

 **EC - Safety Data Sheet****1. Substance / Preparation and company name****1.1 Name of substance or preparation**

DD medical PMMA:

- DD Bio Splint P (clear/transparent)

- DD tempMED (colored)

**1.2 Use of substance / preparation**

**DD tempMED** are pre-colored dental milling blanks out of PMMA for the manufacture of temporary crowns and bridges for long-term application in the oral cavity up to 12 months.

**DD Bio Splint P** are transparent dental milling blanks out of PMMA for the manufacture of splints, therapeutic splints, bite regulators and drilling templates for long-term application in the oral cavity up to 12 months.

**1.3 Company name**

Dental Direkt GmbH

Industriezentrum 106-108

32139 Spenge

Germany

**2. Composition / information on ingredients**

Polymethyl methacrylate (PMMA): 100 weight %

Color pigments (only DD tempMED): ≤ 0.2 weight %

**3. Possible risks**

No classification

**4. First aid measures****Cause**

Inhalation

Skin contact

Eye contact

Swallowing

**Remedy**

Bring into fresh air and drink a lot of water. Contact a doctor if discomfort continues.

Wash thoroughly with cold water and soap. Consult a doctor should skin irritation occur.

Wash out immediately with copious amounts of cool water. Consult a doctor if irritation persists.

Consult a doctor if allergic discomfort continues.

**5. Fire fighting measures****Indication**

Suitable extinguishing agent:

Unsuitable extinguishing agent:

Special risks:

Special protective equipment

for fire fighting:

Additional instructions:

**Comment**Carbon dioxide (CO<sub>2</sub>), extinguishing powder, foam, water

Unknown

Irritant vapors mainly out of methyl acrylate and methyl methacrylate occur in case of fire. Do not inhalation fire and explosive gases.

Wear respiratory protective equipment independent of ambient air in case of fire.

Prevent extinguishing water from penetration surface water or the ground water system

**6. Measures in case of unintended release****6.1 Personal precautionary measures**

Use personal protective equipment.

**6.2 Environmental protection measures**

Prevent from penetrating surface water or the sewer system.

**6.3 Cleaning procedure**

Pick up mechanically, avoid dust formation, fill into labelled, closable containers

## 7. Handling and storage

### 7.1 Handling

This product should only be handled by trained personnel.

Ensure that

- adequate ventilation and a suitable extraction system is available.
- occupational exposure limits (OEL) and / or other limit values are observed

### 7.2 Storage

Ensure that the blanks:

- are stored dry and protected from light in their original packaging
- are not exposed to blows or severe vibration
- are not contaminated
- are stored between 5°C and 50°C.

Instructions for common storage: Adhere to VCI storage system rules

VCI storage class: 11, flammable solids

### 7.3 Specific usage

Please observe instructions for use.

## 8. Exposure control and personal protective equipment

### 8.1 Exposure limits

#### General dust limit value

##### TRGS 900

General dust limit value

Alveolar fraction

Value 3 mg/m<sup>3</sup>

Peak limit 2 (II)

##### TRGS 900

General dust limit value

Inhalable fraction

Value 10 mg/m<sup>3</sup>

Peak limit 2 (II)

#### Methyl methacrylate

CAS no. 80-62-6

EG no. 201-297-1

##### TRGS 900

Value 210 mg/m<sup>3</sup> 50 ml/m<sup>3</sup>

Peak limit 2 (I)

Y = A risk of foetal damage is ceased to fear if AGW and BGW will be complied to.

Indicative occupational exposure limit values - Directive 2009/161/EC 50 ppm

Indicative occupational exposure limit values - Directive 2009/161/EC (15 minutes) 100 ppm

### 8.2 Personal protective equipment

#### Protection

Respiratory protection

Hand protection

Eye protection

Body protection

General protective measures

#### Description

Respiratory protection with particle filter EN 143

Glove materials EN 374-3

Polyvinyl chloride (PVC): Thickness ≥ 0.5 mm

Wear safety glasses during grinding work.

Protective clothing

The precautionary measures usual when handling chemicals should be observed. Store working clothes separately

## 9. Physical and chemical properties

Physical properties	Value	Norm
Flexural strength	≥ 75 MPa	EN ISO 20795
Flexural modulus	2800 ± 0.2	EN ISO 20795
Water absorption	≤ 23 µg/mm <sup>3</sup>	EN ISO 20795
Solubility	0.2 µg/mm <sup>3</sup>	EN ISO 20795
Residual monomer content	0.42 %	EN ISO 20795

### 9.1 General information

#### Description

Appearance	industrially-manufactured solid
Colour	crystal clear (transparent) / coloured
Odour	odourless

### 9.2 Important information regarding health and environmental protection and safety

#### Description

pH value	no data available
Explosion limits	no data available
Self-flammability	no data available
Solubility	water insoluble

## 10. Stability and reactivity

### 10.1 Conditions to be avoided

None known

### 10.2 Substances to be avoided

None known

### 10.3 Hazardous degradation products

Toxic gas mixtures with mainly CO and CO<sub>2</sub> develop at incomplete combustion or carbonization.

### 10.4 Thermal degradation

There can be harmful gases and vapors in case of fire or overheating e. g. improper processing.

## 11. Toxicological information

Toxicological information not available

## 12. Ecological information

### 12.1 Ecotoxicity

The product is insoluble in water.  
No ecological problems should be expected if handled and used correctly.

### 12.2 Mobility

Not applicable

### 12.3 Persistence and degradability

The product is not easily biodegradable.

### 12.4 Bioaccumulation potential

Unknown

### 12.5 Other harmful effects

Unknown

### 13. Disposal instructions

#### 13.1 Product

- Product: - Disposal should conform to federal/national and local regulations  
Packaging: - Non-contaminated and cleaned packaging can be recycled

### 14. Transportation information

#### Specifications

Land transportation ADR/RID

Air transportation ICAO-TI/IATA-DGR

Sea transportation

#### Description

Not hazardous substance

Not hazardous substance

Not hazardous substance

### 15. Legal provisions

#### 15.1 Labelling in compliance with EU Directive

- Product according to the rules 93/42/EEG of medical devices.  
Product according to GefStoffV/EG no subject to labelling.

#### 15.2 National regulations

Water pollution class nwg (not hazardous to water) according to annex 4 VwVwS

### 16. Other information

Information in this safety data sheet is based on the current state of knowledge and experience. The safety data sheet describes products with regard to safety requirements. However, these specifications are no guarantee of product characteristics and do not establish any contractually-legal relationship. The information is designed to provide you with a guide to safe handling of products mentioned in the safety data sheet during storage, transportation, processing and disposal. Insofar as the product named in this safety data sheet is blended, mixed or processed with other materials, or subject to processing, the information in this safety data sheet cannot be transferred to the new material manufactured in this manner, provided nothing else is expressly achieved from this. The information does not have the importance of statements of condition, assurances of certain characteristics or guarantees.