

Nacera Pearl Natural

Revision date: 15.05.2024

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Nacera Pearl Natural

Further trade names

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1.2. Relevant identified uses of the substance or mixture and uses advised against**Use of the substance/mixture**

Nacera Pearl Natural milling blanks are intended for the production of fixed dentures for long-term use.

Uses advised against

No information available.

1.3. Details of the supplier of the safety data sheet

Company name:	Dental Direkt GmbH	
Street:	Industriezentrum 106-108	
Place:	32139 Spenge, Germany	
Telephone:	05225 - 8 63 19-0	Telefax: 05225 - 8 63 19-99
e-mail:	info@dentaldirekt.de	
Internet:	www.dentaldirekt.de	
Responsible Department:	info@dentaldirekt.de	

1.4. Emergency telephone number: +49 (0) 761 19240 (VIZ Freiburg)**Further Information**

Medical device

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements**Regulation (EC) No 1272/2008****Hazard statements**

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273	Avoid release to the environment.
P501	Dispose of contents/container to an appropriate recycling or disposal facility.

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

The product contains: Yttrium zirconium oxide

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Skin protection

Protective clothing.

Respiratory protection

Usually no personal respirative protection necessary. Respiratory protection necessary at: exceeding exposure limit values, dust formation

Use appropriate respiratory protection. Particle filter device (EN 143)

Thermal hazards

No information available.

Environmental exposure controls

See section 7. No additional measures necessary.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state: solid, Powder

Colour: white

Odour: odourless

Changes in the physical state

Melting point/freezing point: No data available

Boiling point or initial boiling point and boiling range: No data available

Sublimation point: No data available

Softening point: No data available

Pour point: No data available

Flash point: No data available

Flammability

Solid/liquid: No data available

Gas: No data available

Explosive properties

No data available

Lower explosion limits: No data available

Upper explosion limits: No data available

Self-ignition temperature

Solid: No data available

Gas: No data available

Decomposition temperature: No data available

pH-Value: No data available

Viscosity / dynamic: No data available

Water solubility: practically insoluble

Solubility in other solvents

No information available.

Partition coefficient n-octanol/water: No data available

Vapour pressure: No data available

Density: No data available

Bulk density: 1.000-1.500 kg/m³

Relative vapour density: No data available

9.2. Other information

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Information with regard to physical hazard classes

Sustaining combustion: No data available
Oxidizing properties
No data available

Other safety characteristics

Solid content: 100,00 %
Evaporation rate: No data available

Further Information

No information available.

SECTION 10: Stability and reactivity**10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No information available.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

MetalOx

Further information

No further relevant information available.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Toxicokinetics, metabolism and distribution**

No information available.

Acute toxicity

Based on available data, the classification criteria are not met.

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

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.

Practical experience

After eye contact: Is féidir le deannach a bheith ina chúis le greannú meicniúil.

Following inhalation: dust/mist May cause respiratory irritation.

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SECTION 12: Ecological information**12.1. Toxicity**

No information available.

12.2. Persistence and degradability

Product/Substance is inorganic.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

Further information

Water hazard class 2

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Disposal recommendations**

Dispose of waste according to applicable legislation. The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. (AVV 200130)
Hazardous waste according to Directive 2008/98/EC (waste framework directive).

Contaminated packaging

Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.

SECTION 14: Transport information**Land transport (ADR/RID)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**Inland waterways transport (ADN)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**Marine transport (IMDG)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**Air transport (ICAO-TI/IATA-DGR)****14.1. UN number or ID number:** No dangerous good in sense of this transport regulation.**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)
 Classification according to Regulation (EC) No 1272/2008 [CLP]

Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

National regulatory information

Water hazard class (D): 2 - obviously hazardous to water

Additional information

Germany:
 Hazardous Substances Ordinance (GefStoffV)
 Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV)

TRGS 201, TRGS 220, TRGS 400, TRGS 420, TRGS 500, TRGS 509, TRGS 510, TRGS 555, TRGS 600, TRGS 900

DGUV Information 213-850

DGUV Information 213-730

15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:
 Dierbium trioxide

SECTION 16: Other information

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 conernat 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
 IATA-DGR: Dangerous Goods Refulations by the "International Air Transport Association" (IATA)
 ICAO: International Civil Aviation Organization
 ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals
 CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures,
 LC50: Lethal concentration, 50 percent
 LD50: Lethal dose, 50 percent
 EC50: Effectice concentration, 50 percent
 DNEL: Derived No Effect Level
 PNEC: Predicted No Effect Concentration
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

DD cubeX²

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Relevant H and EUH statements (number and full text)

H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)