

**DD Bio Splint FLEX**

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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**

plastic (Medical device)

**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	
Contact person:	main office	Telephone: 05225 - 8 63 19-0
Internet:	www.dentaldirekt.de	
Responsible Department:	info@dentaldirekt.de	

**1.4. Emergency telephone number:** +49 (0) 761 19240 (VIZ Freiburg)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****GB CLP Regulation**

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

**2.2. Label elements****2.3. Other hazards**

The melted product can cause severe burns.

May form combustible dust concentrations in air.

Results of PBT and vPvB assessment

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

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Polyethylene terephthalate glycol (PETG)

Polymer (This substance is exempted from the registration provisions according to REACH Article 2 (9).)

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

The melted product can cause severe burns.

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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**After inhalation**

Remove person to fresh air and keep comfortable for breathing. Put victim at rest, cover with a blanket and keep warm. If experiencing respiratory symptoms: Call a doctor.

**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 molten product, cool skin area rapidly with cold water.

**After contact with eyes**

Protect uninjured eye. In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Remove contact lenses, if present and easy to do. Continue rinsing.

**After ingestion**

Call a physician in any case!

Rinse mouth thoroughly with water. Let 1 glass of water be drunken in little sips (dilution effect). Never give anything by mouth to an unconscious person or a person with cramps.

Do NOT induce vomiting.

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

No information available.

**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**

Carbon dioxide (CO<sub>2</sub>), Dry extinguishing powder, Water spray jet

**Unsuitable extinguishing media**

Full water jet

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

Take action to prevent static discharges. Provide earthing of containers, equipment, pumps and ventilation facilities. Use explosion-proof machinery, apparatus, ventilation facilities, tools etc.

May form combustible dust concentrations in air.

Do not inhale explosion and combustion gases.

In case of fire may be liberated:

Carbon dioxide (CO<sub>2</sub>), Carbon monoxide, Nitrogen oxides (NO<sub>x</sub>)

**5.3. Advice for firefighters**

Avoid: Generation/formation of dust

Wear protective gloves/protective clothing.

In case of fire: Wear self-contained breathing apparatus.

**Additional information**

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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****General measures**

See protective measures under point 7 and 8.

Remove all sources of ignition.

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

Provide adequate ventilation.

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Clear spills immediately.

Measures to prevent aerosol and dust generation.

**For non-emergency personnel**

Remove persons to safety.

**For emergency responders**

No data available

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

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

Stop leak if safe to do so.

Take up mechanically, placing in appropriate containers for disposal.

Knock down dust with water spray jet.

**For cleaning up**

Clean with detergents. Avoid solvent cleaners.

**Other information**

Dispose of waste according to applicable legislation.

**6.4. Reference to other sections**

See protective measures under point 7 and 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. Do not allow to enter into surface water or drains.

Avoid: Generation/formation of dust, Dust deposits

Ventilate affected area. In case of inadequate ventilation wear respiratory protection.

**Advice on protection against fire and explosion**

May form combustible dust concentrations in air.

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

Take precautionary measures against static discharges.

Provide earthing of containers, equipment, pumps and ventilation facilities.

Use explosion-proof machinery, apparatus, ventilation facilities, tools etc.

**Advice on general occupational hygiene**

Minimum protective measures according to TRGS 500 (Germany)

Only wear fitting, comfortable and clean protective clothing.

When using do not eat, drink, smoke, sniff.

Wash hands before breaks and after work.

Take off contaminated clothing and wash it before reuse.

Apply skin care products after work.

Make available sufficient washing facilities Provide eye shower and label its location conspicuously

**Further information on handling**

Observe instructions for use.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Keep container tightly closed. Keep only in original packaging. Store in a cool dry place.

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Avoid: UV-radiation/sunlight

### Hints on joint storage

Keep away from: Food and feedingstuffs

Do not store together with: Oxidising agent, strong

### Further information on storage conditions

Keep away from: Heat, extreme temperatures

Protect from sunlight. Store in a well-ventilated place.

Protect from moisture.

### 7.3. Specific end use(s)

plastics

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure limits (EH40)

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
-	Dust, inhalable	-	10		TWA (8 h)	WEL
-	Dust, respirable	-	4		TWA (8 h)	WEL

#### Additional advice on limit values

Observe in addition any national regulations!

### 8.2. Exposure controls

#### Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

Minimum room ventilation rate for handling/application (air changes per hour): 10

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

Provide earthing of containers, equipment, pumps and ventilation facilities.

Use explosion-proof machinery, apparatus, ventilation facilities, tools etc.

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

##### Eye/face protection

Dust protection eye glasses DIN EN 166

In case of warming: Wear face protection.

##### Hand protection

Tested protective gloves must be worn: EN ISO 374

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances.

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.

Thickness of the glove material, Breakthrough times and swelling properties of the material must be taken into consideration.

Observe the wear time limits as specified by the manufacturer.

In case of warming: If the material is heated, wear gloves to protect against thermal burns.

##### Skin protection

Wear suitable protective clothing.

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### Respiratory protection

Respiratory protection necessary at: exceeding exposure limit values, insufficient ventilation, dust formation  
Use appropriate respiratory protection. Full-/half-/quarter-face masks (DIN EN 136/140), Particle filter device (DIN EN 143). Observe the wear time limits according GefStoffV in combination with the rules for using respiratory protection apparatus (BGR 190). 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.

### Thermal hazards

Incineration

### Environmental exposure controls

Clear spills immediately.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	solid (granulate)
Colour:	various
Odour:	characteristic

#### Changes in the physical state

Melting point/freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Sublimation point:	No data available
Softening point:	No data available
Pour point:	No data available
Flash point:	No data available

#### Explosive properties

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

Lower explosion limits:	No data available
Upper explosion limits:	No data available
Auto-ignition temperature:	No data available

#### Self-ignition temperature

Solid:	No data available
Gas:	No data available

Decomposition temperature:	No data available
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#### Oxidizing properties

No data available

pH-Value:	No data available
Water solubility:	poorly soluble

#### Solubility in other solvents

No data available

Partition coefficient n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	>1 g/cm <sup>3</sup>
Relative vapour density:	No data available

### 9.2. Other information

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**Information with regard to physical hazard classes**

Sustaining combustion:

No data available

**Other safety characteristics**

Evaporation rate:

No data available

**Further Information**

No information available.

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

No known hazardous reactions.

**10.2. Chemical stability**

The product is chemically stable under recommended conditions of storage, use and temperature.

**10.3. Possibility of hazardous reactions**

No known hazardous reactions.

**10.4. Conditions to avoid**

The product is stable under storage at normal ambient temperatures.

**10.5. Incompatible materials**

Oxidising agent, strong

**10.6. Hazardous decomposition products**

In case of fire: Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx)

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in GB CLP Regulation****Acute toxicity**

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

**Irritation and corrosivity**

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**

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 information available.

**SECTION 12: Ecological information****12.1. Toxicity**

No information available.

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**12.2. Persistence and degradability**

No information available.

**12.3. Bioaccumulative potential**

No information available.

**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**

No information available.

**12.7. Other adverse effects**

No information available.

**Further information**

Do not allow to enter into surface water or drains.

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

Dispose of waste according to applicable legislation.

Recycle according to official regulations.

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

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

**List of Wastes Code - residues/unused products**

070213 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and man-made fibres; waste plastic

**Contaminated packaging**

Dispose of waste according to applicable legislation.

Recycle according to official regulations.

Completely emptied packages can be recycled.

**SECTION 14: Transport information****Land transport (ADR/RID)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**Inland waterways transport (ADN)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**Marine transport (IMDG)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**Air transport (ICAO-TI/IATA-DGR)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

**14.6. Special precautions for user**

No information available.

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

No information available.

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## SECTION 15: Regulatory information

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

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

**Additional information**

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)  
Classification according to Regulation (EC) No 1272/2008 [CLP]  
DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008  
on waste and repealing certain Directives  
DECISIONS COMMISSION DECISION of 18 December 2014 amending Decision 2000/532/EC on the list of  
waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council

**National regulatory information**

Water hazard class (D): 1 - slightly hazardous to water

**Additional information**

Germany:  
Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)  
To follow: TRGS 500, TRGS 720 ff., TRGS 727, TRGS 900

**15.2. Chemical safety assessment**

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

## SECTION 16: Other information

**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)  
CLP: Classification, labelling and Packaging  
REACH: Registration, Evaluation and Authorization of Chemicals  
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals  
UN: United Nations  
CAS: Chemical Abstracts Service  
DNEL: Derived No Effect Level  
DMEL: Derived Minimal Effect Level  
PNEC: Predicted No Effect Concentration  
ATE: Acute toxicity estimate  
LC50: Lethal concentration, 50%  
LD50: Lethal dose, 50%  
LL50: Lethal loading, 50%  
EL50: Effect loading, 50%  
EC50: Effective Concentration 50%  
ErC50: Effective Concentration 50%, growth rate  
NOEC: No Observed Effect Concentration  
BCF: Bio-concentration factor  
PBT: persistent, bioaccumulative, toxic



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vPvB: very persistent, very bioaccumulative  
MARPOL: International Convention for the Prevention of Marine Pollution from Ships  
IBC: Intermediate Bulk Container  
SVHC: Substance of Very High Concern  
TWA: time-weighted-average  
WEL: working place exposure limits  
STOT: specific target organ toxicity

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#### 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 hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*