

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

Product no.: 81601, 81611, 81612, 81621, 83590
Product name: BISICO Provi Temp K
Trade number: 73540, 73560, 73570, 73580, 73590

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: Temporary material for crowns and bridges

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: Skin Irrit. 2, H315 Causes skin irritation
Eye Irrit. 2, H319 Causes serious eye irritation
Skin Sens. 1; H317 May cause allergic skin reaction
STOT SE 3; H335 May cause respiratory irritation

2.1.2. 67/548/EEC and 1999/45/EC Directives and following amendments and adjustments: The product has 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:** Warning

Hazard statements

H315 Causes skin irritation

H319 Causes serious eye irritation

H317 May cause allergic skin reaction

H335 May cause respiratory irritation

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

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:

mixture of polyfunctional acrylates and methacrylates, unsaturated esters and malonyl urea derivatives

Hazardous components:

Methacrylates

GHS07, H315, H319, H317, H335

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

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: not required

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 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: Store at a dry place. Store tightly closed. Storage temperature <25°C.
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 away from food stuffs.

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:**

Appearance: paste
Colour: tooth colored
Odour: nearly odorless
pH.: neutral.
Melting point / freezing point: Not available.
Initial boiling point: Not available.
Boiling range: Not available.
Flash point: n.d.
Ignition temperature: n.d.
Danger of Explosion: none
Density: 1.52 (20°C) g/cm³
Vapour pressure: Not available.
Solubility: Partially soluble in toluene
Solubility in Water: insoluble
Content of solvents: none
Organic solvents: none

9.2. Other information:

Information not 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 information available
10.4. Conditions to avoid:	Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.
10.5. Incompatible materials:	Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.
10.6. Hazardous decomposition products:	Information not available.

SECTION 11. Toxicological information

11.1. Information on toxicological effects:	<p>Acute toxicity: no data available</p> <p>Primary irritation:</p> <p>skin: irritant</p> <p>eye: irritant</p> <p>Sensitization: sensitization by skin contact possible</p> <p>Additional toxicological information:</p> <p>Allergic reactions to the product after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.</p>
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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:	<p>PBT: not applicable</p> <p>vPvB: not applicable</p>
12.6. Other adverse effects:	Classification of water endangerment: WGK=1 (slightly polluting substance).

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:**

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

15.2. Chemical safety assessment:

No chemical safety assessment has been processed for the mixture and the substances it contains.

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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