

According to Regulation (EC) No 1907/2006  
Revision date: 23.08.2016 Revision No: 02

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## Splint PMMA BioStar

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

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- 1.1 Product identifier:**  
**Commercial product name:** Splint PMMA BioStar
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**  
**Use of the substance/mixture:** Splint PMMA BioStar polymer milling blanks are intended for the fabrication of fixed or removable restorations as well as dental splints.  
**Uses advised against:** No information available.
- 1.3 Details of the supplier of the safety data sheet**
- Manufacturer:** Dental Direkt GmbH  
Street: Industriezentrum 106-108  
Place: DE-32139 Spenge  
Telephone: +49-(0)5225 - 8 63 19-0  
Telefax: +49-(0)5225 - 8 63 19-99  
e-mail: [info@dentaldirekt.de](mailto:info@dentaldirekt.de)  
Internet: [www.dentaldirekt.de](http://www.dentaldirekt.de)  
Responsible Department: [info@dentaldirekt.de](mailto:info@dentaldirekt.de)
- Supplier:** SILADENT Dr. Böhme & Schöps GmbH  
Street / mailbox: Im Klei 26  
Country code. / postal code / city: DE - 38644 Goslar  
Phone: +49 (0) 53 21 / 37 79 - 0  
Fax: +49 (0) 53 21 / 38 96 32  
E-mail / Website: [info@siladent.de](mailto:info@siladent.de) / [www.siladent.de](http://www.siladent.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

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- 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)

### SECTION 3: Composition/information on ingredients

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- 3.2 Mixtures**  
**Chemical characterization:** POLYMETHYL METHACRYLATE  
**Hazardous components:** none (according to Regulation (EC) No 1907/2006 (REACH))  
**Further Information:** No information available

### SECTION 4: First aid measures

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- 4.1 Description of first aid measures**

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<b>General information:</b>	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).
<b>After inhalation:</b>	Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.
<b>After contact with skin:</b>	After contact with skin, wash immediately with plenty of water and soap. If skin irritation occurs: Get medical advice/attention.
<b>After contact with eyes:</b>	Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.
<b>After ingestion:</b>	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.
<b>4.2 Most important symptoms and effects, both acute and delayed:</b>	No information available.
<b>4.3 Indication of any immediate medical attention and special treatment needed:</b>	First Aid, decontamination, treatment of symptoms.

**SECTION 5: Firefighting measures**

<b>5.1 Extinguishing media</b>	
<b>Suitable extinguishing agent:</b>	Dry extinguishing powder, Carbon dioxide (CO <sub>2</sub> ), Foam, Extinguishing powder:
<b>Unsuitable extinguishing media:</b>	Full water jet
<b>5.2 Special hazards arising from the substance or mixture:</b>	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.
<b>5.3 Advice for firefighters:</b>	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.
<b>Additional information:</b>	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.

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

Separate storage of work clothes.

Make available sufficient washing facilities

Draw up and observe skin protection programme.

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**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**

**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

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<b>Hand protection:</b>	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:
<b>Skin protection:</b>	antistatic Protective clothing.
<b>Respiratory protection:</b>	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)
<b>Thermal hazards:</b>	Formation of organic vapours Do not breathe mist/vapours/spray. Incineration
<b>Environmental exposure controls:</b>	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:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flammability	
Solid/liquid:	>300 °C
Gas:	No data available
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

**Test method**

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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.  
 Sustaining combustion: 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: >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:** Heat  
 Generation/formation of dust: Avoid dust formation.  
 Take precautionary measures against static discharges. Take action to prevent static discharges.  
 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

**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 toxicological effects**

**Toxicokinetics, metabolism and distribution:** No information available.

**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.

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<b>STOT-single exposure:</b>	Based on available data, the classification criteria are not met.
<b>STOT-repeated exposure:</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard:</b>	Based on available data, the classification criteria are not met.
<b>Practical experience:</b>	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**

<b>12.1 Toxicity:</b>	No information available.
<b>12.2 Persistence and degradability:</b>	The product is: Not readily biodegradable (according to OECD criteria).
<b>12.3 Bioaccumulative potential:</b>	No information available.
<b>12.4 Mobility in soil:</b>	No information available.
<b>12.5 Results of PBT and vPvB assessment:</b>	The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.
<b>12.6 Endocrine disrupting properties:</b>	This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.
<b>12.7 Other adverse effects:</b>	No information available.
<b>Further information:</b>	water hazard class: non-hazardous to water

**SECTION 13: Disposal considerations**

<b>13.1 Waste treatment methods</b>	
<b>Disposal recommendations:</b>	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, labelled 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.



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**Splint PMMA BioStar****SECTION 14: Transport information****Land transport (ADR/RID)**

- 14.1 UN number or ID number: No dangerous good in sense of this transport regulation.  
 14.2 UN proper shipping name: No dangerous good in sense of this transport regulation.  
 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.

**Inland waterways transport (ADN)**

- 14.1 UN number or ID number: No dangerous good in sense of this transport regulation.  
 14.2 UN proper shipping name: No dangerous good in sense of this transport regulation.  
 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.

**Marine transport (IMDG)**

- 14.1 UN number or ID number: No dangerous good in sense of this transport regulation.  
 14.2 UN proper shipping name: No dangerous good in sense of this transport regulation.  
 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.

**Air transport (ICAO)**

- 14.1 UN number or ID number: No dangerous good in sense of this transport regulation.  
 14.2 UN proper shipping name: No dangerous good in sense of this transport regulation.  
 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 Transport in bulk according to Annex II of Marpol and the IBC Code: 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 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] 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>



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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****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 conernat 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:	Effective 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:

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