

Product Name: AEROSIL® 200 Pharma
Chemical Name: Silicon dioxide, chemically prepared
CAS-No.: 112945-52-5 (also known as 7631-86-9)
Customs Tariff Number: 281122

How to find specific information in this document

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Regulations EU and Germany (FRG)			
Domain	Legal Record	Registration	Remarks
European Pharmacopoeia, currently valid version	Monograph "Silica, colloidal anhydrous"		Compliant
Food additive (EU)	(EU) 231/2012 specifications for food additives regarding (EG) 1333/2008 Annex II and III	As E 551	The purity criteria of E 551 are met. Only product ex Rheinfelden/Germany is produced under the hygienic conditions of regulation (EU) 852/2004.
Food additive (EU)	Regulation (EC) 889/2008 – detailed rules organic production, labelling and control	As E 551	Annex VIII, Section A – Food Additives, including carriers, Anti-caking agent for herbs and spices
Food additive (EU)	Directive 2002/46/EG – food supplements – ANNEX II Vitamin and mineral substances ...	B. Minerals, listed as silicon dioxide	For application details, please visit regulation 1333/2008, Annex II, part E, authorised food additives ..., category number 17
Food additive (EU)	Regulation (EC) 889/2008 – detailed rules organic production, labelling and control	silicon dioxide	Annex VIII a, Products and substances authorised for use or addition in organic products ..., Point 10: Clarification
Animal nutrition (EU)	European Union Register of Feed Additives (current version)	As E 551 b (Colloidal silica)	The purity criteria of E 551b are met. Only product ex Rheinfelden/Germany is produced under HACCP/FAMI-QS
Animal nutrition (EU)	Regulation (EC) 889/2008 – detailed rules organic production, labelling and control	As E 551 b (Colloidal silica)	Annex VI, Feed additives used in animal nutrition..., 1. technological Additives, (d) Binders, anti-caking agents and coagulants
Cosmetics (EU)	Regulation (EC) 1223/2009	INCI CosIng: Silica	No negative-listing, positive listing not necessary

Regulations Canada			
Domain	Legal Record	Registration	Remarks
Health Products & Food Branch Regulations, Division 16, Part B	(1) garlic salt; onion salt	Silicon dioxide 1.0% in accordance with the requirements of paragraphs B.07.020(b) and B.07.027(b), respectively.	Other anti-caking agents may be added up to a total of 2%
Health Products & Food Branch Regulations, Division 16, Part B	(1) Edible vegetable oil-based cookware coating emulsions	Silicon dioxide	Suspending agent
Health Products & Food Branch Regulations, Division 16, Part B	(2) Celery salt; celery pepper – 0.5%	Silicon dioxide	
Health Products & Food Branch Regulations, Division 16, Part B	(4) Icing sugar	Silicon dioxide If either used singly or in combination with calcium phosphate tribasic, calcium silicate, magnesium carbonate, magnesium stearate or sodium aluminum silicate	The total must not exceed 1.5%
Health Products & Food Branch Regulations, Division 16, Part B	(6) Cayenne pepper, chili pepper, chili powder, paprika, red pepper – 2.0 %	Silicon dioxide	
Health Products & Food Branch Regulations, Division 16, Part B	(7) Salt	Silicon dioxide 1.0% except in the case of finely grained salt 2.0% in accordance with the requirements of B17.001(a)	Other anti-caking agents may be added up to a total of 2%
Health Products & Food Branch Regulations, Division 16, Part B	S.1 – silicon dioxide		Additive
Health Products & Food Branch Regulations, Division 16, Part B	Table 1: Anticaking agents	Silicon dioxide	
Health Products & Food Branch Regulations, Division 16, Part B	Table VIII. Miscellaneous Food Additives	Silicon dioxide	

Regulations China			
Domain	Legal Record	Registration	Remarks
Food Additive (China)	GB 2760-2011 GB 25576-2010	CNS No. 02.004 INS No. 551 As anti-caking agent	Purity criteria according to GB 25576-2010
Animal Nutrition (China)	Approved feed additive (2013)	As anti-caking agent	Registration is needed for 1st import
Cosmetics (China)	catalogue of Cosmetics Ingredients used in China (IECIC) 2014		INCI-Name CosIng: Silica

Regulations India			
Domain	Legal Record	Registration	Remarks
Food Additives India	Food Safety and Standards Act, 2006; Act No 34, 2006 and amendments til 2011	Chapter 3.1 Food Additives 3.1.7 Anticaking Agents (1) (c) silicon dioxide (3) silicon dioxide	
Food Additives India	Food Safety and Standards Act, 2006; Act No 34, 2006 and amendments til 2011	Appendix A, Table 2, FA for use in Foods; D. Anticaking Agents – (3) silicon dioxide	FA = Food Additive
Food Additives India	Food Safety and Standards Act, 2006; Act No 34, 2006 and amendments til 2011	Appendix A, Table 12, FA for use in suggar and salt; B. Anticaking Agents – (3) silicon dioxide	FA = Food Additive
Food Additives India	Food Safety and Standards Act, 2006; Act No 34, 2006 and amendments til 2011	Appendix A, Table 13, FA for use in cocoa, chocolate and bubble gum; B. Anticaking Agents – (2) silicon dioxide	FA = Food Additive
Food Additives India	Food Safety and Standards Act, 2006; Act No 34, 2006 and amendments til 2011	Appendix A, Table 14, FA for use in milk products; I. Anticaking Agent – (1) (d) silicon dioxide	FA = Food Additive

Regulations Japan			
Domain	Legal Record	Registration	Remarks
Japanese Pharmacopoeia, currently valid version	Monograph "Silicic Anhydride" under Japanese Standards of Quasi-drug Ingredients		compliant
Animal nutrition (Japan)	Act on Safety Assurance and Quality Improvement of Feeds		Can be used as excipient in Animal nutritions

Regulations USA			
Domain	Legal Record	Registration	Remarks
United States Pharmacopoeia, currently valid version	Monograph "Colloidal Silicon Dioxide"		Compliant
Direct Food Contact	Food Chemical Codex (FCC 9)	Monograph silicon dioxide (Synthetic Amorphous Silica) INS: 551	Compliant
Food Products	21 CFR 133.146	Silicon dioxide Grated cheese; not to exceed 2% by weight	Not to exceed 2% by weight
Food Products	21 CFR 160.105	Silicon dioxide Dried eggs; not more than 1%	Not more than 1%
Food Products	21 CFR 160.185	Dried egg yolks; not more than 1%	Not more than 1%
Color Additives – Food	21 CFR 73.1	Amount reasonably required, not to exceed 2% by weight of ink solids	Diluents in color additive mixtures for food use exempt from certification
Direct Food Contact	EAFUS	Everything Added to Food in the United States Database	EAFUS Document No. 1393

(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)	231–545–4
Europe	REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals)	registered
Europe	C&L inventory (classification and labelling inventory)	notified
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. Under consideration of this detection limit above mentioned silica are considered to be amorphous.

Pharmacopoeia

The above mentioned product fulfils the analytical requirements of the currently valid versions of the European Pharmacopoeia (Ph. Eur.), United States Pharmacopoeia (USP / NF) and Japanese Pharmacopoeia (JP) and is tested and certified according to pharmacopoeia methods. In addition, this product is produced according to International Pharmaceutical Excipients Council (IPEC) GMP guidelines and thus fulfils USP Chapter <1078> “Good Manufacturing Practices for Bulk Pharmaceutical Excipients”.

IPEC-GMP

The above mentioned product is manufactured and packaged in a closed production system according to GMP guidelines established for bulk pharmaceutical excipients by the International Pharmaceutical Excipients Council (IPEC-GMP).

Drug Master File

The above mentioned product is an inert excipient in pharmaceutical applications. A US-Drug Master File exists with the US-DMF-No. 1115.

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/MSDS) 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 MSDS: sds-hu@evonik.com

JECFA Monograph 1 (2006) – Silicon Dioxide, Amorphous, INS Number 551

Above mentioned product is in line with the quality requirements of the mentioned JECFA Monograph.

Acceptable daily intake (ADI)

- Joint FAO/WHO Expert Committee on Food Additives, Report TRS 733-JECFA 29/24 – silicon dioxide “silica”: Acceptable daily intake (ADI) – not specified.
- To the best of our knowledge, an acceptable Daily Intake (ADI) for colloidal silicon dioxide (hydrophilic) has not been set by the FDA. The highest amount of colloidal silicon dioxide (hydrophilic) approved so far per dosage form can be found in the FDA’s Inactive Ingredients Guide Database:

<http://www.fda.gov/Drugs/InformationOnDrugs/ucm113978.htm>

<http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm>

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.

Origin – Materials of human origin

The above mentioned product is chemically produced. In the production process we do not use or intentionally add any of the substances mentioned below:

Human embryo, human embryonic stem cell, material sourced from human embryo, ingredients of human blood source.

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.

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 the 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 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.
- Other additives, preservatives, flavors/fragrances or 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.

Suitability

The above mentioned product is chemically produced. During the production process we do not intentionally use or add any gluten or lactose. It is suitable for Vegetarians, Ovo-lacto Vegetarians, Vegans, Coeliacs and people with lactose intolerance.

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.

Nutritional value

The above mentioned 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. Above mentioned 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-Certificates

The above mentioned product delivered from the below mentioned plant/s

- Germany: Rheinfelden
- USA: Mobile

is in line with Kosher requirements. On special request the according certificates can be made available.

Halal-Certificates

The above mentioned product delivered from the below mentioned plant/s

- Germany: Rheinfelden
- USA: Mobile

is in line with Halal requirements. On special request the according certificates can be made available.

Microbiology

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

Aflatoxins

The above mentioned 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

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.

Undesirable Substances according to directive 2002/32/EC

During the production process of above mentioned 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.

Animal nutrition / re-registration according to 1831/2003

The dossier for the re-registration of E 551 a / b according to 1831/2003 was submitted to EFSA as requested.

Animal Testing

Above mentioned product was tested on animals only in connection with requirements of the current Chemical Laws (i.e. EU-Regulation 793/93/EEC). Animal tests on our product have never been performed because of cosmetic questions.

Cosmetics Regulation – Germany (FRG)

The above mentioned product is neither colorant nor preservative nor UV-Filter, therefore a positive listing is not necessary. As it is not listed on the list of forbidden substances it complies with the Cosmetics Regulation (FRG).

Cosmetics Regulation (EU) 1223/2009

- The above mentioned product is in line with Directive (EU) 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

Above mentioned 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.

NATRUE (Natural and Organic Cosmetics)

Above mentioned product is listed by NATRUE (<http://www.natrue.org>) in – Annex 2b: Nature-identical inorganic pigments and minerals approved in natural cosmetics (http://www.natrue.org/fileadmin/natrue/downloads/Annexes_V2_2.xls) with the INCI-Name Silica and may therefore use in NATRUE conform cosmetic formulations without a NATRUE raw material certification.

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.

Organic solvents / Residual solvents

No organic solvents are used or intentionally added in the manufacture of above mentioned product. To the best of our knowledge above mentioned product contain no residual solvents as cited in recent versions of the European Pharmacopoeia, and United States Pharmacopoeia, (class 1, 2, and 3 or other solvents, USP chapter <467>), 2008 and amendments are present in concentrations above the control limits quoted in USP. For above mentioned product Class 1 residual solvents are tested on a regular basis according to USP/NF: Carbon tetrachloride, 1.2 Dichloroethane, 1.1 Dichloroethene, 1.1.1 Trichloroethane, Benzene. The above mentioned product is also in line with ICH/3QC (CPMP/ICH/283/95), Guideline for Residual Solvents.

Residues of metal catalysts or metal reagents

In the production process of above mentioned product we do not intentionally use or add any catalysts or metal reagents. To the best of our knowledge above mentioned product does not contain any residues of metal catalysts or metal reagents, mentioned in the Guideline CPMP/SWP/QWP/4446/2000. 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. specific limit or threshold value.

“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 EU directive 2002/16/EC
- 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 2014 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
- Substances listed in Sony’s Technical Standards “SS-00259” 12th edition 2013.
- 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
- Narcotic products
- Quaternary ammonium compounds
- 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 Material Safety Data Sheet (MSDS):

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, Water Hazard Class).

Please, pay attention to the national edition of the MSDS!

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

Evonik Resource Efficiency GmbH

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