

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING INFORMATION ON THE PRODUCT 1.1 Product identifier Trade name POLITEM POWDER 1.2 Relevant identifier uses of the substance or mixture and uses advised against Recommended use Material for the fabrication of temporary crowns and bridges. 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. 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 Product contents polymethylmethacrylate, pigments and dibenzoyl peroxide. Hazardous ingredients according to Regulation (EC) No. 1272/2008 Not applicable.	
4. FIRST AID MEASURES 4.1 Description of first aid measures General information Remove contaminated clothing. Inhalation Remove the casualty into fresh air. In case of complaints obtain medical attention. Skin contact Wash off immediately with water. If skin irritation occurs obtain medical attention. Eye contact Rinse opened eye with plenty of water and if it is necessary obtain medical attention.	
Ingestion Do not induce vomiting. Rinse mouth. In case of complaints obtain medical attention. 4.2 Most important symptoms and effects, both acute and delayed	

4.3	None known. Indication of any immediate medical attention and special treatment needed Treat symptomatically.
5.	FIRE – FIGHTING MEASURES 5.1 Extinguishing media Suitable extinguishing media Water spray, foam, dry powder, carbon dioxide. Unsuitable extinguishing media for safety reasons Water with full yet. 5.2 Special hazards arising from the substance or mixture Dangerous gases may be released in case of fire. 5.3 Advice for firefighters Wear self-contained breathing apparatus and suitable protective clothing.
6.	ACCIDENTAL RELEASE MEASURES 6.1 Personal precautions, protective equipment and emergency procedures Avoid dust formation. Ensure suitable personal protection (including respiratory protection) during removal of spillages. 6.2 Environmental precautions Prevent product from getting into drains, surface water or ground water. 6.3 Methods and material for containment and cleaning up Pick up mechanically. Dispose of in accordance with regulations. 6.4 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.
7.	HANDLING AND STORAGE 7.1 Precautions for safe handling Safe handling advice Avoid the formation and deposition of dust. Information on fire and explosion protection No special precautions required.
7.2	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. Empiry date Considering the instructions for safety storage and handling the expiry date of the powder is five years.
7.3	Specific end use(s) None.
8.	EXPOSURE CONTROLS /PERSONAL PROTECTION 8.1 Control parameters Ingredients with limit values that require monitoring at the workplace: The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace. 8.2 Exposure controls 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 <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's 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: A1, A2, A3, A3.5, B3, C2, D3, Incisal

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/cm³): 1,16 at 20 °C

Bulk density (kg/m³): ca. 700 at 20 °C

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

10.6	Strong oxidizing agents. Hazardous decomposition products None when used and stored as prescribed. Dangerous gases may be released in case of fire.
11.	TOXICOLOGICAL INFORMATION
11.1	Information on toxicological effects Acute toxicity No specific test data available. No evidence for hazardous properties. Skin irritation No specific test data available. No evidence for hazardous properties. Eye contact No specific test data available. No evidence for hazardous properties. Sensitization No specific test data available. No evidence for hazardous properties. CMR effects No. Repeated dose toxicity No specific test data available. No evidence for hazardous properties. Further information on toxicology 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.
12.	ECOLOGICAL INFORMATION
12.1	Toxicity Hazardous to the aquatic environment No specific test data available. No evidence for hazardous properties.
12.2	Persistence and degradability No specific test data available. No evidence for hazardous properties.
12.3	Bioaccumulative potential No specific test data available. No evidence for hazardous properties.
12.4	Mobility in soil No specific test data available. 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. 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.
15.2	Chemical Safety Assessment
	A chemical safety assessment has not been carried out for this mixture.
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.
	New versions of Safety Data Sheet will be <i>laying printed</i> for the data compared to the previous version altered.