

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 27.04.2023

Version number 6

Revision: 27.04.2023

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

1.1 Product identifier

Trade name **Kera® starPEEK**

Article number:

11041212TC, 11041216TC, 11041220TC, 11041225TC
11041212SW, 11041216SW, 11041220SW, 11041225SW
11041212GUM, 11041216GUM, 11041220GUM, 11041225GUM

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

No further relevant information available.

Application of the substance / the mixture For the production of dental prostheses in the dental laboratory

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Eisenbacher Dentalwaren ED GmbH
Dr. - Konrad - Wiegand - Straße 9
63939 Würth / Main, Germany
Tel.: 0049 9372 / 94 04 - 0
www.eisenbacher.de

Information:

product management tel.: +49 93 72 - 94 04 - 0
or by mail: info@eisenbacher.de

1.4 Emergency telephone number:

Tel.: +49 (0) 9372 9404 0, Monday to Friday 8.00 a.m. to 5.00 p.m., in German and English, also contact the local poison control centres

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The following classification is not applicable to the alloy but only for the fumes, smokes and dusts formed during the processing and machining.

The product is not classified as hazardous to health or environment, according to the GB CLP regulation.

The substance is not to be classified according to the GB CLP regulation.

2.2 Label elements

Medical devices according EG 2017-745 in their final state are exempted from the GB CLP legislation. The following labelling is not applicable to the alloy but only for the fumes, smokes and dusts formed during the processing and machining.

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the Globally Harmonised System (GHS).

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms Void

Signal word Void

Hazard statements Void

Information pertaining to particular dangers for man and environment

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

SECTION 3: Composition/information on ingredients

3.1 Chemical characterisation: Substances

CAS No. Designation:

Polyetheretherketon, modifiziert

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— GB —

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. **Description:** Polyetheretherketon, modifiziert

SECTION 4: First aid measures

. 4.1 Description of first aid measures

. **General information**

Take affected persons out of danger area and instruct to lie down.

Do not leave affected persons unsupervised.

Keep warm, position comfortably and cover well.

No special measures required.

. **After inhalation :** Supply fresh air; consult doctor in case of symptoms.

. **After skin contact :**

Instantly rinse with water.

The product is not skin irritating.

. **After eye contact :** Rinse opened eye for 15 minutes under running water.

. **After swallowing :** In case of persistent symptoms consult doctor.

. **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

. 5.1 Extinguishing media

. **Suitable extinguishing agents**

Water spray jet

Fire-extinguishing powder

Carbon dioxide

Foam

. 5.2 Special hazards arising from the substance or mixture

Fire can cause release of :

Carbon oxides (CO and CO₂)

. 5.3 Advice for firefighters

. **Protective equipment:** Put on breathing apparatus.

SECTION 6: Accidental release measures

. 6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Avoid causing dust.

Keep away from ignition sources

. **6.2 Environmental precautions:** Do not allow product to reach sewage system or water bodies.

. **6.3 Methods and material for containment and cleaning up:**

Collect mechanically.

Avoid causing dust.

Dispose of the material collected according to regulations.

. **6.4 Reference to other sections**

See section 7 for information on safe handling

See section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Do not inhale the product.
Prevent formation of dust.

Information about protection against explosions and fires:

Dust can combine with air to form an explosive mixture.
Keep away from ignition sources - Do not smoke.
Protect against electrostatic charges.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and containers:

Store in cool location.
Store only in the original container.
Keep out of direct sunlight.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

7.3 Specific end use(s) We are not currently aware of any specific end uses beyond those specified in section 1.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with critical values that require monitoring at the workplace: Not required.

Additional information:

The lists that were valid during compilation were used as a basis.
The general dust limit value of 1.25 mg / m³ (alveolar fraction) and 10 mg / m³ (respirable fraction) must be observed (TRGS 900, 2015).

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.
Wash hands during breaks and at the end of the work.

Breathing equipment:

Use breathing protection in case of insufficient ventilation.
Do not inhale vapours from hot product. If vapours are unintentionally released into the breathing air during thermal processing, wear respirators with filters against organic vapours (e.g. A 2) or a self-contained breathing apparatus.
Required when dusts are generated.
Breathing protection recommended.

Protection of hands:

when using hot product
Wear gloves for the protection against mechanical hazards according to EN 388.
Not required.

Material of gloves Not required.

Penetration time of glove material Not required.

Eye protection: Safety glasses (DIN 58211, EN 166)

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: Solid
 Colour: According to product specification

Smell: Characteristic

Odour threshold: Not determined.

pH-value: Not applicable.

Change in condition

Melting point/freezing point: Not determined

Initial boiling point and boiling range: 300 °C

Flash point: Not applicable

Inflammability (solid, gaseous): Not determined.

Decomposition temperature: Not determined.

Self-inflammability: Product is not selfigniting.

Explosive properties: Product is not explosive.

Critical values for explosion:

Lower: Not determined.

Upper: Not determined.

Dust explosion class:

Oxidising properties: none

Steam pressure: Not applicable.

Density: Not determined

Relative density: Not determined.

Vapour density: Not applicable.

Evaporation rate: Not applicable.

Solubility in / Miscibility with

Water: Insoluble
 Not miscible or difficult to mix

Partition coefficient: n-octanol/water: Not determined.

Viscosity:

dynamic: Not applicable.

kinematic: Not applicable.

Solids content: 100.0 %

9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity: No hazardous reactions when stored and handled according to instructions.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided:

Stable at ambient temperature

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No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

Risk of dust explosion
No exothermic reaction with air up to 225°C

10.4 Conditions to avoid

Avoid extreme temperatures.
Protect from heat and direct sunlight.

10.5 Incompatible materials:

Oxidizers
Acids

10.6 Hazardous decomposition products:

Fire can cause release of :
Carbon oxides (CO and CO₂)

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

Primary irritant effect:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Additional toxicological information:

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Due to the ingredients there is no suspicion of a carcinogenic effect.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity 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.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes:

Not known to be hazardous to water.
Generally not hazardous for water.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation Smaller quantities can be disposed with household garbage.

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- . **Uncleaned packaging:**
- . **Recommendation:**
Dispose of packaging according to regulations on the disposal of packagings.
Empty contaminated packagings thoroughly. They can be recycled after thorough and proper cleaning.
- . **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

- | | |
|--|-----------------|
| . 14.1 UN-Number | |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.2 UN proper shipping name | |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.3 Transport hazard class(es) | |
| . ADR/RID/ADN, IMDG, IATA | |
| . Class | Void |
| . 14.4 Packing group | |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.5 Environmental hazards: | Not applicable. |
| . 14.6 Special precautions for user | Not applicable. |
| . 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| . UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- . **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- . **Directive 2012/18/EU**
- . **Named dangerous substances - ANNEX I** Substance is not listed.
- . **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- . **Contact:** info@eisenbacher.de
- . **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
- . **Sources:** source ECHA: European Chemicals Agency, <http://echa.europa.eu/>
- . *** Data compared to the previous version altered.**