

according to Regulation (EC) No 1907/2006

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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

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 information 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 No data available

boiling range: Flammability

No data available Solid/liquid: 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 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:

Vapour pressure:

Density:

Relative vapour density:

No data available

1,5 g/cm³

No data available

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:

Solid content:

Sublimation point:

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)

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.

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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)

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

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 (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"

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

Changes

This data sheet contains changes from the previous version in section(s): 1,4,5,6,7,8,10,11,13.

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

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.)