

Product name: AEROSIL® 300 Pharma

# SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH) Article 31, Annex II as amended

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Product name:**

AEROSIL® 300 Pharma

**Chemical name:**

Silicon dioxide, chemically prepared

**Additional identification****Chemical name:**

Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)

**Chemical formula:**SiO<sub>2</sub>**INDEX No.**

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**CAS-No.**

112945-52-5

**EC No.**

231-545-4

**REACH Registration No.**

01-2119379499-16-0000 (TPR)

**1.2 Relevant identified uses of the substance or mixture and uses advised against****Identified uses:**

Raw material for pharmaceuticals

**Uses advised against:****1.3 Details of the supplier of the safety data sheet**Company Name : Evonik Operations GmbH  
Rellinghauser Str. 1-11  
45128 Essen  
Germany

Telephone : +49 6181 59 4787

E-mail : sds-hu@evonik.com

**1.4 Emergency telephone number:**

24-Hour Health : +49 7623 919191

Emergency

**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture**

The product has not been classified as hazardous according to the legislation in force.

**Classification according to Regulation (EC) No 1272/2008 as amended.**

Not classified

**2.2 Label Elements**

Not applicable

**Product name: AEROSIL® 300 Pharma**
**2.3 Other hazards**

 Not a PBT, vPvB substance as per the criteria of the REACH Regulation.  
**Results of PBT and vPvB assessment**  
 Not a PBT, vPvB substance as per the criteria of the REACH Regulation.

**SECTION 3: Composition/information on ingredients**
**Chemical name:**

Silicon dioxide, chemically prepared

**3.1 Substances**

<b>Chemical name</b>	Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)
<b>INDEX No.:</b>	
<b>CAS-No.:</b>	112945-52-5
<b>EC No.:</b>	231-545-4
<b>REACH Registration No.:</b>	01-2119379499-16-0000 (TPR)

Chemical name	Concentration	CAS-No.	EC No.	REACH Registration No.	M-Factor:	Notes
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)		112945-52-5	231-545-4	01-2119379499-16	No data available.	#

\* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

# This substance has workplace exposure limit(s).

## This substance is listed as SVHC. **Classification**

Chemical name	Classification	Notes
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	Classification: None known.  Supplemental label information: None known.  Specific concentration limit: None known.  Acute toxicity, oral: LD 50: > 5,000 mg/kg  Acute toxicity, inhalation: None known.  Acute toxicity, dermal: LD 50: > 5,000 mg/kg	No data available.

CLP: Regulation No. 1272/2008.

**SECTION 4: First aid measures**
**4.1 Description of necessary first-aid measures**

**Inhalation:** In case product dust is released: Possible discomfort: cough, sneezing Move to fresh air.

**Skin Contact:** Wash off with plenty of water and soap.

**Eye contact:** Possible discomfort is due to foreign substance effect. Rinse thoroughly with plenty of water keeping eyelid open. In case of persistent discomfort: Consult an ophthalmologist.

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**Ingestion:** Clean mouth with water and drink afterwards plenty of water. After absorbing large amounts of substance / In case of discomfort: Supply with medical care.

**Personal Protection for First-aid Responders:** No data available.

#### 4.2 Most important symptoms and effects, both acute and delayed

**Symptoms:** None known.

**Hazards:** None known.

#### 4.3 Indication of immediate medical attention and special treatment needed

**Treatment:** No hazards which require special first aid measures.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

**Suitable extinguishing media:** Water spray, foam, CO<sub>2</sub>, dry powder. Adapt fire-extinguishing measures to surroundings

**Unsuitable extinguishing media:** Do not use full-force water jet in order to avoid dispersal and spread of the fire.

**5.2 Special hazards arising from the substance or mixture:** None known.

#### 5.3 Advice for firefighters

**Special fire fighting procedures:** Water used to extinguish fire should not enter drainage systems, soil or stretches of water. Ensure there are sufficient retaining facilities for water used to extinguish fire. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

**Special protective equipment for fire-fighters:** No data available.

### SECTION 6: Accidental release measures

**6.1 Personal precautions, protective equipment and emergency procedures:** Use personal protective equipment.

**6.1.1 For non-emergency personnel:** No data available.

**6.1.2 For emergency responders:** No data available.

**6.2 Environmental Precautions:** Do not allow entrance in sewage water, soil stretches of water, groundwater, drainage systems.

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**6.3 Methods and material for containment and cleaning up:** Sweep up or vacuum up spillage and collect in suitable container for disposal.

**6.4 Reference to other sections:** For personal protection see section 8. For disposal considerations see section 13.

<b>SECTION 7: Handling and storage:</b>
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**7.1 Precautions for safe handling**

**Technical measures (e.g. Local and general ventilation):** No data available.

**Safe handling advice:** Handle in accordance with good industrial hygiene and safety practice. If there is the possibility of skin/eye contact, the indicated hand/eye/body protection should be used. If workplace exposure limits are exceeded and/or larger amounts are released (leakage, spilling, dust) the indicated respiratory protection should be used. If necessary: Local ventilation.

**Contact avoidance measures:** No data available.

**7.2 Conditions for safe storage, including any incompatibilities**

**Safe storage conditions:** Keep in a dry place. Take precautionary measures against static discharges.

**Safe packaging materials:** No data available.

**7.3 Specific end use(s):** Applications; see Section 1. No further information available

<b>SECTION 8: Exposure controls/personal protection</b>
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**8.1 Control Parameters**
**Occupational Exposure Limits**

Chemical name	Type	Exposure Limit Values	Source
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9) - Inhalable dust.	TWA	6 mg/m <sup>3</sup>	UK. EH40 Workplace Exposure Limits (WELs), as amended (12 2011)
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9) - Respirable dust.	TWA	2.4 mg/m <sup>3</sup>	UK. EH40 Workplace Exposure Limits (WELs), as amended (12 2011)

Please refer to the latest edition of the appropriate source text and consult an industrial hygienist or similar professional, or local agencies, for further information.

**Biological Limit Values**

No biological exposure limits noted for the ingredient(s).

**8.2 Exposure controls**

**Appropriate Engineering Controls:** No data available.

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**Individual protection measures, such as personal protective equipment**

<b>Eye/face protection:</b>	Safety glasses with side shields If dust occurs: basket-shaped glasses
<b>Hand Protection:</b>	Additional Information: Wear protective gloves made of the following materials: material, rubber, leather. Additional Information: The material thickness and rupture time data do not apply to non-solute solids / dusts.
<b>Skin and Body Protection:</b>	No special protective equipment required. Preventive skin protection
<b>Respiratory Protection:</b>	No special protective equipment required. If dust occurs: Dust mask with P2 particle filter
<b>Hygiene measures:</b>	When using, do not eat, drink or smoke. Wash face and/or hands before break and end of work. To ensure ideal skin protection: use super fatted soaps and skin cream for skin care. Wash contaminated clothing before reuse.
<b>Environmental Controls:</b>	No data available.

<b>SECTION 9: Physical and chemical properties</b>
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**9.1 Information on basic physical and chemical properties**
**Appearance**

<b>Physical state:</b>	solid
<b>Form:</b>	Powder
<b>Color:</b>	White
<b>Odor:</b>	odorless
<b>Odor Threshold:</b>	Not applicable
<b>Melting Point:</b>	Approximate 1,700 °C
<b>Boiling Point:</b>	No data available.
<b>Flammability:</b>	Not applicable
<b>Upper/lower limit on flammability or explosive limits</b>	
<b>Explosive limit - upper:</b>	Not applicable
<b>Explosive limit - lower:</b>	Not applicable
<b>Flash Point:</b>	Not applicable solid
<b>Self Ignition Temperature:</b>	Not applicable
<b>Decomposition Temperature:</b>	> 2,000 °C
<b>pH:</b>	3.5 - 5.5 (40 g/l, 20 °C) Suspension
<b>Viscosity</b>	
<b>Dynamic viscosity:</b>	Not applicable solid
<b>Kinematic viscosity:</b>	Not applicable solid
<b>Flow Time:</b>	Not applicable
<b>Solubility(ies)</b>	
<b>Solubility in Water:</b>	> 1 mg/l
<b>Solubility (other):</b>	No data available.
<b>Partition coefficient (n-octanol/water):</b>	Not applicable
<b>Vapor pressure:</b>	Not applicable
<b>Relative density:</b>	Not applicable
<b>Density:</b>	Approximate 2.2 g/cm <sup>3</sup> (20 °C)

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<b>Bulk density:</b>	Not applicable
<b>Vapor density (air=1):</b>	Not applicable
<b>Particle characteristics</b>	
<b>Particle Size:</b>	Not applicable
<b>Particle Size Distribution:</b>	Not applicable
<b>Specific surface area:</b>	Not applicable
<b>Surface charge/Zeta potential:</b>	Not applicable
<b>Assessment:</b>	Not applicable
<b>Shape:</b>	Not applicable
<b>Crystallinity:</b>	Not applicable
<b>Surface treatment:</b>	Not applicable

## 9.2 Other information

<b>Explosive properties:</b>	Not to be expected in view of the structure
<b>Oxidizing properties:</b>	Not to be expected in view of the structure
<b>Minimum ignition temperature:</b>	Not applicable
<b>Evaporation Rate:</b>	Not applicable
<b>Minimum ignition energy:</b>	Not applicable

## SECTION 10: Stability and reactivity

<b>10.1 Reactivity:</b>	No dangerous reaction known under conditions of normal use.
<b>10.2 Chemical Stability:</b>	Stable under recommended storage conditions.
<b>10.3 Possibility of hazardous reactions:</b>	No hazardous reactions are known if properly handled and stored.
<b>10.4 Conditions to avoid:</b>	No dangerous reaction known under conditions of normal use.
<b>10.5 Incompatible Materials:</b>	None known.
<b>10.6 Hazardous Decomposition Products:</b>	None known. Stable under normal conditions. Product will not undergo hazardous polymerization.

## SECTION 11: Toxicological information

**General information:** Silicosis or other product specific illnesses of the respiratory tract were not observed in association with the product.

### Information on likely routes of exposure

<b>Inhalation:</b>	No data available.
<b>Skin Contact:</b>	No data available.
<b>Eye contact:</b>	No data available.
<b>Ingestion:</b>	No data available.

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**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity (list all possible routes of exposure)****Oral****Product:** LD 50 (Rat): > 5,000 mg/kg (OECD 401) comparable product, Based on available data, the classification criteria are not met.**Components:**Silicon dioxide, LD 50 (Rat) : > 5,000 mg/kg  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)**Dermal****Product:** LD 50 (Rabbit): > 5,000 mg/kg comparable product, Based on available data, the classification criteria are not met.**Components:**Silicon dioxide, LD 50 (Rabbit) : > 5,000 mg/kg  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)**Inhalation****Product:** No data available.**Components:**Silicon dioxide, Not applicable, Vapour  
chemically prepared No data available., Dusts, mists and fumes  
(CAS 112945-52-5 resp.  
7631-86-9)**Repeated dose toxicity****Product:** No data available.**Components:**Silicon dioxide, No data available.  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)**Skin Corrosion/Irritation****Product:** Not irritating analogous OECD method (Rabbit): Not irritating; comparable product, Based on available data, the classification criteria are not met.**Components:**Silicon dioxide, analogous OECD method (Rabbit): Not irritating  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)**Serious Eye Damage/Eye Irritation****Product:** Not irritating Rabbit: Not irritating comparable product Based on available data, the classification criteria are not met.**Components:**Silicon dioxide, Not irritating analogous OECD method Rabbit:  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)**Respiratory or Skin Sensitization****Product:** Not known.**Components:**

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Silicon dioxide,  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)                      No data available.

**Carcinogenicity**

**Product:**                      No evidence that cancer may be caused.

**Components:**  
 Silicon dioxide,  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)                      No evidence that cancer may be caused.

**Germ Cell Mutagenicity**

no evidence of mutagenic effects

**In vitro**

**Product:**                      No data available.

**Components:**  
 Silicon dioxide,  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)                      No data available.

**In vivo**

**Product:**                      No data available.

**Components:**  
 Silicon dioxide,  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)                      No data available.

**Reproductive toxicity**

**Product:**                      no evidence of reproductiontoxic properties

**Components:**  
 Silicon dioxide,  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)                      no evidence of reproductiontoxic properties

**Specific Target Organ Toxicity - Single Exposure**

**Product:**                      no evidence for hazardous properties

**Components:**  
 Silicon dioxide,  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)                      No data available.

**Specific Target Organ Toxicity - Repeated Exposure**

**Product:**                      no evidence for hazardous properties

**Components:**  
 Silicon dioxide,  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)                      No data available.

**Aspiration Hazard**

**Product:**                      Not classified

**Components:**



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Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      Not applicable

**11.2 Information on other hazards****Endocrine disrupting properties**

**Product:** No data available.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**Other hazards**

**Product:** An Expert Judgment stated that no classification is necessary based on present knowledge.; No toxicological tests are available on the product.;

<b>SECTION 12: Ecological information</b>
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**12.1 Toxicity:****Acute hazards to the aquatic environment:****Fish**

**Product:** LC 50 (Brachydanio rerio (zebrafish), 96 h): > 10,000 mg/l The reported toxic effects relate to the nominal concentration.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      LC 50 (Danio rerio, 96 h): > 10,000 mg/l The reported toxic effects relate to the nominal concentration.

**Aquatic Invertebrates**

**Product:** EC 50 (Daphnia magna, 24 h): > 1,000 mg/l The reported toxic effects relate to the nominal concentration.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      EC 50 (Daphnia magna, 24 h): > 1,000 mg/l The reported toxic effects relate to the nominal concentration. Literature

**Toxicity to Aquatic Plants**

**Product:** No data available.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**Toxicity to microorganisms**

**Product:** No data available.

**Components:**

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Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**Chronic hazards to the aquatic environment:****Fish**

**Product:**                      No data available.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**Aquatic Invertebrates**

**Product:**                      No data available.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**Toxicity to Aquatic Plants**

**Product:**                      No data available.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**Toxicity to microorganisms**

**Product:**                      No data available.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**12.2 Persistence and Degradability****Biodegradation**

**Product:**                      The methods for determining biodegradability are not applicable to inorganic substances.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      The methods for determining biodegradability are not applicable to inorganic substances.

**BOD/COD Ratio**

**Product:**                      No data available.

**Components:**  
Silicon dioxide,  
chemically prepared  
(CAS 112945-52-5 resp.  
7631-86-9)                      No data available.

**12.3 Bioaccumulative potential**

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**Bioconcentration Factor (BCF)**

**Product:** Not to be expected.

**Components:**  
 Silicon dioxide, Not to be expected.  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)

**Partition Coefficient n-octanol / water (log Kow)**

**Product:** Log Kow: Not applicable

**Components:**  
 Silicon dioxide, No data available.  
 chemically prepared  
 (CAS 112945-52-5 resp.  
 7631-86-9)

**12.4 Mobility in soil:**

**Product** No remarkable mobility in soil is to be expected.

**Components:**  
 Silicon dioxide, chemically No remarkable mobility in soil is to be expected.  
 prepared (CAS 112945-52-5  
 resp. 7631-86-9)

**12.5 Results of PBT and vPvB assessment:**

**Product** Not a PBT, vPvB substance as per the criteria of the REACH Regulation.

**Components:**  
 Silicon dioxide, chemically Non-classified vPvB substance  
 prepared (CAS 112945-52-5 Non-classified PBT substance  
 resp. 7631-86-9)

**12.7 Other adverse effects:**

**Other hazards**

**Product:** An Expert Judgment stated that no classification is necessary based on present knowledge.

**Additional Information:** No ecotoxicological data is available for this product.

<b>SECTION 13: Disposal considerations</b>
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**13.1 Waste treatment methods**

**General information:** No data available.

**Disposal methods:** No waste key number as per the European Waste Types List can be assigned to this product, since such classification is based on the (as yet undetermined) use to which the product is put by the consumer. Can be disposed of with domestic refuse in accordance with the necessary technical regulations following consultation with waste disposal expert(s) and the responsible authorities. The waste key number must be determined as per the European Waste Types List (decision on EU Waste Types List 2000/532/EC) in cooperation with the disposal firm / producing firm / official authority.

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**Contaminated Packaging:** Offer rinsed packaging material to local recycling facilities. Other countries: observe the national regulations.

#### SECTION 14: Transport information

##### 14.1 UN/ID No.

Not regulated as a dangerous good

##### 14.2 UN proper shipping name

Not regulated as a dangerous good

##### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

##### 14.4 Packing group

Not regulated as a dangerous good

##### 14.5 Environmental hazards

Not regulated as a dangerous good

##### 14.6 Special precautions for user

Not applicable

##### 14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### SECTION 15: Regulatory information

##### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

**EU. Directive 2012/18/EU (SEVESO III) on major accident hazards involving dangerous substances, Annex I:**Not applicable

##### 15.2 Chemical safety assessment:

No exposure or risk assessment is required for this product since it is not classified for health or environmental risks.

##### International regulations

###### Montreal protocol

Not applicable

###### Stockholm convention

Not applicable

###### Rotterdam convention

Not applicable

###### Kyoto protocol

Not applicable

#### SECTION 16: Other information

##### Abbreviations and acronyms:

**ADR** - European Agreement concerning the International Carriage of Dangerous Goods by Road; **ADN** - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; **AGW** - Occupational exposure limit; **ASTM** - American Society for Testing and Materials; **AwSV** - Ordinance on facilities for handling substances that are

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hazardous to water; **BSB** - Biochemical oxygen demand; **c.c.** - closed cup; **CAS** - Chemical Abstract Services; **CESIO** - European Committee of Organic Surfactants and their Intermediates; **CSB** - Chemical oxygen demand; **DMEL** - Derived minimum effect level; **DNEL** - Derived no effect level; **EbC50** - median concentration in terms of reduction of growth; **EC** - Effective concentration; **EINECS** - European Inventory of Existing Commercial Chemical Substances; **EN** - European norm; **ErC50** - median concentration in terms of reduction of growth rate; **GGVSEB** - German ordinance for road, rail and inland waterway transportation of dangerous goods; **GGVSee** - German ordinance for sea transportation of dangerous goods; **GLP** - Good Laboratory Practice; **GMO** - Genetic Modified Organism; **IATA** - International Air Transport Association; **ICAO** - International Civil Aviation Organization; **IMDG** - International Maritime Dangerous Goods; **ISO** - International Organization For Standardization; **LD/LC** - lethal dosis/concentration; **LOAEL** - Lowest observed adverse effect level; **LOEL** - Lowest observed effect level; **M-Factor** - multiplying factor; **NOAEL** - No observed adverse effect level; **NOEC** - no observed effect concentration; **NOEL** - no observed effect level; **o.c.** - open cup; **OECD** - Organisation for Economic Cooperation and Development; **OEL** - Occupational Exposure Limit; **PBT** - Persistent, bioaccumulative, toxic; **PNEC** - Predicted no effect concentration; **REACH** - REACH registration; **RID** - Convention concerning International Carriage by Rail; **SVHC** - Substances of Very High Concern; **TA** - Technical Instructions; **TRGS** - Technical Rules for Hazardous Substances; **vPvB** - very persistent, very bioaccumulative; **WGK** - Water Hazard Class

**Key literature references and sources for data:** No data available.

**Training information:** No data available.

**Revision Information** Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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