

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

Printing date 31.05.2019

Revision: 09.04.2019

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

- **Product identifier**
- **Trade name:** Opal™ Band™ Cement - Base
- **Article number:** 71100
- **Index number:** SDS 219-001.07
- **Relevant identified uses of the substance or mixture and uses advised against** Professional Orthodontic Cement
- **Application of the substance / the mixture** Professional Orthodontic Cement
- **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**



GHS05 corrosion

Skin Corr. 1A H314 Causes severe skin burns and eye damage.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

- **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** GHS05, GHS07
- **Signal word** Danger

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· **Hazard-determining components of labelling:**

Trade Secret

Triethylene Glycol Dimethacrylate

Methacrylic Acid

Diurethane Dimethacrylate

· **Hazard statements**

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

· **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.

P260 Do not breathe dusts or mists.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P405 Store locked up.

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: 20882-04-6 EINECS: 244-096-4	Mono-2-(Methacryloyloxy) Ethyl Succinate ⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319	>2.5-≤10%
	Trade Secret ⚠ Skin Corr. 1A, H314	>2.5-≤10%
CAS: 109-16-0 EINECS: 203-652-6	Triethylene Glycol Dimethacrylate ⚠ Skin Sens. 1, H317	>2.5-≤10%
CAS: 72869-86-4 EINECS: 276-957-5	Diurethane Dimethacrylate ⚠ Skin Sens. 1, H317	>2.5-≤10%
CAS: 79-41-4 EINECS: 201-204-4	Methacrylic Acid ⚠ Acute Tox. 3, H331; ⚠ Skin Corr. 1A, H314; ⚠ Acute Tox. 4, H302; ⚠ Acute Tox. 4, H312	≤2.5%
CAS: 64-17-5 EINECS: 200-578-6	Ethyl Alcohol ⚠ Flam. Liq. 2, H225	≤2.5%

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

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## 4 First aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**  
This product is a thick paste, therefore inhalation is extremely unlikely.  
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:**  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Drink plenty of water and provide fresh air. Call for a doctor immediately.
- **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:**  
Carbon dioxide  
Foam  
Water spray  
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**  
During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters:**
- **Protective equipment:**  
Wear fully protective suit.  
Mouth respiratory protective device.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Mount respiratory protective device.  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Use neutralising agent.  
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.

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## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**  
*Ensure good ventilation/exhaustion at the workplace.  
 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:** *No special requirements.*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:**  
*See product labelling.  
 Keep container tightly sealed.*
- **Specific end use(s)** *Professional Orthodontic Cement*

## 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:**

<b>79-41-4 Methacrylic Acid</b>	
<i>WEL (Great Britain)</i>	<i>Short-term value: 143 mg/m<sup>3</sup>, 40 ppm Long-term value: 72 mg/m<sup>3</sup>, 20 ppm</i>
<b>64-17-5 Ethyl Alcohol</b>	
<i>WEL (Great Britain)</i>	<i>Long-term value: 1920 mg/m<sup>3</sup>, 1000 ppm</i>

- **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.  
 Avoid contact with the eyes and skin.*
- **Respiratory protection:**  
*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**

*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.*

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- **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

- **Body protection:** Protective work clothing

## 9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

**Form:** Paste

**Colour:** Blue

- **Odour:** Sweet

- **Odour threshold:** Not determined.

- **pH-value:** Not applicable (non-aqueous)

- **Change in condition**

**Melting point/freezing point:** Undetermined.

**Initial boiling point and boiling range:** Undetermined.

- **Flash point:** >100 °C

- **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** Not determined.

- **Vapour density** Not determined.

- **Evaporation rate** Not determined.

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

Not miscible or difficult to mix.

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

- **Viscosity:**

**Dynamic:** Not determined.

**Kinematic:** Not determined.

- **Solvent content:**

**VOC (EC)** 0.00 %

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· **Other information**

No further relevant information available.

**10 Stability and reactivity**

- **Reactivity** Polymerization occurs when exposed to amine catalysts, metal, or pressure.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Pressure
- **Incompatible materials:**
  - Amine Catalysts
  - Metals
- **Hazardous decomposition products:** Carbon dioxide

**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:****ATE (Acute Toxicity Estimates)**

Oral	LD50	53,000 mg/kg
Dermal	LD50	25,000 mg/kg
Inhalative	LC50/4 h	355 mg/l

**109-16-0 Triethylene Glycol Dimethacrylate**

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)

**72869-86-4 Diurethane Dimethacrylate**

Oral	LD50	>5,000 mg/kg (rat)
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**79-41-4 Methacrylic Acid**

Oral	LD50	1,250 mg/kg (mouse)
		1,060 mg/kg (rat)
		1,200 mg/kg (rabbit)
Dermal	LD50	86 mg/l (Fish)
		1,000 mg/kg (Guinea pig)
Inhalative	LC50/4 h	500 mg/kg (rabbit)
		7.1 mg/l (rat)

**64-17-5 Ethyl Alcohol**

Oral	LD50	5,600 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
Inhalative	LC50 Fish	>10,000 mg/l (Fish)
		LC50/4 h
		20,000 mg/l (rat)

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- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**  
Causes severe skin burns and eye damage.
- **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**  
May cause respiratory irritation.
- **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**

· <b>Aquatic toxicity:</b>	
<b>109-16-0 Triethylene Glycol Dimethacrylate</b>	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)
<b>72869-86-4 Diurethane Dimethacrylate</b>	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)
<b>79-41-4 Methacrylic Acid</b>	
EC50	<180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
EC50	45 mg/l (Algae) (Toxicity to algae)
<b>64-17-5 Ethyl Alcohol</b>	
Algae Toxicity	1,000 mg/l (Algae)

- **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.  
Must not reach sewage water or drainage ditch undiluted or unneutralised.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Do not allow product to reach sewage system.

- **European waste catalogue**

HP 8	Corrosive
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- |  |                        |
|--|------------------------|
| · <b>UN-Number</b><br>· <b>ADR, ADN, IMDG, IATA</b>                                    | <i>not regulated</i>   |
| · <b>UN proper shipping name</b><br>· <b>ADR, ADN, IMDG, IATA</b>                      | <i>not regulated</i>   |
| · <b>Transport hazard class(es)</b><br>· <b>ADR, ADN, IMDG, IATA</b><br>· <b>Class</b> | <i>not regulated</i>   |
| · <b>Packing group</b><br>· <b>ADR, IMDG, IATA</b>                                     | <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

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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

## 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**  
H225 Highly flammable liquid and vapour.  
H302 Harmful if swallowed.  
H312 Harmful in contact with skin.  
H314 Causes severe skin burns and eye damage.

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H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.  
H331 Toxic if inhaled.

· **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

Flam. Liq. 2: Flammable liquids – Category 2

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

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

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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