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## Safety data sheet according to 1907/2006/EC, Article 31

Printing date 11.07.2022 Version number 3 Revision: 11.07.2022

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

- · 1.1 Product identifier
  - · Trade name: Neo Duroterm 7
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
  - · Application of the substance / the mixture Auxiliary for manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

- · Informing department: E-Mail: msds@kulzer-dental.com
- · 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

### SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture
  - Classification according to Regulation (EC) No 1272/2008

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- · 2.2 Label elements
  - Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

Hazard pictograms



GHS08

- · Signal word Danger
- · Hazard-determining components of labelling:

Quartz (SiO2)

cristobalite

· Hazard statements

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

· 2.3 Other hazards -

- · Results of PBT and vPvB assessment
  - · PBT: Not applicable.
  - vPvB: Not applicable.

#### SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures
  - · Description: -

· Dangerous o	components:
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CAS: 14808-60-7 EINECS: 238-878-4

Quartz (SiO2)

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≥50-≤75%

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cristobalite CAS: 14464-46-1 EINECS: 238-455-4

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≥10-≤25%

Additional information For the wording of the listed hazard phrases refer to section 16.

#### SECTION 4: First aid measures

- · 4.1 Description of first aid measures
  - After inhalation

Supply fresh air.

Seek immediate medical advice.

- · After skin contact Instantly wash with water and soap and rinse thoroughly.
- After eye contact Seek medical treatment.
- After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

#### SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
  - Suitable extinguishing agents

CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · 5.3 Advice for firefighters
  - Protective equipment: No special measures required.
  - Additional information -

#### SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Avoid causing dust.

Use breathing protection against the effects of fumes/dust/aerosol.

- 6.2 Environmental precautions: No special measures required.
- 6.3 Methods and material for containment and cleaning up:

Collect mechanically.

Send for recovery or disposal in suitable containers.

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 information on disposal.

# SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Waste air is to be released into the atmosphere only via suitable separators.

Information about protection against explosions and fires: No special measures required.

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- · 7.2 Conditions for safe storage, including any incompatibilities
  - Storage
    - Requirements to be met by storerooms and containers: No special requirements.
    - Information about storage in one common storage facility: Not required.
  - Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

#### SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
  - · Components with critical values that require monitoring at the workplace:

#### 14808-60-7 Quartz (SiO2)

AGW (European Union) Long-term value: 0.1 mg/m³
BOELV (European Union) Long-term value: 0.1\* mg/m³
\*respirable fraction

- · Additional information: The lists that were valid during the compilation were used as basis.
- · 8.2 Exposure controls
  - Appropriate engineering controls No further data; see item 7.
  - Individual protection measures, such as personal protective equipment
    - General protective and hygienic measures

Keep away from foodstuffs, beverages and food.

Wash hands during breaks and at the end of the work.

- · Breathing equipment: Filter P1.
  - Recommended filter device for short term use: P2 (FFP 2 EN 149) / P3 (FFP 3 EN 149)
- · Hand protection

Check protective gloves prior to each use for their proper condition.

recommended

· 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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR Nitrile rubber, NBR

- · Eye/face protection not absolutely neccessary
- · Body protection: Light weight protective clothing

### SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
  - General Information

· Physical state

· Colour:

· Smell:

meii: · Odour threshold: Solid. Light grey Odourless

Not determined.

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· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and	
boiling range	Not determined
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	Not applicable
· Decomposition temperature:	Not determined.
SADT	
·pH	Not applicable.
· Viscosity:	
· Kinematic viscosity	Not applicable.
· dynamic:	Not applicable.
· Solubility	тот аррпсаыс.
· Water:	Insoluble
	Ilisoluble
Partition coefficient n-octanol/water (log	Not data was in a d
value)	Not determined.
Steam pressure:	Not applicable.
Density and/or relative density	A1 ( 1 ( ) )
Density	Not determined
Relative density	Not determined.
· Vapour density	Not applicable.
<b>9.2 Other information</b> No f	urther relevant information available.
Appearance:	
Form:	Powder
Important information on protection of	
health and environment, and on safety.	
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive.
Expidente properties:	Not determined.
· Solvent content:	Trot dotornimod.
· Solids content:	100.0 %
· Change in condition	100.0 70
· Evaporation rate	Not applicable.
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Information with regard to physical hazard	
classes	
· Explosives	Void
Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
Substances and mixtures, which emit	VOIU
	Void
flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
	Void
· Organic peroxides	1 4.4



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Void

Void

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· Corrosive to metals · Desensitised explosives

### SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
  - 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: None
  - Additional information: -

### **SECTION 11: Toxicological information**

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
  - Acute toxicity Based on available data, the classification criteria are not met.
  - Skin corrosion/irritation Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation Based on available data, the classification criteria are not met.
  - Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
  - Germ cell mutagenicity Based on available data, the classification criteria are not met.
  - Carcinogenicity Based on available data, the classification criteria are not met.
  - Reproductive toxicity 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
  - Causes damage to the lung through prolonged or repeated exposure. Route of exposure:
  - Aspiration hazard Based on available data, the classification criteria are not met.
- 11.2 Information on other hazards
  - Endocrine disrupting properties

None of the ingredients is listed.

#### SECTION 12: Ecological information

- · 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available. 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

· 12.7 Other adverse effects No further relevant information available.



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### SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
  - · Recommendation:

Packagings that cannot be cleaned are to be disposed of in the same manner as the product.

SECTION 14: Transport information	on	
· 14.1 UN number or ID 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 Maritime transport in bulk according IMO instruments	<b>g to</b> Not applicable.	
· Transport/Additional information:	-	
· UN "Model Regulation":	Void	

#### SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - · Directive 2012/18/EU
    - · Water hazard class: Generally not hazardous for water.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H372 Causes damage to organs through prolonged or repeated exposure.

· Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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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)
PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

\* Data compared to the previous version altered.

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