

<p><b>1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING</b></p> <p><b>1.1 Product identifier</b> Trade name</p> <p><b>POLIREPAR S POWDER</b></p> <p><b>1.2 Relevant identifier uses of the substance or mixture and uses advised against</b> <b>Recommended use</b> Material for the fabrication of repairs.</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 (EC) No. 1272/2008</b> The mixture is not classified according to Regulation.</p> <p><b>2.2 Label elements</b> <b>Labelling according to Regulation (EC) No. 1272/2008</b> Not applicable.</p> <p><b>2.3 Other hazards</b> <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> Product contents polymethylmethacrylate, pigments and dibenzoyl peroxide. <b>Hazardous ingredients according to Regulation (EC) No. 1272/2008</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> Remove contaminated clothing. <b>Inhalation</b> Remove the casualty into fresh air. In case of complaints obtain medical attention. <b>Skin contact</b> Wash off immediately with water. If skin irritation occurs obtain medical attention. <b>Eye contact</b> Rinse opened eye with plenty of water and if it is necessary obtain medical attention.</p> <p><b>Ingestion</b> Do not induce vomiting. Rinse mouth. In case of complaints obtain medical attention.</p> <p><b>4.2 Most important symptoms and effects, both acute and delayed</b></p>

	None known.
<b>4.3</b>	<b>Indication of any immediate medical attention and special treatment needed</b> Treat symptomatically.
<b>5.</b>	<b>FIRE – FIGHTING MEASURES</b>
<b>5.1</b>	<b>Extinguishing media</b> <b>Suitable extinguishing media</b> Water spray, foam, dry powder, carbon dioxide. <b>Unsuitable extinguishing media for safety reasons</b> Water with full yet.
<b>5.2</b>	<b>Special hazards arising from the substance or mixture</b> Dangerous gases may be released in case of fire.
<b>5.3</b>	<b>Advice for firefighters</b> Wear self-contained breathing apparatus and suitable protective clothing.
<b>6.</b>	<b>ACCIDENTAL RELEASE MEASURES</b>
<b>6.1</b>	<b>Personal precautions, protective equipment and emergency procedures</b> Avoid dust formation. Ensure suitable personal protection (including respiratory protection) during removal of spillages.
<b>6.2</b>	<b>Environmental precautions</b> Prevent product from getting into drains, surface water or ground water.
<b>6.3</b>	<b>Methods and material for containment and cleaning up</b> Pick up mechanically. Dispose of in accordance with regulations.
<b>6.4</b>	<b>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.</b>	<b>HANDLING AND STORAGE</b>
<b>7.1</b>	<b>Precautions for safe handling</b> <b>Safe handling advice</b> Avoid the formation and deposition of dust. <b>Information on fire and explosion protection</b> No special precautions required.
<b>7.2</b>	<b>Conditions for safe storage, including any incompatibilities</b> <b>Storage</b> <b>Requirements for storage areas</b> Keep the powder only in the original vessel in cool and dry place. <b>Empiry date</b> Considering the instructions for safety storage and handling the expiry date of the powder is five years.
<b>7.3</b>	<b>Specific end use(s)</b> None.
<b>8.</b>	<b>EXPOSURE CONTROLS /PERSONAL PROTECTION</b>
<b>8.1</b>	<b>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</b>	<b>Exposure controls</b> <b>Appropriate engineering controls</b> Do not eat, drink or smoke at the work place. Follow the usual good standards of occupational hygiene and dental practise. Ensure adequate ventilation of work place. Store work clothing separately. Remove contaminated clothing. <b>Individual protection measures, such as personal protective equipment</b> <u>Eye/face protection</u> Wear tightly sealed goggles.



Skin protection

Wear suitable protective gloves.



Material of gloves: Butyl rubber; EN 374

Suitability of gloves should be confirmed with glove manufacturer. Change gloves, if contamination occurs or duration of activity exceed break through time. Breakthrough time of the glove material: refer to the information provided by the glove's producer.

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Respiratory protection

By normal use is not required.

Thermal hazards

None.

**Environmental exposure controls**

Ensure effective control measures when working within the boundaries as specified in section 6.2.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

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

**Appearance**

**Form:** powder

**Colour:** pink shades

**Odour:** odourless

**pH – value:** not applicable

**Changes in condition:** /

**Softening point (°C):** ca. 110

**Boiling point (°C):** not applicable

**Flash point (°C):** > 250

**Relative evaporation rate (Ether=1):** Not available

**Flammability (solid, gas):** Not applicable

**Auto Ignition temperature(°C):** > 400

**Decomposition temperature (°C):** Not applicable

**Lower explosion limit (%vv/v):** Not available

**Upper explosion limit (%vv/v):** Not available

**Vapour pressure (Pa):** Not applicable

**Vapour density (Air=1):** Not applicable

**Density (g/cm<sup>3</sup>):** 1,2 at 20 °C

**Bulk density (kg/m<sup>3</sup>):** Not applicable

**Viscosity (dynamic):** Not applicable

**Solubility in water:** insoluble

**Solubility (quantitative):** in e.g. esters, ketones and chlorinated hydrocarbons: readily soluble

**Partition coefficient (n-Octanol/water):** Not applicable

Explosive properties: Not applicable

Oxidising properties: Not applicable

**9.2 Other information**

None.

**10. STABILITY AND REACTIVITY**

**10.1 Reactivity**

See Section 10.2.

**10.2 Chemical stability**

The product is stable under normal handling and storage conditions. Depolymerization begins at 250°C.

**10.3 Possibility of hazardous reactions**

No dangerous reactions known.

**10.4 Conditions to avoid**

Operations that create dust.

**10.5 Incompatible materials**

	Strong oxidizing agents.
<b>10.6</b>	<b>Hazardous decomposition products</b> None when used and stored as prescribed. Dangerous gases may be released in case of fire.
<b>11.</b>	<b>TOXICOLOGICAL INFORMATION</b>
<b>11.1</b>	<b>Information on toxicological effects</b>
	<b>Acute toxicity</b> No specific test data available. No evidence for hazardous properties.
	<b>Skin irritation</b> No specific test data available. No evidence for hazardous properties.
	<b>Eye contact</b> No specific test data available. No evidence for hazardous properties.
	<b>Sensitization</b> No specific test data available. No evidence for hazardous properties.
	<b>CMR effects</b> No.
	<b>Repeated dose toxicity</b> No specific test data available. No evidence for hazardous properties.
	<b>Further information on toxicology</b> When the product is used and storage as directed, the product does not have any toxicological effects. The fine particles contained in the product may cause mechanical irritation of the skin, eyes and mucous membranes. Avoid product contact with skin and eyes and inhalation of dust.
<b>12.</b>	<b>ECOLOGICAL INFORMATION</b>
<b>12.1</b>	<b>Toxicity</b>
	<b>Hazardous to the aquatic environment</b> No specific test data available. No evidence for hazardous properties.
<b>12.2</b>	<b>Persistence and degradability</b> No specific test data available. No evidence for hazardous properties.
<b>12.3</b>	<b>Bioaccumulative potential</b> No specific test data available. No evidence for hazardous properties.
<b>12.4</b>	<b>Mobility in soil</b> No specific test data available. No evidence for hazardous properties.
<b>12.5</b>	<b>Results of PBT and vPvB assessment</b> <b>PBT:</b> Not applicable. <b>vPvB:</b> Not applicable.
<b>12.6</b>	<b>Other adverse effects:</b> No further relevant information available.
<b>13.</b>	<b>DISPOSAL CONSIDERATIONS</b>
<b>13.1</b>	<b>Waste treatment methods</b> <b>Product:</b> Must not be disposed together with household garbage. Do not allow product to reach sewage system. 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>14.</b>	<b>TRANSPORT INFORMATION</b>
<b>14.1</b>	<b>UN number:</b> Not applicable. The product is not dangerous according to transport regulations.
<b>14.2</b>	<b>UN proper shipping name</b>

<p>See Section 14.1.</p> <p><b>14.3 Transport hazard class(es)</b> See Section 14.1.</p> <p><b>14.4 Packing group</b> ADR, IMDG, IATA: See Section 14.1.</p> <p><b>14.5 Environmental hazards</b> Marine pollutant: Not classified as a marine pollutant.</p> <p><b>14.6 Special precautions for user</b> Not applicable.</p> <p><b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b> Not applicable.</p> <p><b>14.8 Transport additional information</b> Not applicable.</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> Product is a medical device class IIa according to 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 guarantee of certain product's features.</p> <p>New versions of Safety Data Sheet will be <i>laying printed</i> for the data compared to the previous version altered.</p>