

Safety Data Sheet

according to UK REACH Regulation

PEEK BioSolution® / PEEK Nature

Revision date: 28.09.2023 Product code: 199 Page 1 of 6

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

1.1. Product identifier

PEEK BioSolution® / PEEK Nature

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

Use of the substance/mixture

Material for the manufacture of dental medical devices.

Uses advised against

Do not use for private purposes (household).

1.3. Details of the supplier of the safety data sheet

Company name: Merz Dental GmbH

Street: Kieferweg 1

Place: D-24321 Luetjenburg (GERMANY)

Telephone: +49-(0)4381-403-0 Telefax: +49-(0)4381-403-100

e-mail: info@merz-dental.de

Contact person: Dipl. Chem Dr. Thomas Panther Telephone: +49-(0)4381-403-448

e-mail: Thomas.Panther@merz-dental.de

Internet: www.merz-dental.de

Responsible Department: Qualitaetssicherung (Quality Assurance)

1.4. Emergency telephone +49-(0)551-19240 (Giftinformationszentrum-Nord)

number:

Further Information

none

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP Regulation

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

2.2. Label elements

Additional advice on labelling

There is no requirement for the product to be specially labelled according to EC directives or the corresponding national laws.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

polymeric preparation

Hazardous components

none (according to UK REACH Regulation)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

No special measures are necessary.



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After inhalation

Provide fresh air

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After indestion

Rinse mouth immediately and drink plenty of water. No known symptoms to date.

4.2. Most important symptoms and effects, both acute and delayed

none

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings. Water mist, Foam, Carbon dioxide (CO2), Extinguishing powder

Unsuitable extinguishing media

Full water iet

5.2. Special hazards arising from the substance or mixture

Non-flammable. This material is combustible, but will not ignite readily.

5.3. Advice for firefighters

Use appropriate respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Avoid dust formation. Wear breathing apparatus if exposed to vapours/dusts/aerosols. Use personal protection equipment.

6.2. Environmental precautions

No special environmental measures are necessary. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Other information

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal. Wet clean or vacuum up solids. Use approved industrial vacuum cleaner for removal. Do not use a dry brush as dust clouds or static can be created.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13 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

Measures to prevent aerosol and dust generation. Do not breathe dust. Dust should be exhausted directly at the point of origin. If local exhaust ventilation is not possible or not sufficient, the entire working area should be



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ventilated by technical means.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.

Further information on handling

Dust should be exhausted directly at the point of origin.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.

7.3. Specific end use(s)

The product is intended for professional use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



Individual protection measures, such as personal protective equipment

Eye/face protection

Wear eye/face protection.

Hand protection

Wear suitable protective clothing and gloves.

Skin protection

Wear suitable protective clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: solid

Colour:

Flammability:

Odour: none

Test method

Print date: 28.09.2023

Melting point/freezing point: > 300 °C DSC

not determined not applicable

Decomposition temperature: No data available

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:

Density:

1,30 - 1,51 g/cm³

Relative vapour density:

not determined

9.2. Other information

Information with regard to physical hazard classes

Oxidizing properties Not oxidising.



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Other safety characteristics

Evaporation rate: not determined
Solvent separation test: No data available
Solvent content: none
Solid content: 100

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

UV-radiation/sunlight. -> 16.

10.5. Incompatible materials

Sulphuric acid, concentrated Oxidising agent

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in GB CLP Regulation

Toxicocinetics, metabolism and distribution

none

Additional information on tests

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

The product has not been tested.

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

Avoid release to the environment.

SECTION 13: Disposal considerations



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13.1. Waste treatment methods

Disposal recommendations

Remove according to the regulations. May be disposed of in household waste landfill.

Contaminated packaging

Wash with plenty of water. Completely emptied packages can be recycled.

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 information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

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): 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16.

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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IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Key literature references and sources for data

UV-radiation/sunlight.: Nakamura H, Nakamura T, Noguchi T, Imagawa K. Photodegradation of PEEK sheets under tensile stress. Polym Degrad Stab 2006;91:740-746.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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