



**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 07/11/2022

Reviewed on 07/11/2022

## 1 Identification

· **Product identifier**

· **Trade name: Neo Duroterm 7**

· -

· **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: [customer.servicehkna@kulzer-dental.com](mailto:customer.servicehkna@kulzer-dental.com)

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Carcinogenicity 1A

H350 May cause cancer.

Specific Target Organ Toxicity - Repeated Exposure 1

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

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Danger

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

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

crystalite

· **Hazard statements**

May cause cancer.

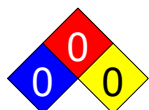
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapors/spray.

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 0

Fire = 0

Reactivity = 0

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**· HMIS-Ratings (Scale 0-4)**

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HEALTH	*0	Health = *0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

**· Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

- **Chemical characterization: Mixtures**
- **Description:** -

**· Dangerous components:**

14808-60-7	Quartz (SiO <sub>2</sub> ) Carcinogenicity 1A, H350; Specific Target Organ Toxicity - Repeated Exposure 1, H372	≥50-≤75%
14464-46-1	cristobalite Carcinogenicity 1A, H350; Specific Target Organ Toxicity - Repeated Exposure 1, H372	≥10-≤25%

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

**4 First-aid measures**

**· Description of first aid measures**

**· After inhalation**

- Supply fresh air.
- Seek immediate medical advice.

**· After skin contact** Immediately 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.
- If symptoms persist consult doctor.

**· Information for doctor**

- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

**5 Fire-fighting measures**

**· Extinguishing media**

**· Suitable extinguishing agents**

- CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

**· Special hazards arising from the substance or mixture**

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

**· Advice for firefighters**

- **Protective equipment:** No special measures required.

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· **Additional information -**

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**6 Accidental release measures**

· **Personal precautions, protective equipment and emergency procedures**

Avoid formation of dust.

Use respiratory protective device against the effects of fumes/dust/aerosol.

· **Environmental precautions: No special measures required.**

· **Methods and material for containment and cleaning up:**

Pick up mechanically.

Send for recovery or disposal in suitable receptacles.

· **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 disposal information.

-

· **Protective Action Criteria for Chemicals**

· **PAC-1:**

All components have the value 0.075 mg/m<sup>3</sup>.

· **PAC-2:**

All components have the value 33 mg/m<sup>3</sup>.

· **PAC-3:**

All components have the value 200 mg/m<sup>3</sup>.

**7 Handling and storage**

· **Handling**

· **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.**

· **Conditions for safe storage, including any incompatibilities**

· **Storage**

· **Requirements to be met by storerooms and receptacles: No special requirements.**

· **Information about storage in one common storage facility: Not required.**

· **Further information about storage conditions: None.**

· **Specific end use(s) No further relevant information available.**

**8 Exposure controls/personal protection**

· **Additional information about design of technical systems: No further data; see item 7.**

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**14808-60-7 Quartz (SiO<sub>2</sub>)**

PEL Long-term value: 0.05\* mg/m<sup>3</sup>  
\*resp. dust; 30mg/m<sup>3</sup>/%SiO<sub>2</sub>+2

REL Long-term value: 0.05\* mg/m<sup>3</sup>  
\*respirable dust; See Pocket Guide App. A

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TLV	Long-term value: 0.025* mg/m <sup>3</sup> *respirable particulate matter, A2
<b>14464-46-1 cristobalite</b>	
PEL	Long-term value: 0.05* mg/m <sup>3</sup> *resp. dust; 1/2 value from resp.dust formulae Quartz
REL	Long-term value: 0.05* mg/m <sup>3</sup> *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m <sup>3</sup> *respirable particulate matter, A2

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.

· **Breathing equipment:** Filter P1.

· **Recommended filter device for short term use:** P2 (FFP 2 EN 149) / P3 (FFP 3 EN 149)

· **Protection of hands:**

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 protection:** Not absolutely necessary.

· **Body protection:** Light weight protective clothing

**9 Physical and chemical properties**

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:** Powder  
· **Color:** Light grey  
· **Odor:** Odorless  
· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· **Melting point/Melting range:** undetermined  
· **Boiling point/Boiling range:** undetermined

· **Flash point:** Not applicable

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· <b>Flammability (solid, gaseous)</b>	Not determined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard. Not determined.
· <b>Explosion limits:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Insoluble
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· <b>dynamic:</b>	Not applicable.
· <b>kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
· <b>Solids content:</b>	100.0 %
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none
- **Additional information:** -

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

All components have the value 1.

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· **NTP (National Toxicology Program)**

All components have the value K.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

**12 Ecological information**

- **Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
  - **Bioaccumulative potential** No further relevant information available.
  - **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

**13 Disposal considerations**

- **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 cleansed are to be disposed of in the same manner as the product.

**14 Transport information**

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b><br>· DOT, ADR, ADN, IMDG, IATA                                | Void            |
| · <b>UN proper shipping name</b><br>· DOT, ADR, ADN, IMDG, IATA                  | Void            |
| · <b>Transport hazard class(es)</b><br>· DOT, ADR, ADN, IMDG, IATA<br>· Class    | Void            |
| · <b>Packing group</b><br>· DOT, ADR, IMDG, IATA                                 | Void            |
| · <b>Environmental hazards:</b><br>· <b>Marine pollutant:</b>                    | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |

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- |  |      |
|--|------|
| · <b>Transport/Additional information:</b> | -    |
| · <b>UN "Model Regulation":</b>            | Void |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

- **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

- **Hazardous Air Pollutants**

None of the ingredients is listed.

- **Proposition 65**

- **Prop 65 - Chemicals known to cause cancer**

All ingredients are listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenicity categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **TLV (Threshold Limit Value)**

All components have the value A2.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

All ingredients are listed.

- **Chemical safety assessment**

- **Water hazard class:** Generally not hazardous for water.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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**

H350 May cause cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

- **Date of preparation / last revision** 07/11/2022 / 2

- **Abbreviations and acronyms:**

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

DOT: US Department of Transportation

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*IATA: International Air Transport Association  
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)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
NIOSH: National Institute for Occupational Safety  
OSHA: Occupational Safety & Health  
TLV: Threshold Limit Value  
PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit  
Carcinogenicity 1A: Carcinogenicity – Category 1A  
Specific Target Organ Toxicity - Repeated Exposure 1: Specific target organ toxicity (repeated exposure) – Category 1*

**\* Data compared to the previous version altered.**

US