

# NACERA® Pearl Q<sup>3</sup>

## Safety Data Sheet

according to US OSHA Hazard Communication Standard (HCS 2012); 29 CFR Part 1910.1200

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Version: 2.01

### SECTION 1: Identification

#### 1.1. Identification

Trade name : NACERA® Pearl Q<sup>3</sup>

#### 1.2. Recommended use and restrictions on use

Use of the substance/mixture : Medical device

Recommended use : For professional use only

#### 1.3. Supplier

##### Supplier

DOCERAM Medical Ceramics GmbH  
Heßlingsweg 65-67  
Dortmund, 44309 - Germany  
T +49-231-92 56 68-0 - F +49-231-92 56 68-60

##### Email competent person

sds@kft.de

##### Distributor

Nacera US Inc.  
Two Bala Plaza, Suite 718  
PO Box 627  
Bala Cynwyd PA 19004  
Dr. Dean Mersky  
Phone 2153455283  
Mail info@nacera.us

##### Other

Information department: See supplier/manufacturer  
Emergency telephone number: Information department

#### 1.4. Emergency telephone number

No additional information available

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Not classified

#### 2.2. GHS Label elements, including precautionary statements

According to the corresponding national regulations there is no labelling obligation for this product.

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

### SECTION 3: Composition/Information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Comments : Zirconium oxide ceramics in pre-sintered discs

Name	Product identifier	%	GHS-US classification
Zirconium oxide (ZrO <sub>2</sub> )	(CAS-No.) 1314-23-4	>= 90	Not classified

Comments : 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.

Full text of hazard classes and H-statements : see section 16

### SECTION 4: First-aid measures

#### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Measures in case of dust release. Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

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First-aid measures after eye contact : Direct eye contact is unlikely. Dust from this product may cause eye irritation. Rinse opened eye for several minutes under running water. Then consult doctor.

First-aid measures after ingestion : Ingestion unlikely. Call a poison center/doctor/physician if you feel unwell.

### 4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after inhalation : Dust from this product may cause respiratory irritation.

Symptoms/effects after skin contact : Dust from this product may cause skin irritation.

Symptoms/effects after eye contact : Dust from this product may cause eye irritation.

### 4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

## SECTION 5: Fire-fighting measures

### 5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Not combustible. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

### 5.2. Specific hazards arising from the chemical

Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

### 5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid dust formation. Do not breathe dust.

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal.

Other information : Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : Manipulations are to be done only by qualified and authorized persons. Extraction to remove dust at its source.

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Store in a dry place. Protect from light.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

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### Zirconium oxide (ZrO<sub>2</sub>) (1314-23-4)

Not applicable

#### 8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station. Local exhaust is recommended where dust may occur.

Environmental exposure controls : Avoid release to the environment.

#### 8.3. Individual protection measures/Personal protective equipment

##### Hand protection:

In case of repeated or prolonged contact wear gloves. EN 374. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

##### Eye protection:

In case of dust production: protective goggles

##### Skin and body protection:

Wear suitable protective clothing

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. EN 149. If dust are formed : Short term exposure, breathing apparatus with filter, P2.

##### Other information:

Do not breathe dust. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product.

## SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: disc-shaped work piece.
Color	: white
Odor	: odorless
Odor threshold	: Not applicable
pH	: Not applicable
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: Not applicable
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Water: Insoluble
Log Pow	: Not applicable
Auto-ignition temperature	: Not self-igniting
Decomposition temperature	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosion limits	: Not applicable
Explosive properties	: Product is not explosive.

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Oxidizing properties : Non oxidizing material.

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified  
(Based on available data, the classification criteria are not met)

#### Zirconium oxide (ZrO<sub>2</sub>) (1314-23-4)

LD50 oral rat	> 5000 mg/kg (OECD 423 method)
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Skin corrosion/irritation : Not classified  
(Based on available data, the classification criteria are not met. Dust from this product may cause skin irritation)  
pH: Not applicable

Serious eye damage/irritation : Not classified  
(Based on available data, the classification criteria are not met. Dust from this product may cause eye irritation)  
pH: Not applicable

Respiratory or skin sensitization : Not classified  
(Based on available data, the classification criteria are not met)

Germ cell mutagenicity : Not classified  
(Based on available data, the classification criteria are not met)

Carcinogenicity : Not classified  
(Based on available data, the classification criteria are not met)

Reproductive toxicity : Not classified  
(Based on available data, the classification criteria are not met)

Specific target organ toxicity – single exposure : Not classified  
(Based on available data, the classification criteria are not met)

Specific target organ toxicity – repeated exposure : Not classified  
(Based on available data, the classification criteria are not met)

Aspiration hazard : Not classified  
(Not relevant)

Symptoms/effects after inhalation : Dust from this product may cause respiratory irritation.

Symptoms/effects after skin contact : Dust from this product may cause skin irritation.

Symptoms/effects after eye contact : Dust from this product may cause eye irritation.

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Zirconium oxide (ZrO <sub>2</sub> ) (1314-23-4)	
LC50 fish 1	> 100 mg/l (96 h; Brachydanio rerio (zebra-fish); (OECD 203 method))
EC50 Daphnia 1	> 100 mg/l (48 h; Daphnia magna; EU Method C.2)

#### 12.2. Persistence and degradability

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Persistence and degradability	Not applicable.

  

Zirconium oxide (ZrO <sub>2</sub> ) (1314-23-4)	
Persistence and degradability	Not applicable for inorganic substances.

#### 12.3. Bioaccumulative potential

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Log Pow	Not applicable
Bioaccumulative potential	Not applicable.

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Other adverse effects

Effect on the global warming : No known effects from this product.  
GWPmix comment : No known effects from this product.

### SECTION 13: Disposal considerations

#### 13.1. Disposal methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not applicable

#### TDG

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

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### 15.2. International regulations

No additional information available

### 15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.

## SECTION 16: Other information

Revision date : 08/07/2017  
Data sources : ECHA (European Chemicals Agency). Information provided by the manufacturer.  
Department issuing data specification sheet: : 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 person : Dr. Johann Klassen

Abbreviations and acronyms:

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ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

Indication of changes:

Version/s 1.00 - 2.00 is/are not available in this language.

KFT SDS US 00

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*