

SECTION 1. Product identification/preparation/company undertaking

1.1. Product identifier:

Product no.: 80005
Trade name: BISICO Plast
Trade number: 00110, 00130

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 Classification according to Regulation (EC) 1272/2008: void

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 the calculation procedure of the „General classification guideline for preparations of the EU“ in the latest valid version.

2.2 Label elements: -

Labeling according to Regulation (EC) 1272/2008: -

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:****3.2. Mixtures:****Chemical characterization:****Description:**

Preparation of silicone polymers and fillers.

Hazardous components: none**SECTION 4. First-aid measures****4.1. Description of first aid measures:****After inhalation:** not applicable**after skin contact:** in general the product is not skin irritative**after eye contact:** Rinse immediately carefully and thoroughly with eye-bath or water. In case of troubles or persistent symptoms, consult an ophthalmologist.**after ingestion:** Seek medical attention if problems persist.**4.2. Most important symptoms and effects, both acute and delayed:**

Information not available

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

Information not available

SECTION 5. Fire fighting measures**5.1 Extinguishing media:** Water fog. Foam. Carbon dioxide (CO₂).**5.2. Special hazards arising from the substance or mixture:**

For more information see chapter 10 "stability and reactivity"

5.3. Advice for firefighters:**Protective equipment:**

Extinguishing materials should be selected according to the surrounding area.

SECTION 6. Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures:**

not required

6.2. Environmental precautions:

Do not empty into drains or the aquatic environment.

6.3. Methods and material for containment and cleaning up:

pick up mechanically

Additional information:

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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:****Information for safe handling:**

No special precautionary measures are necessary.

Recommendation for fire and explosion protection:

No special precautionary measures are necessary.

Further information on handling:

No special precautionary measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities:**Storage:****Requirements at storerooms and containers:**

No special measures required

Requirements for storage with other products:

not required

Further information on storage conditions:

No special requirements.

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 does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace

Additional information:

The lists valid during the making were used as basis.

8.2. Exposure controls:**Personal protective equipment:**

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General measures of protection and hygiene:

The usual precautions when handling chemicals have to be obtained.

Avoid contact with skin, eye and clothing.

Protection of hands:

Single-use gloves.

Suitable material: PE (polyethylene).

Unsuitable materials: NR (Natural rubber (Caoutchouc), Natural latex).

In the cases of special applications, it is recommended to check the chemical resistance with the manufacturer of the gloves.

Eye protection:

not required

Skin protection

Not required.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Environmental exposure controls

Not required.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties:****Appearance:****Form:** Paste**Color:** Base: white, Harder: red**Odor:** odorless

Value	Unit	Method
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Information on change in the physical state**Melting point/melting range:** n.a. °C**Boiling point/boiling range:** n.a. °C**Flash point:** n.a. °C**Autoignition temperature:** n.a.**Danger of explosion:** none**Density:** 1,8 (20°C) g/cm³**Vapor pressure:** n.a. mbar**Viscosity:** Paste**pH:** neutral**Solubility in/miscibility with:** Partially soluble in toluene, petrol ether**Water:** insoluble**Content of solvents:** none**Organic solvents:** -**Water:** -**Content of solids:** n.a.**9.2. Other information:** no information available

SECTION 10. Stability and reactivity**10.1. Reactivity:****10.2. Chemical stability:****Conditions to avoid:**

No decomposition if used according to specification

10.3. Possibility of hazardous reactions:**10.4. Conditions to avoid:****10.5. Incompatible materials:****10.6. Hazardous decomposition products:** none**Further information:**

Please pay attention to the Directions for Use.

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

Acute toxicity: Acute toxicity, oral LD50: > 2000 mg/kg Rat. -

Primary irritation: -

skin: no irritating effect

eye: no irritating effect

Sensitising effects: no danger of sensitization.

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

12.1. Toxicity: product has not been tested.

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:**Further information:**

Do not empty into drains or the aquatic environment.

WGK 1 (German regulation): slightly hazardous for water

Doesn't get into the sewage water as long as the process is carried out according to regulations.

SECTION 13. Disposal consideration**13.1. Waste treatment methods:****Advice on disposal**

Remove according to the regulations.

Additional information:

Waste disposal number of waste from residues/unused products

070217

WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; wastes containing silicones other than those mentioned in 07 02 16

Waste disposal number of used product

200399

MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; municipal wastes not otherwise specified

Contaminated packaging

Completely emptied packings can be re-cycled.

SECTION 14. Transport information

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

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

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

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:****Classification according to EC-guidelines:**

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

National regulatory information:

Water contaminating class (D): 1 - slightly water contaminating

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 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. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.

Preparation by:

S. Zimmermann

Tel.: +49 521 8016800