, 2025). Commercial mineral products derived directly from silica sand, sandstone, and quartzites typically contain 5%, or as much as 25% impurities, and particle size varies (IARC, 1997). The construction industry uses sand in large quantities, and silicon is an important component of steel, electronics, semiconductors, and glass (Housecroft & Sharpe, 2005).

Diatomaceous earth

Diatomaceous earth (DE) is allowed for handling use as a food filtering aid at § 205.605(a)(10), and in post-harvest handling of raw agricultural commodities at § 205.271(c) (NOP, 2016c). It therefore serves as an alternative for some uses of SAS (see *Evaluation Question #10*).

As described in *Composition of the Substance*, amorphous silicon dioxide is abundant within DE deposits (Drees et al., 1989; Flower, 2013; Napierska et al., 2010). However, commercial producers do not typically obtain SAS from DE. Due to contaminants present in the sediments, silica content can vary between 86% and 94% before processing. For comparison, fumed silica typically exceeds 99.8% silica after drying, with alkali and heavy metals in the low ppm range and hydrochloric acid content under 100 ppm. (IARC, 1997; Nattrass et al., 2015).

Diatomaceous earth intended for use as a filter, carrier, or adsorbent undergoes an additional calcining process in order to enlarge and standardize particle size (SCOGS, 1979). When heated to 800 to 1000 °C, some of the amorphous silica converts to a crystalline form, mainly cristobalite (Nattrass et al., 2015). In flux-calcining, a flux agent, such as sodium carbonate (soda ash), is added at about 6% by weight during the heating and is washed away afterward. Calcination can yield up to 65% of crystalline material, while uncalcined DE is 0.1-4.0% crystalline silica (IARC, 1997). The small particle size and limited permeability of uncalcined DE make it less efficient as a filter aid (Dicalite, n.d.). Calcined DE is typically used for fine filtration and clarity; and flux-calcined DE allows for high

flow rates and the most efficient solids removal (Dicalite, n.d.). The final product may be considered synthetic if flux agents remain. Food producers require that anti-caking agents contain no detectable amount of crystalline silica (Hammond & Peirce, 2023).

Other biogenic sources

A variety of plants, especially grasses, also produce biogenic silica (IARC, 1997). It can account for approximately 20% of the dry weight of rushes, rice, and sugar cane (IARC, 1997). Authors of a 2012 patent describe a process for extracting silica from plant material such as rice hulls (see example products in *Evaluation Question #11*) (Hammond & Peirce, 2023).

Rice is among the plants that are naturally high in amorphous silica, and disposing of the hulls has long been a challenge for rice producers (Vershit CH et al., 2023; Xiong et al., 2009; Zou & Yang, 2019). The unprocessed, ground hulls may be used to prevent caking in some applications; however, they may be ineffective for certain hygroscopic powdered carbohydrates such as spices, syrup solids, and oligodextrins (OTA, 2016a).

When rice hulls are burned using at the proper temperature (generally below 800 °C to avoid a crystalline result), the ash offers an abundant and renewable silica source that has not yet been exploited at commercial scale in food applications (Matinfar & Nychka, 2023; Vershit CH et al., 2023; Zou & Yang, 2019). Researchers working with rice hulls have produced gel and powder products containing up to 99% silica (exceeding 65% amorphous) using synthetic processes and even recycled reactants (Xiong et al., 2009; Zou & Yang, 2019). Lin et al. (2024) noted that treatment with hydrochloric or sulfuric acid raises the surface area of the final SAS product. Other novel processes use pressure and heated water, but also require synthetic chemical reactions (Zou & Yang, 2019).

Evaluation Question #10: Describe all nonagricultural nonsynthetic (natural) substances or products which may be used in place of this substance [7 U.S.C. 6517(c)(1)(A)(ii)]. Identify which of those are currently allowed under the NOP regulations.

We have not identified any single material that serves as a substitute for SAS in all applications. Some researchers mention or advocate for a wide variety of materials used for clarifying, filtering, absorbing, adsorbing, and anti-caking; however, there is no consensus on the most suitable materials for these applications. Materials are often used in combination (Marchal & Waters, 2010; Orhan Dereli et al., 2023). The materials listed in *Table 3* are widely available to producers.

By removing solid particles and concentrating the liquid, filtering and clarifying steps help to stabilize a liquid's taste, microbial content, colloidal content, pH, color, and nutrient profile (dos Santos Bernardi et al., 2019; Fillaudeau & Carrère, 2002). These functions may be considered interchangeable depending on the product or industry.

Filtering agents remove impurities that affect appearance, taste, and odor. In beer, they eliminate yeast and colloidal particles responsible for a hazy appearance (dos Santos Bernardi et al., 2019).

Producers use clarifying agents that are suitable for a particular liquid product (*e.g.,* beer, wine, juice), while also considering the materials that are causing turbidity and the chosen production process (*e.g.,* hot, or cold). This helps preserve the desirable components of the product (*e.g.,* color, flavor, polyphenols, antioxidants) (dos Santos Bernardi et al., 2019; Orhan Dereli et al., 2023). Also known as *fining* (especially in wine), this process involves forming a floccular precipitate to absorb or collect the haze-forming particles while the product settles (Marchal & Waters, 2010).

Table 3: Nonagricultural nonsynthetic alternatives to silicon dioxide.

Material	Function(s)	Applications or features	Source
Bentonite	absorbent, anti-caking, clarifying, filtering	Removes proteins and tannins from juices; reduces astringency; reported as effective for strawberry juice. Used very widely to clarify wine but reported as less effective than silica; often combined with gelatin. Used in edible oil production (sometimes combined with activated charcoal) and food packaging [7 CFR 205.605(a)(5)].	(Bates et al., 2001; NOP, 2024; Orhan Dereli et al., 2023; Villota et al., 1986; Yildirim et al., 2018)
Fruit enzymes	clarifying	Beer and fruit juice [§ 205.605(a)(11)]	(Villota et al., 1986; World Health Organization, 2005)
Kaolin	clarifying, filtering	Wine and seed oils [§ 205.605(a)(15)]	(NOP, 2025c; World Health Organization, 2005)
Perlite	clarifying, filtering	Wine and fruit juice [§ 205.605(a)(22)]	(U.S. Geological Survey, 2025; World Health Organization, 2005)
Powdered cellulose	anti-caking, filtering, pelleting	Juice and vinegar, sometimes combined with DE or perlite. Also grated cheese or cheese powder [§ 205.605(b)(11)]	(Adhikari et al., 2001; Bates et al., 2001; NOP, 2001; OTA, 2016b)

Activated charcoal is synthetic but is allowed as a filtering aid at 7 CFR 205.605(b)(2). It is commonly used in alcoholic beverages, fruit juice, oils, and vinegar. It can also serve as a food packaging adsorbent (Janjarasskul & Suppakul, 2018, 2018; Marchal & Waters, 2010; Yildirim et al., 2018).

Diatomaceous earth

In addition to being a nonsynthetic source of silica (see *Evaluation Question #9*), diatomaceous earth (DE) can serve as a direct alternative in filtering applications. Producers choose natural or calcined products depending on the application and potential for exposure to crystalline silica. As a biogenic material, DE's properties are variable (EP Minerals, n.d.); however, it generally displays chemical stability, resistance to abrasion, low bulk density, and high absorptive capacity and surface area (Lauermannová et al., 2021). Filtration (including the cleansing of greases and oils as well as purification of beer, liquors, water, and wine) is the leading end use for DE produced in the U.S. Roughly 65% of DE was used in filtration products in 2024 (U.S. Geological Survey, 2025).

Beverage producers struggle to dispose of spent DE properly after filtration, and are seeking sustainable alternatives (dos Santos Bernardi et al., 2019). Some DE manufacturers work with customers to recycle spent DE as a component of compost (EP Minerals, n.d.). Researchers have also examined using the material in the production of bricks (Ferraz et al., 2011; Lauermannová et al., 2021).

DE, otherwise known as *Kieselguhr,* is already the most common filter choice among beer brewers (dos Santos Bernardi et al., 2019; Peña-Gómez et al., 2020). The material's relatively large pore size (compared to membrane microfiltration) allows for efficient filtering without removing the compounds essential for good color, flavor, and foam (Peña-Gómez et al., 2020). However, this also makes it less effective for removing pathogens compared to membrane microfiltration or heat pasteurization (dos Santos Bernardi et al., 2019; Fillaudeau & Carrère, 2002). In addition to the waste disposal challenge, it can also clog and foul filtering components and membranes (dos Santos Bernardi et al., 2019).

DE is also widely used as an inert carrier for pesticides, as an anticaking agent in animal feeds, and as an absorbent (U.S. Geological Survey, 2025).

Evaluation Question #11: Provide a list of organic agricultural products that could be alternatives for this substance [7 CFR 205.600(b)(1)].

Rice hull-based alternatives

Nevada-based RIBUS offers certified organic products made from rice hulls as alternatives to synthetic additives. They also offer conventional versions made from non-certified crops (Hammond & Peirce, 2023; RIBUS, Inc., 2010). RIBUS marketing materials describe the following organic products:

- Nu-FLOW is an anti-caking agent, flow aid, flavor carrier, and is used for pelletizing/tableting and spray drying. It can be used at similar quantities to silicon dioxide.
  Ingredient: ground organic rice hulls.
- Nu-SORP Oil provides "oil holding capacity" for producing capsules, tablets, powders, and food products.
  Ingredients: organic rice fiber, organic oat fiber, and organic sunflower lecithin.
- Nu-SORP Water provides water holding capacity to produce capsules, tablets, powders, and food products.
  Ingredients: organic rice fiber, organic psyllium fiber, and organic banana flour.

These products are listed in the Organic Integrity Database (USDA, 2025). Manufacturing processes for RIBUS products are not publicly available, but the RIBUS website states (RIBUS, n.d.):

> *Through patented processes, RIBUS adds natural protease enzymes to rice bran to stabilize the lipase enzymes, creating a natural, gluten-free, hypo-allergenic food ingredient that binds oil and water. Rice hulls are a natural source of silica, one of the most effective anti-caking agents in use today. Through our patent-pending processes, RIBUS grinds the hulls so the silica particle size is optimized for use in food formulation as a flow aid or flavor carrier.*

The authors of the RIBUS website also refer to a patent, 8,492,444, for Nu-FLOW: Biogenic Silica from Silica-containing Plant Material Such As Rice Hulls by Hammond and Peirce (2023). This product is intended to provide a biogenic source of amorphous silica from a plant material, which may be certified as organic, for use as an anti-caking agent, excipient, or flavor carrier in foods, drinks, and pharmaceuticals. As described in the patent, rice hulls or other plant material is ground and then screened. The rice hulls can be milled into various particle sizes according to application. The amount of silica may be concentrated by carbon reduction through enzymatic treatment or burning. Enzymes can also be added to rice hulls to digest carbon- or protein-containing compounds under proper conditions (Hammond & Peirce, 2023). We were unable to determine whether the company manufactures this product at sufficient volume to satisfy organic demand.

Other alternatives

We found limited examples of other suitable organic substitutes. Public comments to the NOSB mentioned using the following without further detail:

- Oat, barley, and spelt hulls can be used to filter fruit juices and wine (OTA, 2016b).
- Rice and corn flours can provide some anti-caking function or act as fillers (NOP, 2001).
- Potato starch and other vegetable starches can be used as anti-caking agents in a limited number of food products. Susceptibility to mold contamination is one drawback (NOP, 2001).

Gelatin is available in certified organic products (USDA, 2025); and nonsynthetic, nonorganic gelatin is allowed at 7 CFR 205.606(h) when organic forms are commercially unavailable. Gelatin aids in settling out proteins, yeast, and tannins through hydrogen bonding, and can be used in combination with bentonite and silica (Villota et al., 1986). It clarifies juice by removing high-molecular-weight polyphenols; however, it must then be removed by another additive, usually silica (Orhan Dereli et al., 2023). It is not a suitable alternative for producers who wish to avoid using animal products.

Defoaming agents

Several alternative defoaming agents are available to organic food producers. Carnauba wax and sunflower lecithin are commonly used and widely available. Certified organic products include carriers such as vegetable oil, and are available from multiple suppliers (USDA, 2025).

Evaluation Question #12: Describe if there are any alternative practices that would make the use of this substance unnecessary [7 U.S.C. 6518(m)(6)].

Anti-caking

Adhikari et al. (2001) reviewed techniques for gauging and managing product stickiness (one factor in caking) during food processing and packaging, especially during spray drying and storage. Common methods involve introducing cold air or otherwise changing the temperature during different phases of drying, and mechanical methods such as scraping the drying chamber. Researchers concluded that no single method could reduce stickiness in all products and conditions (Adhikari et al., 2001). Aguilera et al. (1995) note that strictly controlling moisture content and storing at colder temperatures are important for minimizing or preventing caking, regardless of whether the producer uses chemical additives. The following production or environmental factors may affect a product's sticky texture (Adhikari et al., 2001):

- mixing time
- action of particular enzymes
- particle size
- moisture
- temperature
- viscosity
- compression
- fat, protein, and polysaccharide content

Specific ingredients require different techniques and approaches to improve texture. Food handlers already use many of these techniques, often in combination with silicon dioxide or other additives (Adhikari et al., 2001).

Clarifying and stabilizing beverages

Without chemical clarifying agents, beverage makers might achieve the desired settling with time. Cold storage can speed up the settling of larger particles such as yeast (Bates et al., 2001; Orhan Dereli et al., 2023); however, waiting weeks or months is not generally commercially viable for winemaking (Marchal & Waters, 2010). Physical filtration or centrifugation are commonly used for wine, but they do not reliably protect against haze (Marchal & Waters, 2010). Bates et al. (2001) recommend straining and screening, followed by a continuous or decanting centrifuge with automatic desludging for nearly clear juice, or simpler centrifugation for cloudy juices that do not require filtration. Juice producers may also use plastic, ceramic, or metal membranes, often in combination with cellulose pads or DE (Bates et al., 2001).

Pasteurization is widely used for juices, but this process can harm the delicate qualities of craft beer and other beverages (dos Santos Bernardi et al., 2019; Peña-Gómez et al., 2020). Peña-Gómez et al. (2020) studied new silica-based filtering materials as alternatives to thermal pasteurization for stabilizing beer and extending its shelf life. They found that the following techniques have not achieved industrial application due to low efficacy, unwanted changes to food properties, and high investment and production costs:

- high-pressure processing
- pulsed electric fields
- ultraviolet irradiation
- ultrasound

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All individuals comply with Federal Acquisition Regulations (FAR) Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

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