

DD BioSplint C

Revision date: 28.10.2022

Page 1 of 9

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

DD BioSplint C

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

Dental Direkt 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

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 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 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.

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)

DD BioSplint C

Revision date: 28.10.2022

Page 2 of 9

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.

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. 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

First Aid, decontamination, treatment of symptoms.

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

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****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.

DD BioSplint C

Revision date: 28.10.2022

Page 3 of 9

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)

For non-emergency personnel

Remove persons to safety.

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 exhaust 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.

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

DD BioSplint C

Revision date: 28.10.2022

Page 4 of 9

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

Occupational exposure limits

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	23		TWA (8 h)	
		15	70		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	8		TWA (8 h)	
		4	16		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

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

DD BioSplint C

Revision date: 28.10.2022

Page 5 of 9

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
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

DD BioSplint C

Revision date: 28.10.2022

Page 6 of 9

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 productsCarbon dioxide (CO₂), CO**Further information**

No data available

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

DD BioSplint C

Revision date: 28.10.2022

Page 7 of 9

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.

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).

DD BioSplint C

Revision date: 28.10.2022

Page 8 of 9

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)**

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

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 66, 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]

DD BioSplint C

Revision date: 28.10.2022

Page 9 of 9

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: 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.