

SECTION 1. Product identification/preparation/company undertaking

1.1. Product identifier:

Product no.: 80902, 80904
Product name: BISICO Glass Fill Powder
Trade number: 75090, 75091

1.2. Relevant identified uses of the substance or mixture and uses advised against: No further relevant information available.

Application of the substance / the mixture: Dental product

1.3. Details of the supplier of the safety data sheet: BISICO Bielefelder Dentsilicone GmbH & Co. KG
 Johanneswerkstraße 3
 D-33611 Bielefeld
 Tel.: +49 521 8016800
 Fax: +49 521 8016801
 Email: info@Bisico.de
 responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number: BISICO Bielefelder Dentsilicone GmbH & Co. KG
 Tel.: +49 521 8016800 (08:00-16:00 PM)
 Fax: +49 521 8016801
 S. Zimmermann

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture:

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments:

2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments: The product does not have to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

2.2 Label elements: Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements:

Hazard pictograms:

Signal words:

Precautionary statements:

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3. Other hazards:**Results of PBT and vPvB assessment****PBT:** not applicable**vPvB:** not applicable**SECTION 3. Composition/Information of Ingredients****3.1. Substances:****Chemical characterization:** Mixture**3.2. Mixtures:**

Mixture of strontium-fluoro-aluminosilicate glass powder and pigments

Hazardous components:

none

SECTION 4. First-aid measures**4.1. Description of first aid measures:****General information:** no special measures required**after skin contact:** wash with plenty of water and soap**after inhalation:** supply with fresh air**after eye contact:** Rinse opened eye for several minutes under running water and consult a doctor**after swallowing:** seek medical advice if problems persist.**4.2. Most important symptoms and effects, both acute and delayed:**

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available

SECTION 5. Fire fighting measures**5.1. Extinguishing media:**CO₂, 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

5.3. Advice for firefighters:**Protective equipment:** Wear self-contained respiratory protective equipment

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

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:

Take up mechanically. Clean up affected area.

6.4. Reference to other sections:

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information

SECTION 7. Handling and storage

7.1. Precautions for safe handling:

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.
Observe normal care for working with chemicals.

7.2. Conditions for safe storage, including any incompatibilities:

Information about fire and explosion protection:

No special measures required

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

Further information on storage conditions:

Store at dry place, at room temperature (< 25°C, 78°F). Store away from food stuffs. Always store with lid on

7.3. Specific end use(s):

No further relevant information available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters: 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:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs and beverages. Avoid contact with eyes or skin

Hand protection: Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: Safety glasses

Respiratory protection: Required, when aerosols are generated

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Form: fine powder

Color: white

Odor: odorless

Safety relevant basic data

Melting point/melting range: n.a.

Boiling point/boiling range: n.a.

Flash point: n.a.

Ignition temperature: Product is not selfigniting

Danger of explosion: none

Density: Not determined

Vapor pressure: Not applicable (solute substance non volatile)

pH: n.a.

Solubility in/miscibility with:

Water: slightly

Content of solvents: none

Organic solvents: none

9.2. Other information:

no information available

SECTION 10. Stability and reactivity

10.1. Reactivity:	no information available
10.2. Chemical stability:	no information available
10.3. Possibility of hazardous reactions:	No dangerous reaction known
10.4. Conditions to avoid:	No decomposition if used according to specifications. Avoid heat, direct sunlight, reactive materials e.g. peroxides.
10.5. Incompatible materials:	Information not available.
10.6. Hazardous decomposition products:	No dangerous decomposition products known.

SECTION 11. Toxicological information

11.1. Information on toxicological effects:	Acute toxicity: Primary irritation: skin: may cause skin irritation (aerosols) eye: irritating effect (aerosols) Sensitization: no sensitizing effects 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.
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SECTION 12. Ecological information

General information: Avoid transfer into environment

12.1. Toxicity:	Information not available.
12.2. Persistence and degradability:	Information not available.
12.3. Bioaccumulative potential:	Information not available.
12.4. Mobility in soil:	Information not available.
12.5. Results of PBT and vPvB assessment:	PBT: not applicable vPvB: not applicable
12.6. Other adverse effects:	Classification of water endangerment: Do not allow undiluted product or large quantities of it into surface water or sanitary sewer system

SECTION 13. Disposal consideration

13.1. Waste treatment methods:

Product:

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

14.1 UN-Number ADR, ADN, IMDG, IATA: UN1170

14.2 UN proper shipping name ADR, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class:

Land transport ADR/RID and GGVS/GGVE (Germany):

Not classified as dangerous goods in the meaning of transport regulations

Sea transport IMDG:

Not classified as dangerous goods in the meaning of transport regulations

Air transport ICAO-TI and IATA-DGR:

Not classified as dangerous goods in the meaning of 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.

14.4 Packing group ADR, IMDG, IATA: Void

14.5 Environmental hazards Marine pollutant: No

14.6 Special precautions for user: Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable.

UN "Model Regulation": -

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:**

The product is a medical device according to EC-directive 93/42 EEC.

**15.2. Chemical safety
assessment:**

A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information:**Changes compared with the
previous version:**

Adaptation according to 1907/2006/EG, Article 31

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product. This document must not be regarded as a guarantee on any specific product property. The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

Preparation by:

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