

<p><b>1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING</b></p> <p><b>1.1 Product identifier</b> <b>Trade name</b></p> <p><b>PINK CAD-CAM DISC</b></p> <p><b>1.2 Relevant identifier uses of the substance or mixture and uses advised against</b> <b>Recommended use</b> Discs have been used for fabrication of immediate load implant denture as a long term provisional in combination with denture teeth and titanium connectors.</p> <p><b>1.3 Details of the supplier of the Safety Data Sheet</b> <b>Manufacturer/supplier</b> Polident d.o.o., Dental Products Industry Volčja Draga 42, 5293 Volčja Draga, Slovenija Tel.:00386 5 3304840, Fax: 00386 5 3304870 E-mail: <a href="mailto:polident@polident.si">polident@polident.si</a> <b>Information provided by</b> 00386 5 3304859</p> <p><b>1.4 Emergency telephone number</b> 00386 5 3304840</p>
<p><b>2. HAZARDS IDENTIFICATION</b></p> <p><b>2.1 Classification of the substance or mixture</b> <b>Classification according to Regulation 1272/2008/EC:</b> Not applicable</p> <p><b>2.2 Label elements</b> Labelling according to Regulation 1272/2008/EC, Directives 67/548/EC or 1999/45/EC: Not applicable</p> <p><b>2.3 Other hazards:</b> None. <b>Results of PBT and vPvB assessment</b> <b>PBT:</b> Not applicable. <b>vPvB:</b> Not applicable.</p>
<p><b>3. COMPOSITION/INFORMATION ON INGREDIENTS</b></p> <p><b>3.1 Chemical characterization: Mixtures</b> <b>Description</b> Material on the base of polymethylmethacrylate, dimethacrylates and pigments. <b>Regulation 1272/2008/EC:</b> Not applicable <b>Hazardous ingredients as per Directives 67/548/EC or 1999/45/EC:</b> Not applicable</p>
<p><b>4. FIRST AID MEASURES</b></p> <p><b>4.1 Description of first aid measures</b> <b>General information</b> No special measures required. <b>Inhalation</b> Remove the casualty into fresh air. In case of complaints get medical advice. <b>Skin contact</b> Wash off with water and soap. Consult a physician if irritation persists. <b>Eye contact</b> Rinse eye with plenty of water if it is necessary seek medical attention: only mechanical effect.</p>

<b>Ingestion</b> Wash out mouth with water and drink water. In case of complaints get medical advice.
<b>4.2 Most important symptoms and effects, both acute and delayed</b> None known.
<b>4.3 Indication of any immediate medical attention and special treatment needed</b> Treat symptomatically.
<b>5. FIRE – FIGHTING MEASURES</b>
<b>5.1 Extinguishing media</b> <b>Suitable extinguishing media</b> Water, foam, dry powder, carbon dioxide. <b>Unsuitable extinguishing media for safety reasons</b> None.
<b>5.2 Special hazards arising from the substance or mixture</b> May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition.
<b>5.3 Advice for firefighters</b> Wear self-contained breathing apparatus.
<b>6. ACCIDENTAL RELEASE MEASURES</b>
<b>6.1 Personal precautions, protective equipment and emergency procedures</b> Not required.
<b>6.2 Environmental precautions</b> No special measures required.
<b>6.3 Methods and material for containment and cleaning up</b> Pick up mechanically. Dispose of in accordance with regulations.
<b>6.4 Reference to other sections</b> For information on safe handling see Section 7. For information on personal protection equipment see Section 8. For information on disposal information see section 13.
<b>7. HANDLING AND STORAGE</b>
<b>7.1 Precautions for safe handling</b> <b>Safe handling advice</b> Only adequate trained persons may deal with product. For use in dentistry only. Keep away from children. Ensure the area is well ventilated. No eating, drinking or smoking during handling with product. Follow the usual good standards of occupational hygiene. <b>Information on fire and explosion protection</b> No special measures required.
<b>7.2 Conditions for safe storage, including any incompatibilities</b> <b>Storage</b> <b>Requirements for storage areas</b> Keep in dry storage.
<b>7.3 Specific end use(s)</b> None.
<b>8. EXPOSURE CONTROLS /PERSONAL PROTECTION</b>
<b>8.1 Control parameters</b> <b>Ingredients with limit values that require monitoring at the workplace</b> The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
<b>8.2 Exposure controls</b> <b>General protective measures</b> Provide adequate ventilation. <b>Hygiene measures</b> Follow the usual good standards of occupational hygiene and dental practise.

**Respiratory protection**

Avoid contact with powder generated by final working.  
Wear respiratory protective device in case of dust formation.

**Hand protection**

Not required.

**Eye protection**

Wear safety goggles during mechanical processing.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

**Appearance:**

**Form:** firm disc

**Colour:** different colours

**Odour:** odourless

**Changes in condition:** /

**Melting point:** Undetermined

**Boiling point:** Undetermined

**Flash point:** >250°C

**Ignition temperature:** not applicable

**Lower explosion limit:** not determined

**Upper explosion limit:** not determined

**Vapour pressure:** not applicable

**Density:** 1,17 g/cm<sup>3</sup>

**Viscosity (dynamic):** not applicable

**Solubility in water:** insoluble

**pH – value:** not applicable

**9.2 Other information**

None.

**10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

No relevant information available.

**10.2 Chemical stability**

The product is stable under normal handling and storage conditions.

**10.3 Possibility of hazardous reactions**

No hazardous reactions known.

**10.4 Conditions to avoid**

Decompositions begins at appr. 250°C.

**10.5 Incompatible materials**

No relevant information available.

**10.6 Hazardous decomposition products**

None when used as prescribed.

May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition

**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

**Acute oral toxicity**

The similar product has been tested according to EN ISO 10993-5 (2009): Tests for in vitro cytotoxicity. The test article extract met the requirements of the EN ISO 10993-5 (2009).

**Irritation**

The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. An intracutaneous irritation test by intradermal injection in the rabbit has been performed and the test article extract met the requirements of the ISO 10993-10 (2010).

**Sensitization**

The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. According to the EN ISO 10993-10 (2010) the product did not induce delayed sensitization.

<p><b>12. ECOLOGICAL INFORMATION</b></p> <p><b>12.1 Toxicity</b> <b>Hazardous to the aquatic environment:</b> No further relevant information available, no evidence for hazardous properties</p> <p><b>12.2 Persistence and degradability:</b> No further relevant information available, no evidence for hazardous properties</p> <p><b>12.3 Bioaccumulative potential:</b> No further relevant information available, no evidence for hazardous properties</p> <p><b>12.4 Mobility in soil:</b> No further relevant information available, no evidence for hazardous properties</p> <p><b>12.5 Results of PBT and vPvB assessment</b> PBT: Not applicable. vPvB: Not applicable.</p> <p><b>12.6 Other adverse effects:</b> No further relevant information available.</p>
<p><b>13. DISPOSAL CONSIDERATIONS</b></p> <p><b>13.1 Waste treatment methods</b> <b>Product:</b> Disposal should be made in accordance with local, state and national legislation. <b>Uncleaned packaging:</b> Disposal should be made in accordance with local, state and national legislation. <b>Code of waste EWC:</b> 18 01 07</p>
<p><b>14. TRANSPORT INFORMATION</b></p> <p><b>14.1 UN Number:</b> see section 14.2</p> <p><b>14.2 UN proper shipping name</b> <b>Land transport ADR:</b> Not dangerous according to transport regulations. <b>Land transport RID:</b> Not dangerous according to transport regulations. <b>Inland waterway transport ADN:</b> Not dangerous according to transport regulations. <b>Shipment by sea IMDG:</b> Not dangerous according to transport regulations. <b>Air transport ICAO/IATA:</b> Not dangerous according to transport regulations.</p> <p><b>14.3 Transport hazard class(es):</b> see section 14.2</p> <p><b>14.4 Packing group:</b> see section 14.2</p> <p><b>14.5 Environmental hazards:</b> None.</p> <p><b>14.6 Special precautions for user:</b> see section 14.2</p> <p><b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b> None.</p> <p><b>14.8 Transport additional information:</b> None</p>
<p><b>15. REGULATORY INFORMATION</b></p> <p><b>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture</b> <b>National regulations</b> <b>Other regulations, limitations and prohibitive regulations</b> The product is Class IIa medical device according to the EC Directive 93/42/EEC.</p> <p><b>15.2 Chemical Safety Assessment</b> A chemical safety assessment has not been carried out for this mixture.</p>
<p><b>16. OTHER INFORMATION</b> This information is based on our present knowledge and experience. They are intended as a description of the products safety requirements and are not to be seen as a quarantee of certain product`s features. New versions of Safety Data Sheet will be <i>laying printed</i> for the data compared to the previous version altered.</p>