

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

Printing date 06.09.2019

Revision: 26.11.2018

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** UltraCem™ Powder
- **Article number:** 20563
- **Index number:** SDS 319-001.05
- **Relevant identified uses of the substance or mixture and uses advised against**  
Professional Dental Luting Cement, Part 1 of 2
- **Application of the substance / the mixture** Professional Dental Luting Cement, Part 1 of 2
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ultradent Products Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com
  
- **EC Responsible Person**  
Ultradent Products GmbH  
Am Westhoyer Berg 30  
51149 Cologne Germany  
Email: infoDe@ultradent.com  
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.

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- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Precautionary statements**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P314 Get medical advice/attention if you feel unwell.  
P401 Store in a cool and dark area.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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· **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterisation:** Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 65997-18-4	Fluoroalumino Silicate Glass	<20%
EINECS: 266-047-6		

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

### 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**  
Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:**  
Remove contact lenses, if present. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Call a physician if irritation develops or persists.
- **After swallowing:** Rinse mouth with water. Seek medical advice if necessary.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Dry sand  
Carbon dioxide  
Alcohol resistant foam  
Powder
- **Special hazards arising from the substance or mixture** No specific fire or explosion hazard.
- **Advice for firefighters:**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Keep unnecessary personnel away.  
Wear protective clothing.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Wipe up and discard in a suitable container.  
Dispose contaminated material as waste according to item 13.

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- **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.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling:** Avoid contact with eyes, skin, and clothing. Use suitable protective equipment.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **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:** Not required.
- **Further information about storage conditions:** See product labelling.
- **Specific end use(s)** Professional Dental Luting Cement, Part 1 of 2

### 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **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.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Store protective clothing separately.
- **Respiratory protection:** Dusk mask
- **Protection of hands:**
- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
- Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
- For the permanent contact of a maximum of 15 minutes gloves made of the following material are suitable
- Butyl rubber, BR
- Nitrile rubber, NBR
- The selection of 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.
- **Body protection:** Protective work clothing

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### 9 Physical and chemical properties

· <b>Information on basic physical and chemical properties</b>	
· <b>General Information</b>	
· <b>Appearance:</b>	
Form:	Powder
Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
· <b>Change in condition</b>	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Not determined
· Flash point:	Not determined
· Flammability (solid, gas):	Not determined.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density:	Not determined.
· Relative density at 20 °C	~2.3
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· <b>Solvent content:</b>	
VOC (EC)	0.00 %
Solids content:	100.0 %
· Other information	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** Stable under normal temperatures and pressures.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Avoid direct sunlight and high temperature.
- **Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:** None under normal conditions of storage and use.

## 11 Toxicological information

- **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.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Dispose of contents/container to in accordance with local/regional/national/international regulations.  
Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- **UN-Number**
- **ADR, ADN, IMDG, IATA** not regulated

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

**15 Regulatory information**

- **Chemical safety assessment:**  
*Device is biocompatible when used as directed by dental professionals per ISO 10993-1*

**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:** Regulatory Affairs
- **Contact:** Customer Service
- **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*

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