

<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>ORTOPOLI 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 orthodontic appliances by using the spray-on technique and the cold curing.</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. <b>Hazard statements</b> <i>None</i> <b>Precautionary statements</b> <i>P281 Use personal protective equipment as required.</i> <i>P312 Call a poison center or doctor/physician if you feel unwell.</i> <i>P330 Rinse mouth.</i> <i>P501 Dispose of contents/container in accordance with local regulation.</i></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> <i>Product contents polyethylmethacrylate. CAS No.9003-42-3, content &gt;99 %.</i> <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> <i>No special measures required.</i> <b>Inhalation</b></p>

	<p><i>The product is not a respiratory irritant.</i></p> <p><b>Skin contact</b> <i>The product is not skin irritating.</i></p> <p><b>Eye contact</b> <i>Flush with plenty of water. Consult a doctor if irritation occurs.</i></p> <p><b>Ingestion</b> <i>Drink plenty of water. Induce vomiting and consult a doctor.</i></p> <p><b>4.2 Most important symptoms and effects, both acute and delayed</b> None.</p> <p><b>4.3 Indication of any immediate medical attention and special treatment needed</b> <i>No.</i></p>
<b>5. FIRE – FIGHTING MEASURES</b>	
<b>5.1 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 Special hazards arising from the substance or mixture</b>	<i>No.</i>
<b>5.3 Advice for firefighters</b>	<i>Use water spray to cool unopened containers.</i>
<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>6.1 Personal precautions, protective equipment and emergency procedures</b>	<i>No special measures required. No dangerous materials are released.</i>
<b>6.2 Environmental precautions</b>	<i>No special measures required.</i>
<b>6.3 Methods and material for containment and cleaning up</b>	Clean 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>	<i>Only adequately trained personnel should handle the product. Use hygienic measures for dental practise.</i>
<b>Information on fire and explosion protection</b>	No special precautions required.
<b>7.2 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>Expiry date</b>	Considering the instructions for safety storage and handling the expiry date of the powder is five years.
<b>7.3 Specific end use(s)</b>	<i>None.</i>
<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>	<i>Substance contains no components or products of decomposition according to point 10, with limit values related to the place of work, which require monitoring. However, manufacturer recommends: Polyethyl methacrylate CAS No. 9003-42-3, WEL 10 mg/m<sup>3</sup>.</i>
<b>8.2 Exposure controls</b>	

### Appropriate engineering controls

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.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear tightly sealed goggles.



#### Skin protection

Wear suitable protective gloves. *On handling larger quantities wear light weight protective clothing.*



Material of gloves: *In practise, as the product is prepared of several substances, resistance tests of glove materials cannot be conducted in advance and should be performed by the end user prior to application. A suitable glove type should be selected for each work environment. On the whole, for permanent contact in work areas, natural latex (NR) gloves are suitable.*

#### Respiratory protection

By normal use is not required. *If workplace exposure limit is exceeded (leakage, spillage), apply dust mask with P2 particle filter.*

#### 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:** colourless

**Odour:** odourless

**pH – value:** not applicable

**Changes in condition:** /

**Softening point (°C):** /

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

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

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

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

**Ignition temperature(°C):** > 400

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

**Lower explosion limit (%vv/v):** 20 g/m<sup>3</sup>

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

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

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

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

**Viscosity (dynamic):** Not determined

**Solubility in water:** insoluble

**Solubility (quantitative):** *soluble in organic solvents*

**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

*Avoid contact with other chemicals.*

**10.2 Chemical stability**

The product is stable under normal handling and storage conditions *and when used as directed*.  
*Decomposition can occur at elevated temperatures (>250°C), releasing potentially irritating vapours.*

**10.3 Possibility of hazardous reactions**

No dangerous reactions known *when used as directed*.

**10.4 Conditions to avoid**

*The product is supplied in a stable form. Protect from humidity.*

**10.5 Incompatible materials**

*None known.*

**10.6 Hazardous decomposition products**

*Organic products of decomposition. No decomposition occurs when used as directed.*

**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

**Metabolism**

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**Acute oral toxicity**

*LD<sub>50</sub> rat (PEMA) > 10000 mg/kg*

**Acute inhalation toxicity**

*Not toxic.*

**Acute dermal toxicity**

*Not toxic.*

**Caustic burning/Skin irritation**

*No irritant effect.*

**Serious eye damage/Irritation**

*No irritant effect.*

**Respiratory/Skin sensitisation**

*None known.*

**Germ cell mutagenicity**

*None mutagenic.*

**Carcinogenicity**

*None carcinogenic.*

**Reprotoxicity/Teratogenicity**

*Not toxic.*

**General information**

*Product is not subject to classification according to the calculation method of the general EC Classification Guidelines for Preparations. When used and handled according to specifications and GLP, no harmful effects are observed.*

**12. ECOLOGICAL INFORMATION**

**12.1 Toxicity**

**Hazardous to the aquatic environment**

*None, insoluble in water (inert polymer).*

**12.2 Persistence and degradability**

*None persistence and degradability.*

**Biodegradability**

*Product is solid, chemically inert and non-biodegradable. No negative effects are known.*

**12.3 Bioaccumulative potential**

*No evidence for hazardous properties.*

**12.4 Mobility in soil**

*The substance is not water soluble. No evidence for hazardous properties.*

**12.5 Results of PBT and vPvB assessment**

**PBT:** Not applicable.

**vPvB:** Not applicable.

**12.6 Other adverse effects:** No further relevant information available.

<p><b>13. DISPOSAL CONSIDERATIONS</b></p> <p><b>13.1 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. List of waste: 07 02 13 Waste plastic <b>Uncleaned packaging:</b> Disposal should be made in accordance with local, state and national legislation.</p>
<p><b>14. TRANSPORT INFORMATION</b></p> <p><b>14.1 UN number:</b> Not applicable. The product is not dangerous according to transport regulations.</p> <p><b>14.2 UN proper shipping name</b> 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. <i>Product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations.</i></p> <p><b>15.2 Chemical Safety Assessment</b> A chemical safety assessment has not been carried out by the supplier.</p>
<p><b>16. OTHER INFORMATION</b></p> <p>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. <i>The substance is supplied in a stabilised form. The instructions given here are valid only for the substance as supplied, not for derivatives resulting from its use.</i></p> <p>New versions of Safety Data Sheet will be <i>laying printed</i> for the data compared to the previous version altered.</p>

**SAFETY DATA SHEET**  
**according to regulation 1907/2006/EC**  
**ORTOPOLI POWDER**

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