

Product Safety Information
Evonik Resource Efficiency GmbH

Version 11 | May 2017

Product Name: AEROSIL® R 9200
Chemical Name: Silane, dichlorodimethyl-, reaction products with silica
CAS-No.: 68611-44-9
Customs Tariff Number: 382499

How to find specific information in this document

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Regulations EU and Germany (FRG)			
Domain	Legal Record	Registration	Remarks
Food contact articles (FRG)	BfR recommendations: XV, XXI, LII	"Silicic acid, also in silylated form"	Purity criteria acc. to BfR recommendation LII are met
Food contact articles (EU)	Regulation (EU) 10/2011 and amendments	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"
Food contact articles (EU)	CoE Resolution AP 2004 (1) "coatings"	Ref.-No.: 86285 Silicon dioxide, silanated	C. List 1 – Additives
Food contact articles (EU)	CoE Resolution AP 2002 (1) "paper and boards"	Ref.-No.: 86000 Silicic acid, silylated	List 1 of Additives
Food contact articles (EU)	CoE Resolution AP 2004 (4) "rubber"	Ref.-No.: 86000 Silicic acid (silanated)	Appendix 1 – Index list of additives
Food contact articles (EU)	CoE Resolution AP 2004 (5) "silicones"	Ref.-No.: 86000 Silicic acid (silanated)	List 1 No. 3. Additives
Food contact articles (EU)	CoE Resolution AP 2005 (2) "packaging inks"	Ref.-No.: 86285 Silicon Dioxide, silanated	List 1 of Additives
Umweltbundesamt – KTW Guideline for drinking water	Water, Drinking Water, and Water Protection – Lubricant Guideline	Ref.-No.: 86285 Silicium dioxide, reaction product with dimethyldichlorosilane	Annex 1: White list for lubricants
Umweltbundesamt – KTW Guideline for drinking water	Water, Drinking Water, and Water Protection – Rubber materials	Ref.-No.: 86000 Silicic acid, silanated	List 1.1.2 Fillers (Purity requirements according to BfR Recommendation LII. Fillers)

Regulations China			
Domain	Legal Record	Registration	Remarks
Food Contact Additive (China)	GB 9685–2016	FCA0748	application in plastics, max use: PET: 0.1%, PP: 0.5%

Regulations Japan			
Domain	Legal Record	Registration	Remarks
Food contact articles (Japan)	<u>Voluntary standards</u> of "Japan Hygienic Olefin And Styrene Plastics Association (JHOSPA)"	[B]NL-0652	<u>As additives</u> , these products can be used for resins which are defined by JHSOPA

Regulations Switzerland			
Domain	Legal Record	Registration	Remarks
Switzerland – SR 817.023.21	Annex 1 – Additives for plastics II. List of additives	Silicon dioxide, silanated Silicic acid, silylated	
Switzerland – SR 817.023.21	Annex 5; List of valid substances for silicones – part A	Silicic acid, silanated	
Switzerland – SR 817.023.21	Annex 6, List of additives, Part A : evaluated substances	Silicon dioxide, silanated Silicic acid, silylated	

Regulations USA
The product is not represented as suitable for use for human or animal food in the United States of America but qualified for cosmetics. For further information please contact us.

Because above mentioned product meets specific purity criteria (i.e. for heavy metals), it may be used accordingly. The purity criteria were checked as mean-values of arbitrarily selected samples; they are therefore physical-chemical benchmarks (approximate values), but do not represent any specifications. Purity criteria analysis is not used as part of our standard quality and production control.

More information regarding Regulation (EU) 10/2011

- **Declaration of compliance (DoC)**

Above mentioned product is in line with the specification and standards of regulation (EU) 10/2011.

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.

Heavy metals and other metal traces

In the production process of above mentioned 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) as well as the Consumer Product Safety Improvement Act of 2008 (H.R. 4040 – Public Law No. 110-314, August 14, 2008) establishing consumer product safety standards and other safety requirements for children's product.

Heavy metals:

Cadmium (Cd)	Chromium, total (Cr)	Mercury (Hg)	Lead (Pb)
< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm

Other metal-traces:

Antimony (Sb)	Arsenic (As)	Selenium (Se)	Barium (Ba)	Zinc (Zn)	Iron (Fe)	Copper (Cu)	Nickel (Ni)
< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 1 ppm	< 5 ppm	< 1 ppm	< 1 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.)

Registration Status

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	EC (European Community)	registered
Europe	REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals)	registered
Europe	C&L inventory (classification and labelling inventory)	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	CSNN (Chemical Substances Nomination and Notification)	registered
USA	TSCA (Toxic Substances Control Act)	registered

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 0.01% by weight. The determination of arbitrarily selected samples shows no crystalline fraction above the detection limit. Under consideration of this result above mentioned silica are considered to be amorphous.

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

According to regulation (EU) 1907/2006 (REACH) substances of 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

Above mentioned products is not a PBT, vPvB substance as per the criteria of the REACH Regulation.

Information on REACH / Annex XVII (formerly directive 76/769/EEC)

The above mentioned product is not a substance and does not contain any substances that are subject to authorization and/or restriction according to Annex XIV or Annex XVII (formerly Directive 76/769/EEC) of the REACH regulation, respectively. However, testing of these substances is not part of our standard routine quality control and production testing procedures.

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

The above mentioned 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.

GMO

In the production process of the above mentioned product we do not use any Genetically Modified Organisms (GMO). The above mentioned product is no 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.

Allergens

The above mentioned 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.
 - o 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 guaranty the absence of these substances in this product.

Irradiation

The above mentioned 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 on irradiation in this product.

RoHS and WEEE Directives

The above mentioned 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), 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 list for printing inks

During the production process of the above mentioned product we do not intentionally use or add any substance from the EuPIA exclusion list 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 guaranty the absence of these substances in this product.

Ozone Depleting Chemicals

For the above mentioned product we do not use any Class I or Class II Ozone Depleting Chemicals in its production process.

California List of Chemicals, Proposition 65 (USA)

In the production process of above mentioned product we do not intentionally use or add any of the substances on the California list of chemicals (USA), Proposition 65, published December 2015. 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.

C.M.R. classified substances

On the basis of our data, above mentioned product is classified as a non-hazardous substance as defined by CLP directive 1272/2008/EC. It is not carcinogenic, mutagenic or toxic for reproduction. Above mentioned product is a pure substance. During the production process of above mentioned product we do not intentionally use or add any C.M.R. classified substances mentioned in the EU-Directives 2003/34/EC and 2003/36/EC.

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.

End-of life vehicles

The above mentioned 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.

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 ($\leq 0.1\%$) and SVOC's ($\leq 0.1\%$) of the above mentioned 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**
 - Above mentioned 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.

“Substance declaration”

During the production process of the above mentioned 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 August 2015 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), 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” 14th edition 2015.
- Perfluorooctane sulfonates (PFOS) and Perfluorooctanoic acid (PFOA) as described in EC-directive 2006/122/EC
- Isocyanate
- DEHP (diethylhexyl phthalate) and DINP (diisononyl phthalate) or any other phthalates
- Antibiotics
- Asbestos
- Any kind of Bisphenol
- Boron
- Dimethylfumarat (DMF)
- Ethylene oxide
- Ethanol (alcohol)
- Gold, Tantalum, Tin, Tungsten
- Iodine

- Melamine
- Mineral oil saturated hydrocarbons (MOSH)
- Mineral oil aromatic hydrocarbons (MOAH)
- Narcotic products
- Nitrite, Nitrate
- Quaternary ammonium compounds
- Sodium, Sodium chloride
- Steroidal anabolic
- Sweeteners (e.g. Aspartame, Saccharin, Steviosid)
- Uranium

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 can be found 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

Evonik Resource Efficiency GmbH

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Legend

BfR: Bundesinstitut für Risikobewertung
 CAS: Chemical Abstract Services Register Number
 CoE: Council of Europe
 CONEG: Coalition of Northeastern Governors
 FDA: Food and Drug Administration
 INCI: International Nomenclature Cosmetic Ingredients
 JHOSPA: Japan Hygienic Olefin and Styrene Plastics Association
 PBT: persistent, bioaccumulative, toxic
 vPvB: very persistent, very bioaccumulative
 SAS: Synthetic amorphous silicon dioxide, Synthetic amorphous silica