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.	-
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:

1.3 Details of the supplier of the safety data sheet

Company Name : Evonik Resource Efficiency GmbH
RE-ES-PS Hanau
Postfach 1345
63403 Hanau
Germany

Telephone : +49 6181 59 4787

E-mail : sds-hu@evonik.com

1.4 Emergency telephone number:

24-Hour Health Emergency : +49 7623 919191

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

2.3 Other hazards

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

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)

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 (covered by CAS 7631-86-9)	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

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation: In case product dust is released: Possible discomfort: cough, sneezing
Move victims into 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.

4.2 Most important symptoms and effects, both acute and delayed: None known.

4.3 Indication of any immediate medical attention and special treatment needed

Hazards: None known.

Treatment: No hazards which require special first aid measures.

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.

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: No data available.

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: Wear personal protective equipment; see section 8. Disposal considerations; see section 13.

SECTION 7: Handling and storage:

7.1 Precautions for safe handling: 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.

7.2 Conditions for safe storage, including any incompatibilities: Keep in a dry place. Take precautionary measures against static discharges.

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	TWA	6 mg/m3	UK. EH40 Workplace Exposure Limits (WELs), as amended (12 2011)

resp. 7631-86-9) - Inhalable dust.			
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9) - Respirable dust.	TWA	2.4 mg/m3	UK. EH40 Workplace Exposure Limits (WELs), as amended (12 2011)

8.2 Exposure controls

Appropriate Engineering Controls: No data available.

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 material thickness and rupture time data do not apply to non-solute solids / dusts.

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.

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: odourless
Odor Threshold: Not applicable
pH: 3.5 - 5.5 (40 g/l, 20 °C) Suspension
Melting Point: Approximate 1,700 °C
Boiling Point: Not determined.
Flash Point: Not applicable
Evaporation Rate: Not applicable
Flammability (solid, gas): Not applicable
Flammability Limit - Upper (%): Not applicable
Flammability Limit - Lower (%): Not applicable
Vapor pressure: Not applicable
Vapor density (air=1): No data available.
Density: Approximate 2.2 g/cm3 (20 °C)
Relative density: No data available.
Solubility(ies)
Solubility in Water: > 1 mg/l

Solubility (other):	No data available.
Partition coefficient (n-octanol/water):	Not applicable
Self Ignition Temperature:	Not applicable
Decomposition Temperature:	> 2,000 °C
Kinematic viscosity:	No data available.
Dynamic viscosity:	Not applicable

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 energy:	Not applicable
Minimum ignition temperature:	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:	None known.

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

Inhalation:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.
Ingestion:	No data available.

11.1 Information on toxicological effects

Acute toxicity

Oral

Product:	LD0 (Rat): 3,300 mg/kg No deaths occurred. LD 50 (Rat): > 5,000 mg/kg (OECD 401) comparable product
Components:	
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	LD 50 (Rat): > 5,000 mg/kg

Dermal

Product:	LD 50 (Rabbit) > 5,000 mg/kg comparable product
Components:	
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	LD 50 (Rabbit): > 5,000 mg/kg

Inhalation

Product:	LC0 (Rat, 4 h) 0.139 mg/l (analogous OECD method) (maximum concentration attainable in experiments), No deaths occurred.
Components:	
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	LC0 (Rat, 4 h)0.139 mg/l Vapour No data available., Dusts, mists and fumes

Repeated dose toxicity

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

Skin Corrosion/Irritation:	Not irritating
Product:	analogous OECD method (Rabbit): Not irritating
Components:	
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	analogous OECD method (Rabbit): Not irritating

Serious Eye Damage/Eye Irritation:	Not irritating
Product:	analogous OECD method (Rabbit): Not irritating
Components:	
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	analogous OECD method (Rabbit): Not irritating

Respiratory or Skin Sensitization:	
Product:	Not known.
Components:	
Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	No data available.

Germ Cell Mutagenicity

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.

Carcinogenicity

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

Reproductive toxicity

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

Specific Target Organ Toxicity - Repeated Exposure

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

Aspiration Hazard

Product:	Not classified
Components:	

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

Other adverse effects: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity

Acute toxicity

Fish

Product: LC 50 ((Brachydanio rerio), 96 h): > 10,000 mg/l (OECD 203)

Components

Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	LC 50 (Brachydanio rerio, 96 h): > 10,000 mg/l (OECD 203) The reported toxic effects relate to the nominal concentration. literature

Aquatic Invertebrates

Product: EC 50 (Daphnia magna, 24 h): > 10,000 mg/l (OECD 202)

Components

Silicon dioxide, chemically prepared (CAS 112945-52-5 resp. 7631-86-9)	EC 50 (Daphnia magna, 24 h): > 1,000 mg/l (OECD 202) 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

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

Chronic Toxicity

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.

12.2 Persistence and Degradability

Biodegradation

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

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

Product:	Not to be expected.

12.4 Mobility in soil: No remarkable mobility in soil is to be expected.

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

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

12.6 Other adverse effects: No data available.

SECTION 13: Disposal considerations

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.

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

SECTION 14: Transport information

14.1 UN number

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 Transport in bulk according to Annex II of Marpol and the IBC Code

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 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.

Wording of the H-statements in section 2 and 3

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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