

Product name: AEROSIL® 200 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® 200 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:SiO₂**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:**

Pharmaceutical excipient

Uses advised against:

Not determined.

1.3 Details of the supplier of the safety data sheetCompany 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 (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Not classified

Product name: AEROSIL® 200 Pharma**2.2 Label Elements** Not applicable**2.3 Other hazards** **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**General information:** No hazardous ingredients.**Chemical name** Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)**INDEX No.:****CAS-No.:** 112945-52-5**EC No.:** 231-545-4**REACH Registration No.:** 01-2119379499-16-0000 (TPR)

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.**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.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray, foam, CO₂, 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: In the event of fire, wear self-contained breathing apparatus.

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: Avoid dust formation.

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.

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.

SECTION 7: Handling and storage:

7.1 Precautions for safe handling

Technical measures (e.g. Local and general ventilation): Ensure suitable suction/aeration at the work place and with operational machinery. Local ventilation if necessary. see also section 7.

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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

SECTION 8: Exposure controls/personal protection

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 ³	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 ³	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: Ensure suitable suction/aeration at the work place and with operational machinery. Local ventilation if necessary. see also section 7.

Individual protection measures, such as personal protective equipment

Eye/face protection: Safety glasses with side shields If dust occurs: basket-shaped glasses

Hand Protection: Additional Information: Wear protective gloves made of the following materials: material, rubber, leather.
 Additional Information: The data about break through time/strength of material is not valid for undissolved solids/dust.

Skin and Body Protection: No special protective equipment required.

Respiratory Protection: No special protective equipment required. If dust occurs: Dust mask with P2 particle filter

Hygiene measures: 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.

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Environmental Controls: No data available.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****Appearance**

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

Particle characteristics

Particle Size:	No data available
Particle Size Distribution:	No data available
Dustiness:	No data available.
Specific surface area:	No data available
Surface charge/Zeta potential:	No data available
Shape:	No data available
Crystallinity:	Crystallinity: amorphous;
Surface treatment:	Surface treatment /Coatings: No;

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9.2 Other information

Explosive properties:	Not to be expected in view of the structure
Oxidizing properties:	Not to be expected in view of the structure
Minimum ignition temperature:	Not applicable
Dust explosion properties:	Not dust explosive
Evaporation Rate:	Not applicable
Minimum ignition energy:	Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity:	No dangerous reaction known under conditions of normal use.
10.2 Chemical Stability:	Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions:	No hazardous reactions are known if properly handled and stored.
10.4 Conditions to avoid:	No dangerous reaction known under conditions of normal use.
10.5 Incompatible Materials:	None known.
10.6 Hazardous Decomposition Products:	Carbon Monoxide. Carbon Dioxide. 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.

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Inhalation:	Information on effects are given below.
Skin Contact:	Information on effects are given below.
Eye contact:	Information on effects are given below.
Ingestion:	Information on effects are given below.

Acute toxicity (list all possible routes of exposure)

Oral

Product: LD 0 (Rat): 3,300 mg/kg No deaths observed.
 LD 50 (Rat): > 5,000 mg/kg (OECD 401) comparable product, Based on available data, the classification criteria are not met.

Dermal

Product: LD 50 (Rabbit): > 5,000 mg/kg comparable product, Based on available data, the classification criteria are not met.

Inhalation

Product: LC 0 (Rat, 4 h): 0.139 mg/l (analogous OECD method) (maximum

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concentration attainable in experiments), No deaths observed.
Not classified for acute toxicity based on available data.

Repeated dose toxicity

Product: No data available.

Skin Corrosion/Irritation

Product: Not irritating analogous OECD method (Rabbit): Not irritating; Based on available data, the classification criteria are not met.

Serious Eye Damage/Eye Irritation

Product: Not irritating analogous OECD method (Rabbit): Not irritating; Based on available data, the classification criteria are not met.

Respiratory or Skin Sensitization

Product: Not known.

Carcinogenicity

Product: No evidence that cancer may be caused.

Germ Cell Mutagenicity

no evidence of mutagenic effects

In vitro

Product: No data available.

In vivo

Product: No data available.

Reproductive toxicity

Product: no evidence of reproductiontoxic properties

Specific Target Organ Toxicity - Single Exposure

Product: no evidence for hazardous properties

Specific Target Organ Toxicity - Repeated Exposure

Product: no evidence for hazardous properties

Aspiration Hazard

Product: Not classified

11.2 Information on other hazards**Other hazards**

Product: Based on available data, the classification criteria are not met.;

SECTION 12: Ecological information

12.1 Toxicity:**Acute hazards to the aquatic environment:****Fish**

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

Aquatic Invertebrates

Product: EC 50 (Daphnia magna, 24 h): > 10,000 mg/l The details of the toxic effect relate to the nominal concentration.

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Toxicity to Aquatic Plants

Product: No data available.

Toxicity to microorganisms

Product: No data available.

Chronic hazards to the aquatic environment:

Fish

Product: No data available.

Aquatic Invertebrates

Product: No data available.

Toxicity to Aquatic Plants

Product: No data available.

Toxicity to microorganisms

Product: No data available.

12.2 Persistence and Degradability

Biodegradation

Product: inorganic product, Test of the biodegradability cannot be carried out.

BOD/COD Ratio

Product: No data available.

12.3 Bioaccumulative potential

Bioconcentration Factor (BCF)

Product: Not to be expected.

Partition Coefficient n-octanol / water (log Kow)

Product: Log Kow: Not applicable

12.4 Mobility in soil:

Product No remarkable mobility in soil is to be expected.

12.5 Results of PBT and vPvB assessment:

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

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.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product name: AEROSIL® 200 Pharma

- 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.
- 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 Regulations**
- EU. REACH Annex XIV, Substances Subject to Authorization:** none
- EU. REACH Candidate List of Substances of Very High Concern for Authorization (SVHC):** none
- EU. Regulation 2019/1021/EU on persistent organic pollutants (POPs) (recast), as amended:** none
- Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex I, Controlled Substances:** none
- Regulation 1005/2009/EC on substances that deplete the ozone layer, Annex II, New Substances:** none
- Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended:** none

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Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended: none

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended: none

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended: none

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 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

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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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