



**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](mailto: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 (SiO<sub>2</sub>)  
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 components:**

CAS: 14808-60-7 EINECS: 238-878-4	Quartz (SiO <sub>2</sub> )	STOT RE 1, H372	≥50-≤75%
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CAS: 14464-46-1  
EINECS: 238-455-4

cristobalite

STOT RE 1, H372

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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**

CO<sub>2</sub>, 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.

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### 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 (SiO<sub>2</sub>)**

AGW (European Union)	Long-term value: 0.1 mg/m <sup>3</sup>
BOELV (European Union)	Long-term value: 0.1* mg/m <sup>3</sup> *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 through 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 necessary
  - **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** Solid.
- **Colour:** Light grey
- **Smell:** Odourless
- **Odour threshold:** Not determined.

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· <b>Melting point/freezing point:</b>	Not determined
· <b>Boiling point or initial boiling point and boiling range</b>	Not determined
· <b>Flammability</b>	Not determined.
· <b>Lower and upper explosion limit</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Flash point:</b>	Not applicable
· <b>Decomposition temperature:</b>	Not determined.
· <b>SADT</b>	
· <b>pH</b>	Not applicable.
· <b>Viscosity:</b>	
· <b>Kinematic viscosity</b>	Not applicable.
· <b>dynamic:</b>	Not applicable.
· <b>Solubility</b>	
· <b>Water:</b>	Insoluble
· <b>Partition coefficient n-octanol/water (log value)</b>	Not determined.
· <b>Steam pressure:</b>	Not applicable.
· <b>Density and/or relative density</b>	
· <b>Density</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.

· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Powder
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. Not determined.
· <b>Solvent content:</b>	
· <b>Solids content:</b>	100.0 %
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not applicable.

· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void

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· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

### 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: Inhalation.
  - **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**

· **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 to IMO instruments**

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.**

GB