

## Safety Datasheet

according to 1907/2006/EC, Article 31

Printing date 16.02.2018

Version number 1

Revision: 16.02.2018

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

- **1.1 Product identifier**
- **Trade name:** Topdent Mezzo-Mezzo
- **Article number:** Diverse
- **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
- **Additional information:**  
Safety data sheet available on request.
- **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: 8042-47-5 EINECS: 232-455-8	White mineral oil, petroleum	 Asp. Tox. 1, H304	0.5-1.5%
CAS: 14464-46-1 EINECS: 238-455-4 RTECS: VV 7325000	crystalobalite		30-70%

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· **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; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist 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:** Use fire extinguishing methods suitable to surrounding conditions.
- **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**  
Wear protective clothing.  
Avoid contact with eyes and skin
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.
- **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** Keep receptacles tightly sealed.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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:**  
Do not store together with reducing agents, heavy-metal compounds, acids and alkalis.
- **Further information about storage conditions:**  
Store in a cool place.  
Store in dry conditions.

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- **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.
- **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:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **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**  
Butyl rubber, BR  
Fluorocarbon rubber (Viton)  
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 (> 480 min)  
Permeation (Butykautschuk): + Level 6 (> 480 min)  
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.  
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 in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**  
Butyl rubber, BR  
Fluorocarbon rubber (Viton)
- **Eye protection:** Goggles recommended during refilling

### SECTION 9: Physical and chemical properties

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

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· <b>Colour:</b>	Various colours
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b>	
<b>Melting point/freezing point:</b>	n.a. °C
<b>Initial boiling point and boiling range:</b>	Undetermined.
· <b>Flash point:</b>	>100 °C (DIN 51755)
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Ignition temperature:</b>	>400 °C (DIN 51794)
· <b>Decomposition temperature:</b>	>180 °C
· <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 at 20 °C:</b>	<10 hPa
· <b>Density at 20 °C:</b>	1.5 g/cm <sup>3</sup> (DIN 51757)
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <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**  
Reacts with alkali and metals.  
Reacts with alkali, amines and strong acids.
- **10.4 Conditions to avoid** Avoid temperature > 150 °C
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:**  
At temperatures greater than 150 °C can be released in the presence of oxygen formaldehyde.

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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:** *Leuciscus idus/LC 50 (96 h) > 10000 mg/l*
- **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**  
*Must not be disposed together with household garbage. Do not allow product to reach sewage system.*
- **European waste catalogue**  
*18 02 06: chemicals other than those mentioned in 18 02 05  
18 02 08: Medicinal products other than those mentioned in 18 02 07  
20 01 32: Medicinal products other than those mentioned in 20 01 31*
- **Uncleaned packaging:**
- **Recommendation:** *Disposal must be made according to official regulations.*

### SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Void

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· <b>14.2 UN proper shipping name</b> · <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b> · <b>ADR, ADN, IMDG, IATA</b> · <b>Class</b>	Void
· <b>14.4 Packing group</b> · <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	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.

- **Relevant phrases**  
H304 May be fatal if swallowed and enters airways.
- **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
- **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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Asp. Tox. 1: Aspiration hazard – Category 1