

According to Regulation (EC) No 1907/2006

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

- 1.1 Product identifier:**
Commercial product name: Splint Plus BioStar
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Use of the substance/mixture: Splint Plus BioStar 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/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 / www.siladent.de
- 1.4 Emergency telephone number**
SILADENT Dr. Böhme & Schöps GmbH: +49 (0) 53 21 / 37 79 - 0 (Mon-Fri. 8 a.m. - 4 p.m.)
Further Information: Medical devices

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture**
Regulation (EC) No. 1272/2008: This substance is not classified as hazardous according to 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.

SECTION 3: Composition/information on ingredients

- 3.1 Substances**
Chemical characterization: Polycarbonate
Hazardous components: none (according to Regulation (EC) No 1907/2006 (REACH))
Further Information: No information available

SECTION 4: First aid measures

- 4.1 Description of first aid measures**
General information: In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).
Never give anything by mouth to an unconscious person or a person with cramps.
After inhalation: Remove person to fresh air and keep comfortable for breathing. In case of respiratory tract irritation, consult a physician.

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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. Do not peel solidified product off the skin. Immediately call a doctor.

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:

No information available.

4.3 Indication of any immediate medical attention and special treatment needed:

No information available.

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

Dry extinguishing powder, Carbon dioxide (CO₂), Foam, Water spray jet

Unsuitable extinguishing media:

Full water jet

5.2 Special hazards arising from the substance or mixture:

In case of fire may be liberated: Carbon dioxide (CO₂), Carbon monoxide, Nitrogen oxides (NO_x), Hydrogen cyanide (hydrocyanic acid), aldehydes, Phenols
Do not inhale explosion and combustion gases.

5.3 Advice for firefighters:

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 self-contained breathing apparatus.

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**

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.

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	Provide adequate ventilation. Avoid dust formation. In case of inadequate ventilation wear respiratory protection. Avoid contact with skin, eyes and clothes. Special danger of slipping by leaking/spilling product. (granulate) Remove persons to safety.
For non-emergency personnel:	
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). Keep container tightly closed. Avoid contact with skin, eyes and clothes. Avoid release to the environment. Avoid dust formation. Avoid: Dust deposits Do not breathe dust. In case of inadequate ventilation wear respiratory protection. Provide adequate ventilation as well as local exhaustion at critical locations. To follow: Occupational exposure limit values Remove all sources of ignition.
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.

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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

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.

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**

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
80-05-7	Bisphenol A (4,4'-isopropylidenediphenol) (inhalable dust)	-	2		TWA (8 h)	
108-90-7	Chlorobenzene (as monochlorobenzene)	5 15	23 70		TWA (8 h) STEL (15 min)	
-	Dusts non-specific, respirable	-	4		TWA (8 h)	
-	Dusts non-specific, total inhalable	-	10		TWA (8 h)	
108-95-2	Phenol	2 4	8 16		TWA (8 h) STEL (15 min)	

Biological limit values

CAS No	Substance	Parameter	Value	Test material	Sampling time
108-95-2	Phenol	Phenol	120 mg/g	Creatinine	End of shift
108-90-7	Chlorobenzene	4-Chlorocatechol	100 mg/g	Creatinine	End of shift at end of workweek

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.

-chlorobenzene

-phenol

-Bisphenol A; 4,4'-isopropylidenediphenol

-4-tert-butylphenol

8.2 Exposure controls

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Provide adequate ventilation as well as local exhaust ion 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:**

Suitable eye protection: EN 166

Eye glasses with side protection goggles

Hand protection:

Suitable gloves type 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.

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.

Skin protection:

antistatic Protective 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)

Particle filter device (EN 143)

Formation of: vapour

Type A-P3, Self-contained respirator (breathing apparatus)

Thermal hazards:

Formation of organic vapours

Do not breathe mist/vapours/spray.

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:

transparent

Odour:

odourless

Melting point/freezing point:

No data available

Boiling point or initial boiling point and boiling range:

No data available

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Flammability	
Solid/liquid:	No data available
Gas:	No data available
Lower explosion limits:	No data available
Upper explosion limits:	No data available
Flash point:	No data available
Auto-ignition temperature:	>450 °C
Decomposition temperature:	>=380 °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	No information available.
Partition coefficient n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	1,2-1,4 g/cm ³
Bulk density:	600-700 kg/m ³
Relative vapour density:	No data available

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

Explosive properties:	No information available.
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:	No data available
Pour point:	No data available
Viscosity / dynamic:	No data available
Further Information:	No information available.

SECTION 10: Stability and reactivity

10.1 Reactivity:	No information available.
10.2 Chemical stability:	No information available.
10.3 Possibility of hazardous reactions:	May form combustible dust concentrations in air.
10.4 Conditions to avoid:	No information available.
10.5 Incompatible materials:	No information available.
10.6 Hazardous decomposition products:	Carbon dioxide (CO ₂), CO
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.

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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.

11.2 Information on other hazards**Endocrine disrupting properties:**

No data available

Further information:

Calculation method.

SECTION 12: Ecological information

12.1 Toxicity:	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.
12.4 Mobility in soil:	No information available.
12.5 Results of PBT and vPvB assessment:	This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.
12.6 Endocrine disrupting properties:	This substance does not have endocrine disrupting properties with respect to non-target organisms.
12.7 Other adverse effects:	No information available.
Further information:	water hazard class: nwg

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

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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)**

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-TI/IATA-DGR)

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
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14.6 Special precautions for user:

No dangerous good in sense of this transport regulation.
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14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:

No dangerous good in sense of this transport regulation.
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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**

Restrictions on use (REACH, annex XVII):
Information according to 2012/18/EU
(SEVESO III):

Entry 3, Entry 66, Entry 75
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]

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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**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-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.