

EU Safety Data Sheet

According to Attachment II EC Reg. 1907/2006 (REACH)

*The German
spirit of quality
since 1854*



SiLibeads Ceramic beads Type ZY-P Pharma

First created on: 2019-04-03 Updated on: 2021-02-18
Next inspection on: 2021-12-31 Printed on: 2021-02-18

Version: V2/2021

Note: The product is an object defined as an article in the Regulation (EC) No. 1907/2006 (REACH) Art. 3 Par. 3, not classified as dangerous or not containing substances classified as dangerous, so there is no obligation to issue a safety data sheet according to the Regulation (EC) No. 1907/2006 Art. 31 (Requirements for safety data sheets). The following information complies with the obligation according to Art. 32 (for substances on their own or in preparations for which a safety data sheet is not required), and was issued following the structure by Annex II.

1. Identification of the substance / the preparation / the product and identification of the company

1.1 Identification of the substance / the preparation / the product

Trade Name: **SiLibeads – Ceramic beads Type ZY-P Pharma**

1.2 Application of the substance / the preparation / the product

To be used as: Grinding media for the Pharmaceutical Industry. For example nano grinding for the production of active substances and supplies substances. Mixing / dispersing of active substances in high-speed mixers

Unsubscribed use: unknown

1.3 Company identification

Manufacturer / Supplier: Sigmund Lindner GmbH
Oberwarmensteinacher Str. 38
95485 Warmensteinach / GERMANY
Phone: +49-9277-9940
Fax: +49-9277-99499
Web: www.sili.eu
E-Mail: reach@sili.eu

Safety data provided by: Mr. Michael Dressler (Head of Quality))
Mr. Reinhold Schneider (Quality Manager)

1.4 Emergency Call

Emergency information: Phone: +49-9277-9940

We can be reached during office hours (Central European Time):

Monday - Thursday: 7.00 AM - 4.30 PM

Friday: 7.00 AM - 1.00 PM

2. Possible dangers

2.1 Classification of the substance or mixture

Not classified according to Regulation (EG) No. 1272/2008 (CLP).

2.2 Labelling elements

Not subject to labelling according to Regulation (EG) No. 1272/2008 (CLP).

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2.3. Additional danger advice

The product does not contain any substances with PBT or vPvB properties according to REACH Annex XIII. Risk of slipping due to spillage of product!

3. Composition / detailed information on the ingredients

3.1 Substance

Not relevant.

3.2 Mixtures

Description: Ceramic Beads made of Zirconium Oxide, Yttrium stabilized

Components:

Name	Classification	Weight	CAS N°	EINECS	REACH Registry	TSCA Registry
Zirconiumoxide Yttrium stabilised ⁽¹⁾	not classified	99.70 %	64417-98-7	264-885-7	01-2119985905-19	----
others		0.30 %				

⁽¹⁾ Solid solution phase, consisting of: Zirconiumdioxide ZrO_2 + Hafniumdioxide HfO_2 ⁽²⁾: 94.35 %; Yttriumoxide Y_2O_3 : 5.35 %
Analysis according to DIN 51001.

⁽²⁾ natural origin (residue from processing of raw material Zircon sand)

Note: The product is an amorphous inorganic solid composed of the listed individual substances. The material obtained by thermal treatment is inert and its properties are therefore not identical to those of its components.

4. First-aid measures

4.1. Description of first aid measures

4.1.1 General Advice

Remove soiled clothes. In case of health complaints, seek medical treatment. Watch your helpers for self-protection.

4.1.2 After Inhalation

Provide fresh air.

4.1.3 After Skin Contact

Clean skin with water and soap.

4.1.4 After Eye Contact

Remove particle carefully from the affected eye. If needed, remove contact lense. Rinse eye 15 minutes thoroughly with plenty of water. Consult a physician if needed.

4.1.5 After Swallowing

Consult a physician after swallowing large quantities.

4.2. Main acute and delayed symptoms and effects

No information available.

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4.3. Information on immediate medical help or special treatment

Dusty parts of the product may irritate skin, mucous membranes, eyes and respiratory tract. Decontamination and symptomatic treatments are in most cases sufficient.

5. Fire fighting actions

5.1. Extinguishing agents

5.1.1 Suitable extinguishing agents:

The product itself is neither combustible nor explosive. Extinguishing agents have to be coordinated with the surrounding fire.

5.1.2 For safety reason unsuitable extinguishing agents

Unknown.

5.2. Special hazards arising from the substance or mixture

No information available.

5.3. Instructions for fire fighting

Protective equipment has to be coordinated with the surrounding fire.

6. Measures by accidental release

6.1. Personal precautions, protective equipment and emergency procedures

Avoid formation of dust, do not inhale dust.

6.2. Environmental measures

No special actions necessary.

6.3. Methods and materials for retention and cleaning

Sweep up the product and pick it up. Avoid dust formation during cleaning.

6.4. Reference to other sections

Personal protective equipment according to section 8.2, disposal according to section 13.

7. Handling and storage

7.1. Protective measures for safe handling

7.1.1 Notes on safe storage

Increased risk of slipping due to spilled product. Avoid dust formation.

7.1.2 Information on fire and explosion protection

No data available, the product itself is not flammable and not explosive.

7.2. Conditions for safe storage under consideration of incompatibilities

7.2.1 Requirements for storage in rooms and containers

No special storage necessary. Storage in tightly closed (original) container.

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7.2.2 Information on storage in one common storage facility:

Storage class according to TRGS 510: LGK 13 (non-flammable solids)
No incompatible products to mention.

7.3. Specific end uses

See section 1.2.

8. Exposure limits and personal protection

8.1 Parameters to be monitored

Mechanical dry processing of the product can generate a risk of dust: The local limits of dust concentration at the work have to be considered.

Parameter	CAS-Number	EINECS	Limit values dust	
General limit value	----	----	10 mg/m ³ E 1.25 mg/m ³ A	Limit at work (AGW) according to the TRGS 900 Regulation
Zirconium and compounds insoluble in water	7440-67-7	231-176-9	1 mg/m ³ E	Limit at work (AGW) of insoluble zirconium compounds according to the TRGS 900 Regulation

Note: The natural radioactivity of SiLibeads Type ZY-P Pharma remains within the permitted limits of the Directive 96/29/EURATOM (Safety standard for the protection of the health of workers and the general public against the danger arising from ionizing radiation).

8.2 Exposure controls and monitoring

8.2.1 Technical protection measures

An on-site extraction system is required in the event of gathered dust and thermal pollution from the product

8.2.2 Personal protection equipment

8.2.2.1 Respiratory protection



Use respiratory protection in case of dust exposure, e.g. dust mask with particle filter FFP2 or FFP3, according to standard NF EN 149.

Inhalation limitation of the zirconium compound of the Al₂O₃:

- 5 mg/m³ of Zr for 8 hours (TWA) according to ACGIH, DFG-MAK and OSHA
- 10 mg/m³ of Zr for 15 min (STEL) according to ACGIH and OSHA

Inhalation restriction from amorphous silica:

- 4 mg/m³ according to DFG-MAK
- 6 mg/m³ according to OSHA
- 10 mg/m³ for 8 hours (TWA) according to ACGIH

Under normal conditions of use, the load during processing of the product is lower than 1 mSv/year (1760 H/year) (limit values for persons prescribed by EURATOM Directive 96/29).

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8.2.2.2 Hand protection



Protective gloves are generally not required. In case of constant skin contact, gloves are sufficient for low mechanical and material stress, see also BGR 195, e.g.:

Material:	Material thickness	Penetration time:
Butylrubber	mind. 0,4 mm	mind. 30 min. acc. to DIN EN 374

8.2.2.3 Eye protection



Mechanical processing with dust exposure requires safety goggles closed at the side in accordance with DIN 58211 or DIN EN 166.

8.2.2.3 Body protection

Safety shoes to wear the product, as well as normal work clothes are sufficient..

8.2.2.4 General industrial safety and hygiene measures

Do not inhale dust. Avoid contact with eyes. Do not eat, drink or smoke while working. Wash hands before breaks and at the end of work..

8.2.3 Limitation and monitoring of environmental exposure

Environmentally hazardous properties of the product are not known, so that the general operational measures for environmental protection are sufficient..

8.2.4 Limitation and monitoring of the exposure for private end users

No special protective measures necessary as the product is not available for private end users.

9. Physical and chemical properties

9.1 General details

Physical condition:	solid
Shape:	round (beads)
Odor:	odorless
Color:	white

9.2 Important details regarding health- / environmental protection as well as safety

pH value:	Non-applicable
Softening point (temperature):	between 2100 - 2500 °C
Flash point:	Non-applicable
Self-ignition point (Solid/Gas):	Non-applicable
Blaze properties:	Non-applicable
Risk of explosion:	Non-applicable
Vapor pressure:	Non-applicable
Specific weight:	≥ 6.0 kg/dm ³
Bulk density:	between 3.71 - 3.73 kg/dm ³
Water solubility:	Insoluble in water
Partition coefficient n-Octanol/ water:	Non-applicable
Viscosity:	Non-applicable
Vapor density:	Non-applicable
Evaporation speed:	Non-applicable

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9.3 Additional details

There are no further details required regarding safety-relevant parameters.

10. Stability and reactivity

10.1 Reactivity

In case of appropriate handling and storage no dangerous reactions will occur.

10.2 Conditions to be avoided

Unknown.

10.3 Dangerous decomposition products

Unknown.

11. Toxicological data

11.1. Information on toxicological effects

11.1.1 Toxicokinetics, metabolism and distribution

No data available.

11.1.2 Acute toxicity

No data available.

11.1.3 Etching and irritant effects

Product dust can mechanically irritate skin and mucous membrane, eyes and respiratory organs..

11.1.4 Sensitizing effects

No sensitizing effects on skin and respiratory organs known.

11.1.5 Specific organ toxicity at single or repeated exposure

No organotoxic effects known.

11.1.6 Carcinogenicity, mutagenicity and reproductive toxicity

No carcinogenic, mutagenic or toxic to reproduction effects known.

12. Environmental details

12.1. Toxicity

No data available.

12.2. Persistence and degradability

The product is insoluble and the inorganic substances it contains are not bioavailable.

12.3. Bioaccumulation potential

The product is insoluble and the inorganic substances it contains are not bioavailable, thus not bioaccumulative.

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12.4. Mobility in the ground

The product is insoluble and therefore not mobile.

12.5. Results of PBT and vPvB assessment

The product does not contain PBT or vPvB substances according to REACH Annex XIII criteria.

12.6. Other adverse effects

Ozone depletion potential and greenhouse effect are not known.

Ecological and ecotoxicological data are not available. A threat to the environment is not to be expected if the product is handled and disposed of safely.

13. Notes on disposal

13.1 Waste treatment process

The product does not generate any waste that is subject to monitoring in accordance with Regulation (EU) No. 1357/2014. For disposal, national laws and local regulations must be observed.

13.1.1 Product

Product residues should be reused wherever possible.

13.1.2 Uncleaned packaging

Recommendation: Non-contaminated packaging can be reused.
Cleaning agent Water.

14. Information on Transport

- | | |
|---|----------------|
| 14.1 <u>UN-Number</u> | not relevant |
| 14.2 <u>Proper UN shipping name</u> | not relevant |
| 14.3 <u>Transport hazard classes</u> | not relevant |
| 14.4 <u>Packaging group</u> | not relevant |
| 14.5 <u>Environmental hazards</u> | see section 14 |
| 14.6 <u>Special precautions for the user</u> | see section 7 |
| 14.7 <u>Transport in bulk in accordance with Annex II to the MARPOL Convention and the IBC Code</u> | not relevant |

Note: No dangerous goods as defined by ADR/RID/ADN/GGVSEB, ICAO/IATA, IMDG.

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15. Legal provisions

15.1 Safety, health and environmental protection/legislation specific to the substance or mixture

15.1.1 EU-regulations

Classification and labelling: None according to Directive (EC) No. 1272/2008 (CLP) or other known EU regulations.

15.1.2 National regulations

Classification and labelling: None according to the Hazardous Substances Ordinance (GefStoffV) or according to other known national regulations

Employment restrictions: None according to GefStoffV, JArbSchG or MuSchV

Major Accidents Ordinance: The product is not subject to the Major Accidents Ordinance.

Water hazard class: No WGK, not hazardous to water according to AwSV.

15.2 Chemical safety assessment

A chemical safety assessment of the product or its components is not available.

16. Additional information

16.1 Recommended Limitations of Use

SiLibeads Type ZY-P *Pharma* are not a toy and must therefore be stored away from children. A resale as toy requires the EC conformity evaluation and the distributor's compliance with the legal valid regulations. We expressly point out, that a conformity evaluation in this sense has not been carried out by Sigmund Lindner GmbH.

16.2 Further information

Company details: Sigmund Lindner GmbH
Oberwarmensteinacher Str. 38
95485 Warmensteinach / GERMANY
Phone: +49-9277-9940
Fax: +49-9277-99499
Web: www.sili.eu

Technical contact/
information Mr. Udo Weber (Product Manager Ceramic Beads)
Mr: Achim Müller (Product Manager Ceramic Beads)

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16.3 Used abbreviations

A:	alveolar dust
ADR:	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW:	Occupational exposure limit according to TRGS 900
BGW:	Biological limit value according to TRGS 903
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
CLP:	Classification, Labelling and Packaging of Substances and Mixtures
DPD:	Directive 1999/45/EEC (Preparations Directive)
DSD:	Directive 67/548/EEC (Substance Directive)
E:	inhalable dust
GHS:	Globally Harmonized System of Classification and Labelling of Chemicals
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
MAK:	Maximum Workplace Concentration of the German Research Foundation (DFG)
PBT:	Persistent, bioaccumulative and toxic substances
REACH:	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals.
RID:	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
TRGS:	Technical Rules for Hazardous Substances
vPvB:	Very persistent and very bioaccumulative substances
VwVwS:	Administrative regulation on substances hazardous to water, now AwSV
WGK:	Water hazard class

16.4 Remarks

All details noted in this data sheet correspond to our knowledge at the time this data sheet has been put into effect. This information should be used as a guideline for a safe treatment in accordance with the products mentioned in our material safety data sheet, during storage, production, transport and disposal. This information is not applicable to other products, to newly produced materials, if the product mentioned in this material safety data sheet is mixed or blended with other articles or when other transformations are made to it.

Date of the current version: 2021-02-18
Reason for the current version: Update of Specific Weight (Chapter 9.2)
Replaced issue: MSDS en SiLibeads Type ZY-P Pharma, Version 1/2019