



**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 CLP regulation.

· **Hazard pictograms**



GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

Quartz (SiO<sub>2</sub>)

crystalite

· **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%

(Contd. on page 2)



**Safety data sheet**  
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Printing date 11.07.2022

Version number 3

Revision: 11.07.2022

**Trade name: Neo Duroterm 7**

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

cristobalite

STOT RE 1, H372

(Contd. of page 1)

≥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.

(Contd. on page 3)

IE



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Version number 3

Revision: 11.07.2022

**Trade name: Neo Duroterm 7**

(Contd. of page 2)

- **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>)**

OEL (Ireland)	Long-term value: 0.1 mg/m <sup>3</sup>
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

**14464-46-1 cristobalite**

OEL (Ireland)	Long-term value: 0.1 mg/m <sup>3</sup>
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- **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

(Contd. on page 4)



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

Printing date 11.07.2022

Version number 3

Revision: 11.07.2022

**Trade name: Neo Duroterm 7**

(Contd. of page 3)

**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.
- **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**
  - **Water:** Insoluble
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Steam pressure:** Not applicable.
- **Density and/or relative density**
  - **Density** Not determined
  - **Relative density** Not determined.
  - **Vapour density** Not applicable.
- **Particle characteristics** See item 3.

**· 9.2 Other information**

No further 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.  
Not determined.
- **Solvent content:**
- **Solids content:** 100.0 %
- **Change in condition**
- **Evaporation rate** Not applicable.

**· 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

(Contd. on page 5)



**Safety data sheet**  
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Version number 3

Revision: 11.07.2022

**Trade name: Neo Duroterm 7**

(Contd. of page 4)

· <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
· <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.

(Contd. on page 6)



**Safety data sheet  
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**Trade name: Neo Duroterm 7**

(Contd. of page 5)

- **12.6 Endocrine disrupting properties**  
For information on endocrine disrupting properties see section 11.
- **12.7 Other adverse effects** No further relevant information available.

**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.

· **European waste catalogue**

18 01 06\* chemicals consisting of or containing hazardous substances

· **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 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

(Contd. on page 7)

IE



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(Contd. of page 6)

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

no information available

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

no information available

· **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.

· **Date of previous version:** 04.03.2021

· **Version number of previous version:** 2

· **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)

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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