**Safety Information Sheet for Medical Devices**
**following 1907/2006/EG, Article 31**

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This product is a medical device as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body. For this product a safety data sheet is not legally required. The provision of this document is on a voluntary basis.

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier
**Trade name:**
**Bisico Glass Fill Powder**

### 1.2 Relevant identified uses of the substance or mixture and uses advised against
**Identified uses:**
Dental product.

**Restrictions on use:**
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

### 1.3 Details of the supplier of the safety information sheet
**Manufacturer/supplier:**
Bisico GmbH
Johanneswerkstraße 3
33611 Bielefeld, Germany
info@bisico.de

**Distributor:**
Bisico Bielefelder Dentalsilicone GmbH & Co.KG
Johanneswerkstraße 3
33611 Bielefeld, Germany
info@bisico.de

### 1.4 Emergency telephone number
+49 521 80168-00

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture
Medical devices as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/245, which are invasive or used in direct physical contact with the human body are exempt from labeling requirements of Regulation (EC) No. 1272/2008 (CLP/GHS). Although not required, classification and labeling are indicated as follows:

**Classification:**
None.

### 2.2 Label elements
**CLP Regulation (EC) No. 1272/2008**
None.

### 2.3 Other hazards
**Results of PBT and vPvB assessment:**
PBT: not applicable.
vPvB: not applicable.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances
Not applicable.

**3.2 Mixtures**
**Chemical characterization (description):**
Dental glass, polyalkenoate acids.

**Hazardous components:**
None.

## SECTION 4: First aid measures

**4.1 Description of first aid measures**
**General information:**
Seek medical advice, if symptoms occur, which can be caused by the product.

**after skin contact:**
Wash with plenty of water and soap.

**after inhalation:**
Fresh air.

**after eye contact:**
Rinse with plenty of water and consult a doctor.

**after swallowing:**
If symptoms persist consult a doctor.

## SECTION 5: Firefighting measures

**5.1 Extinguishing media**
**Extinguishing media:**
$CO_2$, extinguishing powder, water spray. Use extinguishing method and media suitable to surrounding fire.

**5.2 Special hazards arising from the substance or mixture**
No further relevant information available.

**Protective equipment:**
Wear self-contained respiratory protective equipment.

## SECTION 6: Accidental release measures

**6.1 Personal precautions, protective equipment and emergency procedures**
**Personal precautions:**
Avoid formation of dust.

**6.2 Environmental precautions**
Do not allow to enter drains/surface water/ ground-water.

**6.3 Methods and material for containment and cleaning up**
Pick up mechanically. Clean up affected area.

**6.4 Reference to other sections**
See Section 7: Handling and storage
See Section 8: Exposure controls/personal protection
See Section 13: Disposal considerations

## SECTION 7: Handling and storage

**7.1 Precautions for safe handling**
**Handling:**
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

**Information for safe handling:**
Observe normal care for working with chemicals.

**Information about fire and explosion protection:**
No special measures required.

**7.2 Conditions for safe storage, including any incompatibilities**
**Storage:**
Store at a dry place. Store tightly closed. Storage temperature < 25°C.

**Requirements at storerooms and containers:**
Store only in the original containers.

**Information about storage in one common storage facility:**
Store away from food stuffs.

**Further information on storage conditions:**
None.

**Storage class:**
-

**7.3 Specific end use(s)**
No further relevant information available.

## SECTION 8: Exposure controls/personal protection

**8.1 Control parameters**
**Additional information on the design of technical systems:**
-

**Components with limits of values to be supervised at the workplace:**
The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

**Additional information:**
The lists valid during the making were used as basis.

**8.2 Exposure controls**
**Personal protective equipment:**
**General protective and hygienic measures:**

Normal hygienic measures. The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Avoid contact with eyes or skin.

**Respiratory protection:**
Required, when aerosols are generated.

**Hand protection:**
Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

**Eye protection:**
Safety glasses.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

**Appearance:**

| | |
|---|---|
| Form: | Fine powder |
| Color: | white |
| Odor: | odorless |

**Change in condition:**

| | |
|---|---|
| Melting point/melting range: | not applicable |
| Boiling point/boiling range: | not applicable |
| Flash point: | not applicable |
| Ignition temperature: | not applicable |
| Danger of explosion: | none |
| Density: | not applicable |
| Vapor pressure: | not applicable |
| Solubility in/miscibility with: | |
| Water: | slightly soluble |
| Content of solvents: | none |
| Organic solvents: | none |

## SECTION 10: Stability and reactivity

### 10.1 Reactivity
Expected to be non-reactive under normal conditions of use.

### 10.2 Chemical stability
The product is stable by proper use and storage.

### 10.4 Conditions to avoid
Heat, sunlight.

### 10.6 Hazardous decomposition products
No information available.

## SECTION 11: Toxicological information

**11.1 Information on toxicological effects**
**Acute toxicity:**
No data available.

**Primary irritation:**
**Skin:** may cause skin irritation

**Eye:** irritating effect (aerosols).

**Sensitization:** no sensitizing effect known.

**Additional toxicological information:**
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

## SECTION 12: Ecological information

**General information:**
Avoid transfer into environment.

**Classification of water endangerment:**
WGK=1 (slightly polluting substance).

## SECTION 13: Disposal considerations

**13.1 Waste treatment methods**
**Recommendation:**
Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

**Uncleaned packaging:**
**Recommendation:**
Disposal must be made according to official regulations.

## SECTION 14: Transport information

**Land transport ADR/RID and GGVSE (Germany):**
No subject to transport regulations.

**Sea transport IMDG Code:**
No subject to transport regulations.

**Air transport ICAO-TI and IATA-DGR:**
No subject to transport regulations.

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

## SECTION 15: Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
**National regulations:**
Water endangerment WGK=1 (slightly polluting substance).

**15.2 Chemical safety assessment**
A chemical safety assessment has not been carried out.

## SECTION 16: Other information

For invasive medical devices or medical devices in direct contact with the human body, the Medical Device Regulation does not require a safety data sheet. The safe use of the product is indicated in the instructions for use and/or the labeling.

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties.
Users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.