

Product Dossier
Evonik Operations GmbH

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Product name:	SPHERILEX® DP-0111 ex Hamina, Finland
Chemical name:	Silicon dioxide, chemically prepared
CAS No:	112926-00-8; resp. 7631-86-9
EC No:	231-545-4
Custom Tariff Number:	281122

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Regulations Brazil

Domain	Legal Record	Registration	Remarks
Food Contact Articles	MERCOSUR/GMC/RES. No. 32/07 Mercosur 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 China

Domain	Legal Record	Registration	Remarks
Food Contact Additives	GB 9685-2016	FCA0782 (CAS# 112926-00-8)	Dosage as necessary: plastics (A.1), coatings (A21), rubber (A.3) ink (A.4), paper (A.6),
Food Contact Additive	GB 9685-2016	FCA0759 (CAS# 7631-86-9)	Dosage as necessary: Adhesives (A.5)

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Regulations EU

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 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# 7631–86–9 Silicon dioxide, Silicic acid	Purity criteria according to BfR 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	Ref. No.: 86240 – Silicon dioxide	Annex 1: White list for lubricants 1.2 thickener

Regulations Germany

Domain	Legal Record	Registration	Remarks
Umweltbundesamt – KTW Guideline for drinking water	Water, Drinking Water, and Water Protection – Rubber materials	Ref. No.: 86240 – Silicon dioxide	List 1.1.2 Fillers (Purity requirements according to BfR Recommendation LII. Fillers)

Regulations Switzerland

Domain	Legal Record	Registration	Remarks
Switzerland SR 817.023.21	Annex 2 – Plastics	Nr. 1809 FCM 86240 – Silicon dioxide	Table 1 – List of additives As additive
Switzerland SR 817.023.21	Annex 9 – Silicone products	Nr. 1809 FCM 86240 – Silicon dioxide	Table 1 – List of additives As additive
Switzerland SR 817.023.21	Annex 10 – Printing inks	Nr. 1809 FCM 86240 – Silicon dioxide	Table 1 – List of additives As additive and pigment

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.105 (c)(1) and (c)(5)	Substances for use only as components of adhesives: Adhesives	(c)(1) Substances generally recognized as safe in food (GRAS) – Agency response letter – GRAS Notice No. 000554 – synthetic amorphous silica (silicon dioxide) – (SAS) (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)

Regulations USA

Domain	Legal Record	Registration	Remarks
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)
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) and (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, no limitations provided.
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; Paper and paperboard components	21 CFR 176.170 (a)(1)	Components of paper and paperboard in contact with aqueous and fatty foods	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

Regulations USA

Domain	Legal Record	Registration	Remarks
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)
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)

Regulations USA

Domain	Legal Record	Registration	Remarks
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.
Indirect Food Additives; Polymers	21 CFR 177.1240 (d)(1)	1,4-Cyclohexylene dimethylene	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)

Regulations USA

Domain	Legal Record	Registration	Remarks
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)
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)

Regulations USA

Domain	Legal Record	Registration	Remarks
Indirect Food Additives; Polymers	21 CFR 177.1650 (a)(1)	Polysulfide polymer-polyepoxy 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 177.1660 (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)
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

Regulations USA

Domain	Legal Record	Registration	Remarks
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) and (c)	Reverse osmosis membranes	(b), (c) 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) and (c)(4)(v)	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) (c)(4)(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)
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 178.3570 (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)

Regulations USA

Domain	Legal Record	Registration	Remarks
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)
Substances Generally Recognized As Safe	21 CFR 182.90	Substance migrating from paper & paperboard products	Listed as Silicon Dioxide

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

Silicon dioxide is a dual use additive. The purity criteria of E 551 are met.

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.

Absence of

During the manufacturing process we do not intentionally use or add any of the following substances:

- Acetaldehyde
- Acrylates (e.g. BDDA, DEGDA, IDA, etc.)
- APEO and their derivatives
- Aromatic amines
- Aromatic compounds
- Azo dyes/ azo colorants
- Benzophenone
- Bisphenol A, Bisphenol S
- Brominated flame retardant,
- CFCs or Fluorinated greenhouse gases
- Chloropropanols (MCPD)
- 1,2-dichlorobenzene
- Dichlorophenols (DCP)
- Dimethylformamide (DMF)
- Dyes
- Epoxy derivatives (BADGE, BFDGE, NOGE, ref. Regulation (EC) No 1895/2005)
- Fragrances
- Formaldehyde
- Formaldehyde-releasing substances
- Glycol ethers (EGBE, EGME, EGEE, EGMEA, EGEEA, EGDME, DEGDME, DGME, TEGDME)
- Glyoxal
- Halogenated hydrocarbons
- Halogenated organic substances*
- Hazard air pollutants
- Hydrocarbons
- IPBC (3-iodo-2-propynyl-butyl carbamate, CAS 55406-53-6)
- Isocyanates
- Melamine
- Methanol
- MOAH (mineral oil aromatic hydrocarbons) or MOSH (mineral oil saturated hydrocarbons)
- N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (CAS 2372-82-9)
- Natural rubber or natural dry latex
- N-methyl-2-pyrrolidone (NMP)
- Organo tin compounds
- Oximes
- Ozone depleting substances
- Pentachlorophenol
- Perfluorinated or polyfluorinated chemicals (PFC)
- Phthalates (DBP, DnPP, DNHP, DNOP, BBP, DIBP, DIPP, DINP, DIDP, DMEP, DEHP)
- Plasticizing substances
- Polyaromatic hydrocarbons (PAH)
- Polybrominated or polychlorinated compounds
- Preservatives
- PVC compounds
- Radioactive substances
- Rare earth metals
- Tetrachloroethylene
- TiO₂
- Tributyl tin or triphenyl tin
- Zinc oxide

* Sodium hypochlorite is used to purify the process water.

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.

Allergens

This product is a pure substance. In the manufacturing process we do not intentionally use or add any ingredients usually listed as allergens

- according Regulation (EU) No 1169/2011 – Food information to consumers
- according to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)
- 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

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

California Proposition 65 (USA)

In the manufacturing process of this product we do not intentionally use or add substances listed on the California list of chemicals (USA), Proposition 65, 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.

Conflict minerals

In July 2010 the United States Congress passed legislation requiring public corporations to report the use of conflict minerals in the manufacture of their products. Conflict minerals refer to specific minerals originating from the mines controlled by armed groups in the Democratic Republic of the Congo (DRC) or adjoining countries. These minerals are Gold, Tantalum, Tin and Tungsten. In the manufacturing process of the above-mentioned product no gold, tantalum, tin or tungsten is used and, therefore, it should be considered “DRC Conflict Free.”

Eco-label to outdoor and indoor paints and varnishes according to Commission Decision 2014/312/EU

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

In the manufacturing process of this product we do not intentionally use or add any volatile organic compounds (VOCs) and/or semi-volatile organic compounds (SVOCs). According to

the manufacturing process and to the best of our knowledge we do not expect any VOCs or SVOCs 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, see further information in chapters “Information on CLP Regulation” and “Information on REACH ...” and in the current safety data sheet.

Endocrine disrupting chemicals (EDC)

In the manufacturing process of SPHERILEX® synthetic amorphous silica products we do not intentionally use as a raw material or add substances classified as EDC (category 1 or category 2).

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

In the manufacturing process of this product we do not intentionally use or add any substance listed in 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 cannot warrant or guarantee the absence of these substances in this product.

GMO

In the manufacturing process of this product we do not intentionally use or add any Genetically Modified Organisms (GMO). 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.

Heavy metals

In the manufacturing process 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)	≤ 10 ppm
Lead (Pb)	≤ 5 ppm
Mercury (Pb)	≤ 1 ppm

Other metal traces

Substance	Concentration
Antimony (Sb)	≤ 5 ppm
Arsenic (As)	≤ 3 ppm
Barium (Ba)	≤ 50 ppm
Copper (Cu)	≤ 6 ppm
Iron (Fe)	≤ 400 ppm
Nickel (Ni)	≤ 3 ppm
Selenium (Se)	< 4 ppm
Zink (Zn)	≤ 10 ppm

The analysis for heavy metals or other metals traces is not part of our standard quality and production analyses. The limits given represent typical values from arbitrarily selected samples, but **do not represent any specifications**.

Information on CLP Regulation

Based on our data, synthetic amorphous silica products are not classified nor contain any intentionally added substances classified according to CLP Regulation 1272/2008. Synthetic amorphous silica is not carcinogenic, mutagenic or toxic for reproduction. In the manufacturing process we do not intentionally use or add any substances classified as CMR in the CLP Regulation.

The analysis on CMR 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 / 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, respectively, to REACH Regulation (EC) No. 1907/2006. However, testing of these substances is not part of our standard routine quality control and production testing procedures.

Information on REACH / PBT and vPvB substances

This product is not PBT nor vPvB substance as per the criteria of the REACH Regulation.

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

According to Regulation (EU) 1907/2006 (REACH) Substances of Very High Concern (SVHC) must be listed in the safety data sheet (SDS) when the content is above the threshold limit of 0.1% w/w. This product does not contain any intentionally added SVHC substances. Please, see the current safety data sheet for more information regarding this topic.

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

Nano definitions

Belgian Royal Decree of May 27th, 2014

Synthetic amorphous silica meets the definition of substance produced in nanoparticulate state according to the Belgian Royal Decree of May 27th, 2014.

Commission Recommendation 2011/696/EU

The Recommendation determines nanomaterial as the following: a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm–100 nm. Synthetic amorphous silica meets the definition of nanomaterial according to Recommendation 2011/696/EU.

French Decree 2012–232

Synthetic amorphous silica meets the definition of substance at nanoscale according to the French Decree 2012–232.

Swedish KIFS 2017:7

Synthetic amorphous silica is a nanomaterial according to the definition in Kemikalieinspektionens föreskrifter (KIFS) 2017:7 as amended.

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

This product is chemically prepared from mineral derived and synthetic inorganic raw materials. It does not contain any ingredient of animal or plant origins. It is not contaminated with any animal or plant origin material when it leaves the manufacturing sites and warehouses of the manufacturing company.

Registration Status

Silicon dioxide is registered in the following chemical inventories:

Australia	AICS (Australian Inventory of Chemical Substances)	registered
Canada	DSL (Domestic Substance List)	registered
China	IECSC (Inventory of Existing Chemical Substances)	registered
Europe	EC (European Community)	registered
Europe	REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals)	registered (01–2119379499–16)
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

RoHS

This product fulfils the limitations and requirements of the EU Directive 2015/863 (RoHS 3). In the manufacturing process we do not intentionally use or add substances listed in the RoHS 3:

- Cadmium
- Lead
- Mercury
- Hexavalent chromium
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

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.

Toys – Directive 2009/48/EC and EN 71–3

Concerning the safety qualification for above mentioned application, please, see the chapters 'Heavy metals' and 'Absence of'.

Volatile Organic Compounds and volatile aromatic hydrocarbons (VOCs and VAHs)

Volatile Organic Compounds or volatile aromatic hydrocarbons are not intentionally used or added during manufacturing process of this product. To the best of our knowledge this product does not contain any volatile 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.

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 Very 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!

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

Evonik Operations GmbH

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