

SECTION 1. Product identification/preparation/company undertaking**1.1. Product identifier:**

Product no.: 84000, 84001, 84002, 84003, 84004, 84005, 84020, 84013, 84014, 84015, 84006, 84007, 84008, 84009, 84010

Trade name: BISICO Micro Esthetic, all colours

Trade number: 75000, 75001, 75002, 75003, 75004, 75005, 75007, 75008, 75012, 75100, 75101, 75102, 75103, 75104, 75009

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-filling-material

1.3. Details of the supplier of the safety data sheet:

BISICO Bielefelder Dentalsilicone 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 Dentalsilicone 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 poly- and difunctional methacrylates, barium glass filler, fumed silica, photoinitiator, accelerator, stabilizer

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:

Do not discharge into drains/groundwater.

6.3 Methods for cleaning up:

Wipe out with absorbent material

Additional information: none

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:

Handling:

For dental use only. No special measures required

Information for safe handling:

None with proper storage and handling.

Recommendation for fire and explosion protection:

No special measures required

7.2. Conditions for safe storage, including any incompatibilities:

Storage:

Store in dry place and away from light for quality reasons (< 25°C).

Requirements at storerooms and containers:

dark, cool and dry

Requirements for storage with other products:

Do not store together with food

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.

Personal protective equipment:

-

8.2. Exposure controls:

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:	tooth coloured		
Odor:	odorless		
	<u>Value</u>	<u>Unit</u>	<u>Method</u>

Information on change in the physical state

Melting point/melting range: n.a. °C

Boiling point/boiling range: n.a. °C

Flash point: n.d. °C

Autoignition temperature: n.d.

Danger of explosion: none

Density: 1,90 (20°C) g/cm³

Vapor pressure: n.a.

Viscosity: paste

pH: neutral

Solubility in/miscibility with: Slightly in toluene, silicone oil

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:**

Heat, sunlight, Peroxides, metal powders, strong oxidizers, free radical initiators

10.3. Possibility of hazardous reactions:**10.4. Conditions to avoid:****10.5. Incompatible materials:**

10.6 Hazardous decomposition products: Not known

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

Acute toxicity:	-
Primary irritation:	-
skin:	irritating
eye:	irritating
Sensitization of product:	sensitisation by skin contact

Additional toxicological information:

Allergic reactions to methacrylates are possible by long-term exposure of the product.
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:	Do not allow product to reach sewage system or waters
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:	-

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:**

No classification necessary to actual EEC guidelines

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:

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