

NACERA® Pearl Q³

Safety Data Sheet

according to the Hazardous Products Regulation (February 11, 2015)

Date of issue: 08/07/2017

Revision date: 08/07/2017

Version: 2.01

SECTION 1: Identification

1.1. Product identifier

Trade name : NACERA® Pearl Q³

1.2. Recommended use and restrictions on use

Recommended use : Medical device, For professional use only

1.3. Supplier

Supplier

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

Email competent person

sds@kft.de

Other

Information department: See supplier/manufacturer
Emergency telephone number:
1 800 565 8161 (local callers);
+1 902 470 8161

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

Classification (GHS-CA)

Not classified

2.2. GHS Label elements, including precautionary statements

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

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-CA)

No data available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Zirconium oxide ceramics in pre-sintered discs

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 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.

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.

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

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.

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

4.3. Immediate medical attention and special treatment, if necessary

Other medical advice or treatment : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable extinguishing media

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

5.2. Unsuitable extinguishing media

Unsuitable extinguishing media : None.

5.3. Specific hazards arising from the hazardous product

No additional information available

5.4. 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.

6.2. Methods and materials 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.

6.3. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection"

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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.

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

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

No additional information available

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:

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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
Relative evaporation rate (butyl acetate=1)	: No data available
Relative evaporation rate (ether=1)	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not self-igniting
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: Not applicable
Vapor pressure at 50 °C	: No data available
Relative density	: No data available
Solubility	: Water: Insoluble
Log Pow	: Not applicable
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosive properties	: Product is not explosive.
Oxidizing properties	: Non oxidizing material.
Explosion limits	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	: The product is non-reactive under normal conditions of use, storage and transport.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No dangerous reactions known under normal conditions of use.
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 (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

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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.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

NACERA® Pearl Q³	
Persistence and degradability	Not applicable.

12.3. Bioaccumulative potential

NACERA® Pearl Q³	
Log Pow	Not applicable
Bioaccumulative potential	Not applicable.

12.4. Mobility in soil

NACERA® Pearl Q³	
Log Pow	Not applicable

12.5. Other adverse effects

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

14.1. Basic shipping description

In accordance with TDG

TDG

Not regulated for transport

14.2. Transport information/DOT

DOT

Not regulated for transport

14.3. Air and sea transport

IMDG

Not regulated for transport

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IATA

Not regulated for transport

SECTION 15: Regulatory information

15.1. National regulations

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Canada DSL & NDSL Flags	On or in compliance with the inventory (DSL).

15.2. International regulations

No additional information available

SECTION 16: Other information

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Indication of changes:

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

Data sources : ECHA (European Chemicals Agency). Information provided by the manufacturer.

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Abbreviations and acronyms:

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

KFT SDS CA 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