

Product Safety Information

Evonik Resource Efficiency GmbH

Product Name: AEROSIL® OX 50
 Chemical Name: Silicon dioxide, chemically prepared
 CAS-No.: 112945-52-5, 7631-86-9
 Customs Tariff Number: 281122

How to find specific information in this document

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Regulations Brazil

Domain	Legal Record	Registration	Remarks
Food additive	RDC n. 45, de 03 de novembro de 2010 (ANVISA*) - It provides the food additives approved for use according to Good Manufacturing Practices *ANVISA - Brazilian Health Surveillance Agency	Exemption of registration by RDC n. 27, de 6 de agosto de 2010 (ANVISA) INS 551 - silicon dioxide (Dióxido de silício, sílica). Uses: as Antiumectante/ Antiaglutinante	Max Limits: Dehydrated soups and broths: ≤ 3.0g/100g Dehydrated sauces: ≤ 3.0g/100g Prepared condiments: ≤ 3.0g/100g Salts and added salts: ≤ 1.0g/100g Powders to prepare carbonated drinks and non-carbonated: ≤ 1.0g/100g
Food contact articles	MERCOSUR/GMC/RES. No. 32/07Mercosur technical regulation on "positive list of additives for plastic materials intended for the manufacture of food contact packages and equipment"	Positive list of additives for plastic materials, Appendix I: CAS-No: 7631-86-9 - Silica	No restrictions

Regulations Canada

Domain	Legal Record	Registration	Remarks
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE I - Food Additives That May Be Used as Anticaking Agents	S1 - Silicon dioxide: (6) Cayenne pepper, Chili pepper, Chili powder, Paprika, Red pepper	(6) 2.0%
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE I - Food Additives That May Be Used as Anticaking Agents	S1 - Silicon dioxide: (7) Salt	(7) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a)

Regulations Canada

Domain	Legal Record	Registration	Remarks
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE I - Food Additives That May Be Used as Anticaking Agents	S1 - Silicon dioxide: (4) Icing sugar	(4) If used either singly or in combination with Calcium Phosphate tribasic, Calcium Silicate, Magnesium Carbonate, Magnesium Silicate, Magnesium Stearate or Sodium Aluminum Silicate the total must not exceed 1.5%
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE I - Food Additives That May Be Used as Anticaking Agents	S1 - Silicon dioxide: (3) Unstandardized dry mixes	(3) Good Manufacturing Practice
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE I - Food Additives That May Be Used as Anticaking Agents	S1 - Silicon dioxide: (2) Celery Salt; Celery Pepper	(2) not exceeding 0.5 per cent
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE I - Food Additives That May Be Used as Anticaking Agents	S1 - Silicon dioxide: (1) Garlic salt; Onion salt	(1) 1.0% in accordance with the requirements of paragraphs B.07.020(b) and B.07.027(b), repectively
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE I - Food Additives That May Be Used as Anticaking Agents	S1 - Silicon dioxide, (5) Food sold in tablet form	(3) Good Manufacturing Practice
Food and Drug Regulations C.R.C., c. 870, Divison 16 - Food Additives	TABLE VIII - Miscellaneous Food Additives	S.1.01 - Silicon dioxide Edible vegetable oil-based cookware coating emulsions	Suspending agent - 2.0% of preparation

Regulations China

Domain	Legal Record	Registration	Remarks
Animal nutrition	Approved feed additive (2013)	As anti-caking agent	Product registration is needed for 1st import
Food additive	GB 2760-2014 GB 25576-2010	CNS No. 02.004, INS No. 551 - As anti-caking agent	Purity criteria according to GB 25576-2010 are met
Food contact additive	GB 9685-2016	FCA0782	Application in plastics, coatings, rubber, ink and paper
Food contact additive	GB 9685-2016	FCA0759	Application in plastics, coatings, rubber, ink, paper and adhesives

Regulations Europe

Domain	Legal Record	Registration	Remarks
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Regulations Europe

Domain	Legal Record	Registration	Remarks
Food contact articles	CoE Resolution AP 2002 (1), paper and boards, V4 – 12.02.2009	Ref.-No.: 86240 - Silicon dioxide	A. List 1 of Additives
Food contact articles	CoE Resolution AP 2004 (1), coatings, V3 - 12.02.2009	Ref.-No.: 86240 - Silicon dioxide	C. List 1 of additives
Food contact articles	CoE Resolution AP 2004 (4), rubber products, V1 - 10.06.2004	Ref.-No.: 86240 - Silicon dioxide	Appendix 1 - Index list of additives
Food contact articles	CoE Resolution AP 2004 (5), silicones, V1 - 10.06.2004	Ref.-No.: 86240 - Silicon dioxide	List 1 - No. 3. Additives
Food contact articles	CoE Resolution AP 2005 (2), packaging Inks, 21 December 2006	Ref.-No.: 86240 - Silicon dioxide	3.1 Additives List 1 substances evaluated by SCF/EFSA
Food contact articles	Regulation (EU) 10/2011	FCM substance No.: 504, Ref.-No.: 86240 - Silicon dioxide	Annex I, Substances For more information please see below the chapter "More information regarding regulation (EU) 10/2011"

Regulations Germany

Domain	Legal Record	Registration	Remarks
Food contact articles	BfR recommendations: III, VII, XIV, XV, XXI, XXXVI, XXXVI/1, XXXVI/2, XLIV, LII	CAS-No.: 7631-86-9 - Silicon dioxide, Silicic acid	Purity criteria acc. to BfR recommendation LII are met
Umweltbundesamt - KTW Guideline for drinking water	Guideline for the Hygienic Assessment of Organic Coatings in Contact with Drinking water	Ref.-No.: 86240 - Silicon dioxide	Annex 1: Positive List for coatings in drinking water; 1.5 Additives and accessory agents
Umweltbundesamt - KTW Guideline for drinking water	Water, Drinking Water, and Water Protection - Lubricant Guideline	Silicates, Silicates mixed, without CAS-No	Annex 1: White list for lubricants 1.2 thickener
Umweltbundesamt - KTW Guideline for drinking water	Water, Drinking Water, and Water Protection - Rubber materials	Silicates, Silicates mixed, without CAS-No	List 1.1.2 Fillers (Purity requirements according to BfR Recommendation LII. Fillers)

Regulations India

Domain	Legal Record	Registration	Remarks
Food additive	Food Safety and Standards Act, 2006; Act.No.34, 2006, Regulations 2011 and Compendium Food Additives Regulations 2017	Annex-1, Table 2 - Use of food additives in fats and oil, and fat emulsions. 2.1.3 : Lard, tallow ,fish oil, and other animals fats (Edible fats). Dimethyl polysiloxane (INS No. 900a) in combination with Silicon dioxide INS No. 551.	Recommended Maximum Level - 10 mg/kg

Regulations India

Domain	Legal Record	Registration	Remarks
Food additive	Food Safety and Standards Act, 2006; Act.No.34, 2006, Regulations 2011 and Compendium Food Additives Regulations 2017	Annex-1, Table 14 - Use of additives in beverages excluding dairy products, 14.2.3 : Grape Wines. Silicon dioxide, amorphous INS No. 551.	Recommended Maximum Level - GMP
Food additive	Food Safety and Standards Act, 2006; Act.No.34, 2006, Regulations 2011 and Compendium Food Additives Regulations 2017	Annex-1, Table 14 - Use of additives in beverages excluding dairy products; 14.1.5 : Coffee, coffee / coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa. Silicon dioxide, amorphous INS No. 551	Recommended Maximum Level - GMP
Food additive	Food Safety and Standards Act, 2006; Act.No.34, 2006, Regulations 2011 and Compendium Food Additives Regulations 2017	Annex-1, Table 11 - Use of additives in sweeteners including honey. 11.1.2 : Powdered sugar, powdered dextrose (Icing sugar). Silicon dioxide, amorphous INS No. 551.	Recommended Maximum Level - 15,000 mg/kg
Food additive	Food Safety and Standards Act, 2006; Act.No.34, 2006, Regulations 2011 and Compendium Food Additives Regulations 2017	Annex-A, Table 1 - Use of additives in Dairy Products. 1.8.2 : Dried whey and whey products, excluding whey cheeses & whey powder. Silicon dioxide amorphous INS No. 551.	Recommended Maximum Level - 10,000 mg/kg
Food additive	Food Safety and Standards Act, 2006; Act.No.34, 2006, Regulations 2011 and Compendium Food Additives Regulations 2017	Chapter 3.1 - Food Additives : GMP Conditions for all food categories. 3.1.7 : Anticaking agents, INS No. 551. Functional Classes - Anticaking Agent	GMP Conditions: a) Add lowest possible level to accomplish its desired effect; b) Becomes a component of food as a result of its use in manufacturing, processing or packaging, its doses reduced to the extent reasonably possible; c) Should be of appropriate food grade quality.
Food additive	Food Safety and Standards Act, 2006; Act.No.34, 2006, Regulations 2011 and Compendium Food Additives Regulations 2017	Annex-1, Table 12 - Use of additives in salts, spices, soups, salads and protein products; 12.1.1 : Salt, including edible common salt, iron fortified salt, iodized salt. Silicon dioxide, amorphous INS No. 551.	Recommended Maximum Level - GMP

Regulations Japan

Domain	Legal Record	Registration	Remarks
Animal nutrition	Act on Safety Assurance and Quality Improvement of Feeds	No registration	Can be used as excipient in animal nutrition
Food contact articles	Food Sanitation Act	No registration	Not listed in the negative list (no toxic or harmful substance).

Regulations Switzerland

Domain	Legal Record	Registration	Remarks
Switzerland - SR 817.023.21	Annex 10; Additives for printing inks Table 1 - List of additives	Ref.-No.: 86240 - Silicon dioxide	No remarks
Switzerland - SR 817.023.21	Annex 2; Additives for plastics Table 1 - List of additives	Ref.-No.: 86240 - Silicon dioxide	No remarks
Switzerland - SR 817.023.21	Annex 9; Additives for silicones Table 1 - List of additives	Ref.-No.: 86240 - Silicon dioxide	No remarks

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives	21 CFR 175.105 (c)(5)	Adhesives	silicon dioxide - as defined in 21 CFR 172.480
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.105 (2)(c)(1) and (2)(c)(5)	Silicon dioxide for use only as component of adhesives	(2)(c)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (silicon dioxide) - (SAS) (2)(c)(5) Silicon dioxide as defined in §172.480(a)
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.125 (a)(1), (a)(3) and (b)(1)	Substances for use only as components of adhesives; Pressure-sensitive adhesives	(a)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (silicon dioxide) - (SAS) (a)(3) Color Additives listed for use in or on food in 21 CFR 73 and 74
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.230 (b)(1)	Hot-melt strippable food coatings	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.300 (b)(1)	Resinous and polymeric coatings	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.320 (b)(1)	Resinous and polymeric coatings for polyolefin films	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.350 (d)(1), (d)(3)	Vinyl acetate/crotonic acid copolymer.	(d)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS) (d)(3) Listed as Silica
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.380 (a)	Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins.	substances identified in §175.300(b)(3), with the exception of paragraph (b)(3)(xxxi) and (xxxii) of that section
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.390 (b)(1)	Zinc-silicon dioxide matrix coatings	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.1005 (b)	Hydrogen peroxide solution	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3120 (d)(1)	Animal glue	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3297 (a), (d) and (e)	Colorants for polymers	The color effect as described in 21 CFR 178.3297 (a) - to affect the color of a food-contact material - must be given.
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3570 (a)(1)	Lubricants with incidental food contact	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Adjuvants, Production Aids and Sanitizers	21 CFR 178.3850 (d)(1)	Reinforced wax	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Paper and paperboard components	21 CFR 176.180 (b)(1)	Components of paper and paperboard in contact with aqueous and fatty foods	(a)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Paper and paperboard components	21 CFR 176.180 (b)(1)	Components of paper and paperboard in contact with dry food	Substances that by §176.170 and other applicable regulations in parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.
Indirect Food Additives; Paper and paperboard components	21 CFR 176.200 (d)(1), (d)(3)	Defoaming agents used in coatings	(d)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS) (d)(3) Listed as Silica
Indirect Food Additives; Paper and paperboard components	21 CFR 176.210 (d) and (d)(3)	Defoaming agents used in the manufacture of paper and paperboard	(d) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS); Also listed in (d)(3) as silica
Indirect Food Additives; Polymers	21 CFR 177.1010 (a)	Acrylic and modified acrylic plastics, semirigid and rigid	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1020 (2)(b)	Acrylonitrile/butadiene/styrene copolymer	Adjuvants. The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part ...; Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1030 (b)	Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer	Adjuvants. The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part ...; Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1050 (b)	Acrylonitrile/styrene copolymer modified with butadiene/styrene elastomer	Adjuvants. The copolymer identified in paragraph (a) of this section may contain adjuvant substances required in its production. Such adjuvants may include substances generally recognized as safe in food, substances used in accordance with prior sanction, substances permitted in this part ...; Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1200 (b)(1) and (c)	Cellophane	(b)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS) (c) listed as Silica
Indirect Food Additives; Polymers	21 CFR 177.1211 (b)	Cross-linked polyacrylate copolymers	Adjuvants. The copolymers identified in paragraph (a) of this section ... The optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1240 (d)(1)	1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1320 (a)(1)	Ethylene-ethyl acrylate copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1350 (a)(1)(i)	Ethylene-vinyl acetate copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1400 (b)(1)	Hydroxyethyl cellulose film, water-insoluble	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1440 (b)	4,4'-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1500 (c)(3)(iv)(A)	Nylon resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1520 (b)	Olefin polymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1550 (b)(1)	Perfluorocarbon resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1560 (b)	Polyarylsulfone resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1580 (b)	Polycarbonate resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1630 (e)(1)	Polyethylene phthalate polymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1635 (b)	Poly(p-methylstyrene) and rubber-modified poly(p-methylstyrene)	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1640 (b)	Polystyrene and rubber-modified polystyrene	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1650 (a)(1)	Polysulfide polymer - polyepoxyresin	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1660 (b)	Poly (tetramethylene terephthalate)	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1950 (b)	Vinyl chloride-ethylene copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1970 (b)	Vinyl chloride-lauryl vinyl ether copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.1980 (b)	Vinyl chloride-propylene copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1990 (b)	Vinylidene chloride/methyl acrylate copolymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2000 (b)	Vinylidene chloride/methyl acrylate/methyl methacrylate polymers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2250 (a)	Filters, microporous polymeric	Finely divided silicon dioxide
Indirect Food Additives; Polymers	21 CFR 177.2420 (b)(6)	Polyester resin, cross-linked	Listed as Silicon Dioxide
Indirect Food Additives; Polymers	21 CFR 177.2500 (b)	Polyphenylene sulfone resins	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2550 (b), (c)	Reverse osmosis membranes	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Indirect Food Additives; Polymers	21 CFR 177.2600 (c)(1)	Rubber articles intended for repeated use	(c)(1) Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS). (d)(v) Fillers: Silica
Indirect Food Additives; Polymers	21 CFR 177.2800 (d)(1) and (d)(3)	Textiles and textile fibers	Substances generally recognized as safe in food (GRAS) - Agency response letter GRAS Notice No. 000554 - synthetic amorphous silica (SAS)
Listing of color additives exempt from certification	21 CFR 73.1 (b)(1)(ii)	Listed as silicon dioxide	Not more than 2% of the ink solids
Substances generally recognized as safe	21 CFR 182.90	Substance migrating from paper & paperboard products	Listed as Silicon Dioxide

Purity Criteria

This product meets specific purity criteria (e.g. for heavy metals) and can therefore be used in regulated applications. The purity criteria were determined from mean values of arbitrarily selected samples. The data provided are therefore representative values and do not represent specifications. The analysis of these purity criteria is not part of our routine standard quality and production control.

Amorphous structure

Synthetic amorphous silica manufactured by flame hydrolysis or by precipitation in an aqueous solution is characterized by its amorphous structure. The determination method used on typical samples is enrichment of the crystalline fraction followed by X-ray Diffraction. The detection limit of this method is less than 0.1% by weight. The determination of arbitrarily selected samples shows no crystalline fraction above the detection limit. Under consideration of this result above mentioned silica is considered to be amorphous.

Community eco-label to outdoor and indoor paints according to Commission Decision 2014/312/EU

Criterion 4 - Content of Volatile and Semi-volatile Organic Compounds (VOCs, SVOCs)

During the production process of this product we do not intentionally use or add any volatile organic compounds (VOC's) and/or semi-volatile organic compounds. According to the production process and to the best of our knowledge we do not **expect any VOC's/SVOC's in this product.**

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Criterion 5 - Restriction of hazardous substances and mixtures

This product is not a hazardous substance and not listed as SVHC-Substance. Please visit the product safety information and safety data sheet for detailed information.

Allergens

This product is a pure substance. During the production process we do not intentionally use or add any ingredients usually mentioned to be allergens

- according to EU-Directive 2000/13/EC and amendments
- according Regulation (EU) No 1169/2011 - Food information to consumers
- according the Brazilian resolution RDC No. 26 – requirements for labeling of main foods that cause food allergies
- according to the ALBA-list: Cereals containing gluten (e.g. Wheat, Rye, Barley, Oat, Spelt, Kamut), Maize, Crustaceans, Molluscs, Egg, Fish, Milk, Lactose, Ox, Pig, Hen/Chicken, Peanuts, Soybeans, Almonds, Hazelnut, Walnut, Cashew nut, Pecan nut, Brazil nut, Pistachio, Macadamia nut, Queensland nut, Celery, Mustard, Sesame, Lupines, Leguminous plants, Cinnamon, Vanilla, Coriander, Cocoa, Sulphur dioxide, Sulphites, Yeast, Glutamate (E620 – E625), Benzoic acid (E210 – E219) Azo-colorants/pigments.
- Pine, Chestnuts
- Other additives, preservatives, flavors/fragrances or natural latex.

Since testing of these substances is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guarantee the absence of these substances in this product.

GMO

In the production process of this product we do not use any Genetically Modified Organisms (GMOs). This product is non-GMO, it does not contain any GMO and has not been in contact with any GMO. Therefore Regulations (EC) No 1829/2003 (as amended) and No 1830/2003 (as amended) are not applicable.

Suitability

This product is chemically produced. During the production process we do not intentionally use or add gluten, lactose or any other materials of animal or plant origin. Any testing for these materials are not part of our routine quality and production processes and therefore, we do not guarantee their absence in our product specifications.

We can therefore confirm that this product is suitable for Vegetarians, Ovo-lacto Vegetarians, Vegans, Coeliacs and people with lactose intolerance.

Nutritional value

This product is chemically produced. It is a completely inorganic material. During the production process we do not intentionally use or add any carbohydrates, fats or proteins. This product has no nutritional value. Since testing of these substances is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guaranty the absence of these substances in this product.

Kosher-Certificate

In case your application requires a Kosher certificated raw material, please contact your usual contact by Evonik Resource Efficiency GmbH to clarify this issue and receive the certificate or recommendation for a suitable substitute product.

Halal-Certificate

In case your application requires a Halal certificated raw material, please contact your usual contact by Evonik Resource Efficiency GmbH to clarify this issue and receive the certificate or recommendation for a suitable substitute product.

Microbiology

This product is manufactured on an industrial scale by hydrolysis of chlorosilanes in an oxyhydrogen flame and is therefore sterile during the production process. Although conveying, storage and packaging is not performed under sterile conditions, a microbiological contamination is highly improbable.

Aflatoxins

This product is chemically produced. During the production process, there is practically no risk of contamination.

Therefore, to the best of our knowledge, aflatoxins are not contained in this product.

Analysis on aflatoxins is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Irradiation

This product is chemically produced. During the production process we do not intentionally use or add any irradiated or radioactive raw-materials. The product is also not irradiated. Since testing on irradiation is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guaranty the absence of irradiation in this product.

More information regarding Regulation (EU) 10/2011

• Declaration of compliance (DoC)

This product is in line with the specification and standards of Regulation (EU) 10/2011.

The production process is under the hygienic conditions of Regulation (EU) 852/2004 (HACCP).

• Dual use additive

This product is a dual use additive. The purity criteria of E 551 are met.

Origin - TSE/BSE and Materials of animal or plant origin

This product is chemically produced. In the production process we do not use any raw material of animal or plant origin (as mentioned in EMEA/410/01, current version). In our manufacturing facilities we generally do not use any material of animal or plant origin. Our product is not contaminated with any animal- or plant-based material when it leaves the manufacturing sites and warehouses of the manufacturing company.

Animal nutrition - undesirable Substances according to Directive 2002/32/EC

During the production process of this product we do not intentionally use or add any undesirable substances according to EU-Directive 2002/32/EC (and amendments). The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Information on REACH / Substances of Very High Concern (SVHC)

According to Regulation (EU) 1907/2006 (REACH) substances of very high concern (SVHC) must be mentioned in the safety data sheet (SDS) when the content is above the threshold limit of 0.1% w/w. Please visit the current safety data sheet for more information regarding this issue.

Please use the following e-mail address to order the current SDS: sds-hu@evonik.com

Information on REACH / PBT- and vPvB - substances

This product is not a PBT, vPvB substance as per the criteria of the REACH Regulation.

Information on REACH / Annex XIV or Annex XVII

This product is not a substance and does not contain any substances subject to authorization and/or restriction according to Annex XIV or Annex XVII of the REACH Regulation (EC) No. 1907/2006, respectively. However, testing of these substances is not part of our standard routine quality control and production testing procedures.

RoHS and WEEE Directives

This product fulfils the limitations and requirements of the EU-Directives 2011/65/EU (RoHS), 2012/19/EU (WEEE) and amendments. It is chemically produced. In the production process we do not use or intentionally add the following substances:

pentabromodiphenylether, octabromodiphenylether, lead, cadmium, chromium (total), mercury, polybrominated biphenyls (**PBB's**), **polybrominated diphenylethers (PBDE)**, Di(2-ethylhexyl)phthalate (DEHP), Butylbenzylphthalate (BBP), Dibutylphthalate (DBP), Diisobutylphthalate (DIBP), chlorinated organic compounds, such as PCB, PCN, CP, mirex, organic tin compounds, asbestos, azo compounds, polyvinyl chloride (PVC) and PVC-blends.

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

EuPIA exclusion policy for printing inks

During the production process of this product we do not intentionally use or add any substance from the EuPIA exclusion policy for printing inks. Since testing of these substances is not part of our standard routine quality control and production testing procedures, we therefore cannot warrant or guarantee the absence of these substances in this product.

California List of Chemicals, Proposition 65 (USA)

In the production process of this product we do not intentionally use or add any of the substances on the California list of chemicals (USA), Proposition 65, in the current published version. The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Oeko-Tex Standard 100

For limit values please visit the chapters "Heavy metals", "C.M.R. classified substances" and "Substance declaration".

End-of life vehicles

This product fulfils the limitations and requirements of the EU Directive 2000/53/EC. For limit values, please visit the chapters Heavy metals, C.M.R. classified substances and Substance declaration.

Volatile Organic Compounds (VOC´s)

Volatile Organic Compounds are not used or intentionally added during production process of this product. To the best of our knowledge this product does not contain any Volatile Organic Compounds. The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

“Substance declaration”

During the production process of this product we do not intentionally use or add any of the following substances:
Aromatic amines according to EU Directive 2002/61/EC.

Volatile aromatic hydrocarbons, alkylphenol-ethoxylates, glycol ethers, isothiazolinone compounds, formaldehyde or formaldehyde donators as mentioned in Commission Directive 2002/739/EC.

2,2-bis(4-hydroxyphenyl)propane, bis(2,3-epoxypropyl) ether (BADGE), bis(hydroxyphenyl)methane, bis(2,3-epoxypropyl)ethers (BFDGE) and novolac glycidyl ethers (NOGE) as mentioned in Regulation (EC) No 1895/2005.

Substances mentioned in the “VDA-List of Substances to be Declared” version 2005, in the IMDS International list of reportable substances (ILRS-list), in 2005 replaced by GADSL, version 2019 or its subsequent revision, respectively.
Polychlorinated biphenyls (PCB), polychlorinated naphthalenes (PCN), polychlorinated terphenyls (PCT), pentachlorophenol (PCP) and PCP-salts, chlorinated paraffins (CP), Mirex (perchlorodecone), polycyclic aromatic hydrocarbons (PAHs), polybrominated biphenyls (PBB), polybrominated terphenyls (PBT), polybrominated diphenylethers (PBDE), tetrabromobisphenol-A-bis-(2,3-dibromopropylether) (TBBP-A-bis), halogenated solvents, other halogens, organic tin compounds, asbestos, azo dye, polyvinyl chloride (PVC) and PVC-blends, latex, ozone depleting substances, phthalates, cyanides, radioactive materials, pesticides, biocides.

1,4-Dioxan

Substances listed in Sony’s Technical Standards “SS-00259” 15th edition 2017.

Perfluorooctane sulfonates (PFOS) and Perfluorooctanoic acid (PFOA) as described in EC-directive 2006/122/EC.

Antibiotics

Any kind of Bisphenol

Asbestos

Boron

Cobalt

DEHP (diethylhexyl phthalate) and DINP (diisononyl phthalate) or any other phthalates

Dimethylfumarat (DMF)

Ethanol (alcohol)

Ethylene oxide

Gold, Tantalum, Tin, Tungsten

Iodine

Isocyanate

Melamine

Mineral oil aromatic hydrocarbons (MOAH)

Mineral oil saturated hydrocarbons (MOSH)

Narcotic products

Nitrite, Nitrate

Quaternary ammonium compounds

Sodium, Sodium chloride

Steroidal anabolic

Sweeteners (e.g. Aspartame, Saccharin, Steviosid)

Uranium

Zinc oxide

The analysis on above mentioned substances is not part of our standard quality and production analyses. Therefore, we cannot warrant or guarantee the absence or level of these substances to any specific limit or threshold value.

Registration Status

The above mentioned product is registered in the following inventories:

Australia	AICS (Australian Inventory of Chemical Substances)	registered
Canada	DSL (Domestic Substance List)	registered
China	IECSC (Inventory of Existing Chemical Substances)	registered
Europe	REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals)	registered (01-2119379499-16-0000)
Europe	EC (European Community)	registered (231-545-4)
Japan	ENCS (Existing and New Chemical Substances)	registered
Korea	KECI (Korea Existing Chemicals Inventory)	registered
New Zealand	NZIoC (New Zealand Inventory of Chemicals)	registered
Philippines	PICCS (Philippine Inventory of Chemicals and Chemical Substances)	registered
Taiwan	TCSI (Chemical Substances Nomination and Notification)	registered
USA	TSCA (Toxic Substances Control Act)	registered

The following information is available in our Safety Data Sheet (SDS):

Hazard Identification, Composition/Information on Ingredients, REACH-Registration number (if available), (SVHC) Substances of high concern (if applicable), First Aid, Fire Fighting Measures, Accidental Release Measures, Handling and Storage, Exposure Control/Personal Protection, Physical and Chemical Properties, Stability and Reactivity, Toxicological and Ecological Information, Disposal Considerations, Risk Information (e.g. Transportation, Labeling, Risk Phrases). The Water Hazard Class (WGK) is only in the German version of the safety data sheet available. Please, pay attention to the national edition of the SDS!

The following e-mail address should be used in order to request the SDS: sds-hu@evonik.com

Heavy metals and other metal traces

In the production process of this product we do not intentionally use or add any heavy metal constituents. The overall content of these elements, in their entirety, lies below 100 ppm and is therefore in line with the limits set by the EU Packaging Directive 94/62/EU.

It is also compliant with the requirements of the Coalition of Northeastern Governors (CONEG) model legislation limiting heavy metals (January 1994).

Heavy metals

Substance	Concentration
Cadmium (Cd)	≤ 1 ppm
Chromium, total (Cr)	≤ 3 ppm
Mercury (Hg)	≤ 1 ppm
Lead (Pb)	≤ 1 ppm

Other metal-traces

Substance	Concentration
Arsenic (As)	≤ 1 ppm
Antimony (Sb)	≤ 1 ppm
Selenium (Se)	≤ 1 ppm
Barium (Ba)	≤ 1 ppm
Zinc (Zn)	≤ 1 ppm
Iron (Fe)	≤ 10 ppm

Copper (Cu)	≤ 1 ppm
Nickel (Ni)	≤ 3 ppm

(The analysis for above mentioned metals is not part of our standard quality and production analyses. The limits given represent mean values from arbitrarily selected samples, but do not represent any specifications.)

Disclaimer

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Legend

BfR:	Bundesinstitut für Risikobewertung
CAS:	Chemical Abstract Services Register Number
CoE:	Council of Europe
CONEG:	Coalition of Northeastern Governors
CosIng	European Commission database for information on cosmetic substances and ingredients
FDA:	Food and Drug Administration
INCI:	International Nomenclature Cosmetic Ingredients
JHOSPA:	Japan Hygienic Olefin and Styrene Plastics Association
PBT:	Persistent, Bioaccumulative, Toxic
PCPC	Personal Care Products Council
SAS:	Synthetic Amorphous Silicon dioxide, Synthetic Amorphous Silica
vPvB:	very Persistent, very Bioaccumulative