

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 Lux Tray
- **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:**

71549-84-3	Hexandionsäure, polymer mit 1,2 ethandiol und 5-isocyanat-1-(isocyanatmethyl)-1,3,3-trimethylcyclohexan,2-hydroxyethylacrylatblocker	<10.0%
	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	

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

GB

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.02.2017

Version number 1

Revision: 20.02.2017

Trade name: TopDent Lux Tray

(Contd. of page 1)

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**
 - Take affected persons out of danger area and lay down.
 - 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:** 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 (CO₂)
- **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:** storage temperature: 8 °C-28 °C
- **Storage class:** Storage group: 10-13

(Contd. on page 3)

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

Printing date 20.02.2017

Version number 1

Revision: 20.02.2017

Trade name: TopDent Lux Tray

(Contd. of page 2)

- 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:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **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**
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 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 gloves made of the following materials are suitable:** 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:	Pasty
Colour:	Various colours
Odour:	Characteristic
Odour threshold:	Not determined.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 20.02.2017

Version number 1

Revision: 20.02.2017

Trade name: TopDent Lux Tray

(Contd. of page 3)

· pH-value:	Not applicable.
· Change in condition Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	>250 °C
· Flash point:	>150 °C
· Flammability (solid, gas):	Not determined.
· Ignition temperature:	
Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits: Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density at 20 °C:	2.1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity: Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content: Organic solvents:	0.0 %
VOC (EC)	0.00 %
Solids content:	100.0 %
· 9.2 Other information	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.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

(Contd. on page 5)

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

Printing date 20.02.2017

Version number 1

Revision: 20.02.2017

Trade name: TopDent Lux Tray

(Contd. of page 4)

- **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 (carcinogenity, 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
----------	--------------------------------

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | Not applicabel |
| · 14.2 UN proper shipping name | Not applicable |
| · 14.3 Transport hazard class(es) | Not applicabel |
| · 14.4 Packing group | Not applicable |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |

(Contd. on page 6)

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

Printing date 20.02.2017

Version number 1

Revision: 20.02.2017

Trade name: TopDent Lux Tray

(Contd. of page 5)

- | | |
|--|---|
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | <i>Not applicable.</i> |
| · Transport/Additional information: | <i>Not dangerous according to the above specifications.</i> |
| · ADR | |
| · Remarks: | <i>No Dangerous Goods</i> |
| · IMDG | |
| · Remarks: | <i>No Dangerous Goods</i> |
| · IATA | |
| · Remarks: | <i>Not restricted</i> |

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**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- **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
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2