

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date: 10.05.2013

Version: 1

Revision: 10.05.2013

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

- **1.1 Product identifier**
- **Trade name: Nacera® Pearl 1-5**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against: -**
- **Uses advised against:** Not specified
- **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 Poisons Information Service (NPIS)
24 hour national number is 0844 892 0111 professionals only

National Health Service (NHS)
24 hour national number is 0845 4647 consumer

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **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:**
The 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 EU guidelines:**
The product is not subject to identification regulations under EC Directives and the Ordinance on Hazardous Materials (GefStoffV).
 - **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 characterization: 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).

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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**
Processing only by trained staff.
For subsequent processing observe instructions of the manufacturer.
Prevent formation of dust.
Ensure good ventilation/exhaustion at the workplace.
Avoid inhalation of dust.
- **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.

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- **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 item 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 (EN 149):

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

- **Change in condition:**

Melting point/Melting range: Not determined

Boiling point/Boiling range: Not determined

· **Flash point:** Not applicable

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· 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:**
- **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.
- **on the eye:** Eye irritation is possible after mechanical influence (dust).
- **On respiratory tract:** Light irritation possible
- **Sensitization:** No sensitizing 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

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- **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 27.7.2005 (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

- **14.1 UN-Number**

- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** Void

- **14.4 Packing group**

- **ADR, IMDG, IATA** Void

- **14.5 Environmental hazards:**

- **Marine pollutant:** No

- **14.6 Special precautions for user** Not applicable

- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable

- **Transport/Additional information:**

Not dangerous according to the above regulations

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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
- **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 Harmonized System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

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

- **1.1 Product identifier**
- **Trade name: Nacera® Shell 1-3**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against: -**
- **Uses advised against:** Not specified
- **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 Poisons Information Service (NPIS)
24 hour national number is 0844 892 0111 professionals only

National Health Service (NHS)
24 hour national number is 0845 4647 consumer

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
 - **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:**
The 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 EU guidelines:**
The product is not subject to identification regulations under EC Directives and the Ordinance on Hazardous Materials (GefStoffV).
 - **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 characterization: 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).

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Trade name: Nacera® Shell 1-3

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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**
Processing only by trained staff.
For subsequent processing observe instructions of the manufacturer.
Prevent formation of dust.
Ensure good ventilation/exhaustion at the workplace.
Avoid inhalation of dust.
- **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.

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Trade name: **Nacera® Shell 1-3**

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- **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 item 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 (EN 149):

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: Ivory

· **Odour:** Odourless

· **Odour threshold:** Not applicable

· **pH-value:** Not applicable

- **Change in condition:**

Melting point/Melting range: Not determined

Boiling point/Boiling range: Not determined

· **Flash point:** Not applicable

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Trade name: **Nacera® Shell 1-3**

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· 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:**
- **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.
- **on the eye:** Eye irritation is possible after mechanical influence (dust).
- **On respiratory tract:** Light irritation possible
- **Sensitization:** No sensitizing 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

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- **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 27.7.2005 (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

- **14.1 UN-Number**

- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** Void

- **14.4 Packing group**

- **ADR, IMDG, IATA** Void

- **14.5 Environmental hazards:**

- **Marine pollutant:** No

- **14.6 Special precautions for user** Not applicable

- **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable

- **Transport/Additional information:**

Not dangerous according to the above regulations

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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
- **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 Harmonized System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent