

## Safety data sheet

### according to 1907/2006/EC, Article 31

Printing date 20.02.2017

Version number 1

Revision: 20.02.2017

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

- **1.1 Product identifier**
- **Trade name:** TopDent Hartgips
- **Article number:** according to Catalog
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use** SU20 Health services
- **Environmental release category** ERC2 Formulation into mixture
- **Application of the substance / the mixture** Dental material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Kentzler-Kaschner Dental GmbH  
Mühlgraben 36  
D-73479 Ellwangen  
Tel: +49/7961/90730  
Fax: +49/7961/52031  
E-Mail: info@kkd-topdent.de
- **Further information obtainable from:**  
During normal business hours  
Monday-Thursday 08:30 - 12:30 and 13:00 - 16:30 CET  
Friday 08:30 - 12:30 and 13:00 - 15:00 CET
- **1.4 Emergency telephone number:** Vergiftungs-Informations-Zentrale Freiburg, Tel. +49 761 19240

#### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Dental material

· **Dangerous components:**

CAS: 7778-18-9	calcium sulphate, natural	70-99%
EINECS: 231-900-3		

- **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**
- **General information:**  
Take affected persons out of danger area and lay down.

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Do not leave affected persons unattended.

No special measures required.

Take affected persons out into the fresh air.

- **After inhalation:** Take affected persons into fresh air and keep quiet.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Inform doctor. Do not give milk or fatty oils.
- **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>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** Carbon dioxide (CO<sub>2</sub>)
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information**  
Collect contaminated fire fighting water separately. It must not enter the sewage system.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **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 disposal information.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:**  
Do not spray onto a naked flame or any incandescent material.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** None.
- **Storage class:** Storage group: 10-13
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

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

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- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
*The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.*
- **Additional information:** *The lists valid during the making were used as basis.*
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
*The usual precautionary measures are to be adhered to when handling chemicals.*
- **Respiratory protection:**  
DGUV 112-190 Breathing apparatus  
Suitable respiratory protective device recommended.  
Filter P1  
*In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.*
- **Protection of hands:**  
*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*
- **Material of gloves**  
Fluorocarbon rubber (Viton)  
Butyl rubber, BR  
Recommended material thickness:  
Butylkautschuk: 0,50 mm +/- 0,10 mm  
Fluorkautschuk: 0,75 mm +/- 0,10 mm  
*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**  
Basis: DGUV 212-007  
Permeation (Fluorkautschuk): + Level 6 (> 240 min)  
Permeation (Butykautschuk): + Level 6 (> 480 min)  
*The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.*  
*The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.*
- **For the permanent contact gloves made of the following materials are suitable:**  
Fluorocarbon rubber (Viton)  
Butyl rubber, BR
- **Not suitable are gloves made of the following materials:** Plastic gloves
- **Eye protection:** Not required.

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Crystalline
Colour:	Various colours
Odour:	Nearly odourless

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· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	7 (in wässriger Lösung)
· <b>Change in condition</b> <b>Melting point/freezing point:</b>	1450 °C
<b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	Not applicable.
· <b>Flammability (solid, gas):</b>	Not determined.
· <b>Ignition temperature:</b>	
<b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density at 20 °C:</b>	2.24-2.96 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with 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>Organic solvents:</b>	0.0 %
<b>VOC (EC)</b>	0.00 %
<b>Solids content:</b>	100.0 %
· <b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** Open fire, hot surfaces, high temperatures
- **10.5 Incompatible materials:** oxidants, acids, bases
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

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### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### 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.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.

- **European waste catalogue**

07 07 99	wastes not otherwise specified
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |                                       |                |
|---------------------------------------|----------------|
| · <b>14.1 UN-Number</b>               | Not applicabel |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void           |
| · <b>14.2 UN proper shipping name</b> | Not applicable |
| · <b>ADR, ADN, IMDG, IATA</b>         | Void           |

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· 14.3 Transport hazard class(es)	Not applicabel
· ADR, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	Not applicable
· ADR, IMDG, IATA	Void
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· ADR	
· Remarks:	No Dangerous Goods
· IMDG	
· Remarks:	No Dangerous Goods
· IATA	
· Remarks:	Not restricted
· 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
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing SDS:  
LOGAR Günther Hasel e.K.  
Baden-Airpark, Airport Boulevard B 210  
D-77836 Rheinmünster  
Tel: +49(0)7229-1868-163  
Fax: +49(0)7229-1868-165
- Contact: info@logar.de
- 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)  
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)  
VOC: Volatile Organic Compounds (USA, EU)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative