

**SAFETY DATA SHEET (EC 1907/2006)****AEROSIL® 200 Pharma**

Material no. 99034594  
Specification 132139  
VA-Nr 04699509

Version 2.27 / GB  
Revision date 20.10.2015  
Print Date 2/24/2016  
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**1. Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Trade name AEROSIL® 200 Pharma  
Chemical Name Silicon dioxide, chemically prepared  
CAS-No. 112945-52-5, 7631-86-9  
REACH Registration No.: 01-2119379499-16-0000 (TPR)

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

Relevant applications identified Raw material for pharmaceuticals

**1.3. Details of the supplier of the safety data sheet**

Company Evonik Resource Efficiency GmbH  
RE-ES-PS Hanau  
Postfach 1345  
D-63403 Hanau  
Telephone +49 (0)6181 59-4787  
Telefax +49 (0)6181 59-4205  
Email address sds-hu@evonik.com

**1.4. Emergency telephone number**

Emergency information +49 (0)7623-919191 (international)

**2. Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not a hazardous substance according to Regulation (EC) No. 1272/2008.

**Classification as per Directive 67/548/EC or Directive 1999/45/EC**

Not a hazardous substance or preparation according to EC-directives 67/548/EEC or 1999/45/EC.

**2.2. Label elements****Labelling as per (EU) 1272/2008**

Statutory basis Labelling not required according to EU-CLP Ordinance (1272/2008).

**2.3. Other hazards**

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

**3. Composition/information on ingredients****3.1. Substances****Information on ingredients / Hazardous components as per EU-CLP Regulation (EC) No. 1272/2008****\* Silicon dioxide, chemically prepared**

|         |                                                                                  |        |           |           |                             |
|---------|----------------------------------------------------------------------------------|--------|-----------|-----------|-----------------------------|
| CAS-No. | 112945-52-5                                                                      | EC-No. | 231-545-4 | REACH-No. | 01-2119379499-16-0000 (TPR) |
| Remarks | Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008. |        |           |           |                             |



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Information on ingredients / Hazardous components as per Directive 67/548/EC or Directive 1999/45/EC

**• Silicon dioxide, chemically prepared**

|         |             |        |           |           |                       |
|---------|-------------|--------|-----------|-----------|-----------------------|
| CAS-No. | 112945-52-5 | EC-No. | 231-545-4 | REACH-No. | 01-2119379499-16-0000 |
|         | 7631-86-9   |        |           |           | (TPR)                 |

Texts of H phrases, see in Chapter 16  
See chapter 16 for text of risk phrases

**3.2. Mixtures**

-

**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****Symptoms**

None known

**Hazards**

None known

**4.3. Indication of any immediate medical attention and special treatment needed**

No hazards which require special first aid measures.

**5. Fire-fighting 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**

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.

**6. Accidental release measures**

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

**6.2. Environmental precautions**

**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.

**7. Handling and storage**

**7.1. Precautions for safe handling**  
If necessary: Local ventilation.

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

**Advice on protection against fire and explosion**  
Take precautionary measures against static discharges.

**Storage**  
Keep in a dry place.

**7.3. Specific end use(s)**

Applications; see Section 1.  
No further information available

**8. Exposure controls/personal protection**

**8.1. Control parameters**

| • Silicon dioxide, chemically prepared |                               |                                        |           |
|----------------------------------------|-------------------------------|----------------------------------------|-----------|
| CAS-No.                                | 112945-52-5<br>7631-86-9      | EC-No.                                 | 231-545-4 |
| Control parameters<br>type of exposure | 2.4 mg/m3<br>Respirable dust. | Time Weighted Average (TWA):(EH40 WEL) |           |
| Control parameters<br>type of exposure | 6 mg/m3<br>Inhalable dust.    | Time Weighted Average (TWA):(EH40 WEL) |           |

**8.2. Exposure controls**

**Personal protective equipment**

**Respiratory protection**

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

**Hand protection**

Wear protective gloves made of the following materials: material, rubber, leather.  
The material thickness and rupture time data do not apply to non-solute solids / dusts.

**Eye protection**

Safety glasses with side-shields  
If dust occurs: basket-shaped glasses

**Skin and body protection**

No special protective equipment required.

**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 re-use.

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**Protective measures**

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.

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

|                |           |
|----------------|-----------|
| Form           | powder    |
| Colour         | white     |
| physical state | solid     |
| Odour          | odourless |

Odour threshold: not applicable

pH 3.5 - 5.5 (40 g / l) (20 °C)  
(suspension)

Melting point/range ca. 1700 °C

Boiling point/range not determined

Flash point not applicable

Evaporation rate not applicable

Flammability (solid, gas) not applicable

Lower explosion limit not applicable

Upper explosion limit not applicable

Vapour pressure not applicable

Density ca. 2.2 g/cm<sup>3</sup> (20 °C)

Water solubility > 1 mg/l

Partition coefficient: n-octanol/water not applicable

Autoinflammability not applicable

Thermal decomposition > 2000 °C

Viscosity, dynamic not applicable

Explosiveness Not to be expected in view of the structure

Oxidizing properties Not to be expected in view of the structure

**9.2. Other information**

Ignition temperature not applicable

Minimum ignition energy not applicable

Tapped density ca. 50 g / l

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Method: DIN / ISO 787/11

Vapour density not applicable

**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**

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

Stable under normal conditions.

Product will not undergo hazardous polymerization.

**11. Toxicological information****11.1. Information on toxicological effects**

Acute oral toxicity

LD0 Rat: 3300 mg/kg

No deaths occurred.

LD50 Rat: > 5000 mg/kg

Method: OECD Test Guideline 401  
comparable product

Acute inhalation toxicity

LC0 Rat: 0.139 mg/l / 4 h

Method: analogous OECD method  
(maximum concentration attainable in experiments)  
No deaths occurred.

Acute dermal toxicity

LD50 Rabbit: > 5000 mg/kg  
comparable product

Skin irritation

Rabbit  
not irritating

Method: analogous OECD method

Eye irritation

Rabbit  
not irritating

Method: analogous OECD method

Sensitization

not known

Assessment of STOT single exposure

No data available

Assessment of STOT repeat exposure

No data available

Risk of aspiration toxicity

No aspiration toxicity classification

Mutagenicity assessment

no evidence of mutagenic effects

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|                          |                                                                                                                           |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Carcinogenicity          | No evidence that cancer may be caused.                                                                                    |
| Toxicity to reproduction | no evidence of reproductiontoxic properties                                                                               |
| Human experience         | Silicosis or other product specific illnesses of the respiratory tract were not observed in association with the product. |
| Further information      | The classification criteria are not met based on the available data.                                                      |

**12. Ecological information****12.1. Toxicity**

|                                   |                                                                   |
|-----------------------------------|-------------------------------------------------------------------|
| Toxicity to fish                  | LC50 (Brachydanio rerio): > 10000 mg/l / 96 h<br>Method: OECD 203 |
| Toxicity in aquatic invertebrates | EC50 Daphnia magna: > 10000 mg/l / 24 h<br>Method: OECD 202       |

**12.2. Persistence and degradability**

|                  |                                                                        |
|------------------|------------------------------------------------------------------------|
| Biodegradability | inorganic product, Test of the biodegradability cannot be carried out. |
|------------------|------------------------------------------------------------------------|

**12.3. Bioaccumulative potential**

|                 |                     |
|-----------------|---------------------|
| Bioaccumulation | Not to be expected. |
|-----------------|---------------------|

**12.4. Mobility in soil**

|          |                                                   |
|----------|---------------------------------------------------|
| Mobility | 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.

**12.6. Other adverse effects****Ecotoxicology Assessment**

|                        |                                                                      |
|------------------------|----------------------------------------------------------------------|
| Acute aquatic toxicity | The classification criteria are not met based on the available data. |
|------------------------|----------------------------------------------------------------------|

**13. Disposal considerations****13.1. Waste treatment methods****Product**

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.

**Uncleaned packaging**

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

**Waste Key Number**

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. 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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**14. Transport information**

**Not dangerous according to transport regulations.**

- 14.1. UN number: --  
14.2. UN proper shipping name: --  
14.3. Transport hazard class(es): --  
14.4. Packing group: --  
14.5. Environmental hazards: --  
14.6. Special precautions for user: No

**15. Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National legislation****15.2. Chemical safety assessment**

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

**16. Other information****Risk phrase (R phrase) texts****Texts of the H-phrases****Further information**

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

This information and all further technical advice is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

**Legend**

|                  |                                                                                                 |
|------------------|-------------------------------------------------------------------------------------------------|
| <b>ADR</b>       | European Agreement concerning the International Carriage of Dangerous Goods by Road             |
| <b>ADN</b>       | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| <b>ASTM</b>      | American Society for Testing and Materials                                                      |
| <b>ATP</b>       | Adaptation to Technical Progress                                                                |
| <b>BCF</b>       | Bioconcentration factor                                                                         |
| <b>BetrSichV</b> | German Ordinance on Industrial Safety and Health                                                |
| <b>c.c.</b>      | closed cup                                                                                      |
| <b>CAS</b>       | Chemical Abstract Services                                                                      |
| <b>CESIO</b>     | European Committee of Organic Surfactants and their Intermediates                               |
| <b>ChemG</b>     | German Chemicals Act                                                                            |
| <b>CMR</b>       | carcinogenic-mutagenic-toxic for reproduction                                                   |
| <b>DIN</b>       | German Institute for Standardization                                                            |
| <b>DMEL</b>      | Derived minimum effect level                                                                    |
| <b>DNEL</b>      | Derived no effect level                                                                         |



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|                  |                                                                                                                    |
|------------------|--------------------------------------------------------------------------------------------------------------------|
| <b>EINECS</b>    | European Inventory of Existing Commercial Chemical Substances                                                      |
| <b>EC50</b>      | half maximal effective concentration                                                                               |
| <b>GefStoffV</b> | German Ordinance on Hazardous Substances                                                                           |
| <b>GGVSEB</b>    | German ordinance for road, rail and inland waterway transportation of dangerous goods                              |
| <b>GGVSee</b>    | German ordinance for sea transportation of dangerous goods                                                         |
| <b>GLP</b>       | Good Laboratory Practice                                                                                           |
| <b>GMO</b>       | Genetic Modified Organism                                                                                          |
| <b>IATA</b>      | International Air Transport Association                                                                            |
| <b>ICAO</b>      | International Civil Aviation Organization                                                                          |
| <b>IMDG</b>      | International Maritime Dangerous Goods                                                                             |
| <b>ISO</b>       | International Organization For Standardization                                                                     |
| <b>LOAEL</b>     | Lowest observed adverse effect level                                                                               |
| <b>LOEL</b>      | Lowest observed effect level                                                                                       |
| <b>NOAEL</b>     | No observed adverse effect level                                                                                   |
| <b>NOEC</b>      | no observed effect concentration                                                                                   |
| <b>NOEL</b>      | no observed effect level                                                                                           |
| <b>o. c.</b>     | open cup                                                                                                           |
| <b>OECD</b>      | Organisation for Economic Cooperation and Development                                                              |
| <b>OEL</b>       | Occupational Exposure Limit                                                                                        |
| <b>PBT</b>       | Persistent, bioaccumulative, toxic                                                                                 |
| <b>PEC</b>       | Predicted effect concentration                                                                                     |
| <b>PNEC</b>      | Predicted no effect concentration                                                                                  |
| <b>REACH</b>     | REACH registration                                                                                                 |
| <b>RID</b>       | Convention concerning International Carriage by Rail                                                               |
| <b>STOT</b>      | Specific Target Organ Toxicity                                                                                     |
| <b>SVHC</b>      | Substances of Very High Concern                                                                                    |
| <b>TA</b>        | Technical Instructions                                                                                             |
| <b>TPR</b>       | Third Party Representative (Art. 4)                                                                                |
| <b>TRGS</b>      | Technical Rules for Hazardous Substances                                                                           |
| <b>VCI</b>       | German chemical industry association                                                                               |
| <b>vPvB</b>      | very persistent, very bioaccumulative                                                                              |
| <b>VOC</b>       | volatile organic compounds                                                                                         |
| <b>VwVwS</b>     | German Administrative Regulation on the Classification of Substances Hazardous to Waters into Water Hazard Classes |
| <b>WGK</b>       | Water Hazard Class                                                                                                 |
| <b>WHO</b>       | World Health Organization                                                                                          |