

Printing date 22.02.2017 Version number 1 Revision: 22.02.2017

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

· 1.1 Product identifier

· Trade name: TopDent TopLiner

· Article number: according to Catalog

· CAS Number: 142844-00-6

• EC number: 266-046-0

- · 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



GHS08 health hazard

Carc. 1A H350i May cause cancer by inhalation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

· Hazard pictograms



GHS08

- · Signal word Danger
- · Hazard-determining components of labelling:

Aluminiumsilikatwolle amorph

· Hazard statements

H350i May cause cancer by inhalation.

· Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

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P103 Read label before use.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· PBT: Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.1 Chemical characterisation: Substances
- · CAS No. Description

142844-00-6 Aluminiumsilikatwolle amorph

- · Identification number(s)
- · EC number: 266-046-0
- · Description: Dental material

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.

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.

Immediately rinse with water.

- · 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:

CO2, 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 (CO2)
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

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· 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 product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 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

Ensure good ventilation/exhaustion at the workplace.

Open and handle receptacle with care.

· Information about fire - and explosion protection:

Do not spray onto a naked flame or any incandescent material.

Keep respiratory protective device available.

- · 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: Keep container tightly sealed.
- · Storage class: VCI: 10
- · 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: Not required.
- · 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.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· Respiratory protection:

DGUV 112-190 Breathing apparatus

Suitable respiratory protective device recommended.

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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:



Protective gloves

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:

Fluorocarbon rubber (Viton)

Butyl rubber, BR

· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

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

Form: Powder
Colour: White

• Odour: Odourless

• Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point: Undetermined.

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Initial boiling point and boiling range	e: Undetermined.	
· Flash point:	Not applicable.	
· Flammability (solid, gas):	Product is not flammable.	
· Ignition temperature:		
Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Not determined.	
· Explosive properties:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapour pressure:	Not applicable.	
· Density:	Not determined.	
· 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.
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- $\cdot \textit{Serious eye damage/irritation } \textit{Based on available data, the classification criteria are not met.} \\$
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

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- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity

May cause cancer by inhalation.

- · 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.
- $\cdot \textit{Additional ecological information:}$
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · 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

07 07 99 wastes not otherwise specified

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

· 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.	

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· 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 Substance is not listed.
- · National regulations:
- · Information about limitation of use:

Workers are not allowed to be exposed to this hazardous material. Exceptions can be made by the authorities in certain cases.

· 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:

Abteilung Produktsicherheit

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· 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

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 Carc. 1A: Carcinogenicity – Category 1Ai

- GB