

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 14.10.2016

Version: 2.00

Revision: 14.10.2016

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

- **1.1 Product identifier**
- **Trade name: Nacera® Pearl Shaded**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against: -**
- **Application of the substance / the preparation:**
Medical device
Professional application
- **1.3 Details of the supplier of the safety data sheet**
- **Supplier/Manufacturer:**
DOCERAM Medical Ceramics GmbH
Heßlingsweg 65-67
44309 Dortmund
Germany
Tel.: +49-231-92 56 68-0
Fax: +49-231-92 56 68-60
- **Email competent person:** sds@kft.de
- **Information department:** See supplier/manufacturer
- **1.4 Emergency telephone number:**
National Poison Information Service (NPIS)
24 hour national number professionals only
0844 892 0111

- National Health Service (NHS)
24 hour national number consumer
England and Scotland: 111
Wales: 0845 46 47
Northern Ireland: call your local General Practitioner

- Call 999 if there is a life-threatening incident.

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008** The product is not classified according to the CLP regulation.
- **Additional information:**
For this substance/mixture no safety data sheet needs to be generated according to Article 31(1) of Regulation (EC) No 1907/2006.
The here presented safety data sheet may therefore not fulfil all requirements of Annex II of this regulation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
 - **Description:** Zirconium oxide ceramics in pre-sintered discs
 - **Dangerous components:**
- | | |
|---|---------|
| CAS: 1314-23-4 zirconium dioxide | 50-100% |
| EINECS: 215-227-2 substance with a Community workplace exposure limit | |

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 14.10.2016

Version: 2.00

Revision: 14.10.2016

Trade name: Nacera® Pearl Shaded

(Contd. of page 1)

- **Additional information:**

The product is not a chemical preparation but an article.

Upon machining (e.g. grinding) dust may be formed (see chapter 8).

For further components with national limit values which require monitoring at the workplace please see chapter 8.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**

- **General information:** If symptoms persist or in case of doubt, seek medical advice.

- **After inhalation:** If dust is inhaled, supply fresh air; consult a doctor in case of complaints.

- **After skin contact:**

After contact with swarf:

Clean affected skin thoroughly with water and a mild cleansing agent. No residues shall remain on the skin.

- **After eye contact:**

This product is an inert solid substance. If particles get into the eyes, remove as customary for foreign bodies.

Rinse opened eye for several minutes under running water.

If symptoms persist, consult a doctor.

- **After swallowing:** void

- **4.2 Most important symptoms and effects, both acute and delayed** Local irritation symptoms

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

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**

- **Suitable extinguishing agents:**

The product is not combustible and does not support any combustion.

Use fire fighting measures suiting the environment.

- **For safety reasons unsuitable extinguishing agents:** No data available

- **5.2 Special hazards arising from the substance or mixture** No specific hazards known.

- **5.3 Advice for firefighters**

- **Protective equipment:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.

- **6.2 Environmental precautions:** No special measures required.

- **6.3 Methods and material for containment and cleaning up:** No special measures required.

- **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 disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of dust.

Avoid inhalation of dust.

For subsequent processing observe instructions of the manufacturer.

Processing only by trained staff.

- **Information about protection against explosions and fires:** Observe the general rules of industrial fire protection.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 14.10.2016

Version: 2.00

Revision: 14.10.2016

Trade name: **Nacera® Pearl Shaded**

(Contd. of page 2)

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

- **Requirements to be met by storerooms and receptacles:** Not required
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**

Store under dry conditions.
Protect from exposure to light.

- **Storage class:** 13 Non combustible solid

· 7.3 Specific end use(s)

In case of thermic and/or mechanic processing, apply appropriate extraction system at the machines respectively at the workplace in order to fall below the threshold values mentioned in chapter 8.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.

· 8.1 Control parameters

- **Components with limit values that require monitoring at the workplace:**

1314-23-4 zirconium dioxide

WEL (Great Britain) Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

- **CAS No. Designation of material % Type Value Unit**
- **Additional Occupational Exposure Limit Values for possible hazards during processing:**
Observe general threshold limit for dust.

· 8.2 Exposure controls

· Personal protective equipment:

- **General protective and hygienic measures:** The usual protective measures based on the application have to be followed.

· Breathing equipment:

When material is mechanically machined and dust is formed:

Short term filter device:

Filter P2

- **Protection of hands:** Protective gloves

· Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

- **Penetration time of glove material:** -

· Eye protection:

In case of mechanical processing:

Safety glasses

- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information:

· Appearance:

Form: disc-shaped work piece

Colour: White

· **Odour:** Odourless

· **Odour threshold:** Not applicable

· **pH-value:** Not applicable

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 14.10.2016

Version: 2.00

Revision: 14.10.2016

Trade name: **Nacera® Pearl Shaded**

(Contd. of page 3)

· Change in condition:	
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
· Flash point: Not applicable	
· Ignition temperature:	
Decomposition temperature:	Not determined
· Self ignition temperature: Product is not self-igniting.	
· Danger of explosion: Product does not present an explosion hazard.	
· Explosion limits:	
Lower:	Not applicable
Upper:	Not applicable
· Oxidizing properties: Non-oxidizing	
· Density: Not determined	
· Solubility in / Miscibility with Water: Insoluble	
· Partition coefficient (n-octanol/water): Not applicable	
· Viscosity:	
dynamic:	Not applicable
kinematic:	Not applicable
· 9.2 Other information No further relevant information available	

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used and stored according to specifications
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available
- **10.5 Incompatible materials:** No further relevant information available
- **10.6 Hazardous decomposition products:**
No hazardous decomposition products if instructions for storage and handling are followed

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values that are relevant for classification:** No adverse effects known
- **Primary irritant effect:**
- **Skin corrosion/irritation** Swarf may be irritant to skin and respiratory tract.
- **Serious eye damage/irritation** Eye irritation is possible after mechanical influence (dust).
- **On respiratory tract:** Light irritation possible
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Other information (about experimental toxicology):**
- **Carcinogenic, mutagenic effects and adverse effects on reproduction:**
Presently available data show no carcinogenic, mutagenic or teratogenic effects.
- **Subacute to chronic toxicity:**
- **STOT-single exposure** No data available
- **STOT-repeated exposure:** No data available
- **Aspiration hazard** Not relevant

(Contd. on page 5)
— GB —

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 14.10.2016

Version: 2.00

Revision: 14.10.2016

Trade name: **Nacera® Pearl Shaded**

(Contd. of page 4)

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**
- **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** Not applicable
- **12.3 Bioaccumulative potential** No further relevant information available
- **12.4 Mobility in soil** No further relevant information available
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous to water
According to appendix 4 of VwVwS dated 17.05.1999 (German regulation)
- **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:**
Disposal according to instructions of local authorities
Contact manufacturer for recycling information.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---|----------------|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable |
| <ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable |

(Contd. on page 6)

— GB —

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 14.10.2016

Version: 2.00

Revision: 14.10.2016

Trade name: **Nacera® Pearl Shaded**

(Contd. of page 5)

· Transport/Additional information:	Not dangerous according to the above regulations
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations**
- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water
- **Further information:** Version/s 1 is/are not available in this language.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Reasons for amendments:** Version/s 1 is/are not available in this language.
- **Replaces version dated:** 22.01.2008

· **Department issuing SDS:**
 KFT Chemieservice GmbH
 Im Leuschnerpark. 3 64347 Griesheim
 Postfach 1451 64345 Griesheim
 Germany

Phone: +49 6155 8981 400 Fax: +49 6155 8981 500
 Safety Data Sheet Service: +49 6155 8981 522

- **Contact:** Dr. Daniela Krimm
- **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
 GHS: Globally Harmonised 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 (division of the American Chemical Society)
 MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative