1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product information

Trade name	AEROPERL® 300 Pharma
Company	Evonik Industries AG Inorganic Materials Produktsicherheit IM-PT-PS Postfach 1345 D-63403 Hanau
Telephone	+49 (0)6181 59-4787
Telefax	+49 (0)6181 59-4205
Email address	sds-im@evonik.com
Emergency telephone number	+49 (0)7623-919191
Use of the Substance / Preparation	Raw material for pharmaceuticals

REACH Registration No.: if available listed in Chapter. 3

2. HAZARDS IDENTIFICATION

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Remarks Not a hazardous substance or mixture 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.

GHS-Labelling

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

Other Hazards

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Information on ingredients / Hazardous components as per EU-CLP Regulation (EC) No. 1272/2008

- **Silicon dioxide, chemically prepared**

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

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

- **Silicon dioxide, chemically prepared**

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

4. 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.

Most important symptoms and effects, both acute and delayed

Symptoms

None known

Hazards

None known

Indication of any immediate medical attention and special treatment needed

No hazards which require special first aid measures.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

All extinguishing substances suitable.

Special hazards arising from the substance or mixture

None known

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

Personal precautions, protective equipment and emergency procedures

Wear personal protective equipment.

Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal.

7. HANDLING AND STORAGE

Handling

Precautions for safe handling

If necessary: Local ventilation.

Advice on protection against fire and explosion

Take precautionary measures against static discharges.

Storage

Conditions for safe storage, including any incompatibilities

Keep in a dry place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

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

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.

Protective measures

Handle in accordance with good industrial hygiene and safety practices.
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

Appearance

Form	powder
Colour	white
Odour	odourless
physical state	solid

Information on basic physical and chemical properties

pH	3.5 - 5.5 (40 g / l) (20 °C) (suspension)
Melting point/range	ca. 1700 °C
Boiling point/range	not applicable
Flash point	not applicable
Flammability (solid, gas)	not applicable
Ignition temperature	not applicable
Autoinflammability	not applicable
Thermal decomposition	> 2000 °C
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Minimum ignition energy	not applicable
Vapour pressure	not applicable
Density	ca. 2.2 g/cm3 (20 °C)
Tapped density	ca. 280 g / l Method: DIN / ISO 787/11
Water solubility	hardly soluble
Partition coefficient (n-octanol/water)	not applicable
Viscosity, dynamic	not applicable

10. STABILITY AND REACTIVITY

Hazardous decomposition products	None known

11. TOXICOLOGICAL INFORMATION

Acute oral toxicity	LD50 Rat: > 10000 mg/kg Method: literature

Acute inhalation toxicity	LC0 Rat: 0.139 mg/l / 4 h Method: literature (maximum concentration attainable in experiments) No deaths occurred.
Acute dermal toxicity	LD50 Rabbit: > 5000 mg/kg Method: literature
Skin irritation	Rabbit / literature not irritating
Eye irritation	Rabbit / literature not irritating
Repeated dose toxicity	inhalative No irreversible changes and no indication of silicosis. Oral no negative effects
Gentoxicity in vitro	no evidence of mutagenic effects literature
Gentoxicity in vivo	no evidence of mutagenic effects literature
Carcinogenicity	no negative effects
Toxicity to reproduction	no negative effects
Human experience	Silicosis or other product specific illnesses of the respiratory tract were not observed in association with the product.

12. ECOLOGICAL INFORMATION

Ecotoxicity effects

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

Results of PBT assessment

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

13. DISPOSAL CONSIDERATIONS

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.

14. TRANSPORT INFORMATION

Transport/further information

Not dangerous according to transport regulations.

15. REGULATORY INFORMATION

National legislation

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.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Legend

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
ADNR	European agreement concerning the international carriage of dangerous goods by inland waterways (ADN)
ASTM	American Society for Testing and Materials
ATP	Adaptation to Technical Progress
BCF	Bioconcentration Factor
BetrSichV	German Ordinance on Industrial Safety and Health
c. c.	closed cup
CAS	Chemical Abstract Services
CESIO	European Committee of Organic Surfactants and their Intermediates
ChemG	German Chemicals Act
CMR	Carcinogenic-Mutagenic-toxic for Reproduction
DIN	German Institute for Standardization
DNEL	Derived No Effect Level
EINECS	European Inventory of Existing Commercial Chemical Substances
GefStoffV	German Ordinance on Hazardous Substances
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 DGR	International Air Transport Association – Dangerous Goods Regulations
ICAO-TI	International Civil Aviation Organisation - Technical Instructions
IMDG Code	International Maritime Dangerous Goods Code
ISO	International Organization For Standardization
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
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
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
TA	Technical Instructions (German Ordinance)
TPR	Third Party Representative (Art. 4)
TRGS	Technical Rules for Hazardous Substances (German Regulations)
VCI	German "Verband der Chemischen Industrie e. V."
vPvB	Very Persistent, Very Bioaccumulative
VOC	Volatile Organic Compounds
VwVwS	German Administrative Regulation on the Classification of Substances Hazardous to Waters into Water Hazard Classes
WGK	German Water Hazard Class
WHO	World Health Organization