

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



**Date Issued :** 01/09/2012  
**SDS No :** 319-001.3  
**Date Revised :** 07/14/2015  
**Revision No :** 2

**UltraCem® Powder****SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

**Product code** : 20563  
**Product name** : UltraCem® Powder  
**Product description** : Two-Part Resin Reinforced Glass Ionomer Luting Cement, Part 1 of 2

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Relevant identified uses** : Professional Dental Luting Cement

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Ultradent Products, Inc.  
 505 W. 10200 S.  
 South Jordan, UT 84095

**Distributor**

Ultradent Products GmbH  
 Am Westhover Berg 30  
 51149 Cologne Germany  
 Email: infoDE@ultradent.com  
**Emergency Phone** : +49(0)2203-35-92-0

**1.4. Emergency telephone number**

**CHEMTREC (NORTH AMERICA)** :(800) 424 - 9300  
**(INTERNATIONAL)** :+1(703) 527 - 3887

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Danger symbols** : Xi

**R phrases** : R36

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Health** : Skin Sensitization, Category 1  
 Target Organ Toxicity (Repeated exposure), Central nervous system, Category 2  
 Carcinogenicity, Category 1A

**Environmental** : Aquatic Toxicity, Chronic Category 3

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xi



Irritant

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**R&S statement(s)** : R36: Irritating to eyes.

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Hazard pictogram(s)** :



**Signal Word** : DANGER

**Hazard statement(s)** : H317: May cause an allergic skin reaction.  
 H373: May cause damage to Central Nervous System.  
 H350: May cause cancer through inhalation.  
 H412: Harmful to aquatic life with long lasting effects.

**Precautionary statement(s)**

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response** : P305: IF IN EYES:  
 P351: Rinse cautiously with water for several minutes.  
 P313: Get medical advice/attention.  
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
 P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

**Storage** : P103: Read label before use.

**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-10/11/2003)

**2.3. Other hazards**

**Immediate concerns** : Harmful if inhaled.

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Fluoroaluminosilicateglass	65997-18-4	266-047-6	< 100	Xi; R36	Aquatic Tox., Chronic 3; Skin Sens., Cat. 1; STOT RE, Cat 2; Carc., Cat. 1A; H317; H412; H350; H373

For full text of H-statements and R-phrases: see SECTION 16.

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

- Following eyes** : Flush eye with water for 15 minutes. Get medical attention.  
**Following skin** : Wash with soap and water.  
**Following ingestion** : No special measures required.  
**Following inhalation** : Ventilate the premises

**4.2. Most important symptoms and effects, both acute and delayed**

- Eyes** : May be mildly irritating to eyes.  
**Skin** : May cause sensitization to skin.  
**Ingestion** : None expected for this product.  
**Inhalation** : Harmful if inhaled

**4.3. Indication of any immediate medical attention and special treatment needed**

- Notes to physician** : May cause cancer if inhaled.

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

- Hazardous combustion products** : None known.  
**Explosion hazards** : Not Determined  
**Fire explosion** : Not Determined  
**Sensitive to static discharge** : Not Determined

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**Sensitivity to impact** : Not Determined

**5.3. Advice for firefighters**

**Fire fighting procedures** : As in any fire, wear self-contained breathing apparatus pressure-demand, (MSHA/NIOSH approved or equivalent) and full protective gear.

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**General procedures** : Refer to Section 8 for Personal Protective Equipment.

**6.2. Environmental precautions**

**Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

**6.3. Methods and material for containment and cleaning up**

**Small spill** : Wipe up and discard in a suitable container.

**6.4. Reference to other sections**

**Reference to other sections** : Not Applicable

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling** : Avoid prolonged inhalation.

**Storage** : See product labeling.

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

**Shelf life** : See product labeling

**7.3. Specific end use(s)**

**Specific end use(s)** : Professional Dental Luting Cement

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection.

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : In case of insufficient ventilation, wear suitable respiratory equipment.

**SECTION 9: Physical and chemical properties**

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

**Appearance** : White powder

**Odour** : Odorless or no characteristic odor

**Solubility in water** : Insoluble

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**9.2. Other information**

**Percent volatile** : Not Determined

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

**Reactivity** : Stable

**10.2. Chemical stability**

**Chemical stability** : Stable when stored and handled under recommended conditions.

**10.3. Possibility of hazardous reactions**

**Hazardous polymerization** : None

**10.4. Conditions to avoid**

**Conditions to avoid** : None known.

**10.5. Incompatible materials**

**Incompatible materials** : None known.

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None known.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

**Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

**Persistence and degradability** : Not Determined

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not Determined

**12.4. Mobility in soil**

**Mobility in soil** : Not Determined

**12.5. Results of PBT and vPvB assessment**

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**Results of PBT and vPvB assessment** : Not Determined

**12.6. Other adverse effects**

**Environmental data** : Not Determined

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : N/A

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : N/A

**14.4. Packing group**

**Packing group** : N/A

**14.5. Environmental hazards**

**Marine pollutant #1** : N/A

**14.6. Special precautions for user**

**ADR - road** : Not Dangerous Goods

**RID - rail** : Not Dangerous Goods

**IMDG - sea** : Not Dangerous Goods

**IATA - air** : Not Dangerous Goods

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

**Transport in bulk** : Not Dangerous Goods

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**Additional information** : This product is not considered dangerous for transportation.  
 May cause cancer if inhaled

**SECTION 16: Other information**

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**UltraCem® Powder****Relevant R-phrases and/or H-statements (number and full text)**

: R36: Irritating to eyes.  
 Aquatic Tox., Chronic 3: Aquatic Toxicity, Chronic. 3  
 Carc., Cat. 1A: Carcinogenicity, Category 1A  
 STOT RE, Cat 2: Target Organ Toxicity (Repeated exposure), Central nervous system, Category 2  
 Skin Sens., Cat. 1: Skin Sensitization, Category 1  
 H317: May cause an allergic skin reaction.  
 H350: May cause cancer through inhalation.  
 H373: May cause damage to Central Nervous System.  
 H412: Harmful to aquatic life with long lasting effects.

**Prepared by**

: Anu Kattoju

**Revision summary**

: This SDS replaces the 04/20/2012 SDS. Revised: **Section 1:** GENERAL USE, PREPARED BY, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INGESTION, INHALATION, SKIN ). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, WATER SPILL, . **Section 7:** SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT ( EYES AND FACE, RESPIRATORY, PROTECTIVE CLOTHING ), . **Section 9:** PERCENT VOLATILE. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABILITY, STABLE. **Section 11:** ACUTE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 13:** DISPOSAL METHOD. **Section 14:** ROAD AND RAIL (ADR/RID) ( ROAD AND RAIL (ADR/RID), MARINE POLLUTANT #1 ), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, RoHS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

**General statements**

: N/A= Not Applicable

**Manufacturer disclaimer**

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.