

Product Safety Information

Evonik Operations GmbH

Product Name: AEROSIL® R 972
 Chemical Name: Silane, dichlorodimethyl-, reaction products with silica
 CAS-No.: 68611-44-9,
 Customs Tariff Number: 382499

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Regulations Brazil

Domain	Legal Record	Registration	Remarks
Food contact articles	MERCOSUR/GMC/RES. No. 39/19 Mercosur technical regulation on "positive list of additives for plastic materials intended for the manufacture of food contact packages and equipment"	List of authorized Additives for plastic materials and polymeric coatings, Appendix I: Mercosur substance number: 87, European reference-number: 86285	The particle size specification for silicon dioxide, silanated will be fulfilled.

Regulations Canada

Domain	Legal Record	Registration	Remarks
Cosmetics Regulations	Silica Dimethyl Silylate is included in the ICI dictionary	Cosmetic Regulations CRC c 869: ingredients included in the International Cosmetic Ingredient Dictionary (ICI), and materials with INCI are recognized as possible approved ingredients for cosmetic use.	No remarks

Regulations China

Domain	Legal Record	Registration	Remarks
Cosmetics	Catalogue of Cosmetics Ingredients used in China (IECIC) 2015	INCI-Name PCPC: Silica Dimethyl Silylate, INCI-Name CosIng: Silica Dimethyl Silylate	No remarks
Food contact additive	GB 9685-2016	FCA0748 (A1)	Application in plastic, max use: PET - 0.1%, PP -0.5%, use temperature of materials produced from it should be less than 100°C

Regulations China

Domain	Legal Record	Registration	Remarks
Food contact additive	NHFPC Year 2017 No.9	No registration necessary	Application in plastic: PVDF - 50%; Used as processing agent only. For PVDF materials produced by this substance, the maximum food contact temperature is 100°C.
Food contact additive	NHFPC Year 2018 No.11	No registration necessary	Application in plastic: PP:0.02%, coating and coating layer: 0.5%; For PP materials and coating, coating layer produced by this substance, the maximum food contact temperature is 121°C.

Regulations Europe

Domain	Legal Record	Registration	Remarks
Cosmetics	Regulation (EC) 1223/2009	INCI CosIng: Silica Dimethyl Silylate	The purity criteria of E 551 are met. Production only on special request according to HACCP/hygienic conditions of regulation (EU) 852/2004
Food contact articles	CoE Resolution AP 2002 (1), paper and boards, V4 – 12.02.2009	Ref.-No.: 86000 - Silicic acid, silylated, Ref.-No.: 86285 - Silicon dioxide, silanated	A. List 1 of Additives
Food contact articles	CoE Resolution AP 2004 (1), coatings, V3 - 12.02.2009	Ref.-No.: 86000 - Silicic acid, silylated, Ref.-No.: 86285 - Silicon dioxide, silanated	C. List 1 of additives
Food contact articles	CoE Resolution AP 2004 (4), rubber products, V1 - 10.06.2004	Ref.-No.: 86000 - Silicic acid, silanated	Appendix 1 - Index list of additives
Food contact articles	CoE Resolution AP 2004 (5), silicones, V1 - 10.06.2004	Ref.-No.: 86000 - Silicic acid, silanated	List 1 - No. 3. Additives
Food contact articles	CoE Resolution AP 2005 (2), packaging Inks, 21 December 2006	Ref.-No.: 86285 - Silicon Dioxide, silanated	List 1 of Additives
Food contact articles	Regulation (EU) 10/2011	FCM substance No.: 87 - Ref.-No.: 86285 Silicon dioxide, silanated	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: XXI, LII	"Silicic acid, also in silylated form"	Purity criteria acc. to BfR recommendation LII are met

Regulations Germany

Domain	Legal Record	Registration	Remarks
Umweltbundesamt - Assessment Basis for plastics and other organic materials in contact with drinking water (KTW-BWGL)	Attachments for Plastics and other organic Materials in contact with drinking water - Polymer specific part	B.3.1 Positive list of starting materials for the production of organic coatings; B.3.1.2 Fillers/colourants; Ref.-No.: 86285 - Silicon Dioxide, silanated	The purity criteria according KTW-BWGL, 5.4.2 Requirements for fillers will be fulfilled

Regulations Japan

Domain	Legal Record	Registration	Remarks
Cosmetics	Monograph "Methylsilyl Silicic Anhydride" under Japanese Standards of Quasi-drug Ingredients	No registration necessary	Purity criteria are met, however, we can not inspect according to the monograph.
Food contact articles	Japan's positive list for plastic as Food Contact Materials, Section 1, Table 2 - Additives	Reference number: 800, serial number: 839, substance: silylated silicic acid	Please consider the distinction limit for the use of synthetic resins, special notes and other limitations.

Regulations Switzerland

Domain	Legal Record	Registration	Remarks
Switzerland - SR 817.023.21	Annex 10; Additives for printing inks Table 1 - List of additives	FCM substance No.: 5080, Ref-No.: 86285 - Silicon dioxide, silanated	For more information please see below the chapter "More information regarding regulation (CH) 817.023.21"
Switzerland - SR 817.023.21	Annex 2; Additives for plastics Table 1 - List of additives	FCM substance No.: 5080, Ref-No.: 86285 - Silicon dioxide, silanated	For more information please see below the chapter "More information regarding regulation (CH) 817.023.21"

Regulations USA

Domain	Legal Record	Registration	Remarks
Cosmetics	PCPC - Monograph available	INCI PCPC: Silica Dimethyl Silylate	No remarks
Indirect Food Additives; Adhesives and components of coatings	21 CFR 175.105 (a)(1)	(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section, subject to any prescribed limitations. (Listed as Silicon dioxide, limitation: Not to exceed 2% by weight)	Regulation stipulates that adhesives must be separated from the food by a functional barrier and assumed that cannot be otherwise be reasonably expected to become a component of the food in significant amounts

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.

Safety of toys – directive 2009/48/EG, EN 71-3

Concerning the qualification for above mentioned application please visit the chapters 'Heavy metals' and 'Substance declaration'.

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)

The content of VOC's ($\leq 0.2\%$) and SVOC's ($\leq 0.2\%$) of this product were checked as mean-values of arbitrarily selected samples; they are therefore physical-chemical benchmarks (approximate values), and not specifications.

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.

Cosmetics Regulation (EC) 1223/2009

This product is in line with Regulation (EC) 1223/2009 and is

- not listed in Annex II – **“prohibited substances”**
- not listed in Annex III – **“restricted substances”**
- no colorant, preservative or UV-filter

Allergens:

This product is chemically produced. During the production process we do not add or use intentionally any of the **substances usually mentioned to be allergens. This includes also the substances with the hint “can cause an allergic reaction”, in the Regulation mentioned above.**

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.

Animal Testing

Animal tests, in general, are not performed for every single product grade. But animal tests may be necessary within the framework of chemical legislation (e.g. EU Regulation 1907/2006 REACH). On this product animal tests have never been performed or will never be done for any cosmetic purposes.

Statement concerning the use in vegan cosmetic products

Above mentioned product is chemically produced. During the production process we do not intentionally use or add materials of animal origin and therefore it can be considered as vegan.

Any testing for these materials is not part of our routine quality and production processes and therefore, we do not guarantee their absence in our product specification.

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.

Kosher-Certificate

In case your application requires a Kosher certificated raw material, please contact your usual sales contact 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.

Information concerning Regulation (EC) No 1935/2004 on materials and articles

This product meets the requirements of the Framework Regulation (EC) 1935/2004 for substances in contact with food.

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.

More information regarding hydrophobic silica without particle specification and Ordinance SR 817.023.21

The current version does not contain a particle specification for hydrophobic silica. From the Swiss authority (Eidgenössisches Departement des Innern EDI) we received the following statement:

The Commission Regulation (EU) 2016/1416 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, will be included in the next revision of the Ordinance.

The additive list from the EDI's old regulation on commodities (SR 817.023.21), in contrast to EU Regulation 10/2011 and the new Regulation (SR 817.023.21, Mai 2017), was not a "positive" list. It was not exhaustive and complete. A manufacturer could use an additive which is not listed in the current list if the general requirements (Art. 49 of the Food and Consumer Goods Ordinance SR 817.02) are met. An additive which is listed in Regulation 10/2011 (with its possible restrictions (SML, QM, etc.) fulfils these requirements.

More information regarding Regulation (CH) 817.023.21

• Declaration of compliance (DoC)

This product is in line with the specification and standards of regulation (CH) 817.023.21.

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.

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 (PBBs), 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" and "Substance declaration".

C.M.R. classified substances

The following EU-Directives are since 2008 no longer in force: 2003/34/EC, 2003/36/EC and 76/769/EEC ("restrictions of dangerous substances and preparations"). This class of substances is now regulated under REACH-SVHC.

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" and "Substance declaration".

“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-Dioxane

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

Perfluorooctanoic acid (PFOA), Perfluorononanoic acid (PFNA), Perfluorohexane sulfonic acid (PFHxS), Perfluorooctane sulfonates (PFOS) or other PFAS as described in the Scientific Opinion of EFSA (j.efsa.2020.6223) formerly regulated in 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

Steroid 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 in China)	registered
Europe	REACH - all basic substances and treatment agents are registered and therefore it is	exempted
Europe	EC (European Community)	registered
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)	≤ 1 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
Iron (Fe)	≤ 10 ppm
Copper (Cu)	≤ 1 ppm
Nickel (Ni)	≤ 1 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)

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Evonik Operations GmbH | Smart Materials | Production & Technology | Product Safety | Special Regulations & Applications
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Registered Office: Essen | Register Court: Essen | Local Court | Commercial Registry B 20227

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
FSMA	Food safety modernisation act
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