

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING 1.1 Product identifier Trade name ORTOPOLI POWDER 1.2 Relevant identifier uses of the substance or mixture and uses advised against Recommended use Material for the fabrication of orthodontic appliances by using the spray-on technique and the cold curing. 1.3 Details of the supplier of the Safety Data Sheet Manufacturer/supplier Polident d.o.o., Dental Products Industry Volčja Draga 42, 5293 Volčja Draga, Slovenija Tel.:00386 5 3304840, Fax: 00386 5 3304870 E-mail: polident@polident.si Information provided by 00386 5 3304859 1.4 Emergency telephone number 00386 5 3304840	
2. HAZARDS IDENTIFICATION 2.1 Classification of the substance or mixture Classification according to Regulation (EC) No. 1272/2008 The mixture is not classified according to Regulation. 2.2 Label elements Labelling according to Regulation (EC) No. 1272/2008 Not applicable. Hazard statements <i>None</i> Precautionary statements <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> 2.3 Other hazards Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.	
3. COMPOSITION/INFORMATION ON INGREDIENTS 3.1 Chemical characterization: Mixtures Description <i>Product contents polyethylmethacrylate. CAS No.9003-42-3, content >99 %.</i> Hazardous ingredients according to Regulation (EC) No. 1272/2008 Not applicable.	
4. FIRST AID MEASURES 4.1 Description of first aid measures General information <i>No special measures required.</i> Inhalation	

	<p><i>The product is not a respiratory irritant.</i></p> <p>Skin contact <i>The product is not skin irritating.</i></p> <p>Eye contact <i>Flush with plenty of water. Consult a doctor if irritation occurs.</i></p> <p>Ingestion <i>Drink plenty of water. Induce vomiting and consult a doctor.</i></p> <p>4.2 Most important symptoms and effects, both acute and delayed None.</p> <p>4.3 Indication of any immediate medical attention and special treatment needed No.</p>
<p>5.</p> <p>5.1</p>	<p>FIRE – FIGHTING MEASURES</p> <p>Extinguishing media Suitable extinguishing media Water spray, foam, dry powder, carbon dioxide. Unsuitable extinguishing media for safety reasons Water with full yet.</p> <p>5.2 Special hazards arising from the substance or mixture No.</p> <p>5.3 Advice for firefighters <i>Use water spray to cool unopened containers.</i></p>
<p>6.</p> <p>6.1</p> <p>6.2</p> <p>6.3</p> <p>6.4</p>	<p>ACCIDENTAL RELEASE MEASURES</p> <p>Personal precautions, protective equipment and emergency procedures <i>No special measures required. No dangerous materials are released.</i></p> <p>Environmental precautions <i>No special measures required.</i></p> <p>Methods and material for containment and cleaning up Clean up mechanically. Dispose of in accordance with regulations.</p> <p>Reference to other sections 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.</p>
<p>7.</p> <p>7.1</p> <p>7.2</p> <p>7.3</p>	<p>HANDLING AND STORAGE</p> <p>Precautions for safe handling Safe handling advice <i>Only adequately trained personnel should handle the product. Use hygienic measures for dental practise.</i></p> <p>Information on fire and explosion protection No special precautions required.</p> <p>Conditions for safe storage, including any incompatibilities Storage Requirements for storage areas Keep the powder only in the original vessel in cool and dry place. Expiry date Considering the instructions for safety storage and handling the expiry date of the powder is five years.</p> <p>Specific end use(s) None.</p>
<p>8.</p> <p>8.1</p> <p>8.2</p>	<p>EXPOSURE CONTROLS /PERSONAL PROTECTION</p> <p>Control parameters Ingredients with limit values that require monitoring at the workplace: <i>Substance contains no componenets 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/m³.</i></p> <p>Exposure controls</p>

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/m³

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

Vapour pressure (Pa): Not applicable

Vapour density (Air=1): Not applicable

Density (g/cm³): 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

/

Acute oral toxicity

LD₅₀ 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.

13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods Product: 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 Uncleaned packaging: Disposal should be made in accordance with local, state and national legislation.
14. TRANSPORT INFORMATION
14.1 UN number: Not applicable. The product is not dangerous according to transport regulations.
14.2 UN proper shipping name See Section 14.1.
14.3 Transport hazard class(es) See Section 14.1.
14.4 Packing group ADR, IMDG, IATA: See Section 14.1.
14.5 Environmental hazards Marine pollutant: Not classified as a marine pollutant.
14.6 Special precautions for user Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.
14.8 Transport additional information Not applicable.
15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture 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>
15.2 Chemical Safety Assessment A chemical safety assessment has not been carried out by the supplier.
16. OTHER INFORMATION 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> New versions of Safety Data Sheet will be <i>laying printed</i> for the data compared to the previous version altered.

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

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