

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

Printing date 19.09.2019

Revision: 26.11.2018

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

- **Product identifier**
- **Trade name:** UltraCem™ Liquid
- **Article number:** 20564
- **Index number:** SDS 320-001.04
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Luting Cement, Part 2 of 2
- **Application of the substance / the mixture** Professional Dental Luting Cement, Part 2 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**



GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
2-Hydroxyethyl Methacrylate
- **Hazard statements**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

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· Precautionary statements

- P101 *If medical advice is needed, have product container or label at hand.*
- P102 *Keep out of reach of children.*
- P103 *Read label before use.*
- P261 *Avoid breathing dust/fume/gas/mist/vapours/spray.*
- P280 *Wear protective gloves/protective clothing/eye protection/face protection.*
- P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
- P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*
- P337+P313 *If eye irritation persists: Get medical advice/attention.*
- P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

· Other hazards**· Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· Chemical characterisation: Mixtures

· **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 868-77-9 EINECS: 212-782-2	2-Hydroxyethyl Methacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	10-20%
CAS: 9003-01-4 EC number: 618-347-7	Polyacrylic Acid	<35%
CAS: 7732-18-5 EINECS: 231-791-2	Water	<40%

· **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:** Immediately remove any clothing soiled by the product.

· After inhalation:

Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

· 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.

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5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
 - Powder
 - Alcohol resistant foam
 - Carbon dioxide
 - Dry sand
- Use fire extinguishing methods suitable to surrounding conditions.
- **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:**
 - Dilute with plenty of water.
 - 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.
 - Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 - Dispose contaminated material as waste according to item 13.
 - Ensure adequate ventilation.
- **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:**
 - Keep away from heat and direct sunlight.
 - Avoid contact with eyes, skin, and clothing. Use suitable protective equipment.
 - Ensure good ventilation/exhaustion at the workplace.
 - Open and handle receptacle with care.
 - Prevent formation of aerosols.
- **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:**
 - Store in a cool and dry place out of direct sunlight.
 - Keep separated from organic peroxides.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
 - See product labelling.

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Keep container tightly sealed.

· **Specific end use(s)** Professional Dental Luting Cement, Part 2 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:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

· **Respiratory protection:**

Dusk mask

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**

Protective gloves

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

Nitrile rubber, NBR

Butyl rubber, BR

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:**

Tightly sealed goggles

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· **Body protection:** Protective work clothing

9 Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Liquid
· Colour:	Clear
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value at 20 °C:** 2.7

· **Change in condition**

· Melting point/freezing point:	Not determined
· Initial boiling point and boiling range:	100 °C

· **Flash point:** Not determined

· **Flammability (solid, gas):** Not applicable.

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.

· **Relative density at 20 °C**

· Vapour density	~1.2
· Evaporation rate	Not determined.

· **Solubility in / Miscibility with water:**

Fully miscible.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **Solvent content:**

· Water:	35.0 %
· VOC (EC)	0.00 %

· **Solids content:** >35.0 %

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.

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- **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:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None by intended use.

11 Toxicological information

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

- **LD/LC50 values relevant for classification:**

868-77-9 2-Hydroxyethyl Methacrylate

Oral	LD50	3,275 mg/kg (mouse) >5,000 mg/kg (rat)
	LC50 Fish	>100 mg/l (Fish)
Dermal	LD50	>3,000 mg/kg (rabbit)
	LC50(Daphnia magna)	24.1 mg/l (daphnia)

150-76-5 Hydroquinone Monomethyl Ether

Oral	LD50	500 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **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:**

868-77-9 2-Hydroxyethyl Methacrylate

EC50	345 mg/l (Algae)
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- **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.

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- **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.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

HP4	Irritant - skin irritation and eye damage
HP13	Sensitising

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

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

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **Chemical safety assessment:**
Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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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.

· **Relevant phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· **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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

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

Skin Sens. 1: Skin sensitisation – Category 1