

according to Regulation (EC) No 1907/2006

DD peek MED

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

1.1. Product identifier

DD peek MED

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	+49 (0) 761 19240 (VIZ Freiburg) Poisons info	ormation Centre of Ireland +353 1
number:	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 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

3.2. Mixtures

Chemical characterization PEEK: Polyetheretherketone

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



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General information

First aider: Pay attention to self-protection!

In case of allergic symptoms, especially in the breathing area, seek medical advice immediately. 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 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, Gases/vapours, irritant

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.

Avoid dust formation. In case of inadequate ventilation wear respiratory protection.

Avoid contact with skin, eyes and clothes.



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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).
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. 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.

Further information on handling

Observe instructions for use.

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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: Acid (sulphuric acid), 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/m³	fib/cm³	Category	Origin
-	Dusts non-specific, respirable	-	4		TWA (8 h)	
-	Dusts non-specific, total inhalable	-	10		TWA (8 h)	

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

Suitable eye protection: EN 166 Eye glasses with side protection goggles

Hand protection

Tested protective gloves must be worn: EN 388 / EN ISO 374

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. Wear cotton undermitten if possible.

Use heat-insulating protective gloves for thermal processing.

Skin protection

antistatic Protective clothing.

Respiratory protection

Respiratory protection necessary at: exceeding exposure limit values, Generation/formation of dust 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)

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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:		>300 °C
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
Decomposition temperature:		>400 °C
pH-Value:		No data available
Water solubility:	The study doe	s not need to be conducted
	•	e 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:		1,5 g/cm
Relative vapour density:		No data available
2. Other information		
Information with regard to physical ha	azard classes	
Explosive properties		
May form combustible dust concent	rations in air.	N I 177 111
Sustaining combustion:		No data available
Self-ignition temperature		
Solid: Gas:		No data available No data available
		NO GALA AVAIIADIO
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.

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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

UV-radiation/sunlight, 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

Acids, Oxidizing agent

10.6. Hazardous decomposition products

Carbon dioxide (CO2), Carbon monoxide

Further information

No data available

SECTION 11: Toxicological information

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

Toxicocinetics, 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.

Practical experience

The melted product can cause severe burns.

11.2. Information on other hazards

Endocrine disrupting properties

No information available.

Further information

There are no data available on the preparation/mixture itself. Calculation method.



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SECTION 12: Ecological information

12.1. Toxicity

The product is not: Soluble in: Water

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

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

No further relevant information available.

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)

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



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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)	No deserve wood in some of this transport your dation	
<u>14.1. UN number or ID number:</u> 14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation. 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 tra		
14.7. Maritime transport in bulk according to		
No dangerous good in sense of this tra	ansport regulation.	
EU regulatory information Information according to 2012/18/EU	Not subject to 2012/18/EU (SEVESO III)	
(SEVESO III):		
Additional information		
2008/98/EC on waste		
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: Spritzgie	eßen"	
Verordnung über Anlagen zum Umgar	ng mit wassergefährdenden Stoffen (AwSV)	
TRGS 220, TRGS 400ff., TRGS 500, ⁻	TRGS 722-724, TRGS 800, TRGS 900	
15.2. Chemical safety assessment		
10.2. Onemical salety assessment	standad in this mixture ware not corriad out	
Chemical safety assessments for subs	stances in this mixture were not carried out.	
Chemical safety assessments for subs		

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)



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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 Refulations 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: Effectice concentration, 50 percent DNFL: 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.)

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