

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/10/2012

SDS No : 320-001.3

Date Revised : 07/14/2015

Revision No : 2

UltraCem® Liquid

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

1.1. Product identifier

Product code : 20564
Product name : UltraCem® Liquid
Product description : Resin Reinforced Glass Ionomer Luting Cement, Part 2 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 : R36/37/38,R43

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

Health : Eye Irritation, Category 2
 Skin Irritation, Category 2
 Skin Sensitization, Category 1

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/37/38: Irritating to eyes, respiratory system and skin.
 R43: May cause sensitization by skin contact.

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

Hazard pictogram(s)

:

Exclamation
mark

Signal Word

: WARNING

Hazard statement(s)

: H319: Causes serious eye irritation.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

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.

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

: Possible sensitizer

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]
Poly Acrylic acid	9003-01-4	N/A	< 35	Xi; R36/37/38	Not classified
2-hydroxyethyl Methacrylate	868-77-9	212-782-2	< 20	Xi; R43; R36/38	Eye Irr., Cat. 2; Skin Irr., Cat. 2; Skin Sens., Cat. 1; H315; H317; H319
PEGDMA	25852-47-5	N/A	< 15	Xi; R37/38; R41	Not classified

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** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

- Eyes** : May cause eye irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : None expected for this product.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Not Applicable

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

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Fire explosion : Not Determined

Sensitive to static discharge : Not Determined

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.

Fire fighting equipment : CO₂, Dry chemical, Dry sand, Foam.

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 : Not Applicable

6.3. Methods and material for containment and cleaning up

Small spill : Absorb liquid in sawdust, sand or inert absorbent. 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 contact with eyes and skin.

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 : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

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9.1. Information on basic physical and chemical properties

Appearance	: Clear liquid
Odour	: Characteristic odor
pH	: < 3
Solubility in water	: Soluble

9.2. Other information

Percent volatile	: Not Determined
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	: Stable
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10.2. Chemical stability

Chemical stability	: Stable when stored and handled under recommended conditions.
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10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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10.4. Conditions to avoid

Conditions to avoid	: Heat, flames, ignition sources, direct light, and incompatibles.
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10.5. Incompatible materials

Incompatible materials	: Avoid organic peroxide or strong acids or strong bases.
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10.6. Hazardous decomposition products

Hazardous decomposition products	: None known.
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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.
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SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

96-hour LC ₅₀	: Not Determined
48-hour EC ₅₀	: Not Determined
96-hour EC ₅₀	: Not Determined

12.2. Persistence and degradability

Persistence and degradability	: Not Determined
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12.3. Bioaccumulative potential

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Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

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

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Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R36/37/38: Irritating to eyes, respiratory system and skin.
 R36/38: Irritating to eyes and skin.
 R37/38: Irritating to respiratory system and skin.
 R41: Risk of serious damage to eyes.
 R43: May cause sensitization by skin contact.
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 Skin Sens., Cat. 1: Skin Sensitization, Category 1
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/19/2012 SDS. Revised: **Section 1:** GENERAL USE, PREPARED BY, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** . **Section 4:** INGESTION, INHALATION, 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:** HANDLING, SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT (EYES AND FACE, PROTECTIVE CLOTHING), . **Section 9:** PERCENT VOLATILE, pH. **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, STABILITY, STABLE. **Section 11:** ACUTE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, 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

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recommendations in the specific context of the intended use and determine whether they are appropriate.