

Synthetic Amorphous Silica (Silicon Dioxide)

CAS# 112926-00-8/ Generic:7631-86-9

Frequently Asked Questions and Answers

1. Q- What is Synthetic Amorphous Silica (SAS)?
A. Synthetic Amorphous Silica, also known as silicon dioxide or silica, is produced by two basic methods, a wet method (precipitated silica), and a pyrogenic method (fumed silica). Each method results in amorphous silica particles with differing physical characteristics. Pyrogenic silica is manufactured by the vapor phase hydrolysis of volatile chlorosilanes in an oxyhydrogen flame. Precipitated silica is produced from sodium silicate, sulfuric acid and water. (Naturally occurring forms of amorphous silica also exist).
2. Q-Does (SAS) contain Genetically Modified Organisms (GMO)?
A. No, it is inorganic, not natural and does not contain any plant or animal derivatives.
3. Q-What allergens are associated with Synthetic Amorphous Silica?
A. SAS does not contain any known food allergens (including peanuts, tree nuts, dairy products, eggs, soy or soy protein derivatives, wheat, crustaceans, mollusks, fish, seeds, legumes, sulfites, colors, oils or MSG).
4. Q-Is Synthetic Amorphous Silica listed on California Proposition 65?
A. No, it is crystalline free and is not classified as a known carcinogen on the California Proposition 65 list. SAS is not expected to cause a carcinogenic or reproductive/developmental risk. It is not adsorbed through the skin and is inert when ingested.
5. Q-What are some of the uses for Synthetic Amorphous Silica?
A. Silicon dioxide uses include, but are not limited to:
 - food, cosmetics, pharmaceutical and a variety of industrial applications.
 - Animal Feed carrier for vitamin handling and dosage
 - Low rolling resistance tires
 - Battery electrical conductivity
 - In processing aids such as defoamers, and mold release products, and as fillers.
6. Q- What is the main difference between Synthetic Silica and Natural Silica?
A. Although some forms of naturally occurring silica are amorphous, the majority of naturally occurring silica is of crystalline structure. Crystalline silica is associated with significant respiratory related health concerns. Synthetic Amorphous Silica does not exhibit this health risk.
7. Q- What are the Global Chemical Inventory approvals for untreated SAS?

A. The Chemical Inventory approvals are as follows:

- USA: TSCA
- Canada: DSL
- Mexico: INSQ
- EU: EINECS
- China: IECSC
- Japan: ENCS/CSCL
- Korea: KECL
- Taiwan: TCSI
- Australia: AICS
- New Zealand: NZIoC
- Philippine: PICCS

8. Q- Is Synthetic Amorphous Silica reportable under the TSCA 8(a) Nanomaterial Reporting Rule?

A. Based on the rule and the EPA Guidance Document, it is the opinion of the members of the Synthetic Amorphous Silica and Silicate Industry Association (SASSI) that Synthetic Amorphous Silica (SAS) is not a reportable substance. This opinion is based on EPA's definition of a "reportable chemical substance," which must meet a particle size requirement and also exhibit unique and novel properties that are the result of the particle size. SAS, therefore, is specifically exempted from the reporting because these materials do not exhibit "unique or novel properties" that "are any size-dependent properties that vary from those associated with other forms or sizes of the same chemical substance not in the size range of 1-100 nm, and such properties are a reason that the chemical substance is manufactured or processed in that form or size."

9. Q - Is Synthetic Amorphous Silica (SAS) compliant with European Directive for Waste Electrical and Electronic Equipment Directive (WEEE Directive) 2012/19/EU?

A. Yes, SAS is compliant with the EU WEEE Directive.

10. Q- Is Synthetic Amorphous Silica (SAS) compliant with Directive 2015/863/EU (RoHS 3)?

A. Yes, SAS is compliant

- Cadmium (Cd): < 100 ppm
- Lead (Pb): < 1000 ppm
- Mercury (Hg): < 1000 ppm
- Hexavalent Chromium: (Cr VI) < 1000 ppm
- Polybrominated Biphenyls (PBB): < 1000 ppm
- Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
- Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
- Benzyl butyl phthalate (BBP): < 1000 ppm
- Dibutyl phthalate (DBP): < 1000 ppm

- Diisobutyl phthalate (DIBP): < 1000 ppm

11. Q - Is this product fully composed of substances set out in Annex 1 (lists I, II and III of plastics) and in Annex 10 (lists I - V of packaging inks) of the SWISS Ordinance of the FDHA on Materials and Articles (817.023.21) and subject to the requirements set out therein?

A. Yes, Silicon Dioxide is on the list.

12. Q – Are animal derived proteins, TSE (transmissible spongiform encephalopathies), and BSE (bovine spongiform encephalopathies) present in this material?

A. SAS is a synthetic inorganic substance and does not contain any animal derivatives.

13. Q – Are Halogenated compounds, Chlorinated paraffins, Pentachlorophenol or derivatives, Ozone depleting compounds/substances, PFOS (Perfluorooctane sulphonate) and PFOA (Perfluorooctanoic acid) or its salts used to manufacture Synthetic Amorphous Silica?

A. No

14. Q. Does SAS contain Substances of Very High Concern (SVHC) as published by European Chemicals Agency (ECHA)?

A. The manufacturing process for Silicon Dioxide does not use materials considered to be harmful substances for food, cosmetic, drug applications, or for the environment and therefore the Candidate list of SVHC substances would not be present in the final product. We also confirm that these products do not contain any Annex XIV chemicals at a concentration of $\geq 0.1\%$ by weight.

15. Q. Has Synthetic Amorphous Silica been registered for REACH?

A. Yes, the registration number is 01-2119379499-16

16. Q - Is this product safe for use in Vegetarian and Vegan diets?

A. Synthetic Amorphous Silica products are produced from raw materials that are not plant or of animal origin and thereby considered suitable for Vegetarian (lacto-ovo, lacto, ovo), and Vegan diets. These products are also safe for people with gluten and lactose intolerances. SAS does not contain any of the major food allergens which require labeling under Public Law 108-282 (FALCPA)

17. Q – What is the Heavy Metal content of pyrogenic Silica?

- A. No heavy metals are used in the manufacture of Synthetic Amorphous Silica. It is produced by flame hydrolysis at very high temperatures. Typical data for heavy metals are listed as:

Antimony (Sb) - < 1 ppm
Arsenic (As) - < 2 ppm
Barium (Ba) - < 1 ppm
Cadmium (Cd) - < 2 ppm
Chromium (Cr), total - < 4 ppm
Lead (Pb) - < 5 ppm
Mercury (Hg) - < 1 ppm
Nickel (Ni) - < 3 ppm
Selenium (Se) - < 1 ppm
Zinc (Zn) - < 1 ppm

18. Q – What Nutritional value does SAS have?

- A. There is no nutritional value associated with Synthetic Amorphous Silica. These products are primarily used as conditioning agents for powders or carriers for liquids in the food and feed industries. The ingredient label may list SAS as silica, silicon dioxide or anti-caking agent.

19. Q - Does Silica have any Microbiological concerns?

- A. Synthetic Amorphous Silica/pyrogenic is a pure substance which is chemically manufactured on an industrial scale using oxygen/hydrogen flame hydrolysis and is therefore sterile during the production process. Although the conveyance, silation and packaging of these products are not conducted under sterile conditions, a resulting contamination is considered highly improbable.

20. Q – What FDA approvals exists for Silicon Dioxide?

- A. Synthetic Amorphous Silica, fumed and precipitated, are GRAS for use as an anti-caking agent, defoaming agent, stabilizer, adsorbent carrier, conditioning agent, chill-proofing agent, filter aid, emulsifying agent, viscosity control agent, and anti-settling agent at maximum levels of 2% (w/w) in a broad range of food categories and as an indirect additive in the manufacture of adhesives, coatings, defoaming agents, greases and lubricants, paper and paperboard and polymers that are used as components of food packaging materials which at the subject of GRAS Notifications GRN 000321 and GRN 000554.

SILICON DIOXIDE

CAS Reg. No. (or other ID):

Substance:

7631-86-9

SILICON DIOXIDE

Other Names:

◆ SILICA
◆ SILICON
DIOXIDE

Used for (Technical Effect):

ANTICAKING
AGENT OR FREE-
FLOW AGENT,
ANTIOXIDANT,
COLOR OR
COLORING
ADJUNCT,
DRYING AGENT,
EMULSIFIER OR
EMULSIFIER
SALT,
FLAVORING
AGENT OR
ADJUVANT,
FORMULATION
AID,
HUMECTANT,
LUBRICANT OR
RELEASE AGENT,

Color additive regulations (21 CFR Parts 73, 74, 81, 82):

73.1

73.575

Food additive and GRAS regulations (21 CFR Parts 170-186):

172.230

172.480

173.340

175.105

175.300

175.320

176.170

176.180

176.200

176.210

177.1200

177.2250

177.2420

177.2600

182.90

Food labeling and standards regulations (21 CFR Parts 100-169):

160.105 , 160.185

You can find monographs on Silicon dioxide in the Food Chemical Codex, and USP/NF.

Silica is also cleared for use as an Inert Ingredient under 40CFR 180.950 in FIFRA regulated pesticide formulations.