

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 22.04.2015

Version: 2. 0

Revision: 22.04.2015

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

- **1.1 Product identifier**
- **Trade name:** Nacera® Pearl Multi Shade
- **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.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** not applicable
- **Information concerning particular hazards for human and environment:**  
No hazards to be particularly mentioned. Please note the information of this Material Safety Data Sheet.
- **Classification system:**  
This product is a medical device which is not within the scope of the European regulations regarding the labelling of hazardous substances.
  
- **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

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 22.04.2015

Version: 2. 0

Revision: 22.04.2015

Trade name: **Nacera® Pearl Multi Shade**

(Contd. of page 1)

### 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

· **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.

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 22.04.2015

Version: 2. 0

Revision: 22.04.2015

Trade name: **Nacera® Pearl Multi Shade**

(Contd. of page 2)

### 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.

#### 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/m<sup>3</sup>Long-term value: 5 mg/m<sup>3</sup>

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

— GB —

(Contd. on page 4)

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 22.04.2015

Version: 2. 0

Revision: 22.04.2015

Trade name: Nacera® Pearl Multi Shade

(Contd. of page 3)

#### SECTION 9: Physical and chemical properties

· <b>9.1 Information on basic physical and chemical properties</b>	
· <b>General Information:</b>	
· <b>Appearance:</b>	
Form:	disc-shaped work piece
Colour:	White
· Odour:	Odourless
· Odour threshold:	Not applicable
· pH-value:	Not applicable
· <b>Change in condition:</b>	
Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined
· Flash point:	Not applicable
· <b>Ignition temperature:</b>	
Decomposition temperature:	Not determined
· Self ignition temperature:	Product is not self-igniting.
· Danger of explosion:	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not applicable
Upper:	Not applicable
· Oxidizing properties:	Non-oxidizing
· Density:	Not determined
· <b>Solubility in / Miscibility with</b>	
Water:	Insoluble
· <b>Partition coefficient (n-octanol/water):</b> Not applicable	
· <b>Viscosity:</b>	
dynamic:	Not applicable
kinematic:	Not applicable
· <b>9.2 Other information</b>	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:**
- **LD/LC50 values that are relevant for classification:** No adverse effects known
- **Primary irritant effect:**
- **on the skin:** Swarf may be irritant to skin and respiratory tract.

(Contd. on page 5)

— GB —

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 22.04.2015

Version: 2. 0

Revision: 22.04.2015

---

**Trade name: Nacera® Pearl Multi Shade**


---

(Contd. of page 4)

- **on the eye:** Eye irritation is possible after mechanical influence (dust).
  - **On respiratory tract:** Light irritation possible
  - **Sensitisation:** No sensitising effects known
  - **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
  - **Additional toxicological information:**  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- 

### 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:**  
Contact manufacturer for recycling information.  
Disposal according to instructions of local authorities
  - **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.
- 

### SECTION 14: Transport information

- |   |      |
|---|------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | Void |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void |

(Contd. on page 6)

— GB —

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date: 22.04.2015

Version: 2. 0

Revision: 22.04.2015

Trade name: **Nacera® Pearl Multi Shade**

(Contd. of page 5)

· <b>14.5 Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable
· <b>Transport/Additional information:</b>	Not dangerous according to the above regulations
· <b>UN "Model Regulation":</b>	-

### 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.

- **Replaces version dated:** 22.01.2008
- **Department issuing MSDS:**  
KFT Chemieservice GmbH  
Im Leuschnerpark. 3 64347 Griesheim  
Postfach 1451 64345 Griesheim  
Germany
- Phone: +49 6155 86829-0 Fax: +49 6155 86829-25  
Safety Data Sheet Service: +49 6155 86829-22
- **Contact:** Angelika Torges
- **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