

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

**Product no.:** 81651, 81655  
**Product name:** BISICO Provi Bond K  
**Trade number:** 03710, 03720

**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 dental cement

**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](mailto: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:** Acute aquatic toxicity, Category 1, H400 Very toxic to aquatic life  
Chronic aquatic toxicity, Category 1, H410 Very toxic to aquatic life with long lasting effects  
Skin Irritation, Category 2; H315 Causes skin irritation  
Eye Irritation, Category 2; H319 Causes serious eye irritation  
STOT SE, Category 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.

**Classification system:**

The classification corresponds to actual EU-lists, and completed with details from technical literature and company data.

**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**

H400 Very toxic to aquatic life

H315 Causes skin irritation

H319 Causes serious eye irritation

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 P273 Avoid release to the environment

**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:**

Modified acrylic acid, poly acrylic acid, methacrylates, catalysts, stabilizers in ethanol

**Hazardous components:**

Zinc Oxide [CAS-No. 1314-13-2]	GHS09, H410, H411
Methacrylates (607-134-00-4 Index No.)	GHS07, H315, H319, H335
Mixture of organic acids	GHS07, H315, H319, H335

**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 opened eye for several minutes under running water and consult a doctor  
**after swallowing:** Seek medical advice immediately

**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:**

CO<sub>2</sub>, 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:**

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**

- |   |   |
|---|---|
| <b>7.1. Precautions for safe handling:</b>                                | This product should only be supplied or handled to dentists or dental technicians or upon their instructions.<br>Observe normal care for working with chemicals.  |
| <b>7.2. Conditions for safe storage, including any incompatibilities:</b> | <p><b>Information about fire and explosion protection:</b> No special measures required</p> <p><b>Requirements at storerooms and containers:</b> Store only in the original containers</p> <p><b>Further information on storage conditions:</b></p> <p>Store at dry place, storage temperature 8 - 25°C. Store away from food stuffs.</p> |
| <b>7.3. Specific end use(s):</b>  | No further relevant information available   |

**SECTION 8. Exposure controls/personal protection**

- |                                 |   |
|---------------------------------|---|
| <b>8.1. Control parameters:</b> | <p>Components with limits of values to be supervised at the workplace:<br/>The product contains no relevant quantities of components with limit values to be supervised at the workplace.</p> <p><b>Additional information:</b> The lists valid during the making were used as basis</p>  |
| <b>8.2. Exposure controls:</b>  | <p><b>Personal protective equipment:</b></p> <p><b>General protective and hygienic measures:</b></p> <p>The usual precautionary measures are to be adhered to when handling chemicals.</p> <p>Keep away from foodstuffs and beverages. Avoid contact with eyes or skin</p> <p><b>Hand protection:</b> Protective gloves.</p> <p>Due to missing tests no recommendation to the glove material can be given for the product.</p> <p><b>Eye protection:</b> Safety glasses</p> <p><b>Respiratory protection:</b> Required, when aerosols are generated</p> |

**SECTION 9. Physical and chemical properties****9.1. Information on basic physical and chemical properties:**

Appearance: paste  
Colour: white yellowish  
Odour: odourless  
Melting point / freezing point: Not available.  
Initial boiling point: n.a.  
Boiling range: n.a.  
Flash point: n.a.  
Ignition temperature: Product is not selfigniting  
Danger of Explosion: none  
Density: 1.71 (20°C) g/cm<sup>3</sup>  
Vapour pressure: Not applicable (non Volatile)  
Solubility: slightly in toluene, organic solvents  
Solubility in Water: insoluble  
Content of solvents: none  
Organic solvents: none

**9.2. Other information:**

no information available

**SECTION 10. Stability and reactivity****Thermal decomposition:**

No decomposition if used according to specifications.

**10.1. Reactivity:**

No dangerous reaction known

**10.2. Chemical stability:**

no information available

**10.3. Possibility of hazardous reactions:**

no information available

**10.4. Conditions to avoid:**

avoid heat, direct sunlight

**10.5. Incompatible materials:**

Peroxides, metal powders, strong oxidizers, free radical initiators

**10.6. Hazardous decomposition products:**

No dangerous decomposition products known.

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

Allergic reactions to methacrylates by chronic exposure to the product are possible

**Acute toxicity:****Primary irritation:**

**skin:** slight irritating

**eye:** irritating effect

**Sensitization:** no sensitizing effect 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.

**SECTION 12. Ecological information**

<b>12.1. Toxicity:</b>	-
	<b>Aquatic toxicity:</b> May cause long term adverse effect in the aquatic environment
<b>12.2. Persistence and degradability:</b>	Information not available.
<b>12.3. Bioaccumulative potential:</b>	Information not available.
<b>12.4. Mobility in soil:</b>	Information not available.
<b>12.5. Results of PBT and vPvB assessment:</b>	<b>PBT:</b> not applicable <b>vPvB:</b> not applicable
<b>12.6. Other adverse effects:</b>	<b>General information:</b> Do not allow product into surface water or sanitary sewer system

**SECTION 13. Disposal consideration**

<b>13.1. Waste treatment methods:</b>	<b>Product:</b>
	<b>Recommendation:</b>
	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
	<b>Uncleaned packaging:</b> Handle contaminated packaging in the same way as the substance itself.
	<b>Recommendation:</b>
	Disposal must be made according to official regulations

**SECTION 14. Transport information**

<b>14.1 UN-Number ADR, ADN, IMDG, IATA:</b>	UN 3077
<b>14.2 UN proper shipping name ADR, ADN, IMDG, IATA:</b>	Void
<b>14.3 Transport hazard class(es) ADR, ADN, IMDG, IATA Class:</b>	
<b>Land transport ADR/RID and GGVS/GGVE (Germany):</b>	
	UN 3077 UMWELTGEFÄHRDENDER STOFF, FEST N.A.G (Zinkoxid), III, 9
<b>Sea transport IMDG:</b>	
	IMDG-Code
	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

EmS: F-A S-F

**Air transport ICAO-TI and IATA-DGR:**

CAO, PAX

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,  
SOLID, N.O.S. (zinc oxide), 9, III

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:**

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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