



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

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

· **1.1 Product identifier**

· Trade name: **PreVISION CEM**

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture**

Dental cement
One-component cement for temporary cementation

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

· **Manufacturer/Supplier:**

Kulzer GmbH
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· **Informing department:** E-Mail: msds@kulzer-dental.com

· **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

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

· **Hazard pictograms**



GHS09

· **Signal word** Warning

· **Hazard statements**

H410 Very toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P273 Avoid release to the environment.

P391 Collect spillage.

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.

GB

(Contd. on page 2)



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Revision: 03.06.2017

Trade name: PreVISION CEM

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: -

Dangerous components:

	zinc oxide Aquatic Acute 1, H400; Aquatic Chronic 1, H410	25-50%
	Methylsiliconharz, methoxyfunktionell Flam. Liq. 3, H226	10-25%
CAS: 3087-37-4 EINECS: 221-411-3	titanium tetrapropanolate Flam. Liq. 3, H226; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	0-5%

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 skin contact Instantly wash with water and soap and rinse thoroughly.

After eye contact Rinse opened eye for several minutes under running water.

After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms 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

CO₂, sand, extinguishing powder. Do not use water.

Use fire fighting measures that suit the environment.

For safety reasons unsuitable extinguishing agents Water.

5.2 Special hazards arising from the substance or mixture No further relevant information available.

5.3 Advice for firefighters

Protective equipment: No special measures required.

Additional information -

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Not required.

6.2 Environmental precautions:

Inform respective authorities in case product reaches water or sewage system.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Do not flush with water or aqueous cleansing agents

(Contd. on page 3)

GB



Safety data sheet
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Version number 3

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Trade name: PreVISION CEM

(Contd. of page 2)

· **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 information on disposal.

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SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Please observe the additional instructions in the product's instructions for use.

- **Information about protection against explosions and fires:** No special measures required.

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

· **Storage**

- **Requirements to be met by storerooms and containers:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.

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

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

- **Components with critical 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 that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

- **Personal protective equipment**

- **General protective and hygienic measures**

The usual precautionary measures should be adhered to in handling the chemicals.

- **Breathing equipment:** Not required.

- **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

(Contd. on page 4)

GB



Safety data sheet
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Version number 3

Revision: 03.06.2017

Trade name: PreVISION CEM

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

(Contd. of page 3)

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Colour:**

White

· **Smell:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable.

· **Change in condition**

· **Melting point/Melting range:**

Not determined

· **Boiling point/Boiling range:**

110 °C

· **Flash point:**

162 °C

· **Inflammability (solid, gaseous)**

Not determined.

· **Ignition temperature:**

380 °C

· **Decomposition temperature:**

Not determined.

· **Self-inflammability:**

Product is not selfigniting.

· **Danger of explosion:**

Product is not explosive.

· **Critical values for explosion:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Steam pressure at 20 °C:**

47 hPa

· **Density at 20 °C**

1.64 g/cm³

· **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:**

· **Solids content:**

54.3 %

· **9.2 Other information**

No further relevant information available.

GB

(Contd. on page 5)



Safety data sheet
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Revision: 03.06.2017

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(Contd. of page 4)

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
 - **Additional information:** -

SECTION 11: Toxicological information

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

· **LD/LC50 values that are relevant for classification:**

68909-20-6 hochdisperse Kieselsäure

Oral | LD50 | >5000 mg/kg (rat)

93685-79-1 Isoparaffingemisch

Oral | LD50 | >5000 mg/kg (rat)

- **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.
 - **Ecotoxicological effects:**
 - **Remark:** Very toxic for fish
 - **Additional ecological information:**
 - **General notes:**
 - Do not allow product to reach ground water, water bodies or sewage system.
 - Danger to drinking water if even small quantities leak into soil.
 - Also poisonous for fish and plankton in water bodies.
 - Very toxic for aquatic organisms

(Contd. on page 6)



Safety data sheet
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Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Trade name: PreVISION CEM

(Contd. of page 5)



- **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 of together with household garbage. Do not allow product to reach sewage system.
- **European waste catalogue**
18 01 06* | chemicals consisting of or containing dangerous substances
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
 - **ADR, IMDG, IATA** UN3077
- **14.2 UN proper shipping name**
 - **ADR** 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
 - **IMDG, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
- **14.3 Transport hazard class(es)**
 - **ADR**

 - **Class** 9 (M7) Miscellaneous dangerous substances and articles.
 - **Label** 9
 - **IMDG**



 - **Class** 9 Miscellaneous dangerous substances and articles.

(Contd. on page 7)



Safety data sheet
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Version number 3

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(Contd. of page 6)

· Label	9
· IATA	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group	
· ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· Special marking (ADR):	Symbol (fish and tree)
· Special marking (IATA):	Symbol (fish and tree)
· 14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
· Kemler Number:	90
· EMS Number:	F-A,S-F
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	-
· ADR	
· Limited quantities (LQ)	5 kg
· Transport category	3
· Tunnel restriction code	E
· UN "Model Regulation":	UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

SECTION 15: Regulatory information

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

SECTION 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**

- H226 Flammable liquid and vapour.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.

(Contd. on page 8)



Safety data sheet
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(Contd. of page 7)

H410 Very toxic to aquatic life with long lasting effects.

· **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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