

SECTION 1. Product identification/preparation/company undertaking

1.1. Product identifier:

Trade name: BISICO Regidur I (various packaging sizes)

Trade number: 71570, 71575

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 impression silicone

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:**

mixture of Polydimethylpolymethyl-hydrogensiloxan, Vinylmethylpolymethyl-siloxan, Paraffin and Siliciumdioxid

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 eye contact:	rinse with plenty of water and consult a doctor
after swallowing:	If symptoms persist consult a doctor

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:** CO₂, water**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:**

no special measures required

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

not required

6.2. Environmental precautions:

no special measures required

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: For dental use only. No special measures required

Recommendation for fire and explosion protection: No special measures required

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: none

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: -

General measures of protection and hygiene: normal hygienic measures

Respiratory protection: not required

Protection of hands: not required

Eye protection: not absolute required

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Appearance:

Form: Paste

Color: A-Comp.: white, B-Comp.: magenta

Odor: odorless

Value Unit Method

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:	1,52 (20°C)	g/cm ³
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

SECTION 11. Toxicological information

11.1. Information on toxicological effects:

Acute toxicity:	-
Primary irritation:	-
skin:	no irritating effect
eye:	no irritating effect

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

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|--|---|
| 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:

WGK 1 (German regulation): slightly hazardous for water

SECTION 13. Disposal consideration

13.1. Waste treatment methods:

Product:

Recommendation:

Small quantities can be disposed of with household waste.

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: | 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.

15.2. Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information:

Changes compared with the previous version: 1.1 Product identifier

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:

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