

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

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

Distributor

Ultrudent Products GmbH
Am Westhoven 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) :  
 Exclamation mark Health hazard

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 LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : 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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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

Revision summary

: Anu Kattoju

: 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 EC₅₀, 96-HOUR EC₅₀), 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.