

**DD Bio Splint P HI**

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1. Product identifier**

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**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Use of the substance/mixture**

Dental Direkt plastic milling blanks are intended for the fabrication of fixed or removable dentures and dental splints.

**Uses advised against**

No information available.

**1.3. Details of the supplier of the safety data sheet**

Company name:	Dental Direkt GmbH	
Street:	Industriezentrum 106-108	
Place:	D-32139 Spenge	
Telephone:	05225 - 8 63 19-0	Telefax: 05225 - 8 63 19-99
E-mail:	info@dentaldirekt.de	
Internet:	www.dentaldirekt.de	
Responsible Department:	info@dentaldirekt.de	

**1.4. Emergency telephone number:**

+49 (0) 761 19240 (VIZ Freiburg); Poisons information Centre of Ireland +353 1 809 21 66; <http://www.poisons.ie/Public>

**Further Information**

Medical device

**SECTION 2: Hazards identification**

**2.1. Classification of the substance or mixture**

**Regulation (EC) No 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

**2.2. Label elements**

**2.3. Other hazards**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

Dust can form an explosive mixture with air.  
Comb. Dust (Combustible Dust)

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria. This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

**SECTION 3: Composition/information on ingredients**

**3.2. Mixtures**

**Chemical characterization**

POLYMETHYL METHACRYLATE

**Relevant ingredients**

none (according to Regulation (EC) No 1907/2006 (REACH))

**Further Information**

No information available.

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**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

In case of allergic symptoms, especially in the breathing area, seek medical advice immediately.  
Never give anything by mouth to an unconscious person or a person with cramps.  
In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

**After inhalation**

Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.

**After contact with skin**

After contact with skin, wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.

**After contact with eyes**

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

**After ingestion**

IF SWALLOWED: Call a doctor if you feel unwell.  
Rinse mouth immediately and drink 1 glass of water.  
Never give anything by mouth to an unconscious person or a person with cramps.

**4.2. Most important symptoms and effects, both acute and delayed**

Reference to other sections: 11

**4.3. Indication of any immediate medical attention and special treatment needed**

First Aid, decontamination, treatment of symptoms.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Dry extinguishing powder, Carbon dioxide (CO<sub>2</sub>), Foam, Extinguishing powder

**Unsuitable extinguishing media**

Full water jet

**5.2. Special hazards arising from the substance or mixture**

In case of fire may be liberated: Methyl acrylate, Methyl methacrylate, styrene, butyl acrylate  
Do not inhale explosion and combustion gases.  
May form combustible dust concentrations in air.

**5.3. Advice for firefighters**

In case of fire: Evacuate area.  
Move undamaged containers from immediate hazard area if it can be done safely.  
Special protective equipment for firefighters: Flame-retardant protective clothing  
In case of fire: Wear a self-contained breathing apparatus and chemical protective clothing.

**Additional information**

Use water spray to cool containers.  
Do not allow run-off from fire-fighting to enter drains or water courses.  
Residues of fire and contaminated water have to be disposed according to the local regulations.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

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**General advice**

See protective measures under point 7 and 8.  
Personal protection equipment: see section 8  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Remove all sources of ignition. Take precautionary measures against static discharges.  
Provide adequate ventilation.  
Avoid dust formation. In case of inadequate ventilation wear respiratory protection.  
Avoid contact with skin, eyes and clothes.

**For non-emergency personnel**

Remove persons to safety.  
Stop leak if safe to do so.

**For emergency responders**

Knock down dust with water spray jet.

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains.  
Do not allow to enter into soil/subsoil.

**6.3. Methods and material for containment and cleaning up****For containment**

Take up mechanically. Use approved industrial vacuum cleaner for removal. Avoid dust formation. Collect in closed and suitable containers for disposal. Dispose of waste according to applicable legislation.

**For cleaning up**

Cleaning agent: Water

Dust:

Do not use a brush or compressed air for cleaning surfaces or clothing. Do not use a dry brush as dust clouds or static can be created. Use approved industrial vacuum cleaner for removal.

**Other information**

Provide fresh air.

**6.4. Reference to other sections**

Safe handling: see section 7  
Personal protection equipment: see section 8  
Disposal: see section 13

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Wear personal protection equipment (refer to section 8).  
Avoid contact with skin, eyes and clothes.  
Avoid release to the environment.  
Avoid dust formation. Devices with local exhaust  
In case of inadequate ventilation wear respiratory protection.  
Floors, walls and other surfaces in the hazard area must be cleaned regularly.

**Advice on protection against fire and explosion**

Use explosion-proof machinery, apparatus, ventilation facilities, tools etc.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
May form combustible dust concentrations in air.  
Take precautionary measures against static discharges.

**Advice on general occupational hygiene**

Work in well-ventilated zones or use proper respiratory protection.  
Only wear fitting, comfortable and clean protective clothing.  
Wash hands before breaks and after work.

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Separate storage of work clothes.  
 Make available sufficient washing facilities  
 Draw up and observe skin protection programme.

#### Further information on handling

Observe instructions for use.  
 Working places should be designed to allow cleaning at any time .

#### 7.2. Conditions for safe storage, including any incompatibilities

##### Requirements for storage rooms and vessels

Store in a dry place. Keep only in the original container in a cool, well-ventilated place.

##### Hints on joint storage

Keep away from food, drink and animal feedingstuffs.  
 Keep away from: Oxidizing agent

##### Further information on storage conditions

Keep away from: Frost, Heat, UV-radiation/sunlight  
 Handle with care - avoid bumps, friction and impact.

#### 7.3. Specific end use(s)

Reference to other sections: 1.2

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

CAS No	Substance	ppm	mg/m <sup>3</sup>	fib/cm <sup>3</sup>	Category	Origin
-	Dusts non-specific, respirable	-	4		TWA (8 h)	
-	Dusts non-specific, total inhalable	-	10		TWA (8 h)	
96-33-3	Methyl acrylate	2	7		TWA (8 h)	
80-62-6	Methyl methacrylate	50	-		TWA (8 h)	
		100	-		STEL (15 min)	
141-32-2	n-Butyl acrylate	2	11		TWA (8 h)	
		10	53		STEL (15 min)	
100-42-5	Styrene	20	85		TWA (8 h)	
		40	170		STEL (15 min)	

#### Biological limit values

CAS No	Substance	Parameter	Value	Test material	Sampling time
100-42-5	Styrene	Mandelic acid plus phenylglyoxylic acid	400 mg/g	Creatinine	End of shift

#### Additional advice on limit values

When processing this product, especially in the thermal process, the regulations for the substances listed below must be observed. By using effective devices for ventilation and extraction at the discharge points , the limit values of any vapours that may be generated can be complied with.

- methyl 2-methylprop-2-enoate; methyl 2-methylpropenoate; methyl methacrylate
- butyl acrylate
- styrene
- methyl acrylate; methyl propenoate

### 8.2. Exposure controls

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**Appropriate engineering controls**

Provide adequate ventilation as well as local exhaustion at critical locations.  
dust formation: Provide earthing of containers, equipment, pumps and ventilation facilities.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

IF exposed or concerned: Suitable eye protection: EN 166  
Eye glasses with side protection  
goggles

**Hand protection**

The selection and use of protective gloves and protective clothing should be based on a work area analysis. Factors such as exposure limit values, concentration of the hazardous substance, frequency and duration of exposure, physical conditions such as temperature should be taken into account when making the selection. To select suitable materials, please consult the manufacturers of personal protective equipment.

Suitable gloves type EN ISO 374  
Suitable material: PVC (polyvinyl chloride)  
Thickness of the glove material:  $\geq 0,5$  mm

Breakthrough times and swelling properties of the material must be taken into consideration. Observe the wear time limits as specified by the manufacturer.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.  
Wear cotton undermitten if possible.

Use heat-insulating protective gloves for thermal processing.

**Skin protection**

antistatic Protective clothing.  
Wear fire resistant or flame retardant clothing.

**Respiratory protection**

Respiratory protection necessary at: exceeding exposure limit values, Formation of: dust/mist/vapour  
If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Particle filter device (EN 143)

Formation of: vapour  
Type A2, Self-contained respirator (breathing apparatus)

**Thermal hazards**

Formation of organic vapours  
Do not breathe mist/vapours/spray.  
Incineration

**Environmental exposure controls**

Dust must be exhausted directly at the point of origin.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	solid
Colour:	various
Odour:	odourless

Melting point/freezing point:

**Test method**  
No data available

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Boiling point or initial boiling point and boiling range:	No data available
Flammability:	>300 °C
Lower explosion limits:	No data available
Upper explosion limits:	No data available
Flash point:	No data available
Decomposition temperature:	>350 °C
pH-Value:	No data available
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.
Solubility in other solvents	
miscible with most organic solvents	
Partition coefficient n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	~1,17 g/cm <sup>3</sup>
Relative vapour density:	not determined

**9.2. Other information****Information with regard to physical hazard classes**

## Explosive properties

May form combustible dust concentrations in air.

## Sustained combustibility:

No data available

## Self-ignition temperature

Solid:

No data available

Gas:

No data available

## Oxidizing properties

Not oxidising.

**Other safety characteristics**

## Evaporation rate:

No data available

## Solid content:

100%

## Sublimation point:

No data available

## Softening point:

&gt;90°C °C ISO 306

## Pour point:

No data available

## Viscosity / dynamic:

No data available

**Further Information**

No information available.

**SECTION 10: Stability and reactivity****10.1. Reactivity**

This material is considered to be non-reactive under normal use conditions.

**10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

**10.3. Possibility of hazardous reactions**

May form combustible dust concentrations in air.

**10.4. Conditions to avoid**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Generation/formation of dust: Avoid dust formation.

Take precautionary measures against static discharges. Take action to prevent static discharges.

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**10.5. Incompatible materials**

Oxidizing agent

**10.6. Hazardous decomposition products**

Carbon dioxide (CO<sub>2</sub>), Carbon monoxide, Monomers

**Further information**

No data available

**SECTION 11: Toxicological information**

**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

**Toxicokinetics, metabolism and distribution**

No information available.

**Acute toxicity**

Based on available data, the classification criteria are not met.

**ATEmix calculated**

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

**Irritation and corrosivity**

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

**Sensitising effects**

Based on available data, the classification criteria are not met.

**Carcinogenic/mutagenic/toxic effects for reproduction**

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Based on available data, the classification criteria are not met.

**STOT-single exposure**

Based on available data, the classification criteria are not met.

**STOT-repeated exposure**

Based on available data, the classification criteria are not met.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Practical experience**

The melted product can cause severe burns.

**11.2. Information on other hazards**

**Endocrine disrupting properties**

No data available

**Further information**

Calculation method.

**SECTION 12: Ecological information**

**12.1. Toxicity**

Based on available data, the classification criteria are not met.

No information available.

**12.2. Persistence and degradability**

The product is: Not readily biodegradable (according to OECD criteria)

**12.3. Bioaccumulative potential**

No information available.

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**12.4. Mobility in soil**

No information available.

**12.5. Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

**12.6. Endocrine disrupting properties**

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

**12.7. Other adverse effects**

No information available.

**Further information**

water hazard class: non-hazardous to water

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations**

Dispose of waste according to applicable legislation. The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. (AVV 120105, 160306)

Non hazardous waste according to Directive 2008/98/EC (waste framework directive).

flue-gas dust / Dust

place in a designated, labeled waste container  
Put lids on containers immediately after use.**List of Wastes Code - residues/unused products**

160306 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; off-specification batches and unused products; organic wastes other than those mentioned in 16 03 05

**Contaminated packaging**Dispose of waste according to applicable legislation.  
Completely emptied packages can be recycled.  
Collect the waste separately.**SECTION 14: Transport information****Land transport (ADR/RID)**

<b><u>14.1. UN number or ID number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of this transport regulation.

**Inland waterways transport (ADN)**

<b><u>14.1. UN number or ID number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of this transport regulation.

**Marine transport (IMDG)**

<b><u>14.1. UN number or ID number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of this transport regulation.

**Air transport (ICAO-TI/IATA-DGR)**

<b><u>14.1. UN number or ID number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.

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**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.

**14.4. Packing group:** No dangerous good in sense of this transport regulation.

**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

**14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

**14.7. Maritime transport in bulk according to IMO instruments**

No dangerous good in sense of this transport regulation.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Information according to Directive 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

**Additional information**

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)  
Classification according to Regulation (EC) No 1272/2008 [CLP]  
COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)  
Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste  
Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

**National regulatory information**

Water hazard class (D): - - non-hazardous to water

**Additional information**

Germany To follow:  
<https://sicheres-dentallabor.bgetem.de/dentallabor>  
DGUV Regel 113-606 "Teil 1: Spritzgießen"  
Dust fires and dust explosions - Hazards - assessment - safety measures

Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)

TRGS 220, TRGS 400ff., TRGS 500, TRGS 722-724, TRGS 800, TRGS 900

**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: Other information****Changes**

This data sheet contains changes from the previous version in section(s): 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15.

**Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road )  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer  
(Regulations Concerning the International Transport of Dangerous Goods by Rail )  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
ICAO: International Civil Aviation Organization  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures,  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
EC50: Effect concentration, 50 percent  
DNEL: Derived No Effect Level  
PNEC: Predicted No Effect Concentration  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative

**Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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*(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*