Evonik Operations GmbH - D-63403 Hanau

Inspection Certificate 3.1 according to EN 10204

Date	27.07.2023
Delivery Number / Item	3009687990 / 900010

Product	AEROSIL® 200 VV Pharma 20 x 20 KG / 44.00 lbs Paper Bag - / CP3 Wood pallet
Material	99034601
Your material no	144163-BGPA000020KG0
Quantity	400 KG = 20 BAG
Batch	113052414
Production date	May 24, 2023
Expiration date	May 23, 2025
Delivery date	Jul 27, 2023
Spec. No.	K01, Ver. 12.07.2018
Sign of Car / Wagon	CA-YY-82X5
Sign of Trailer	DN-335TC

Delivery date = Estimated time of dispatch / departure

Property	Test Method	Unit	Value	Target	Min	Max
Specific surface area	ISO 9277, modified	m^2/g	193	200	175	225
Identification	tested acc. to Ph.Eur.		Conforms	pass		
Assay (SiO2 content)	tested acc. to Ph.Eur.	%	100,1		99.0	100,5
pH value	tested acc. to Ph.Eur.		4,9		3,5	5,5
Chlorides <=250ppm	tested acc. to Ph.Eur.		Conforms	pass		
Loss on ignition	tested acc. to Ph.Eur.	%	0,4			5,0
As content <=8ppm	tested acc. to USP/NF		Conforms	pass		
Loss on drying	tested acc. to USP/NF	%	0,2			2,5
Loss on ignition	tested acc. to USP/NF	%	0,3			2,0
Identification, A and B	tested acc. to USP/NF		Conforms	pass		

EVONIK
Leading Beyond Chemistry

Product	AEROSIL® 200 VV Pharma 20 x 20 KG / 44.00 lbs Paper Bag - / CP3 Wood pallet		Page 2 of 3
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Property	Test Method	Unit	Value	Target	Min	Max
pH value	tested acc. to USP/NF		4,7		3,5	5,5
Assay (SiO2 content)	tested acc. to USP/NF	%	100,0		99,0	100,5

AEROSIL® 200 VV Pharma:

Colloidal Silicon Dioxide tested according to Ph.Eur. and USP/NF (current Version)
Manufactured and packaged in a dedicated closed production system according to GMP guidelines established for bulk pharmaceutical excipients by the International Pharmaceutical Excipients Council (IPEC/GMP).

White, fine, amorphous powder.

Elemental Impurities:
Elemental Impurities are not intentionally added to the production process.
The elemental impurities of the ICH Q3D are tested on a regular basis acc. to USP 233 and Ph. Eur. 5.20.

Residual solvents:
No organic solvents are used in the manufacture of above mentioned product. For this reason, constitutionally no residual solvents as cited in recent versions of the European Pharmacopoeia, (class 1, 2 and 3 or other solvents, USP chapter 467), 2008 and amendments are present in concentration about 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 Dichlorethane, 1,1 Dichlorethene, 1,1,1 Trichlorethane and Benzene.

TSE/BSE and materials of plant origin:
No raw materials of animal or plant origin (as mentioned in EMEA/410/01, current version) are used in the production process of AEROSIL® Pharma products. AEROSIL® Pharma products have not been in contact with and constitutionally do not include any material of animal or plant origin.
We generally do not use any material of animal or plant origin in our production facilities. AEROSIL® Pharma products are not contaminated with material of animal or plant origin when they leave our production and warehouses.

This product is manufactured in Site Rheinfelden, Untere Kanalstrasse 3, 79618 Rheinfelden, Deutschland.

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Dr. Martina Altemöller
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This document is computer printed and therefore without signature. All warranty claims in respect to the conformity of our product are subject to our General Terms and Conditions of Sale and Delivery. The data listed above reflects the results of our internal quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when despatched from the works.

*** End ***

Product Safety Information — Evonik Resource Efficiency GmbH

Version 14 | February 2018

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

How to find specific information in this document
This document is an Adobe standard document. Please press the buttons "Strg" and "F" on your keyboard to open the search function, type the search item in the box and press Enter.

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	Purity criteria for E 551 are met, product is not produced according to HACCP.
Animal nutrition (EU)	European Union Register of Feed Additives (current version)	As E 551 b (Colloidal silica)	Purity criteria are met. Product is not produced according to FAMI-QS.
Cosmetics (EU)	Regulation (EC) 1223/2009	INCI CosIng: Silica	No negative-listing, positive listing not necessary

Regulations China			
Domain	**Legal Record**	**Registration**	**Remarks**
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) 2015		INCI-Name CosIng: Silica

Regulations Japan			
Domain	**Legal Record**	**Registration**	**Remarks**
Japanese Pharmacopoeia, currently valid version	Monograph "Silicic Anhydride" under Japanese Standards of Quasi-drug Ingredients		Purity criteria are met, however, we can not inspect according to the monograph.

Regulations USA			
Domain	**Legal Record**	**Registration**	**Remarks**
United States Pharmacopoeia / National Formulary, current valid version	Monograph "Colloidal Silicon Dioxide""		Compliant
Cosmetics (USA)	PCPC - Monograph ID No. 2793	INCI PCPC: Silica	

Heavy metals concerning the use as food additive / animal nutrition

Cadmium (Cd)	Arsenic (As)	Mercury (Hg)	Lead (Pb)
< 1 ppm	< 1 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.)

Metal Reagent Residues / Elemental Impurities – ICH Q3D Guideline for elemental Impurities / EMA/CHMP/ICH/353369/2013

Hereby we confirm that above mentioned product meets the maximum impurity levels of the elements mentioned in the ICH Q3D elemental impurity guideline given in the table below:

	Limit values
Cadmium (Cd)	< 0,5 µg/g
Lead (Pb)	< 0,5 µg/g
Arsenic (As)	< 1,5 µg/g
Mercury (Hg)	< 3 µg/g
Cobald (Co)	< 5 µg/g
Vanadium	< 10 µg/g
Nickel (Ni)	< 20 µg/g
Thallium (Tl)	< 0,8 µg/g
Gold (Au)	< 10 µg/g
Palladium	< 10 µg/g
Iridium	< 10 µg/g
Osmium (OS)	< 10 µg/g
Rhodium (Rh)	< 10 µg/g
Ruthenium (Ru)	< 10 µg/g
Selenium (Se)	< 15 µg/g
Silver (Ag)	< 15 µg/g
Platinium (Pt)	< 10 µg/g
Lithium (Li)	< 55 µg/g
Antimony (Sb)	< 120 µg/g
Barium (Ba)	< 140 µg/g
Molybdenium (Mo)	< 300 µg/g
Chopper (Cu)	< 300 µg/g
Tin (Sn)	< 600 µg/g
Chromium (Cr)	< 1100 µg/g

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
USA	TSCA (Toxic Substances Control Act)	registered
Taiwan	CSNN (Chemical Substances Nomination and Notification)	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.

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 Pharmacopeia (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".

Japanese Pharmacopoeia

Because the above mentioned product does not fulfill the required JP "Volume Test" this product is not tested according to the JP. It is, however, in line with the other requirements of the JP.

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).

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

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 / 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.

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 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.
    - 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.

Suitability

The above mentioned product is chemically produced. During the production process we do not intentionally use or add gluten, lactose or any other materials of animal or plant origin. Any testing for these materials are not part of our routine quality and production processes and therefore, we do not guarantee their absence in our product specifications.
We can therefore confirm that this product is suitable for Vegetarians, Ovo-lacto Vegetarians, Vegans, Coeliacs and people with lactose intolerance.

Nutritional value

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

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

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.

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 (EC) 1223/2009

- The above mentioned 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
  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 does not contain any 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 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" 15th edition 2017.
- 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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Registered Office Essen, Register Court, City Local Court Essen, Commercial Registry B 25783

Legend

BfR:	Bundesinstitut für Risikobewertung
CAS:	Chemical Abstract Services Register Number
CoE:	Council of Europe
CONEG:	Coalition of Northeastern Govenors
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 dixide, Synthetic amorphous silica